

FDA REAUTHORIZATION ACT OF 2017

JULY 11, 2017.—Committed to the Committee of the Whole House on the State of the Union and ordered to be printed

Mr. WALDEN, from the Committee on Energy and Commerce, submitted the following

R E P O R T

[To accompany H.R. 2430]

The Committee on Energy and Commerce, to whom was referred the bill (H.R. 2430) to amend the Federal Food, Drug, and Cosmetic Act to revise and extend the user-fee programs for prescription drugs, medical devices, generic drugs, and biosimilar biological products, and for other purposes, having considered the same, report favorably thereon with an amendment and recommend that the bill as amended do pass.

CONTENTS

	Page
Purpose and Summary	36
Background and Need for Legislation	37
Hearings	37
Committee Consideration	38
Committee Votes	39
Committee Oversight Findings	41
Statement of General Performance Goals and Objectives	41
New Budget Authority, Entitlement Authority, and Tax Expenditures	41
Earmark, Limited Tax Benefits, and Limited Tariff Benefits	41
Committee Cost Estimate	41
Congressional Budget Office Estimate	41
Federal Mandates Statement	41
Duplication of Federal Programs	41
Disclosure of Directed Rule Makings	41
Advisory Committee Statement	42
Applicability to Legislative Branch	42
Section-by-Section Analysis of the Legislation	42
Changes in Existing Law Made by the Bill, as Reported	50

The amendment is as follows:

Strike all after the enacting clause and insert the following:

SECTION 1. SHORT TITLE.

This Act may be cited as the “FDA Reauthorization Act of 2017”.

SEC. 2. TABLE OF CONTENTS.

The table of contents for this Act is as follows:

- Sec. 1. Short title.
Sec. 2. Table of contents.

TITLE I—FEES RELATING TO DRUGS

- Sec. 101. Short title; finding.
Sec. 102. Authority to assess and use drug fees.
Sec. 103. Reauthorization; reporting requirements.
Sec. 104. Sunset dates.
Sec. 105. Effective date.
Sec. 106. Savings clause.

TITLE II—FEES RELATING TO DEVICES

- Sec. 201. Short title; findings.
Sec. 202. Definitions.
Sec. 203. Authority to assess and use device fees.
Sec. 204. Reauthorization; reporting requirements.
Sec. 205. Conformity assessment pilot program.
Sec. 206. Reauthorization of review.
Sec. 207. Electronic format for submissions.
Sec. 208. Savings clause.
Sec. 209. Effective date.
Sec. 210. Sunset clause.

TITLE III—FEES RELATING TO GENERIC DRUGS

- Sec. 301. Short title; finding.
Sec. 302. Definitions.
Sec. 303. Authority to assess and use human generic drug fees.
Sec. 304. Reauthorization; reporting requirements.
Sec. 305. Sunset dates.
Sec. 306. Effective date.
Sec. 307. Savings clause.

TITLE IV—FEES RELATING TO BIOSIMILAR BIOLOGICAL PRODUCTS

- Sec. 401. Short title; finding.
Sec. 402. Definitions.
Sec. 403. Authority to assess and use biosimilar fees.
Sec. 404. Reauthorization; reporting requirements.
Sec. 405. Sunset dates.
Sec. 406. Effective date.
Sec. 407. Savings clause.

TITLE V—REAUTHORIZATIONS AND IMPROVEMENTS RELATED TO DRUGS

- Sec. 501. Reauthorization of provision relating to exclusivity of certain drugs containing single enantiomers.
Sec. 502. Reauthorization of orphan grants program.
Sec. 503. Reauthorization of pediatric study of drugs.
Sec. 504. Protecting and strengthening the drug supply chain.
Sec. 505. Sense of Congress on lowering the cost of prescription drugs.

TITLE VI—DEVICE INSPECTION AND REGULATORY IMPROVEMENTS

Subtitle A—Improving the Process for Inspections of Device Establishments

- Sec. 601. Risk-based inspections for devices.
Sec. 602. Recognition of foreign government inspections.
Sec. 603. Improvements to inspections process for device establishments.
Sec. 604. Certificates to foreign governments for devices.
Sec. 605. Facilitating international harmonization.
Sec. 606. Reauthorization of inspection program.

Subtitle B—Other Provisions

- Sec. 611. Reauthorization of pediatric humanitarian device exceptions.
Sec. 612. Reauthorization of pediatric device consortia.
Sec. 613. Regulation of over-the-counter hearing aids.
Sec. 614. Report on ensuring quality, safety, and continued effectiveness of devices that have been serviced.
Sec. 615. Device pilot projects to generate reliable and timely safety and active surveillance data.
Sec. 616. Risk-based classification of accessories.

TITLE VII—GENERIC DRUG ACCESS AND COMPETITION

- Sec. 701. Competitive Generic Therapies.
Sec. 702. Enhancing regulatory transparency To enhance generic competition.
Sec. 703. Incentivizing competitive generic therapy development.
Sec. 704. Tropical disease product application.
Sec. 705. GAO study of issues regarding first cycle approvals of generic medicines.

TITLE VIII—FOSTERING INNOVATION IN MEDICAL IMAGING

- Sec. 801. Approval of applications for certain diagnostic medical imaging devices.
Sec. 802. Applications for approval of contrast agents intended for use with certain diagnostic medical imaging devices.

TITLE IX—ADDITIONAL PROVISIONS

- Sec. 901. Technical corrections.
Sec. 902. Reauthorization of the critical path public-private partnerships.

TITLE I—FEES RELATING TO DRUGS

SEC. 101. SHORT TITLE; FINDING.

(a) SHORT TITLE.—This title may be cited as the “Prescription Drug User Fee Amendments of 2017”.

(b) FINDING.—The Congress finds that the fees authorized by the amendments made in this title will be dedicated toward expediting the drug development process and the process for the review of human drug applications, including postmarket drug safety activities, as set forth in the goals identified for purposes of part 2 of subchapter C of chapter VII of the Federal Food, Drug, and Cosmetic Act, in the letters from the Secretary of Health and Human Services to the Chairman of the Committee on Health, Education, Labor, and Pensions of the Senate and the Chairman of the Committee on Energy and Commerce of the House of Representatives, as set forth in the Congressional Record.

SEC. 102. AUTHORITY TO ASSESS AND USE DRUG FEES.

(a) TYPES OF FEES.—

(1) IN GENERAL.—Section 736(a) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 379h(a)) is amended—

(A) in the matter preceding paragraph (1), by striking “fiscal year 2013” and inserting “fiscal year 2018”;

(B) in the heading of paragraph (1), by striking “AND SUPPLEMENT”;

(C) in paragraph (1), by striking “or a supplement” and “or supplement” each place either appears;

(D) in paragraph (1)(A)—

(i) in clause (i), by striking “(c)(4)” and inserting “(c)(5)”; and

(ii) in clause (ii), by striking “A fee established” and all that follows through “are required.” and inserting the following: “A fee established under subsection (c)(5) for a human drug application for which clinical data (other than bioavailability or bioequivalence studies) with respect to safety or effectiveness are not required for approval.”;

(E) in the heading of paragraph (1)(C), by striking “OR SUPPLEMENT”;

(F) in paragraph (1)(F)—

(i) in the heading, by striking “OR INDICATION”; and

(ii) by striking the second sentence;

(G) by striking paragraph (2) (relating to a prescription drug establishment fee);

(H) by redesignating paragraph (3) as paragraph (2);

(I) in the heading of paragraph (2), as so redesignated, by striking “PRESCRIPTION DRUG PRODUCT FEE” and inserting “PRESCRIPTION DRUG PROGRAM FEE”;

(J) in subparagraph (A) of such paragraph (2), by amending the first sentence to read as follows: “Except as provided in subparagraphs (B) and (C), each person who is named as the applicant in a human drug application, and who, after September 1, 1992, had pending before the Secretary a human drug application or supplement, shall pay the annual prescription drug program fee established for a fiscal year under subsection (c)(5) for each prescription drug product that is identified in such a human drug application approved as of October 1 of such fiscal year.”;

(K) in subparagraph (B) of such paragraph (2)—

(i) in the heading of subparagraph (B), by inserting after “EXCEPTION” the following: “FOR CERTAIN PRESCRIPTION DRUG PRODUCTS”; and

(ii) by striking “A prescription drug product shall not be assessed a fee” and inserting “A prescription drug program fee shall not be assessed for a prescription drug product”; and

(L) by adding at the end of such paragraph (2) the following:

“(C) LIMITATION.—A person who is named as the applicant in an approved human drug application shall not be assessed more than 5 prescription drug program fees for a fiscal year for prescription drug products identified in such approved human drug application.”

(2) CONFORMING AMENDMENT.—Subparagraph (C) of section 740(a)(3) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 379j–12(a)(3)) is amended to read as follows:

“(C) LIMITATION.—An establishment shall be assessed only one fee per fiscal year under this section.”

(b) FEE REVENUE AMOUNTS.—Subsection (b) of section 736 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 379h) is amended to read as follows:

“(b) FEE REVENUE AMOUNTS.—

“(1) IN GENERAL.—For each of the fiscal years 2018 through 2022, fees under subsection (a) shall, except as provided in subsections (c), (d), (f), and (g), be established to generate a total revenue amount under such subsection that is equal to the sum of—

“(A) the annual base revenue for the fiscal year (as determined under paragraph (3));

“(B) the dollar amount equal to the inflation adjustment for the fiscal year (as determined under subsection (c)(1));

“(C) the dollar amount equal to the capacity planning adjustment for the fiscal year (as determined under subsection (c)(2));

“(D) the dollar amount equal to the operating reserve adjustment for the fiscal year, if applicable (as determined under subsection (c)(3));

“(E) the dollar amount equal to the additional direct cost adjustment for the fiscal year (as determined under subsection (c)(4)); and

“(F) additional dollar amounts for each fiscal year as follows:

“(i) \$20,077,793 for fiscal year 2018.

“(ii) \$21,317,472 for fiscal year 2019.

“(iii) \$16,953,329 for fiscal year 2020.

“(iv) \$5,426,896 for fiscal year 2021.

“(v) \$2,769,609 for fiscal year 2022.

“(2) TYPES OF FEES.—Of the total revenue amount determined for a fiscal year under paragraph (1)—

“(A) 20 percent shall be derived from human drug application fees under subsection (a)(1); and

“(B) 80 percent shall be derived from prescription drug program fees under subsection (a)(2).

“(3) ANNUAL BASE REVENUE.—For purposes of paragraph (1), the dollar amount of the annual base revenue for a fiscal year shall be—

“(A) for fiscal year 2018, \$878,590,000; and

“(B) for fiscal years 2019 through 2022, the dollar amount of the total revenue amount established under paragraph (1) for the previous fiscal year, not including any adjustments made under subsection (c)(3) or (c)(4).”.

(c) ADJUSTMENTS; ANNUAL FEE SETTING.—Subsection (c) of section 736 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 379h) is amended to read as follows:

“(c) ADJUSTMENTS; ANNUAL FEE SETTING.—

“(1) INFLATION ADJUSTMENT.—

“(A) IN GENERAL.—For purposes of subsection (b)(1)(B), the dollar amount of the inflation adjustment to the annual base revenue for each fiscal year shall be equal to the product of—

“(i) such annual base revenue for the fiscal year under subsection (b)(1)(A); and

“(ii) the inflation adjustment percentage under subparagraph (B).

“(B) INFLATION ADJUSTMENT PERCENTAGE.—The inflation adjustment percentage under this subparagraph for a fiscal year is equal to the sum of—

“(i) the average annual percent change in the cost, per full-time equivalent position of the Food and Drug Administration, of all personnel compensation and benefits paid with respect to such positions for the first 3 years of the preceding 4 fiscal years, multiplied by the proportion of personnel compensation and benefits costs to total costs of the process for the review of human drug applications (as defined in section 735(6)) for the first 3 years of the preceding 4 fiscal years; and

“(ii) the average annual percent change that occurred in the Consumer Price Index for urban consumers (Washington-Baltimore, DC-MD-VA-WV; Not Seasonally Adjusted; All items; Annual Index) for the first 3 years of the preceding 4 years of available data multiplied by the proportion of all costs other than personnel compensation and benefits costs to total costs of the process for the review of human drug applications (as defined in section 735(6)) for the first 3 years of the preceding 4 fiscal years.

“(2) CAPACITY PLANNING ADJUSTMENT.—

“(A) IN GENERAL.—For each fiscal year, after the annual base revenue established in subsection (b)(1)(A) is adjusted for inflation in accordance with paragraph (1), such revenue shall be adjusted further for such fiscal year, in accordance with this paragraph, to reflect changes in the resource capacity needs of the Secretary for the process for the review of human drug applications.

“(B) INTERIM METHODOLOGY.—

“(i) IN GENERAL.—Until the capacity planning methodology described in subparagraph (C) is effective, the adjustment under this paragraph for a fiscal year shall be based on the product of—

“(I) the annual base revenue for such year, as adjusted for inflation under paragraph (1); and

“(II) the adjustment percentage under clause (ii).

“(ii) ADJUSTMENT PERCENTAGE.—The adjustment percentage under this clause for a fiscal year is the weighted change in the 3-year average ending in the most recent year for which data are available, over the 3-year average ending in the previous year, for—

“(I) the total number of human drug applications, efficacy supplements, and manufacturing supplements submitted to the Secretary;

“(II) the total number of active commercial investigational new drug applications; and

“(III) the total number of formal meetings scheduled by the Secretary, and written responses issued by the Secretary in lieu of such formal meetings, as identified in section I.H of the letters described in section 101(b) of the Prescription Drug User Fee Amendments of 2017.

“(C) CAPACITY PLANNING METHODOLOGY.—

“(i) DEVELOPMENT; EVALUATION AND REPORT.—The Secretary shall obtain, through a contract with an independent accounting or consulting firm, a report evaluating options and recommendations for a new methodology to accurately assess changes in the resource and capacity needs of the process for the review of human drug applications. The capacity planning methodological options and recommendations presented in such report shall utilize and be informed by personnel time reporting data as an input. The report shall be published for public comment no later than the end of fiscal year 2020.

“(ii) ESTABLISHMENT AND IMPLEMENTATION.—After review of the report described in clause (i) and any public comments thereon, the Secretary shall establish a capacity planning methodology for purposes of this paragraph, which shall—

“(I) replace the interim methodology under subparagraph (B);

“(II) incorporate such approaches and attributes as the Secretary determines appropriate; and

“(III) be effective beginning with the first fiscal year for which fees are set after such capacity planning methodology is established.

“(D) LIMITATION.—Under no circumstances shall an adjustment under this paragraph result in fee revenue for a fiscal year that is less than the sum of the amounts under subsections (b)(1)(A) (the annual base revenue for the fiscal year) and (b)(1)(B) (the dollar amount of the inflation adjustment for the fiscal year).

“(E) PUBLICATION IN FEDERAL REGISTER.—The Secretary shall publish in the Federal Register notice under paragraph (5) the fee revenue and fees resulting from the adjustment and the methodologies under this paragraph.

“(3) OPERATING RESERVE ADJUSTMENT.—

“(A) INCREASE.—For fiscal year 2018 and subsequent fiscal years, the Secretary may, in addition to adjustments under paragraphs (1) and (2), further increase the fee revenue and fees if such an adjustment is necessary to provide for not more than 14 weeks of operating reserves of carryover user fees for the process for the review of human drug applications.

“(B) DECREASE.—If the Secretary has carryover balances for such process in excess of 14 weeks of such operating reserves, the Secretary shall decrease such fee revenue and fees to provide for not more than 14 weeks of such operating reserves.

“(C) NOTICE OF RATIONALE.—If an adjustment under subparagraph (A) or (B) is made, the rationale for the amount of the increase or decrease (as applicable) in fee revenue and fees shall be contained in the annual Federal Register notice under paragraph (5) establishing fee revenue and fees for the fiscal year involved.

“(4) ADDITIONAL DIRECT COST ADJUSTMENT.—

“(A) IN GENERAL.—The Secretary shall, in addition to adjustments under paragraphs (1), (2), and (3), further increase the fee revenue and fees—

“(i) for fiscal year 2018, by \$8,730,000; and

“(ii) for fiscal year 2019 and subsequent fiscal years, by the amount determined under subparagraph (B).

“(B) AMOUNT.—The amount determined under this subparagraph is—

“(i) \$8,730,000, multiplied by

“(ii) the Consumer Price Index for urban consumers (Washington-Baltimore, DC-MD-VA-WV; Not Seasonally Adjusted; All Items; Annual Index) for the most recent year of available data, divided by such Index for 2016.

“(5) ANNUAL FEE SETTING.—The Secretary shall, not later than 60 days before the start of each fiscal year that begins after September 30, 2017—

“(A) establish, for the next fiscal year, human drug application fees and prescription drug program fees under subsection (a), based on the revenue amounts established under subsection (b) and the adjustments provided under this subsection; and

“(B) publish such fee revenue and fees in the Federal Register.

“(6) LIMIT.—The total amount of fees charged, as adjusted under this subsection, for a fiscal year may not exceed the total costs for such fiscal year for the resources allocated for the process for the review of human drug applications.”

(d) FEE WAIVER OR REDUCTION.—Section 736(d) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 379h(d)) is amended—

(1) in paragraph (1)—

(A) by inserting “or” at the end of subparagraph (B);

(B) by striking subparagraph (C); and

(C) by redesignating subparagraph (D) as subparagraph (C);

(2) by striking paragraph (3) (relating to use of standard costs);

(3) by redesignating paragraph (4) as paragraph (3); and

(4) in paragraph (3), as so redesignated—

(A) in subparagraphs (A) and (B), by striking “paragraph (1)(D)” and inserting “paragraph (1)(C)”; and

(B) in subparagraph (B)—

(i) by striking clause (ii);

(ii) by striking “shall pay” through “(i) application fees” and inserting “shall pay application fees”; and

(iii) by striking “; and” at the end and inserting a period.

(e) EFFECT OF FAILURE TO PAY FEES.—Section 736(e) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 379h(e)) is amended by striking “all fees” and inserting “all such fees”.

(f) LIMITATIONS.—Section 736(f)(2) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 379h(f)(2)) is amended by striking “supplements, prescription drug establishments, and prescription drug products” and inserting “prescription drug program fees”.

(g) CREDITING AND AVAILABILITY OF FEES.—Section 736(g) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 379h(g)) is amended—

(1) in paragraph (3)—

(A) by striking “2013 through 2017” and inserting “2018 through 2022”;

and

(B) by striking “and paragraph (4) of this subsection”; and

(2) by striking paragraph (4).

(h) ORPHAN DRUGS.—Section 736(k) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 379h(k)) is amended by striking “product and establishment fees” each place it appears and inserting “prescription drug program fees”.

SEC. 103. REAUTHORIZATION; REPORTING REQUIREMENTS.

Section 736B of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 379h–2) is amended—

(1) in subsection (a)(1)—

(A) in the matter before subparagraph (A), by striking “2013” and inserting “2018”; and

(B) in subparagraph (A), by striking “Prescription Drug User Fee Amendments of 2012” and inserting “Prescription Drug User Fee Amendments of 2017”;

(2) in subsection (b), by striking “2013” and inserting “2018”; and

(3) in subsection (d), by striking “2017” each place it appears and inserting “2022”.

SEC. 104. SUNSET DATES.

(a) AUTHORIZATION.—Sections 735 and 736 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 379g; 379h) shall cease to be effective October 1, 2022.

(b) REPORTING REQUIREMENTS.—Section 736B of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 379h–2) shall cease to be effective January 31, 2023.

(c) PREVIOUS SUNSET PROVISION.—Effective October 1, 2017, subsections (a) and (b) of section 105 of the Food and Drug Administration Safety and Innovation Act (Public Law 112–144) are repealed.

SEC. 105. EFFECTIVE DATE.

The amendments made by this title shall take effect on October 1, 2017, or the date of the enactment of this Act, whichever is later, except that fees under part 2 of subchapter C of chapter VII of the Federal Food, Drug, and Cosmetic Act shall be assessed for all human drug applications received on or after October 1, 2017, regardless of the date of the enactment of this Act.

SEC. 106. SAVINGS CLAUSE.

Notwithstanding the amendments made by this title, part 2 of subchapter C of chapter VII of the Federal Food, Drug, and Cosmetic Act, as in effect on the day before the date of the enactment of this title, shall continue to be in effect with respect to human drug applications and supplements (as defined in such part as of such day) that on or after October 1, 2012, but before October 1, 2017, were accepted by the Food and Drug Administration for filing with respect to assessing and collecting any fee required by such part for a fiscal year prior to fiscal year 2018.

TITLE II—FEES RELATING TO DEVICES

SEC. 201. SHORT TITLE; FINDINGS.

(a) SHORT TITLE.—This title may be cited as the “Medical Device User Fee Amendments of 2017”.

(b) FINDINGS.—The Congress finds that the fees authorized under the amendments made by this title will be dedicated toward expediting the process for the review of device applications and for assuring the safety and effectiveness of devices, as set forth in the goals identified for purposes of part 3 of subchapter C of chapter VII of the Federal Food, Drug, and Cosmetic Act in the letters from the Secretary of Health and Human Services to the Chairman of the Committee on Health, Education, Labor, and Pensions of the Senate and the Chairman of the Committee on Energy and Commerce of the House of Representatives, as set forth in the Congressional Record.

SEC. 202. DEFINITIONS.

Section 737 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 379i) is amended—

- (1) by redesignating paragraphs (8) through (13) as paragraphs (9) through (14), respectively;
- (2) by inserting after paragraph (7) the following new paragraph:

“(8) The term ‘de novo classification request’ means a request made under section 513(f)(2)(A) with respect to the classification of a device.”;
- (3) in subparagraph (D) of paragraph (10) (as redesignated by paragraph (1)), by striking “and submissions” and inserting “submissions, and de novo classification requests”; and
- (4) in paragraph (11) (as redesignated by paragraph (1)), by striking “2011” and inserting “2016”.

SEC. 203. AUTHORITY TO ASSESS AND USE DEVICE FEES.

(a) TYPES OF FEES.—Section 738(a) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 379j(a)) is amended—

- (1) in paragraph (1), by striking “fiscal year 2013” and inserting “fiscal year 2018”; and
- (2) in paragraph (2)—
 - (A) in subparagraph (A)—
 - (i) in the matter preceding clause (i), by striking “October 1, 2012” and inserting “October 1, 2017”;
 - (ii) in clause (viii), by striking “2” and inserting “3.4”; and
 - (iii) by adding at the end the following new clause:

“(xi) For a de novo classification request, a fee equal to 30 percent of the fee that applies under clause (i).”; and
 - (B) in subparagraph (B)(v)(I), by striking “or premarket notification submission” and inserting “premarket notification submission, or de novo classification request”.

(b) FEE AMOUNTS.—Section 738(b) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 379j(b)) is amended to read as follows:

“(b) FEE AMOUNTS.—

“(1) IN GENERAL.—Subject to subsections (c), (d), (e), and (h), for each of fiscal years 2018 through 2022, fees under subsection (a) shall be derived from the base fee amounts specified in paragraph (2), to generate the total revenue amounts specified in paragraph (3).

“(2) BASE FEE AMOUNTS SPECIFIED.—For purposes of paragraph (1), the base fee amounts specified in this paragraph are as follows:

“Fee Type	Fiscal Year 2018	Fiscal Year 2019	Fiscal Year 2020	Fiscal Year 2021	Fiscal Year 2022
Premarket Application	\$294,000	\$300,000	\$310,000	\$328,000	\$329,000
Establishment Registration	\$4,375	\$4,548	\$4,760	\$4,975	\$4,978

“(3) TOTAL REVENUE AMOUNTS SPECIFIED.—For purposes of paragraph (1), the total revenue amounts specified in this paragraph are as follows:

“(A) \$183,280,756 for fiscal year 2018.

“(B) \$190,654,875 for fiscal year 2019.

“(C) \$200,132,014 for fiscal year 2020.

“(D) \$211,748,789 for fiscal year 2021.

“(E) \$213,687,660 for fiscal year 2022.”.

(c) ANNUAL FEE SETTING; ADJUSTMENTS.—Section 738(c) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 379j(c)) is amended—

(1) in paragraph (1), by striking “2012” and inserting “2017”;

(2) in paragraph (2)—

(A) in subparagraph (A), by striking “2014” and inserting “2018”;

(B) by striking subparagraph (B) and inserting the following new subparagraph:

“(B) APPLICABLE INFLATION ADJUSTMENT.—The applicable inflation adjustment for fiscal year 2018 and each subsequent fiscal year is the product of—

“(i) the base inflation adjustment under subparagraph (C) for such fiscal year; and

“(ii) the product of the base inflation adjustment under subparagraph (C) for each of the fiscal years preceding such fiscal year, beginning with fiscal year 2016.”;

(C) in subparagraph (C), in the heading, by striking “TO TOTAL REVENUE AMOUNTS”; and

(D) by amending subparagraph (D) to read as follows:

“(D) ADJUSTMENT TO BASE FEE AMOUNTS.—For each of fiscal years 2018 through 2022, the Secretary shall—

“(i) adjust the base fee amounts specified in subsection (b)(2) for such fiscal year by multiplying such amounts by the applicable inflation adjustment under subparagraph (B) for such year; and

“(ii) if the Secretary determines necessary, increase (in addition to the adjustment under clause (i)) such base fee amounts, on a uniform proportionate basis, to generate the total revenue amounts under subsection (b)(3), as adjusted for inflation under subparagraph (A).”; and

(3) in paragraph (3)—

(A) by striking “2014 through 2017” and inserting “2018 through 2022”; and

(B) by striking “further adjusted” and inserting “increased”.

(d) SMALL BUSINESSES; FEE WAIVER AND FEE REDUCTION REGARDING PREMARKET APPROVAL FEES.—Section 738(d) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 379j(d)) is amended—

(1) in paragraph (1), by striking “specified in clauses (i) through (v) and clauses (vii), (ix), and (x)” and inserting “specified in clauses (i) through (vii) and clauses (ix), (x), and (xi)”; and

(2) in paragraph (2)(C)—

(A) by striking “supplement, or” and inserting “supplement,”; and

(B) by inserting “, or a de novo classification request” after “class III device”.

(e) SMALL BUSINESSES; FEE REDUCTION REGARDING PREMARKET NOTIFICATION SUBMISSIONS.—Section 738(e)(2)(C) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 379j(e)(2)(C)) is amended by striking “50” and inserting “25”.

(f) FEE WAIVER OR REDUCTION.—

(1) REPEAL.—Section 738 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 379j) is amended by striking subsection (f).

(2) CONFORMING CHANGES.—

(A) Section 515(c)(4)(A) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360e(c)(4)(A)) is amended by striking “738(h)” and inserting “738(g)”.

(B) Section 738 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 379j), as amended by paragraph (1), is further amended—

(i) by redesignating subsections (g) through (l) as subsections (f) through (k);

(ii) in subsection (a)(2)(A), by striking “(d), (e), and (f)” and inserting “(d) and (e)”; and

(iii) in subsection (a)(3)(A), by striking “and subsection (f)”.

(g) **EFFECT OF FAILURE TO PAY FEES.**—Subsection (f)(1), as redesignated, of section 738 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 379j) is amended—

(1) by striking “or periodic reporting concerning a class III device” and inserting “periodic reporting concerning a class III device, or de novo classification request”; and

(2) by striking “all fees” and inserting “all such fees”.

(h) **CONDITIONS.**—Subsection (g)(1)(A), as redesignated, of section 738 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 379j) is amended by striking “\$280,587,000” and inserting “\$320,825,000”.

(i) **CREDITING AND AVAILABILITY OF FEES.**—Subsection (h), as redesignated, of section 738 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 379j) is amended—

(1) in paragraph (3)—

(A) by striking “2013 through 2017” and inserting “2018 through 2022”; and

(B) by striking “subsection (c)” and all that follows through the period at the end and inserting “subsection (c).”; and

(2) by striking paragraph (4).

SEC. 204. REAUTHORIZATION; REPORTING REQUIREMENTS.

(a) **PERFORMANCE REPORTS.**—Section 738A(a) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 379j–1(a)) is amended—

(1) in paragraph (1)—

(A) in subparagraph (A)—

(i) by striking “2013” and inserting “2018”; and

(ii) by striking “the Medical Device User Fee Amendments of 2012” and inserting “the Medical Device User Fee Amendments of 2017”; and

(B) in subparagraph (B), by striking “the Medical Device User Fee Amendments Act of 2012” and inserting “the Medical Device User Fee Amendments of 2017”; and

(2) in paragraph (2), by striking “2013 through 2017” and inserting “2018 through 2022”.

(b) **REAUTHORIZATION.**—Section 738A(b) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 379j–1(b)) is amended—

(1) in paragraph (1), by striking “2017” and inserting “2022”; and

(2) in paragraph (5), by striking “2017” and inserting “2022”.

SEC. 205. CONFORMITY ASSESSMENT PILOT PROGRAM.

(a) **IN GENERAL.**—Section 514 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360d) is amended by adding at the end the following:

“(d) **PILOT ACCREDITATION SCHEME FOR CONFORMITY ASSESSMENT.**—

“(1) **IN GENERAL.**—The Secretary shall establish a pilot program under which—

“(A) testing laboratories may be accredited, by accreditation bodies meeting criteria specified by the Secretary, to assess the conformance of a device with certain standards recognized under this section; and

“(B) subject to paragraph (2), determinations by testing laboratories so accredited that a device conforms with such standard or standards shall be accepted by the Secretary for purposes of demonstrating such conformity under this section unless the Secretary finds that a particular such determination shall not be so accepted.

“(2) **SECRETARIAL REVIEW OF ACCREDITED LABORATORY DETERMINATIONS.**—The Secretary may—

“(A) review determinations by testing laboratories accredited pursuant to this subsection, including by conducting periodic audits of such determinations or processes of accredited bodies or testing laboratories and, following such review, taking additional measures under this Act, such as suspension or withdrawal of accreditation of such testing laboratory under paragraph (1)(A) or requesting additional information with respect to such device, as the Secretary determines appropriate; and

“(B) if the Secretary becomes aware of information materially bearing on safety or effectiveness of a device assessed for conformity by a testing laboratory so accredited, take such additional measures under this Act as the Secretary determines appropriate, such as suspension or withdrawal of accreditation of such testing laboratory under paragraph (1)(A), or requesting additional information with regard to such device.

“(3) IMPLEMENTATION AND REPORTING.—

“(A) PUBLIC MEETING.—The Secretary shall publish in the Federal Register a notice of a public meeting to be held no later than September 30, 2018, to discuss and obtain input and recommendations from stakeholders regarding the goals and scope of, and a suitable framework and procedures and requirements for, the pilot program under this subsection.

“(B) PILOT PROGRAM GUIDANCE.—The Secretary shall—

“(i) not later than September 30, 2019, issue draft guidance regarding the goals and implementation of the pilot program under this subsection; and

“(ii) not later than September 30, 2021, issue final guidance with respect to the implementation of such program.

“(C) PILOT PROGRAM INITIATION.—Not later than September 30, 2020, the Secretary shall initiate the pilot program under this subsection.

“(D) REPORT.—The Secretary shall make available on the website of the Food and Drug Administration an annual report on the progress of the pilot program under this subsection.

“(4) SUNSET.—As of October 1, 2022—

“(A) the authority for accreditation bodies to accredit testing laboratories pursuant to paragraph (1)(A) shall cease to have force or effect;

“(B) the Secretary—

“(i) may not accept a determination pursuant to paragraph (1)(B) made by a testing laboratory after such date; and

“(ii) may accept such a determination made prior to such date;

“(C) except for purposes of accepting a determination described in subparagraph (B)(ii), the Secretary shall not continue to recognize the accreditation of testing laboratories accredited under paragraph (1)(A); and

“(D) the Secretary may take actions in accordance with paragraph (2) with respect to the determinations made prior to such date and recognition of the accreditation of testing laboratories pursuant to determinations made prior to such date.”.

SEC. 206. REAUTHORIZATION OF REVIEW.

Section 523 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360m) is amended—

(1) in subsection (a)(3)—

(A) in subparagraph (A), by striking clauses (ii) and (iii) and inserting the following:

“(ii) a device classified under section 513(f)(2) or designated under section 515C(d); or

“(iii) a device that is of a type, or subset of a type, listed as not eligible for review under subparagraph (B)(iii).”;

(B) by striking subparagraph (B) and inserting the following:

“(B) DESIGNATION FOR REVIEW.—The Secretary shall—

“(i) issue draft guidance on the factors the Secretary will use in determining whether a class I or class II device type, or subset of such device types, is eligible for review by an accredited person, including—

“(I) the risk of the device type, or subset of such device type; and

“(II) whether the device type, or subset of such device type, is permanently implantable, life sustaining, or life supporting;

“(ii) not later than 24 months after the date on which the Secretary issues such draft guidance, finalize such guidance; and

“(iii) beginning on the date such guidance is finalized, designate and post on the internet website of the Food and Drug Administration, an updated list of class I and class II device types, or subsets of such device types, and the Secretary’s determination with respect to whether each such device type, or subset of a device type, is eligible or not eligible for review by an accredited person under this section based on the factors described in clause (i).”;

(C) by adding at the end the following:

“(C) INTERIM RULE.—Until the date on which the updated list is designated and posted in accordance with subparagraph (B)(iii), the list in ef-

- fect on the date of enactment the Medical Device User Fee Amendments of 2017 shall be in effect.”;
- (2) in subsection (b)—
- (A) in paragraph (2)—
 - (i) by striking subparagraph (D); and
 - (ii) by redesignating subparagraph (E) as subparagraph (D); and
 - (B) in paragraph (3)—
 - (i) by redesignating subparagraph (E) as subparagraph (F);
 - (ii) in subparagraph (F) (as so redesignated), by striking “The operations of” and all that follows through “it will—” and inserting “Such person shall agree, at a minimum, to include in its request for accreditation a commitment to, at the time of accreditation, and at any time it is performing any review pursuant to this section—”; and
 - (iii) by inserting after subparagraph (D) the following new subparagraph:
 - “(E) The operations of such person shall be in accordance with generally accepted professional and ethical business practices.”; and
- (3) in subsection (c), by striking “2017” and inserting “2022”.

SEC. 207. ELECTRONIC FORMAT FOR SUBMISSIONS.

Section 745A(b) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 379k–1(b)) is amended by adding at the end the following new paragraph:

- “(3) PRESUBMISSIONS AND SUBMISSIONS SOLELY IN ELECTRONIC FORMAT.—
- “(A) IN GENERAL.—Beginning on such date as the Secretary specifies in final guidance issued under subparagraph (C), presubmissions and submissions for devices described in paragraph (1) (and any appeals of action taken by the Secretary with respect to such presubmissions or submissions) shall be submitted solely in such electronic format as specified by the Secretary in such guidance.
- “(B) DRAFT GUIDANCE.—The Secretary shall, not later than October 1, 2019, issue draft guidance providing for—
- “(i) any further standards for the submission by electronic format required under subparagraph (A);
 - “(ii) a timetable for the establishment by the Secretary of such further standards; and
 - “(iii) criteria for waivers of and exemptions from the requirements of this subsection.
- “(C) FINAL GUIDANCE.—The Secretary shall, not later than 12 months after the close of the public comment period on the draft guidance issued under subparagraph (B), issue final guidance described in clauses (i) through (iii) of such subparagraph.”.

SEC. 208. SAVINGS CLAUSE.

Notwithstanding the amendments made by this title, part 3 of subchapter C of chapter VII of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 379i et seq.), as in effect on the day before the date of the enactment of this title, shall continue to be in effect with respect to the submissions listed in section 738(a)(2)(A) of such Act (as defined in such part as of such day) that on or after October 1, 2012, but before October 1, 2017, were accepted by the Food and Drug Administration for filing with respect to assessing and collecting any fee required by such part for a fiscal year prior to fiscal year 2018.

SEC. 209. EFFECTIVE DATE.

The amendments made by this title shall take effect on October 1, 2017, or the date of the enactment of this Act, whichever is later, except that fees under part 3 of subchapter C of chapter VII of the Federal Food, Drug, and Cosmetic Act shall be assessed for all submissions listed in section 738(a)(2)(A) of such Act received on or after October 1, 2017, regardless of the date of the enactment of this Act.

SEC. 210. SUNSET CLAUSE.

- (a) AUTHORIZATION.—Sections 737 and 738 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 739i; 739j) shall cease to be effective October 1, 2022.
- (b) REPORTING REQUIREMENTS.—Section 738A (21 U.S.C. 739j–1) of the Federal Food, Drug, and Cosmetic Act (regarding reauthorization and reporting requirements) shall cease to be effective January 31, 2023.
- (c) PREVIOUS SUNSET PROVISION.—Effective October 1, 2017, section 207(a) of the Medical Device User Fee Amendments of 2012 (Public Law 112–144) is repealed.

TITLE III—FEES RELATING TO GENERIC DRUGS

SEC. 301. SHORT TITLE; FINDING.

(a) **SHORT TITLE.**—This title may be cited as the “Generic Drug User Fee Amendments of 2017”.

(b) **FINDING.**—The Congress finds that the fees authorized by the amendments made in this title will be dedicated to human generic drug activities, as set forth in the goals identified for purposes of part 7 of subchapter C of chapter VII of the Federal Food, Drug, and Cosmetic Act, in the letters from the Secretary of Health and Human Services to the Chairman of the Committee on Health, Education, Labor, and Pensions of the Senate and the Chairman of the Committee on Energy and Commerce of the House of Representatives, as set forth in the Congressional Record.

SEC. 302. DEFINITIONS.

Section 744A of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 379j–41) is amended—

(1) in paragraph (1)(B), by striking “application for a positron emission tomography drug.” and inserting “application—

“(i) for a positron emission tomography drug; or

“(ii) submitted by a State or Federal governmental entity for a drug that is not distributed commercially.”;

(2) by redesignating paragraphs (5) through (12) as paragraphs (6) through (13), respectively; and

(3) by inserting after paragraph (4) the following:

“(5) The term ‘contract manufacturing organization facility’ means a manufacturing facility of a finished dosage form of a drug approved pursuant to an abbreviated new drug application, where such manufacturing facility is not identified in an approved abbreviated new drug application held by the owner of such facility or an affiliate of such owner or facility.”.

SEC. 303. AUTHORITY TO ASSESS AND USE HUMAN GENERIC DRUG FEES.

(a) **TYPES OF FEES.**—Section 744B(a) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 379j–42(a)) is amended—

(1) in the matter preceding paragraph (1), by striking “fiscal year 2013” and inserting “fiscal year 2018”;

(2) in paragraph (1), by adding at the end the following:

“(E) **SUNSET.**—This paragraph shall cease to be effective October 1, 2022.”;

(3) in paragraph (2)—

(A) by amending subparagraph (C) to read as follows:

“(C) **NOTICE.**—Not later than 60 days before the start of each of fiscal years 2018 through 2022, the Secretary shall publish in the Federal Register the amount of the drug master file fee established by this paragraph for such fiscal year.”; and

(B) in subparagraph (E)—

(i) in clause (i)—

(I) by striking “no later than the date” and inserting “on the earlier of—

“(I) the date”;

(II) by striking the period and inserting “; or”; and

(III) by adding at the end the following:

“(II) the date on which the drug master file holder requests the initial completeness assessment.”; and

(ii) in clause (ii), by striking “notice provided for in clause (i) or (ii) of subparagraph (C), as applicable” and inserting “notice provided for in subparagraph (C)”;

(4) in paragraph (3)—

(A) in the heading, by striking “AND PRIOR APPROVAL SUPPLEMENT”;

(B) in subparagraph (A), by striking “or a prior approval supplement to an abbreviated new drug application”;

(C) by amending subparagraphs (B) and (C) to read as follows:

“(B) **NOTICE.**—Not later than 60 days before the start of each of fiscal years 2018 through 2022, the Secretary shall publish in the Federal Register the amount of the fees under subparagraph (A) for such fiscal year.

“(C) FEE DUE DATE.—The fees required by subparagraphs (A) and (F) shall be due no later than the date of submission of the abbreviated new drug application or prior approval supplement for which such fee applies.”;

(D) in subparagraph (D)—

(i) in the heading, by inserting “, IS WITHDRAWN PRIOR TO BEING RECEIVED, OR IS NO LONGER RECEIVED” after “RECEIVED”; and

(ii) by striking “The Secretary shall” and all that follows through the period and inserting the following:

“(i) APPLICATIONS NOT CONSIDERED TO HAVE BEEN RECEIVED AND APPLICATIONS WITHDRAWN PRIOR TO BEING RECEIVED.—The Secretary shall refund 75 percent of the fee paid under subparagraph (A) for any abbreviated new drug application that the Secretary considers not to have been received within the meaning of section 505(j)(5)(A) for a cause other than failure to pay fees, or that has been withdrawn prior to being received within the meaning of section 505(j)(5)(A).

“(ii) APPLICATIONS NO LONGER RECEIVED.—The Secretary shall refund 100 percent of the fee paid under subparagraph (A) for any abbreviated new drug application if the Secretary initially receives the application under section 505(j)(5)(A) and subsequently determines that an exclusivity period for a listed drug should have prevented the Secretary from receiving such application, such that the abbreviated new drug application is no longer received within the meaning of section 505(j)(5)(A).”;

(E) in subparagraph (E), by striking “or prior approval supplement”; and (F) in the matter preceding clause (i) of subparagraph (F)—

(i) by striking “2012” and inserting “2017”; and

(ii) by striking “subsection (d)(3)” and inserting “subsection (d)(2)”;

(5) in paragraph (4)—

(A) in subparagraph (A)—

(i) in the matter preceding clause (i) and in clause (iii), by striking “, or intended to be identified, in at least one generic drug submission that is pending or” and inserting “in at least one generic drug submission that is”;

(ii) in clause (i), by striking “or intended to be identified in at least one generic drug submission that is pending or” and inserting “in at least one generic drug submission that is”;

(iii) in clause (ii), by striking “produces,” and all that follows through “such a” and inserting “is identified in at least one generic drug submission in which the facility is approved to produce one or more active pharmaceutical ingredients or in a Type II active pharmaceutical ingredient drug master file referenced in at least one such”; and

(iv) in clause (iii), by striking “to fees under both such clauses” and inserting “only to the fee attributable to the manufacture of the finished dosage forms”; and

(B) by amending subparagraphs (C) and (D) to read as follows:

“(C) NOTICE.—Within the timeframe specified in subsection (d)(1), the Secretary shall publish in the Federal Register the amount of the fees under subparagraph (A) for such fiscal year.

“(D) FEE DUE DATE.—For each of fiscal years 2018 through 2022, the fees under subparagraph (A) for such fiscal year shall be due on the later of—

“(i) the first business day on or after October 1 of each such year; or

“(ii) the first business day after the enactment of an appropriations

Act providing for the collection and obligation of fees for such year under this section for such year.”;

(6) by redesignating paragraph (5) as paragraph (6); and

(7) by inserting after paragraph (4) the following:

“(5) GENERIC DRUG APPLICANT PROGRAM FEE.—

“(A) IN GENERAL.—A generic drug applicant program fee shall be assessed annually as described in subsection (b)(2)(E).

“(B) AMOUNT.—The amount of fees established under subparagraph (A) shall be established under subsection (d).

“(C) NOTICE.—Within the timeframe specified in subsection (d)(1), the Secretary shall publish in the Federal Register the amount of the fees under subparagraph (A) for such fiscal year.

“(D) FEE DUE DATE.—For each of fiscal years 2018 through 2022, the fees under subparagraph (A) for such fiscal year shall be due on the later of—

“(i) the first business day on or after October 1 of each such fiscal year; or

“(ii) the first business day after the date of enactment of an appropriations Act providing for the collection and obligation of fees for such fiscal year under this section for such fiscal year.”.

(b) FEE REVENUE AMOUNTS.—Section 744B(b) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 379j–42(b)) is amended—

(1) in paragraph (1)—

(A) in subparagraph (A)—

- (i) in the heading, by striking “2013” and inserting “2018”;
- (ii) by striking “2013” and inserting “2018”;
- (iii) by striking “\$299,000,000” and inserting “\$493,600,000”; and
- (iv) by striking “Of that amount” and all that follows through the end of clause (ii); and

(B) in subparagraph (B)—

- (i) in the heading, by striking “2014 THROUGH 2017” and inserting “2019 THROUGH 2022”;
- (ii) by striking “2014 through 2017” and inserting “2019 through 2022”;
- (iii) by striking “paragraphs (2) through (4)” and inserting “paragraphs (2) through (5)”;
- (iv) by striking “\$299,000,000” and inserting “\$493,600,000”; and

(2) in paragraph (2)—

(A) in the matter preceding subparagraph (A)—

- (i) by striking “paragraph (1)(A)(ii) for fiscal year 2013 and paragraph (1)(B) for each of fiscal years 2014 through 2017” and inserting “such paragraph for a fiscal year”; and
- (ii) by striking “through (4)” and inserting “through (5)”;

(B) in subparagraph (A), by striking “Six percent” and inserting “Five percent”;

(C) by amending subparagraphs (B) and (C) to read as follows:

“(B) Thirty-three percent shall be derived from fees under subsection (a)(3) (relating to abbreviated new drug applications).

“(C) Twenty percent shall be derived from fees under subsection (a)(4)(A)(i) (relating to generic drug facilities). The amount of the fee for a contract manufacturing organization facility shall be equal to one-third the amount of the fee for a facility that is not a contract manufacturing organization facility. The amount of the fee for a facility located outside the United States and its territories and possessions shall be \$15,000 higher than the amount of the fee for a facility located in the United States and its territories and possessions.”;

(D) in subparagraph (D)—

- (i) by striking “Fourteen percent” and inserting “Seven percent”;
- (ii) by striking “not less than \$15,000 and not more than \$30,000” and inserting “\$15,000”; and
- (iii) by striking “, as determined” and all that follows through the period at the end and inserting a period; and

(E) by adding at the end the following:

“(E)(i) Thirty-five percent shall be derived from fees under subsection (a)(5) (relating to generic drug applicant program fees). For purposes of this subparagraph, if a person has affiliates, a single program fee shall be assessed with respect to that person, including its affiliates, and may be paid by that person or any one of its affiliates. The Secretary shall determine the fees as follows:

“(I) If a person (including its affiliates) owns at least one but not more than 5 approved abbreviated new drug applications on the due date for the fee under this subsection, the person (including its affiliates) shall be assessed a small business generic drug applicant program fee equal to one-tenth of the large size operation generic drug applicant program fee.

“(II) If a person (including its affiliates) owns at least 6 but not more than 19 approved abbreviated new drug applications on the due date for the fee under this subsection, the person (including its affiliates) shall be assessed a medium size operation generic drug applicant program fee equal to two-fifths of the large size operation generic drug applicant program fee.

“(III) If a person (including its affiliates) owns 20 or more approved abbreviated new drug applications on the due date for the fee under this subsection, the person (including its affiliates) shall be assessed a large size operation generic drug applicant program fee.

“(ii) For purposes of this subparagraph, an abbreviated new drug application shall be deemed not to be approved if the applicant has submitted a written request for withdrawal of approval of such abbreviated new drug application by April 1 of the previous fiscal year.”.

(c) ADJUSTMENTS.—Section 744B(c) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 379j–42(c)) is amended—

(1) in paragraph (1)—

(A) by striking “2014” and inserting “2019”;

(B) by inserting “to equal the product of the total revenues established in such notice for the prior fiscal year multiplied” after “a fiscal year,”; and

(C) by striking the flush text following subparagraph (C); and

(2) in paragraph (2)—

(A) by striking “2017” each place it appears and inserting “2022”;

(B) by striking “the first 3 months of fiscal year 2018” and inserting “the first 3 months of fiscal year 2023”; and

(C) by striking “Such fees may only be used in fiscal year 2018.”.

(d) ANNUAL FEE SETTING.—Section 744B(d) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 379j–42(d)) is amended—

(1) by striking paragraphs (1) and (2) and inserting the following:

“(1) FISCAL YEARS 2018 THROUGH 2022.—Not more than 60 days before the first day of each of fiscal years 2018 through 2022, the Secretary shall establish the fees described in paragraphs (2) through (5) of subsection (a), based on the revenue amounts established under subsection (b) and the adjustments provided under subsection (c).”;

(2) by redesignating paragraph (3) as paragraph (2); and

(3) in paragraph (2) (as so redesignated), in the matter preceding subparagraph (A), by striking “fees under paragraphs (1) and (2)” and inserting “fee under paragraph (1)”.

(e) IDENTIFICATION OF FACILITIES.—Section 744B(f) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 379j–42(f)) is amended—

(1) by striking paragraph (1);

(2) by redesignating paragraphs (2) through (4) as paragraphs (1) through (3), respectively;

(3) in paragraph (1) (as so redesignated)—

(A) by striking “paragraph (4)” and inserting “paragraph (3)”; and

(B) by striking “Such information shall” and all that follows through the end of subparagraph (B) and inserting “Such information shall, for each fiscal year, be submitted, updated, or reconfirmed on or before June 1 of the previous fiscal year.”; and

(4) in paragraph (2), as so redesignated—

(A) in the heading, by striking “CONTENTS OF NOTICE” and inserting “INFORMATION REQUIRED TO BE SUBMITTED”;

(B) in the matter preceding subparagraph (A), by striking “paragraph (2)” and inserting “paragraph (1)”;

(C) in subparagraph (A), by striking “or intended to be identified”;

(D) in subparagraph (D), by striking “and” at the end;

(E) in subparagraph (E), by striking the period and inserting “; and”; and

(F) by adding at the end the following:

“(F) whether the facility is a contract manufacturing organization facility.”.

(f) EFFECT OF FAILURE TO PAY FEES.—Section 744B(g) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 379–42(g)) is amended—

(1) in paragraph (1), by adding at the end the following: “This paragraph shall cease to be effective on October 1, 2022.”;

(2) in paragraph (2)(C)(ii), by striking “of 505(j)(5)(A)” and inserting “of section 505(j)(5)(A)”;

(3) by adding at the end the following:

“(5) GENERIC DRUG APPLICANT PROGRAM FEE.—

“(A) IN GENERAL.—A person who fails to pay a fee as required under subsection (a)(5) by the date that is 20 calendar days after the due date, as specified in subparagraph (D) of such subsection, shall be subject to the following:

“(i) The Secretary shall place the person on a publicly available arrears list.

“(ii) Any abbreviated new drug application submitted by the generic drug applicant or an affiliate of such applicant shall not be received, within the meaning of section 505(j)(5)(A).

“(iii) All drugs marketed pursuant to any abbreviated new drug application held by such applicant or an affiliate of such applicant shall be deemed misbranded under section 502(aa).

“(B) APPLICATION OF PENALTIES.—The penalties under subparagraph (A) shall apply until the fee required under subsection (a)(5) is paid.”

(g) LIMITATIONS.—Section 744B(h)(2) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 379–42(h)(2)) is amended by striking “for Type II active pharmaceutical ingredient drug master files, abbreviated new drug applications and prior approval supplements, and generic drug facilities and active pharmaceutical ingredient facilities”.

(h) CREDITING AND AVAILABILITY OF FEES.—Section 744B(i) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 379–42(i)) is amended—

(1) in paragraph (2)—

(A) by striking subparagraph (C) (relating to fee collection during first program year);

(B) in subparagraph (D)—

(i) in the heading, by striking “IN SUBSEQUENT YEARS”; and

(ii) by striking “(after fiscal year 2013)”; and

(C) by redesignating subparagraph (D) as subparagraph (C); and

(2) in paragraph (3), by striking “fiscal years 2013 through 2017” and inserting “fiscal years 2018 through 2022”.

(i) INFORMATION ON ABBREVIATED NEW DRUG APPLICATIONS OWNED BY APPLICANTS AND THEIR AFFILIATES.—Section 744B of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 379–42) is amended by adding at the end the following:

“(o) INFORMATION ON ABBREVIATED NEW DRUG APPLICATIONS OWNED BY APPLICANTS AND THEIR AFFILIATES.—

“(1) IN GENERAL.—By April 1 of each year, each person that owns an abbreviated new drug application, or any affiliate of such person, shall submit, on behalf of the person and its affiliates, to the Secretary a list of—

“(A) all approved abbreviated new drug applications owned by such person; and

“(B) if any affiliate of such person also owns an abbreviated new drug application, all affiliates that own any such abbreviated new drug applications and all approved abbreviated new drug applications owned by any such affiliate.

“(2) FORMAT AND METHOD.—The Secretary shall specify in guidance the format and method for submission of lists under this subsection.”.

SEC. 304. REAUTHORIZATION; REPORTING REQUIREMENTS.

Section 744C of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 379j–43) is amended—

(1) in subsection (a)—

(A) by striking “2013” and inserting “2018”; and

(B) by striking “Generic Drug User Fee Amendments of 2012” and inserting “Generic Drug User Fee Amendments of 2017”;

(2) in subsection (b), by striking “2013” and inserting “2018”; and

(3) in subsection (d), by striking “2017” each place it appears and inserting “2022”.

SEC. 305. SUNSET DATES.

(a) AUTHORIZATION.—Sections 744A and 744B of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 379j–41; 379j–42) shall cease to be effective October 1, 2022.

(b) REPORTING REQUIREMENTS.—Section 744C of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 379j–43) shall cease to be effective January 31, 2023.

(c) PREVIOUS SUNSET PROVISION.—Effective October 1, 2017, subsections (a) and (b) of section 304 of the Food and Drug Administration Safety and Innovation Act (Public Law 112–144) are repealed.

SEC. 306. EFFECTIVE DATE.

The amendments made by this title shall take effect on October 1, 2017, or the date of the enactment of this Act, whichever is later, except that fees under part 7 of subchapter C of chapter VII of the Federal Food, Drug, and Cosmetic Act shall be assessed for all abbreviated new drug applications received on or after October 1, 2017, regardless of the date of the enactment of this Act.

SEC. 307. SAVINGS CLAUSE.

Notwithstanding the amendments made by this title, part 7 of subchapter C of chapter VII of the Federal Food, Drug, and Cosmetic Act, as in effect on the day before the date of the enactment of this title, shall continue to be in effect with respect to abbreviated new drug applications (as defined in such part as of such day) that on or after October 1, 2012, but before October 1, 2017, were received by the

Food and Drug Administration within the meaning of section 505(j)(5)(A) of such Act (21 U.S.C. 355(j)(5)(A)), prior approval supplements that were submitted, and drug master files for Type II active pharmaceutical ingredients that were first referenced with respect to assessing and collecting any fee required by such part for a fiscal year prior to fiscal year 2018.

TITLE IV—FEES RELATING TO BIOSIMILAR BIOLOGICAL PRODUCTS

SEC. 401. SHORT TITLE; FINDING.

(a) **SHORT TITLE.**—This title may be cited as the “Biosimilar User Fee Amendments of 2017”.

(b) **FINDING.**—The Congress finds that the fees authorized by the amendments made in this title will be dedicated to expediting the process for the review of biosimilar biological product applications, including postmarket safety activities, as set forth in the goals identified for purposes of part 8 of subchapter C of chapter VII of the Federal Food, Drug, and Cosmetic Act, in the letters from the Secretary of Health and Human Services to the Chairman of the Committee on Health, Education, Labor, and Pensions of the Senate and the Chairman of the Committee on Energy and Commerce of the House of Representatives, as set forth in the Congressional Record.

SEC. 402. DEFINITIONS.

(a) **ADJUSTMENT FACTOR.**—Section 744G(1) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 379j–51(1)) is amended to read as follows:

“(1) The term ‘adjustment factor’ applicable to a fiscal year is the Consumer Price Index for urban consumers (Washington-Baltimore, DC–MD–VA–WV; Not Seasonally Adjusted; All items; Annual Index) for October of the preceding fiscal year divided by such Index for October 2011.”

(b) **BIOSIMILAR BIOLOGICAL PRODUCT.**—Section 744G(3) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 379j–51(3)) is amended by striking “means a product” and inserting “means a specific strength of a biological product in final dosage form”.

SEC. 403. AUTHORITY TO ASSESS AND USE BIOSIMILAR FEES.

(a) **TYPES OF FEES.**—Section 744H(a) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 379j–52(a)) is amended—

(1) in the matter preceding paragraph (1), by striking “fiscal year 2013” and inserting “fiscal year 2018”;

(2) in the heading of paragraph (1), by striking “BIOSIMILAR” and inserting “BIOSIMILAR BIOLOGICAL PRODUCT”;

(3) in paragraph (1)(A)(i), by striking “(b)(1)(A)” and inserting “(c)(5)”;

(4) in paragraph (1)(B)(i), by striking “(b)(1)(B) for biosimilar biological product development” and inserting “(c)(5) for the biosimilar biological product development program”;

(5) in paragraph (1)(B)(ii), by striking “annual biosimilar biological product development program fee” and inserting “annual biosimilar biological product development fee”;

(6) in paragraph (1)(B)(iii), by striking “annual biosimilar development program fee” and inserting “annual biosimilar biological product development fee”;

(7) in paragraph (1)(B), by adding at the end the following:

“(iv) **REFUND.**—If a person submits a marketing application for a biosimilar biological product before October 1 of a fiscal year and such application is accepted for filing on or after October 1 of such fiscal year, the person may request a refund equal to the annual biosimilar development fee paid by the person for the product for such fiscal year. To qualify for consideration for a refund under this clause, a person shall submit to the Secretary a written request for such refund not later than 180 days after the marketing application is accepted for filing.”;

(8) in paragraph (1)(C), by striking “for a product effective October 1 of a fiscal year by,” and inserting “for a product, effective October 1 of a fiscal year, by,”;

(9) in paragraph (1)(D)—

(A) in clause (i) in the matter preceding subclause (I), by inserting “, if the person seeks to resume participation in such program,” before “pay a fee”;

(B) in clause (i)(I), by inserting after “grants a request” the following: “by such person”; and

- (C) in clause (i)(II), by inserting after “discontinued)” the following: “by such person”;
- (10) in the heading of paragraph (1)(E), by striking “BIOSIMILAR DEVELOPMENT PROGRAM”;
- (11) in paragraph (1)(F)—
- (A) in the subparagraph heading, by striking “BIOSIMILAR DEVELOPMENT PROGRAM” before “FEES”; and
- (B) by amending clause (i) to read as follows:
- “(i) REFUNDS.—Except as provided in subparagraph (B)(iv), the Secretary shall not refund any initial or annual biosimilar biological product development fee paid under subparagraph (A) or (B), or any reactivation fee paid under subparagraph (D).”;
- (12) in paragraph (2)—
- (A) in the paragraph heading, by striking “AND SUPPLEMENT”;
- (B) by amending subparagraphs (A) and (B) to read as follows:
- “(A) IN GENERAL.—Each person that submits, on or after October 1, 2017, a biosimilar biological product application shall be subject to the following fees:
- “(i) A fee established under subsection (c)(5) for a biosimilar biological product application for which clinical data (other than comparative bioavailability studies) with respect to safety or effectiveness are required for approval.
- “(ii) A fee established under subsection (c)(5) for a biosimilar biological product application for which clinical data (other than comparative bioavailability studies) with respect to safety or effectiveness are not required for approval. Such fee shall be equal to half of the amount of the fee described in clause (i).
- “(B) RULE OF APPLICABILITY; TREATMENT OF CERTAIN PREVIOUSLY PAID FEES.—Any person who pays a fee under subparagraph (A), (B), or (D) of paragraph (1) for a product before October 1, 2017, but submits a biosimilar biological product application for that product after such date, shall—
- “(i) be subject to any biosimilar biological product application fees that may be assessed at the time when such biosimilar biological product application is submitted; and
- “(ii) be entitled to no reduction of such application fees based on the amount of fees paid for that product before October 1, 2017, under such subparagraphs (A), (B), or (D).”;
- (C) in the heading of subparagraph (D), by striking “OR SUPPLEMENT”;
- (D) in subparagraphs (C) through (F), by striking “or supplement” each place it appears; and
- (E) in subparagraph (D), by striking “or a supplement”;
- (13) by amending paragraph (3) to read as follows:
- “(3) BIOSIMILAR BIOLOGICAL PRODUCT PROGRAM FEE.—
- “(A) IN GENERAL.—Each person who is named as the applicant in a biosimilar biological product application shall pay the annual biosimilar biological product program fee established for a fiscal year under subsection (c)(5) for each biosimilar biological product that—
- “(i) is identified in such a biosimilar biological product application approved as of October 1 of such fiscal year; and
- “(ii) as of October 1 of such fiscal year, does not appear on a list, developed and maintained by the Secretary, of discontinued biosimilar biological products.
- “(B) DUE DATE.—The biosimilar biological product program fee for a fiscal year shall be due on the later of—
- “(i) the first business day on or after October 1 of each such year; or
- “(ii) the first business day after the enactment of an appropriations Act providing for the collection and obligation of fees for such year under this section.
- “(C) ONE FEE PER PRODUCT PER YEAR.—The biosimilar biological product program fee shall be paid only once for each product for each fiscal year.
- “(D) LIMITATION.—A person who is named as the applicant in a biosimilar biological product application shall not be assessed more than 5 biosimilar biological product program fees for a fiscal year for biosimilar biological products identified in such biosimilar biological product application.”.
- (b) FEE REVENUE AMOUNTS.—Subsection (b) of section 744H of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 379j–52) is amended to read as follows:
- “(b) FEE REVENUE AMOUNTS.—
- “(1) FISCAL YEAR 2018.—For fiscal year 2018, fees under subsection (a) shall be established to generate a total revenue amount equal to the sum of—

- “(A) \$45,000,000; and
“(B) the dollar amount equal to the fiscal year 2018 adjustment (as determined under subsection (c)(4)).
- “(2) SUBSEQUENT FISCAL YEARS.—For each of the fiscal years 2019 through 2022, fees under subsection (a) shall, except as provided in subsection (c), be established to generate a total revenue amount equal to the sum of—
“(A) the annual base revenue for the fiscal year (as determined under paragraph (4));
“(B) the dollar amount equal to the inflation adjustment for the fiscal year (as determined under subsection (c)(1));
“(C) the dollar amount equal to the capacity planning adjustment for the fiscal year (as determined under subsection (c)(2)); and
“(D) the dollar amount equal to the operating reserve adjustment for the fiscal year, if applicable (as determined under subsection (c)(3)).
- “(3) ALLOCATION OF REVENUE AMOUNT AMONG FEES; LIMITATIONS ON FEE AMOUNTS.—
“(A) ALLOCATION.—The Secretary shall determine the percentage of the total revenue amount for a fiscal year to be derived from, respectively—
“(i) initial and annual biosimilar development fees and reactivation fees under subsection (a)(1);
“(ii) biosimilar biological product application fees under subsection (a)(2); and
“(iii) biosimilar biological product program fees under subsection (a)(3).
“(B) LIMITATIONS ON FEE AMOUNTS.—Until the first fiscal year for which the capacity planning adjustment under subsection (c)(2) is effective, the amount of any fee under subsection (a) for a fiscal year after fiscal year 2018 shall not exceed 125 percent of the amount of such fee for fiscal year 2018.
“(C) BIOSIMILAR BIOLOGICAL PRODUCT DEVELOPMENT FEES.—The initial biosimilar biological product development fee under subsection (a)(1)(A) for a fiscal year shall be equal to the annual biosimilar biological product development fee under subsection (a)(1)(B) for that fiscal year.
“(D) REACTIVATION FEE.—The reactivation fee under subsection (a)(1)(D) for a fiscal year shall be equal to twice the amount of the annual biosimilar biological product development fee under subsection (a)(1)(B) for that fiscal year.
- “(4) ANNUAL BASE REVENUE.—For purposes of paragraph (2), the dollar amount of the annual base revenue for a fiscal year shall be the dollar amount of the total revenue amount for the previous fiscal year, excluding any adjustments to such revenue amount under subsection (c)(3).”
- (c) ADJUSTMENTS; ANNUAL FEE SETTING.—Section 744H of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 379j–52) is amended—
(1) by redesignating subsections (c) through (h) as subsections (d) through (i), respectively;
(2) in subsections (a)(2)(F) and (h) (as redesignated by paragraph (1)), by striking “subsection (c)” and inserting “subsection (d)”;
(3) in subsection (a)(4)(A), by striking “subsection (b)(1)(F)” and inserting “subsection (c)(5)”; and
(4) by inserting after subsection (b) the following:
“(c) ADJUSTMENTS; ANNUAL FEE SETTING.—
“(1) INFLATION ADJUSTMENT.—
“(A) IN GENERAL.—For purposes of subsection (b)(2)(B), the dollar amount of the inflation adjustment to the annual base revenue for each fiscal year shall be equal to the product of—
“(i) such annual base revenue for the fiscal year under subsection (b); and
“(ii) the inflation adjustment percentage under subparagraph (B).
“(B) INFLATION ADJUSTMENT PERCENTAGE.—The inflation adjustment percentage under this subparagraph for a fiscal year is equal to the sum of—
“(i) the average annual percent change in the cost, per full-time equivalent position of the Food and Drug Administration, of all personnel compensation and benefits paid with respect to such positions for the first 3 years of the preceding 4 fiscal years, multiplied by the proportion of personnel compensation and benefits costs to total costs of the process for the review of biosimilar biological product applications (as defined in section 744G(13)) for the first 3 years of the preceding 4 fiscal years; and

“(ii) the average annual percent change that occurred in the Consumer Price Index for urban consumers (Washington-Baltimore, DC-MD-VA-WV; Not Seasonally Adjusted; All items; Annual Index) for the first 3 years of the preceding 4 years of available data multiplied by the proportion of all costs other than personnel compensation and benefits costs to total costs of the process for the review of biosimilar biological product applications (as defined in section 744G(13)) for the first 3 years of the preceding 4 fiscal years.

“(2) CAPACITY PLANNING ADJUSTMENT.—

“(A) IN GENERAL.—Beginning with the fiscal year described in subparagraph (B)(ii)(II), the Secretary shall, in addition to the adjustment under paragraph (1), further increase the fee revenue and fees under this section for a fiscal year to reflect changes in the resource capacity needs of the Secretary for the process for the review of biosimilar biological product applications.

“(B) CAPACITY PLANNING METHODOLOGY.—

“(i) DEVELOPMENT; EVALUATION AND REPORT.—The Secretary shall obtain, through a contract with an independent accounting or consulting firm, a report evaluating options and recommendations for a new methodology to accurately assess changes in the resource and capacity needs of the process for the review of biosimilar biological product applications. The capacity planning methodological options and recommendations presented in such report shall utilize and be informed by personnel time reporting data as an input. The report shall be published for public comment not later than September 30, 2020.

“(ii) ESTABLISHMENT AND IMPLEMENTATION.—After review of the report described in clause (i) and receipt and review of public comments thereon, the Secretary shall establish a capacity planning methodology for purposes of this paragraph, which shall—

“(I) incorporate such approaches and attributes as the Secretary determines appropriate; and

“(II) be effective beginning with the first fiscal year for which fees are set after such capacity planning methodology is established.

“(C) LIMITATION.—Under no circumstances shall an adjustment under this paragraph result in fee revenue for a fiscal year that is less than the sum of the amounts under subsections (b)(2)(A) (the annual base revenue for the fiscal year) and (b)(2)(B) (the dollar amount of the inflation adjustment for the fiscal year).

“(D) PUBLICATION IN FEDERAL REGISTER.—The Secretary shall publish in the Federal Register notice under paragraph (5) the fee revenue and fees resulting from the adjustment and the methodologies under this paragraph.

“(3) OPERATING RESERVE ADJUSTMENT.—

“(A) INTERIM APPLICATION; FEE REDUCTION.—Until the first fiscal year for which the capacity planning adjustment under paragraph (2) is effective, the Secretary may, in addition to the adjustment under paragraph (1), reduce the fee revenue and fees under this section for a fiscal year as the Secretary determines appropriate for long-term financial planning purposes.

“(B) GENERAL APPLICATION AND METHODOLOGY.—Beginning with the first fiscal year for which the capacity planning adjustment under paragraph (2) is effective, the Secretary may, in addition to the adjustments under paragraphs (1) and (2)—

“(i) reduce the fee revenue and fees under this section as the Secretary determines appropriate for long-term financial planning purposes; or

“(ii) increase the fee revenue and fees under this section if such an adjustment is necessary to provide for not more than 21 weeks of operating reserves of carryover user fees for the process for the review of biosimilar biological product applications.

“(C) FEDERAL REGISTER NOTICE.—If an adjustment under subparagraph (A) or (B) is made, the rationale for the amount of the increase or decrease (as applicable) in fee revenue and fees shall be contained in the annual Federal Register notice under paragraph (5) establishing fee revenue and fees for the fiscal year involved.

“(4) FISCAL YEAR 2018 ADJUSTMENT.—

“(A) IN GENERAL.—For fiscal year 2018, the Secretary shall adjust the fee revenue and fees under this section in such amount (if any) as needed to reflect an updated assessment of the workload for the process for the review of biosimilar biological product applications.

“(B) **METHODOLOGY.**—The Secretary shall publish under paragraph (5) a description of the methodology used to calculate the fiscal year 2018 adjustment under this paragraph in the Federal Register notice establishing fee revenue and fees for fiscal year 2018.

“(C) **LIMITATION.**—No adjustment under this paragraph shall result in an increase in fee revenue and fees under this section in excess of \$9,000,000.

“(5) **ANNUAL FEE SETTING.**—For fiscal year 2018 and each subsequent fiscal year, the Secretary shall, not later than 60 days before the start of each such fiscal year—

“(A) establish, for the fiscal year, initial and annual biosimilar biological product development fees and reactivation fees under subsection (a)(1), biosimilar biological product application fees under subsection (a)(2), and biosimilar biological product program fees under subsection (a)(3), based on the revenue amounts established under subsection (b) and the adjustments provided under this subsection; and

“(B) publish such fee revenue and fees in the Federal Register.

“(6) **LIMIT.**—The total amount of fees assessed for a fiscal year under this section may not exceed the total costs for such fiscal year for the resources allocated for the process for the review of biosimilar biological product applications.”.

(d) **APPLICATION FEE WAIVER FOR SMALL BUSINESS.**—Subsection (d)(1) of section 744H of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 379j–52), as redesignated by subsection (c)(1), is amended—

(1) by striking subparagraph (B);

(2) by striking “shall pay—” and all that follows through “application fees” and inserting “shall pay application fees”; and

(3) by striking “; and” at the end and inserting a period.

(e) **EFFECT OF FAILURE TO PAY FEES.**—Subsection (e) of section 744H of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 379j–52), as redesignated by subsection (c)(1), is amended by striking “all fees” and inserting “all such fees”.

(f) **CREDITING AND AVAILABILITY OF FEES.**—Subsection (f) of section 744H of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 379j–52), as redesignated by subsection (c)(1), is amended—

(1) in paragraph (2)—

(A) by striking subparagraph (C) (relating to fee collection during first program year) and inserting the following:

“(C) **COMPLIANCE.**—The Secretary shall be considered to have met the requirements of subparagraph (B) in any fiscal year if the costs described in such subparagraph are not more than 15 percent below the level specified in such subparagraph.”; and

(B) in subparagraph (D)—

(i) in the heading, by striking “IN SUBSEQUENT YEARS”; and

(ii) by striking “(after fiscal year 2013)”; and

(2) in paragraph (3), by striking “2013 through 2017” and inserting “2018 through 2022”.

SEC. 404. REAUTHORIZATION; REPORTING REQUIREMENTS.

Section 744I of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 379j–53) is amended—

(1) in subsection (a)—

(A) by striking “2013” and inserting “2018”; and

(B) by striking “Biosimilar User Fee Act of 2012” and inserting “Biosimilar User Fee Amendments of 2017”;

(2) in subsection (b), by striking “2013” and inserting “2018”;

(3) by striking subsection (d);

(4) by redesignating subsection (e) as subsection (d); and

(5) in subsection (d), as so redesignated, by striking “2017” each place it appears and inserting “2022”.

SEC. 405. SUNSET DATES.

(a) **AUTHORIZATION.**—Sections 744G and 744H of the Federal Food, Drug, and Cosmetic Act, as amended by section 403 of this Act, shall cease to be effective October 1, 2022.

(b) **REPORTING REQUIREMENTS.**—Section 744I of the Federal Food, Drug, and Cosmetic Act, as amended by section 404 of this Act, shall cease to be effective January 31, 2023.

(c) **PREVIOUS SUNSET PROVISION.**—

(1) **IN GENERAL.**—Effective October 1, 2017, section 404 of the Food and Drug Administration Safety and Innovation Act (Public Law 112–144) is repealed.

(2) CONFORMING AMENDMENT.—The Food and Drug Administration Safety and Innovation Act (Public Law 112–144) is amended in the table of contents in section 2 by striking the item relating to section 404.

SEC. 406. EFFECTIVE DATE.

The amendments made by this title shall take effect on October 1, 2017, or the date of the enactment of this Act, whichever is later, except that fees under part 8 of subchapter C of chapter VII of the Federal Food, Drug, and Cosmetic Act shall be assessed for all biosimilar biological product applications received on or after October 1, 2017, regardless of the date of the enactment of this Act.

SEC. 407. SAVINGS CLAUSE.

Notwithstanding the amendments made by this title, part 8 of subchapter C of chapter VII of the Federal Food, Drug, and Cosmetic Act, as in effect on the day before the date of the enactment of this title, shall continue to be in effect with respect to biosimilar biological product applications and supplements (as defined in such part as of such day) that were accepted by the Food and Drug Administration for filing on or after October 1, 2012, but before October 1, 2017, with respect to assessing and collecting any fee required by such part for a fiscal year prior to fiscal year 2018.

TITLE V—REAUTHORIZATIONS AND IMPROVEMENTS RELATED TO DRUGS

SEC. 501. REAUTHORIZATION OF PROVISION RELATING TO EXCLUSIVITY OF CERTAIN DRUGS CONTAINING SINGLE ENANTIOMERS.

Section 505(u)(4) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(u)(4)) is amended by striking “2017” and inserting “2022”.

SEC. 502. REAUTHORIZATION OF ORPHAN GRANTS PROGRAM.

Section 5(c) of the Orphan Drug Act (21 U.S.C. 360ee(c)) is amended by striking “2013 through 2017” and inserting “2018 through 2022”.

SEC. 503. REAUTHORIZATION OF PEDIATRIC STUDY OF DRUGS.

Section 409I(e)(1) of the Public Health Service Act (42 U.S.C. 284m(e)(1)) is amended by striking “2013 through 2017” and inserting “2018 through 2022”.

SEC. 504. PROTECTING AND STRENGTHENING THE DRUG SUPPLY CHAIN.

(a) DIVERTED DRUGS.—Paragraph (1) of section 801(d) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 381(d)) is amended—

- (1) by striking “(d)(1) Except as” and inserting “(d)(1)(A) Except as”; and
- (2) by adding at the end the following:

“(B) Except as authorized by the Secretary in the case of a drug that appears on the drug shortage list in effect under section 506E, no drug that would be subject to section 503(b), and which is manufactured outside the United States and intended by the manufacturer or labeled to be marketed outside the United States, may be imported into the United States for sale or commercial use.”

(b) COUNTERFEIT DRUGS.—Subsection (b) of section 303 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 333) is amended by adding at the end the following:

“(8) Notwithstanding subsection (a), any person who violates section 301(i)(3) by knowingly making, selling or dispensing, or holding for sale or dispensing, a counterfeit drug shall be imprisoned for not more than 10 years or fined in accordance with title 18, United States Code, or both.”

SEC. 505. SENSE OF CONGRESS ON LOWERING THE COST OF PRESCRIPTION DRUGS.

It is the sense of the Congress that the Secretary of Health and Human Services should commit to engaging with the House of Representatives and the Senate to take administrative actions and enact legislative changes that—

- (1) will lower the cost of prescription drugs for consumers and reduce the burden of such cost on taxpayers; and
- (2) in lowering such cost, will—
 - (A) balance the need to encourage innovation with the need to improve affordability; and
 - (B) strive to increase competition in the pharmaceutical market, prevent anticompetitive behavior, and promote the timely availability of affordable, high-quality generic drugs and biosimilars.

TITLE VI—DEVICE INSPECTION AND REGULATORY IMPROVEMENTS

Subtitle A—Improving the Process for Inspections of Device Establishments

SEC. 601. RISK-BASED INSPECTIONS FOR DEVICES.

Paragraph (2) of section 510(h) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360(h)) is amended to read as follows:

“(2) RISK-BASED SCHEDULE FOR DEVICES.—

“(A) IN GENERAL.—The Secretary, acting through one or more officers or employees duly designated by the Secretary, shall inspect establishments described in paragraph (1) that are engaged in the manufacture, propagation, compounding, or processing of a device or devices (referred to in this subsection as ‘device establishments’) in accordance with a risk-based schedule established by the Secretary.

“(B) FACTORS AND CONSIDERATIONS.—In establishing the risk-based schedule under subparagraph (A), the Secretary shall—

“(i) apply, to the extent applicable for device establishments, the factors identified in paragraph (4); and

“(ii) consider the participation of the device establishment, as applicable, in international device audit programs in which the United States participates or which the United States recognizes for purposes of inspecting device establishments.”.

SEC. 602. RECOGNITION OF FOREIGN GOVERNMENT INSPECTIONS.

Subsection (a)(1) of section 809 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 384e(a)(1)) is amended by inserting “or 510(h)(2) (as applicable)” before the semicolon at the end.

SEC. 603. IMPROVEMENTS TO INSPECTIONS PROCESS FOR DEVICE ESTABLISHMENTS.

(a) IN GENERAL.—Section 704 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 374) is amended by adding at the end the following:

“(h)(1) In the case of inspections other than for-cause inspections, the Secretary shall review processes and standards applicable to inspections of domestic and foreign device establishments in effect as of the date of the enactment of this subsection, and update such processes and standards through the adoption of uniform processes and standards applicable to such inspections. Such processes and standards shall provide for—

“(A) exceptions to such processes and standards, as appropriate;

“(B) announcing the inspection of the establishment within a reasonable time before such inspection occurs, including by providing to the owner, operator, or agent in charge of the establishment a notification regarding the type and nature of the inspection;

“(C) a reasonable estimate of the timeframe for the inspection, an opportunity for advance communications between the officers or employees carrying out the inspection under subsection (a)(1) and the owner, operator, or agent in charge of the establishment concerning appropriate working hours during the inspection, and, to the extent feasible, advance notice of some records that will be requested in order to expedite the inspection; and

“(D) regular communications during the inspection with the owner, operator, or agent in charge of the establishment regarding inspection status, which may be recorded by either party with advance notice and mutual consent.

“(2)(A) The Secretary shall, with respect to a request described in subparagraph (B), provide nonbinding feedback with respect to such request not later than 45 days after the Secretary receives such request.

“(B) A request described in this subparagraph is a request for feedback—

“(i) that is made by the owner, operator, or agent in charge of such establishment in a timely manner; and

“(ii) with respect to actions proposed to be taken by a device establishment in a response to a report received by such establishment pursuant to subsection (b) that involve a public health priority, that implicate systemic or major actions, or relate to emerging safety issues (as determined by the Secretary).

“(3) Nothing in this subsection limits the authority of the Secretary to conduct inspections otherwise permitted under this Act in order to ensure compliance with this Act.”.

(b) GUIDANCE.—

(1) **DRAFT GUIDANCE.**—Not later than 18 months after the date of enactment of this section, the Secretary of Health and Human Services shall issue draft guidance that—

(A) specifies how the Food and Drug Administration will implement the process described in paragraph (1) of subsection (h) of section 704 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 374), as added by subsection (a), and the requirements described in paragraph (2) of such subsection;

(B) provides for standardized methods for communications described in such paragraphs;

(C) establishes, with respect to inspections of both domestic and foreign device establishments (as referred to in section 510(h)(2) of the Federal Food, Drug, and Cosmetic Act, as amended by subsection (a)), a standard timeframe for such inspections—

(i) that occurs over consecutive days; and

(ii) to which each investigator conducting such an inspection shall adhere unless the investigator identifies to the establishment involved a reason that more time is needed to conduct such investigation; and

(D) identifies practices for investigators and device establishments to facilitate the continuity of inspections of such establishments.

(2) **FINAL GUIDANCE.**—Not later than 1 year after providing notice and opportunity for public comment on the draft guidance issued under paragraph (1), the Secretary of Health and Human Services shall issue final guidance to implement subsection (h) of section 704 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 374), as added by subsection (a).

SEC. 604. CERTIFICATES TO FOREIGN GOVERNMENTS FOR DEVICES.

(a) **IN GENERAL.**—Subsection (e)(4) of section 801 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 381(e)(4)) is amended—

(1) by adding at the end the following:

“(E)(i) If the Secretary denies a request made under subparagraph (A)(ii) for certification with respect to a device, the Secretary shall provide, in writing, to the person seeking such certification the basis for such denial, and specifically identify the finding upon which such denial is based.

“(ii) If the denial of a request as described in clause (i) is based on—

“(I) grounds other than an injunction proceeding pursuant to section 302, seizure action pursuant to section 304, or a recall designated Class I or Class II pursuant to part 7, title 21, Code of Federal Regulations, and

“(II) an establishment being considered out of compliance with part 820, title 21, Code of Federal Regulations,

the Secretary shall provide a substantive summary of the specific grounds for non-compliance so identified, if such grounds have not been previously communicated to the manufacturer.

“(iii) With respect to a device manufactured in an establishment that has received a report under section 704(b), the Secretary shall not deny a request for certification under subparagraph (A)(ii) based exclusively on the issuance of that report if the owner, operator, or agent in charge of such establishment has agreed to a plan of correction in response to such report.

“(F)(i) The Secretary shall provide a process for a person who is denied a certification as described in subparagraph (E)(i) to request a review that conforms to the standards of section 517A(b).

“(ii) Notwithstanding any previous review conducted pursuant to clause (i), a person who has been denied a certification for a device as described in subparagraph (E)(i) may, at any time, request a review of that denial in order to present new information relating to actions taken by such person to address the reasons identified by the Secretary for such denial, including evidence that corrective actions are being or have been implemented to address the grounds for noncompliance identified by the Secretary under subparagraph (E)(ii).

“(G)(i) This paragraph applies to requests for certification on behalf of any device establishment registered under section 510, whether the establishment is located in the United States or another country.

“(ii) The Secretary may charge a fee for the issuance of a certification described in clause (i), and such fee is subject to the same conditions and requirements as a fee charged under subparagraph (B) for a certification issued under such subparagraph.”; and

(2) by moving the margins of subparagraphs (C) and (D) 4 ems to the left.

(b) **GUIDANCE.**—Not later than 1 year after date of the enactment of this section, the Secretary of Health and Human Services shall issue guidance providing for a process to carry out subparagraph (F) of section 801(e)(4) of the Federal Food, Drug,

and Cosmetic Act (21 U.S.C. 381(e)(4)), as added by subsection (a). Not later than 12 months after the comment period closes for the draft guidance, the Secretary shall issue final guidance.

SEC. 605. FACILITATING INTERNATIONAL HARMONIZATION.

Section 704(g) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 374(g)) is amended by adding at the end the following:

“(15) Notwithstanding any other provision of this subsection, for purposes of conducting inspections of establishments that manufacture, prepare, propagate, compound, or process devices except types of devices licensed under section 351 of the Public Health Service Act, which inspections are required under section 510(h) or are inspections of such establishments required to register pursuant to section 510(i), the Secretary may recognize auditing organizations that are recognized by organizations established by governments to facilitate international harmonization. Nothing in this paragraph affects the authority of the Secretary to inspect any device establishment pursuant to this Act. Nothing in this paragraph affects the authority of the Secretary to determine the official classification of an inspection.”.

SEC. 606. REAUTHORIZATION OF INSPECTION PROGRAM.

Section 704(g)(11) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 374(g)(11)) is amended by striking “October 1, 2017” and inserting “October 1, 2022”.

Subtitle B—Other Provisions

SEC. 611. REAUTHORIZATION OF PEDIATRIC HUMANITARIAN DEVICE EXCEPTIONS.

Section 520(m)(6)(A)(iv) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360j(m)(6)(A)(iv)) is amended by striking “2017” and inserting “2022”.

SEC. 612. REAUTHORIZATION OF PEDIATRIC DEVICE CONSORTIA.

Section 305(e) of the Pediatric Medical Device Safety and Improvement Act of 2007 (Public Law 110–85; 42 U.S.C. 282 note) is amended by striking “2013 through 2017” and inserting “2018 through 2022”.

SEC. 613. REGULATION OF OVER-THE-COUNTER HEARING AIDS.

(a) **IN GENERAL.**—Section 520 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360j) is amended by adding at the end the following:

“(p) **REGULATION OF OVER-THE-COUNTER HEARING AIDS.**—

“(1) **DEFINITION.**—

“(A) In this subsection, the term ‘over-the-counter hearing aid’ means a device—

“(i) that uses the same fundamental scientific technology as air conduction hearing aids (as defined in section 874.3300 of title 21, Code of Federal Regulations) (or any successor regulation) or wireless air conduction hearing aids (as defined in section 874.3305 of title 21, Code of Federal Regulations) (or any successor regulation);

“(ii) that is intended to be used by adults over the age of 18 to compensate for perceived mild to moderate hearing impairment;

“(iii) that, through tools, tests, or software, allows the user to control the over-the-counter hearing aid and customize it to the user’s hearing needs;

“(iv) that may—

“(I) use wireless technology; or

“(II) include tests for self-assessment of hearing loss; and

“(v) that is available over-the-counter, without the supervision, prescription, or other order, involvement, or intervention of a licensed person, to consumers through in-person transactions, by mail, or online.

“(B) Such term does not include a personal sound amplification product intended to amplify sound for nonhearing impaired consumers in situations including hunting and bird-watching.

“(2) **REGULATION.**—An over-the-counter hearing aid shall be subject to the regulations promulgated in accordance with section 613(b) of the FDA Reauthorization Act of 2017 and shall be exempt from sections 801.420 and 801.421 of title 21, Code of Federal Regulations (or any successor regulations).”.

(b) **REGULATIONS TO ESTABLISH CATEGORY.**—

(1) **IN GENERAL.**—The Secretary of Health and Human Services (referred to in this section as the “Secretary”), not later than 3 years after the date of enactment of this Act, shall promulgate proposed regulations to establish a category of over-the-counter hearing aids, as defined in subsection (p) of section 520 of

the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360j) as amended by subsection (a), and, not later than 180 days after the date on which the public comment period on the proposed regulations closes, shall issue such final regulations.

(2) REQUIREMENTS.—In promulgating the regulations under paragraph (1), the Secretary shall—

(A) include requirements that provide reasonable assurances of the safety and efficacy of over-the-counter hearing aids;

(B) include requirements that establish or adopt output limits appropriate for over-the-counter hearing aids;

(C) include requirements for appropriate labeling of the over-the-counter hearing aid, including requirements that such labeling include a conspicuous statement that the device is only intended for adults over the age of 18, information on how consumers may report adverse events, information on any contraindications, conditions, or symptoms of medically treatable causes of hearing loss, and advisements to consult promptly with a licensed physician; and

(D) describe the requirements under which the sale of over-the-counter hearing aids is permitted, without the supervision, prescription, or other order, involvement, or intervention of a licensed person, to consumers through in-person transactions, by mail, or online.

(3) PREMARKET NOTIFICATION.—The Secretary shall make findings under section 510(m) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360(m)) to determine whether over-the-counter hearing aids (as defined in section 520(p) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360j), as amended by subsection (a)) require a report under section 510(k) to provide reasonable assurance of safety and effectiveness.

(4) EFFECT ON STATE LAW.—No State or local government shall establish or continue in effect any law, regulation, order, or other requirement specifically related to hearing products that would restrict or interfere with the servicing, marketing, sale, dispensing, use, customer support, or distribution of over-the-counter hearing aids (as defined in section 520(p) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360j), as amended by subsection (a)) through in-person transactions, by mail, or online, that is different from, in addition to, or otherwise not identical to, the regulations promulgated under this subsection, including any State or local requirement for the supervision, prescription, or other order, involvement, or intervention of a licensed person for consumers to access over-the-counter hearing aids.

(5) NO EFFECT ON PRIVATE REMEDIES.—Nothing in this section shall be construed to modify or otherwise affect the ability of any person to exercise a private right of action under any State or Federal product liability, tort, warranty, contract, or consumer protection law.

(c) NEW GUIDANCE ISSUED.—Not later than the date on which final regulations are issued under subsection (b), the Secretary shall update and finalize the draft guidance of the Department of Health and Human Services entitled “Regulatory Requirements for Hearing Aid Devices and Personal Sound Amplification Products”, issued on November 7, 2013. Such updated and finalized guidance shall clarify which products, on the basis of claims or other marketing, advertising, or labeling material, meet the definition of a device in section 201 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321) and which products meet the definition of a personal sound amplification product, as set forth in such guidance.

(d) REPORT.—Not later than 2 years after the date on which the final regulations described in subsection (b)(1) are issued, the Secretary of Health and Human Services shall submit to Congress a report analyzing any adverse events relating to over-the-counter hearing aids (as defined in subsection (p)(1) of section 520 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360j)).

SEC. 614. REPORT ON ENSURING QUALITY, SAFETY, AND CONTINUED EFFECTIVENESS OF DEVICES THAT HAVE BEEN SERVICED.

(a) IN GENERAL.—Not later than 180 days after the date of enactment of this Act, the Secretary of Health and Human Services, acting through the Commissioner of Food and Drugs, shall submit to the Committee on Energy and Commerce of the House of Representatives and the Committee on Health, Education, Labor and Pensions of the Senate a report on how the Food and Drug Administration intends to ensure the quality, safety, and continued effectiveness of devices (as defined in section 201(h) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 301(h))) with respect to which servicing (as defined in subsection (c)) has been performed by any entity engaging in such servicing.

(b) CONTENTS.—The report submitted under subsection (a) shall contain—

(1) the status of, and findings to date with respect to, the notice entitled “Refurbishing, Reconditioning, Rebuilding, Remarketing, Remanufacturing, and Servicing of Medical Devices Performed by Third-Party Entities and Original Equipment Manufacturers; Request for Comments” published by the Food and Drug Administration on April 25, 2016 (81 Fed. Reg. 24041 et seq.), including how the Food and Drug Administration intends to define the specific activities performed on a device by the manufacturer of the device or other entities;

(2) a description of the statutory or regulatory authority of the Food and Drug Administration used to oversee and regulate servicing conducted with respect to devices;

(3) details on how the Food and Drug Administration intends to protect the public health by ensuring consistent quality, safety, and continued effectiveness of devices with respect to which servicing has been performed by any entity engaging in such servicing;

(4) information on how the Food and Drug Administration can better understand the device servicing industry, including the size, scope, location, and composition of entities performing such servicing and the rate of adverse events related to such servicing;

(5) information regarding the current regulation by States, the Joint Commission, or other regulatory bodies of servicing conducted with respect to devices by all entities, including original equipment manufacturers, third-party entities, and hospitals; and

(6) any additional information determined by the Secretary (acting through the Commissioner) to be relevant to ensuring the quality, safety, and continued effectiveness of devices with respect to which servicing has been performed, including whether additional Federal statutory authority is necessary to ensure such quality, safety, and continued effectiveness.

(c) **SERVICING DEFINED.**—In this section, the term “servicing” includes, with respect to a device, refurbishing, reconditioning, rebuilding, remarketing, remanufacturing, repairing, or other servicing of the device by a person other than the manufacturer of the device.

SEC. 615. DEVICE PILOT PROJECTS TO GENERATE RELIABLE AND TIMELY SAFETY AND ACTIVE SURVEILLANCE DATA.

(a) **IN GENERAL.**—Section 519 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360i) is amended by adding at the end the following:

“(i) **PILOT PROJECTS TO GENERATE RELIABLE AND TIMELY SAFETY AND ACTIVE SURVEILLANCE DATA.**—

“(1) **IN GENERAL.**—The Secretary shall, not later than one year after the date of the enactment of the FDA Reauthorization Act of 2017, initiate one or more pilot projects relating to providing timely and reliable information on the safety and effectiveness of devices approved under section 515, cleared under section 510(k), or classified under section 513(f)(2), in which a manufacturer or manufacturers of a device or device type voluntarily participate. Any such project shall meet each of the following criteria:

“(A) The project is designed to efficiently generate reliable and timely safety and active surveillance data for use by the Secretary or manufacturers of the devices that are involved in the pilot project.

“(B) The project informs, to the extent applicable, the development of methods, systems, data criteria, and programs that could be used to support safety and active surveillance activities for any device.

“(C) The project shall be designed and conducted in coordination with a comprehensive system for evaluating device technology that operates under a governing board with appropriate representation of stakeholders, including patient groups and device manufacturers.

“(D) The project uses electronic health data including, as appropriate, claims data, patient survey data, and any other data, as the Secretary determines appropriate.

“(E) The project prioritizes devices and device types that meet one or more of the following criteria:

“(i) Devices and device types for which the collection and analysis of real world evidence regarding a device’s safety and effectiveness is likely to advance public health.

“(ii) Devices and device types that are widely used.

“(iii) Devices and device types, the failure of which has significant health consequences.

“(iv) Devices and device types for which the Secretary—

“(I) has received public recommendations in accordance with paragraph (2)(B); and

“(II) has determined to meet one of the criteria under clause (i), (ii), or (iii) and is appropriate for such a pilot project.

“(2) PARTICIPATION.—The Secretary shall establish the conditions and processes—

“(A) under which a manufacturer of a device may voluntarily participate in a pilot project described in paragraph (1); and

“(B) for facilitating public recommendations for devices to be prioritized under such a pilot project, including requirements for the data necessary to support such a recommendation.

“(3) CONTINUATION OF ONGOING PROJECTS.—The Secretary may continue or expand projects, with respect to providing timely and reliable information on the safety and effectiveness of devices approved under section 515, cleared under section 510(k), or classified under section 513(f)(2), that are being carried out as of the date of the enactment of the FDA Reauthorization Act of 2017. The Secretary shall, beginning on such date of enactment, take such steps as may be necessary—

“(A) to ensure such projects meet the requirements of subparagraphs (A) through (E) of paragraph (1); and

“(B) to increase the voluntary participation in such projects of manufacturers of devices and facilitate public recommendations for any devices prioritized under such a project.

“(4) IMPLEMENTATION.—

“(A) CONTRACTING AUTHORITY.—The Secretary may carry out a pilot project meeting the criteria specified in subparagraphs (A) through (E) of paragraph (1) or a project continued or expanded under paragraph (3) by entering into contracts, cooperative agreements, grants, or other appropriate agreements with public or private entities that have a significant presence in the United States and meet the following conditions:

“(i) If such an entity is a component of another organization, the entity and the organization have established an agreement under which appropriate security measures are implemented to maintain the confidentiality and privacy of the data described in paragraph (1)(D) and such agreement ensures that the entity will not make an unauthorized disclosure of such data to the other components of the organization in breach of requirements with respect to confidentiality and privacy of such data established under such security measures.

“(ii) In the case of the termination or nonrenewal of such a contract, cooperative agreement, grant, or other appropriate agreement, the entity or entities involved shall comply with each of the following:

“(I) The entity or entities shall continue to comply with the requirements with respect to confidentiality and privacy referred to in clause (i) under this subparagraph with respect to all data disclosed to the entity under such an agreement.

“(II) The entity or entities shall return any data disclosed to such entity pursuant to this subsection and to which it would not otherwise have access or, if returning such data is not practicable, destroy the data.

“(iii) The entity or entities shall have one or more qualifications with respect to—

“(I) research, statistical, epidemiologic, or clinical capability and expertise to conduct and complete the activities under this subsection, including the capability and expertise to provide the Secretary access to de-identified data consistent with the requirements of this subsection;

“(II) an information technology infrastructure to support electronic data and operational standards to provide security for such data, as appropriate;

“(III) experience with, and expertise on, the development of research on, and surveillance of, device safety and effectiveness using electronic health data; or

“(IV) such other expertise which the Secretary determines necessary to carry out such a project.

“(B) REVIEW OF CONTRACT IN THE EVENT OF A MERGER OR ACQUISITION.—The Secretary shall review any contract, cooperative agreement, grant, or other appropriate agreement entered into under this paragraph with an entity meeting the conditions specified in subparagraph (A) in the event of a merger or acquisition of the entity in order to ensure that the requirements specified in this subsection will continue to be met.

“(5) COMPLIANCE WITH REQUIREMENTS FOR RECORDS OR REPORTS ON DEVICES.—The participation of a manufacturer in pilot projects under this subsection shall not affect the eligibility of such manufacturer to participate in any quarterly reporting program with respect to devices carried out under section 519 or 522. The Secretary may determine that, for a specified time period to be determined by the Secretary, a manufacturer’s participation in a pilot project under this subsection or a project continued or expanded under paragraph (3) may meet the applicable requirements of section 519 or 522, if—

“(A) the project has demonstrated success in capturing relevant adverse event information; and

“(B) the Secretary has established procedures for making adverse event and safety information collected from such project public, to the extent possible.

“(6) PRIVACY REQUIREMENTS.—With respect to the disclosure of any health information collected through a project conducted under this subsection—

“(A) individually identifiable health information so collected shall not be disclosed when presenting any information from such project; and

“(B) any such disclosure shall be made in compliance with regulations issued pursuant to section 264(c) of the Health Insurance Portability and Accountability Act of 1996 (42 U.S.C. 1320d–2 note) and sections 552 and 552a of title 5, United States Code.

“(7) LIMITATIONS.—

“(A) IN GENERAL.—No pilot project under this subsection undertaken in coordination with the comprehensive system described in paragraph (1)(C), shall allow for an entity participating in such program, other than the Secretary or the Secretary’s designee, to make determinations of safety or effectiveness, or substantial equivalence, for purposes of the Act.

“(B) NO USE OF FEES.—Pilot projects initiated under this subsection may not primarily utilize funds collected pursuant to the Medical Device User Fee Amendments of 2017.

“(8) OTHER PROJECTS REQUIRED TO COMPLY.—Paragraphs (1)(B), (4)(A)(i), (4)(A)(ii), (5), and (6) shall apply with respect to any pilot program undertaken in coordination with the comprehensive system described in paragraph (1)(C) that relates to the use of real world evidence for devices in the same manner and to the same extent as such paragraphs apply with respect to pilot projects conducted under this subsection.

“(9) REPORT TO CONGRESS.—Not later than 18 months after the date of enactment of this Act, and annually thereafter, the Secretary shall submit to the Committee on Energy and Commerce of the House of Representatives and the Committee on Health, Education, Labor and Pensions of the Senate a report containing a description of the pilot projects being conducted under this subsection and projects continued or expanded pursuant to paragraph (3), including for each such project—

“(A) how the project is being implemented in accordance with paragraph (4), including how such project is being implemented through a contract, cooperative agreement, grant, or other appropriate agreement, if applicable;

“(B) the number of manufacturers that have agreed to participate in such project;

“(C) the data sources used to conduct such project;

“(D) the devices or device categories involved in such project;

“(E) the number of patients involved in such project; and

“(F) the findings of the project in relation to device safety, including adverse events, malfunctions, and other safety information.

“(10) SUNSET.—The Secretary may not carry out a pilot project initiated by the Secretary under this subsection after October 1, 2022.”

(b) REPORT.—Not later than January 31, 2021, the Secretary of Health and Human Services, acting through the Commissioner of Food and Drugs, may conduct a review through an independent third party to evaluate the strengths, limitations, and appropriate use of evidence collected pursuant to real world evidence pilot projects described in the letters described in section 201(b) of the Medical Device User Fee Amendments of 2017 and subsection (i) of section 519 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360i), as added by subsection (a)—

(1) for purposes of informing premarket and postmarket decisionmaking for multiple device types; and

(2) to determine whether the methods, systems, and programs carried out through such pilot projects efficiently generate reliable and timely evidence about the effectiveness of the surveillance of devices with respect to safety.

SEC. 616. RISK-BASED CLASSIFICATION OF ACCESSORIES.

(a) IN GENERAL.—Subsection (f) of section 513 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360c) is amended by adding at the end the following new paragraph:

“(6)(A) Subject to the succeeding subparagraphs of this paragraph, the Secretary shall, by written order, classify an accessory under this section based on the risks of the accessory when used as intended and the level of regulatory controls necessary to provide a reasonable assurance of safety and effectiveness of the accessory, notwithstanding the classification of any other device with which such accessory is intended to be used.

“(B) The classification of any accessory distinct from another device by regulation or written order issued prior to December 13, 2016, shall continue to apply unless and until the accessory is reclassified by the Secretary, notwithstanding the classification of any other device with which such accessory is intended to be used. Nothing in this section shall preclude the Secretary’s ability to initiate the classification of an accessory through regulation or written order, as appropriate.

“(C)(i) In the case of an accessory that has been granted marketing authorization as part of a submission under section 515(c), 510(k), or paragraph (2) of this subsection with another device with which such accessory is intended to be used, and with respect to which the Secretary has issued a written order classifying such accessory type distinct from another device in accordance with subparagraph (A), the manufacturer or importer of such accessory may, in lieu of submitting a request for classification of such accessory, submit a written request to the Secretary identifying such classification. A request under this clause shall include such information to support the request as may be specified by the Secretary.

“(ii) A request under clause (i) shall include a recommendation for the proper classification of the accessory pursuant to subparagraph (A), and shall include such information as may be necessary for the Secretary to evaluate, based on the least burdensome approach, the appropriate class for the accessory under subsection (a).

“(iii) The Secretary shall respond to a request under clause (i) within 90 calendar days by granting or denying the request for reclassification of the accessory.

“(iv) Within 30 calendar days after granting a request submitted under clause (i), the Secretary shall publish a notice in the Federal Register announcing such response.

“(v) A written notification that the Secretary disagrees with the classification recommended in a request pursuant to clause (ii) shall include a detailed description and justification for the determination to disagree.

“(D)(i) In the case of a device intended to be used with an accessory, where the accessory has been included in an application for premarket approval of such device under section 515 or a report under section 510(k) for clearance of such device and the Secretary has not classified such accessory distinctly from another device in accordance with subparagraph (A), the person filing the application or report (as applicable) at the time such application or report is filed—

“(I) may include a written request for the proper classification of the accessory pursuant to subparagraph (A);

“(II) shall include in any such request such information as may be necessary for the Secretary to evaluate, based on the least burdensome approach, the appropriate class for the accessory under subsection (a); and

“(III) shall, if the request under subclause (I) is requesting classification of the accessory in class II, include in the application an initial draft proposal for special controls, if special controls would be required pursuant to subsection (a)(1)(B).

“(ii) The Secretary’s response under section 515(d) or section 510(n) (as applicable) to an application or report described in clause (i) shall also contain the Secretary’s granting or denial of the request for classification of the accessory involved.

“(iii) The Secretary’s evaluation of an accessory under clause (i) shall constitute an order establishing a new classification for such accessory for the specified intended use or uses of such accessory and for any accessory with the same intended use or uses as such accessory.

“(E) For accessories that have been granted marketing authorization as part of a submission for another device with which the accessory involved is intended to be used, through an application for such other device under section 515(c), a report under section 510(k), or a request for classification under paragraph (2) of this subsection, and that have not been classified by the Secretary based on the risks and appropriate level of regulatory controls in accordance with subparagraph (A):

“(i) Not later than the date that is one year after the date of enactment of the FDA Reauthorization Act of 2017 and at least once every 5 years thereafter, and as the Secretary otherwise deems appropriate, pursuant to this paragraph, the Secretary shall publish in the Federal Register a notice proposing a list of

such accessories that the Secretary believes may be suitable for a distinct classification in class I and the proposed regulations for such classifications. In developing such lists, the Secretary shall consider recommendations from sponsors of device submissions and other stakeholders for accessories to be included on such lists. The notices shall provide for a period of not less than 60 calendar days for public comment. Within 180 days after the end of the comment period, the Secretary shall publish in the Federal Register a final action classifying such suitable accessories into class I.

“(ii) A manufacturer or importer of an accessory that has been granted such marketing authorization may submit to the Secretary a written request for the appropriate classification of the accessory based on the risks and appropriate level of regulatory controls as described in subparagraph (A) or (C), and shall, if the request is requesting classification of the accessory in class II, include in the submission an initial draft proposal for special controls, if special controls would be required pursuant to subsection (a)(1)(B). Such request shall include such information as may be necessary for the Secretary to evaluate, based on the least burdensome approach, the appropriate class for the accessory under subsection (a). The Secretary shall provide an opportunity for a manufacturer or importer to meet with appropriate personnel of the Food and Drug Administration to discuss the appropriate classification of such accessory prior to submitting a written request under this clause for classification of the accessory.

“(iii) The Secretary shall respond to a request made under clause (ii) not later than 90 calendar days after receiving such submission by granting or denying the request for classification of the accessory, and the Secretary shall by written order classify such accessory or deny the request. If the Secretary does not agree with the recommendation for classification submitted by the manufacturer or importer, the response shall include a detailed description and justification for such determination. Within 30 calendar days after granting such a request, the Secretary shall publish a notice in the Federal Register announcing such response.

“(F) Nothing in this paragraph may be construed as precluding a manufacturer of an accessory of a new type from using the classification process described in subsection (f)(2) to obtain classification of such accessory in accordance with the criteria and requirements set forth in that subsection.”

(b) CONFORMING CHANGE.—Section 513(b) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360c(b)) is amended by striking paragraph (9) (relating to classification of an accessory).

(c) EFFECTIVE DATE.—The amendments made by subsections (a) and (b) shall take effect on the date that is 60 days after the date of enactment of this Act.

TITLE VII—GENERIC DRUG ACCESS AND COMPETITION

SEC. 701. COMPETITIVE GENERIC THERAPIES.

(a) IN GENERAL.—Chapter V of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 351 et seq.) is amended by inserting after section 506G the following:

“SEC. 506H. COMPETITIVE GENERIC THERAPIES.

“(a) IN GENERAL.—The Secretary shall, at the request of the sponsor of a drug that is designated as a competitive generic therapy pursuant to subsection (b), expedite the development and review of such drug pursuant to section 505(j).

“(b) DESIGNATION PROCESS.—

“(1) REQUEST.—The sponsor of a drug may request the Secretary to designate the drug as a competitive generic therapy.

“(2) TIMING.—A request under paragraph (1) may be made concurrently with, or at any time prior to, the submission of an abbreviated new drug application for the drug under section 505(j).

“(3) CRITERIA.—A drug is eligible for designation as a competitive generic therapy under this section if the Secretary determines that there is inadequate generic competition.

“(4) DESIGNATION.—Not later than 60 calendar days after the receipt of a request under paragraph (1), the Secretary shall—

“(A) determine whether the drug that is the subject of the request meets the criteria described in paragraph (3); and

“(B) if the Secretary finds that the drug meets such criteria, designate the drug as a competitive generic therapy.

“(c) ACTIONS.—In expediting the development and review of a drug under subsection (a), the Secretary shall, as requested by the sponsor, take actions including the following:

“(1) Hold meetings with the sponsor and the review team throughout the development of the drug prior to submission of the application for such drug under section 505(j).

“(2) Provide timely advice to, and interactive communication with, the sponsor regarding the development of the drug to ensure that the development program to gather the data necessary for approval is as efficient as practicable.

“(3) Involve senior managers and experienced review staff, as appropriate, in a collaborative, coordinated review, including with respect to drug-device combination products and other complex products.

“(4) Assign a cross-disciplinary project lead for the Food and Drug Administration review team—

“(A) to facilitate an efficient review of the development program and application, including manufacturing inspections; and

“(B) to serve as a scientific liaison between the review team and the sponsor.

“(d) DEFINITIONS.—In this section:

“(1) The term ‘generic drug’ means a drug that is approved pursuant to section 505(j).

“(2) The term ‘inadequate generic competition’ means, with respect to a product, there is not more than one approved drug product on the list of products described in section 505(j)(7)(A) (not including products on the discontinued section of such list) that is—

“(A) the reference listed drug; or

“(B) a generic drug with the same reference listed drug as the drug for which designation as a competitive generic therapy is sought.

“(3) The term ‘reference listed drug’ means the listed drug (as such term is used in section 505(j)) for the drug involved.”.

(b) GUIDANCE; AMENDED REGULATIONS.—

(1) IN GENERAL.—

(A) ISSUANCE.—The Secretary of Health and Human Services shall—

(i) not later than 18 months after the date of enactment of this Act, issue draft guidance on the provisions of section 506H of the Federal Food, Drug, and Cosmetic Act, as added by subsection (a); and

(ii) not later than 1 year after the close of the comment period for the draft guidance, issue final guidance on such provisions.

(B) CONTENTS.—The guidance issued under this subsection shall—

(i) specify the process and criteria by which the Secretary makes a designation under section 506H of the Federal Food, Drug, and Cosmetic Act, as added by subsection (a);

(ii) specify the actions the Secretary will take to expedite the development and review of a competitive generic therapy pursuant to such a designation; and

(iii) include good review management practices for competitive generic therapies.

(2) AMENDED REGULATIONS.—

(A) IN GENERAL.—If the Secretary of Health and Human Services determines that it is necessary to amend the regulations under title 21, Code of Federal Regulations, in order to implement section 506H of the Federal Food, Drug, and Cosmetic Act, as added by subsection (a), the Secretary shall amend such regulations not later than 2 years after the date of enactment of this Act.

(B) PROCEDURE.—In carrying out subparagraph (A), and in issuing any other regulations to implement such section 506H, the Secretary shall—

(i) issue a notice of proposed rulemaking that includes the proposed regulation;

(ii) provide a period of not less than 60 days for comments on the proposed regulation; and

(iii) publish the final regulation not less than 30 days before the effective date of the regulation.

SEC. 702. ENHANCING REGULATORY TRANSPARENCY TO ENHANCE GENERIC COMPETITION.

Section 505(j) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355) is amended by adding at the end the following:

“(11) Upon the request of an applicant regarding one or more specified pending applications under this subsection, the Secretary shall—

“(A) by telephone or electronic mail, provide review status updates; and

“(B) indicate in such updates the categorical status of the applications by each relevant review discipline.”.

SEC. 703. INCENTIVIZING COMPETITIVE GENERIC THERAPY DEVELOPMENT.

Section 505(j)(5) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(j)(5)) is amended—

(1) in subparagraph (B), by adding at the end the following:

“(v) 180-DAY EXCLUSIVITY PERIOD FOR COMPETITIVE GENERIC THERAPIES.—

“(I) EFFECTIVENESS OF APPLICATION.—Subject to subparagraph (D)(iv), if the application is for a drug that is the same as a competitive generic therapy for which any first approved applicant has commenced commercial marketing, the application shall be made effective on the date that is 180 days after the date of the first commercial marketing of the competitive generic therapy (including the commercial marketing of the listed drug) by any first approved applicant.

“(II) LIMITATION.—The exclusivity period under subclause (I) shall not apply with respect to a competitive generic therapy that has previously received an exclusivity period under subclause (I).

“(III) DEFINITIONS.—In this clause and subparagraph (D)(iv):

“(aa) The term ‘competitive generic therapy’ means a drug—

“(AA) that is designated as a competitive generic therapy under section 506H; and

“(BB) for which there are no unexpired patents or blocking exclusivities on the list of products described in section 505(j)(7)(A) at the time of approval.

“(bb) The term ‘first approved applicant’ means any applicant that has submitted an application that—

“(AA) is for a competitive generic therapy that is approved on the first day on which any application for such competitive generic therapy is approved;

“(BB) is not eligible for a 180-day exclusivity period under clause (iv) for the drug that is the subject of the application for the competitive generic therapy; and

“(CC) is not for a drug for which all drug versions have forfeited eligibility for a 180-day exclusivity period under clause (iv) pursuant to subparagraph (D).”; and

(2) in subparagraph (D), by adding at the end the following:

“(iv) SPECIAL FORFEITURE RULE FOR COMPETITIVE GENERIC THERAPY.—

The 180-day exclusivity period described in subparagraph (B)(v) shall be forfeited by a first approved applicant if the applicant fails to market the competitive generic therapy within 75 days after the date on which the approval of the first approved applicant’s application for the competitive generic therapy is made effective.”.

SEC. 704. TROPICAL DISEASE PRODUCT APPLICATION.

Subparagraph (A) of section 524(a)(4) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360n(a)(4)) is amended—

(1) in clause (i), by striking “and” at the end; and

(2) by adding at the end the following:

“(iii) that contains reports of one or more new clinical investigations (other than bioavailability studies) that are essential to the approval of the application and conducted or sponsored by the sponsor of such application; and

“(iv) that contains an attestation from the sponsor of the application that such reports were not submitted as part of an application for marketing approval or licensure by a regulatory authority in India, Brazil, Thailand, or any country that is a member of the Pharmaceutical Inspection Convention or the Pharmaceutical Inspection Cooperation Scheme prior to September 27, 2007.”.

SEC. 705. GAO STUDY OF ISSUES REGARDING FIRST CYCLE APPROVALS OF GENERIC MEDICINES.

(a) STUDY BY GAO.—The Comptroller General of the United States shall conduct a study to determine the following:

(1) The rate of first cycle approvals and tentative approvals for generic drug applications submitted during the period beginning on October 1, 2012, and ending on September 30, 2017. The rate of first cycle approvals and tentative approvals shall be determined and reported per each GDUFA cohort year during this period.

(2) If the rate determined pursuant to paragraph (1) for any GDUFA cohort year is lower than 20 percent, the reasons contributing to the relatively low rate of first cycle approvals and tentative approvals for generic drug applications shall be itemized, assessed, and reported. In making the assessment required by this paragraph, the Comptroller General shall consider, among other things, the role played by—

(A) the Food and Drug Administration's implementation of approval standards for generic drug applications;

(B) the extent to which those approval standards are communicated clearly to industry and applied consistently during the review process;

(C) the procedures for reviewing generic drug applications, including timelines for review activities by the Food and Drug Administration;

(D) the extent to which those procedures are followed consistently (and those timelines are met) by the Food and Drug Administration;

(E) the processes and practices for communication between the Food and Drug Administration and sponsors of generic drug applications; and

(F) the completeness and quality of original generic drug applications submitted to the Food and Drug Administration.

(3) Taking into account the determinations made pursuant to paragraphs (1) and (2) and any review process improvements implemented pursuant to this Act, whether there are ways the review process for generic drugs could be improved to increase the rate of first cycle approvals and tentative approvals for generic drug applications. In making this determination, the Comptroller General shall consider, among other things, options for increasing review efficiency and communication effectiveness.

(b) COMPLETION DATE.—Not later than the expiration of the 2-year period beginning on the date of enactment of this Act, the Comptroller General shall complete the study under subsection (a) and submit a report describing the findings and conclusions of the study to the Secretary, the Committee on Energy and Commerce of the House of Representatives, and the Committee on Health, Education, Labor, and Pensions of the Senate.

(c) DEFINITIONS.—For purposes of this section:

(1) The term “GDUFA cohort year” means a fiscal year.

(2) The term “generic drug” means a drug that is approved or is seeking approval under section 505(j) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(j)).

(3) The term “generic drug application” means an abbreviated new drug application for the approval of a generic drug under section 505(j) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(j)).

(4) The term “Secretary” means the Secretary of Health and Human Services.

(5)(A) The term “first cycle approvals and tentative approvals” means the approval or tentative approval of a generic drug application after the Food and Drug Administration's complete review of the application and without issuance of one or more complete response letters.

(B) For purposes of this paragraph, the term “complete response letter” means a written communication to the sponsor of a generic drug application or holder of a drug master file (DMF) from the Food and Drug Administration describing all of the deficiencies that the Administration has identified in the generic drug application (including pending amendments) or drug master file that must be satisfactorily addressed before the generic drug application can be approved.

TITLE VIII—FOSTERING INNOVATION IN MEDICAL IMAGING

SEC. 801. APPROVAL OF APPLICATIONS FOR CERTAIN DIAGNOSTIC MEDICAL IMAGING DEVICES.

Section 520 of the Federal Food, Drug, and Cosmetic Act (42 U.S.C. 360j), as amended by section 613, is further amended by adding at the end the following:

“(q) DIAGNOSTIC IMAGING DEVICES INTENDED FOR USE WITH CONTRAST AGENTS.—

“(1) The Secretary may, subject to the succeeding provisions of this subsection, approve an application (or a supplement to such an application) submitted under section 515 with respect to an applicable medical imaging device, or, in the case of an applicable medical imaging device for which a notification is submitted under section 510(k), may make a substantial equivalence determination with respect to an applicable medical imaging device, or may grant a request submitted under section 513(f)(2) for an applicable medical imaging

device, if the indications and conditions of use proposed in such application, notification, or request involve the use of a contrast agent that is not—

“(A) in a concentration, rate of administration, or route of administration that is different from those described in the approved labeling of the contrast agent, except that the Secretary may approve such application, make such substantial equivalence determination, or grant such request if the Secretary determines that such differences in concentration, rate of administration, or route of administration exist but do not adversely affect the safety and effectiveness of the contrast agent when used with the device;

“(B) in a region, organ, or system of the body that is different from those described in the approved labeling of the contrast agent, except that the Secretary may approve such application, make such substantial equivalence determination, or grant such request if the Secretary determines that such differences in region, organ, or system of the body exist but do not adversely affect the safety and effectiveness of the contrast agent when used with the device;

“(C) in a patient population that is different from those described in the approved labeling of the contrast agent, except that the Secretary may approve such application, make such substantial equivalence determination, or grant such request if the Secretary determines such differences in patient population exist but do not adversely affect the safety and effectiveness of the contrast agent when used with the device; or

“(D) in an imaging modality (such as an ultrasound, an x-ray, diagnostic radiopharmaceutical-based technologies, fluorescent imaging technology, or magnetic resonance) that is different from those described in the approved labeling of the contrast agent.

“(2) The agency center charged with premarket review of devices shall have primary jurisdiction with respect to the review of an application, notification, or request described in paragraph (1). In conducting such review, such agency center may—

“(A) consult with the agency center charged with the premarket review of drugs or biological products; and

“(B) review information and data provided to the Secretary by the sponsor of a contrast agent in an application submitted under section 505 of this Act or section 351 of the Public Health Service Act, so long as the sponsor of such contrast agent has provided to the sponsor of the applicable medical imaging device that is the subject of such review a right of reference and the application is submitted in accordance with this subsection.

“(3) An application submitted under section 515, a notification submitted under section 510(k), or a request submitted under section 513(f)(2), as described in paragraph (1), with respect to an applicable medical imaging device shall be subject to the requirements of such respective section. Such application, notification, or request shall only be subject to the requirements of this Act applicable to devices.

“(4) For purposes of this subsection and section 505(y)—

“(A) the term ‘applicable medical imaging device’ means a device intended to be used in conjunction with a contrast agent (or class of contrast agents) for an imaging use that is not described in the approved labeling of such contrast agent (or the approved labeling of any contrast agent in the same class as such contrast agent); and

“(B) the term ‘contrast agent’ means a drug that is approved under section 505 or licensed under section 351 of the Public Health Service Act, is intended for use in conjunction with an applicable medical imaging device, and—

“(i) is a diagnostic radiopharmaceutical, as defined in section 315.2 and 601.31 of title 21, Code of Federal Regulations (or any successor regulations); or

“(ii) is a diagnostic agent that improves the visualization of structure or function within the body by increasing the relative difference in signal intensity within the target tissue, structure, or fluid.”.

SEC. 802. APPLICATIONS FOR APPROVAL OF CONTRAST AGENTS INTENDED FOR USE WITH CERTAIN DIAGNOSTIC MEDICAL IMAGING DEVICES.

Section 505 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355) is amended by adding at the end the following:

“(y) CONTRAST AGENTS INTENDED FOR USE WITH APPLICABLE MEDICAL IMAGING DEVICES.—

“(1) The sponsor of a contrast agent for which an application has been approved under this section may submit a supplement to the application seeking approval for the use of the contrast agent for a new indication and conditions

of use following the authorization of a premarket submission for an applicable medical imaging device for that use with the contrast agent pursuant to section 520(q)(1).

“(2) In reviewing a supplement submitted under this subsection, the agency center charged with the premarket review of drugs may—

“(A) consult with the center charged with the premarket review of devices; and

“(B) review information and data submitted to the Secretary by the sponsor of an applicable medical imaging device pursuant to section 515, 510(k), or 513(f)(2) so long as the sponsor of such applicable medical imaging device has provided to the sponsor of the contrast agent a right of reference.

“(3) For purposes of this subsection—

“(A) the term ‘new indication’ means a use of a contrast agent that is described in the approved labeling of an applicable medical imaging device described in section 520(q), but that is not described in the approved labeling of the contrast agent; and

“(B) the term ‘applicable medical imaging device’ and ‘contrast agent’ have the meanings given such terms in section 520(q).”.

TITLE IX—ADDITIONAL PROVISIONS

SEC. 901. TECHNICAL CORRECTIONS.

(a) Section 3075(a) of the 21st Century Cures Act (Public Law 114–255) is amended—

(1) in the matter preceding paragraph (1), by striking “as amended by section 2074” and inserting “as amended by section 3102”; and

(2) in paragraph (2), by striking “section 2074(1)(C)” and inserting “section 3102(1)(C)”.

(b) Section 506G(b)(1)(A) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 356g(b)(1)(A)) is amended by striking “identity” and inserting “identify”.

(c) Section 505F(b) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355g(b)) is amended by striking “randomized” and inserting “traditional”.

(d) Section 505F(d) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355g(d)) is amended by striking “2” and inserting “3”.

(e) Effective as of the enactment of the 21st Century Cures Act (Public Law 114–255)—

(1) section 3051(a) of such Act is amended by striking “by inserting after section 515B” and inserting “by inserting after section 515A”; and

(2) section 515C of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360e–3), as inserted by such section 3051(a), is redesignated as section 515B.

(f) Section 515B(f)(2) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360e–3(f)(2)), as redesignated by subsection (e)(2) of this section, is amended by striking “a proposed guidance” and inserting “a draft version of that guidance”.

(g) Section 513(b)(5)(D) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360c(b)(5)(D)) is amended by striking “medical device submissions” and inserting “medical devices that may be specifically the subject of a review by a classification panel”.

SEC. 902. REAUTHORIZATION OF THE CRITICAL PATH PUBLIC-PRIVATE PARTNERSHIPS.

Section 566(f) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360bbb–5(f)) is amended by striking “2013 through 2017” and inserting “2018 through 2022”.

PURPOSE AND SUMMARY

The Food and Drug Administration (FDA) Reauthorization Act of 2017 enables FDA to continue to collect user fees from regulated industry to supplement Congressional appropriations. Specifically, the bill revises and reauthorizes the Prescription Drug User Fee Act (PDUFA), the Medical Device User Fee Amendments (MDUFA), the Generic Drug User Fee Amendments (GDUFA), and the Biosimilars User Fee Act (BsUFA) through 2022. In addition, the bill makes a number of changes to improve the regulation of medical products, supports the development of pediatric drugs and medical devices, and will encourage increased generic competition.

BACKGROUND AND NEED FOR LEGISLATION

Since 1992, pursuant to PDUFA, Congress has authorized FDA to collect fees from regulated industry to supplement Congressional appropriations. Revenues generated from these fees have been used on specific activities related to the review and regulation of medical products. FDA also commits to meeting certain performance goals, such as completing product reviews within specified timeframes. FDA's ability to collect such fees must be reauthorized every five years following a process laid out in statute that involves negotiations between the agency and regulated industry and recommendations provided to Congress. The reauthorization process allows for input for other interested stakeholders, including patient and consumer groups, and provides opportunity for broader public comment.

Based in large part on the positive impact PDUFA had on expediting new drug product review times and improving related regulatory activities at FDA, medical device user fees were authorized in 2002 and the Medical Device User Fee Amendments (MDUFA) were reauthorized in 2007 and 2012, along with PDUFA.

Due to growing concerns from a wide range of stakeholders about the time it was taking FDA to review generic drug applications (known as "abbreviated new drug applications" or "ANDAs") and the backlog of such applications pending at the agency, Congress passed the Generic Drug User Fee Amendments (GDUFA) in 2012, as part of the Food and Drug Administration Safety and Innovation Act (FDASIA).

Pursuant to the Biologics Price Competition and Innovation Act (BCPIA) of 2009, Congress established a new regulatory authority for FDA to create an abbreviated approval pathway for biological products demonstrated to be "highly similar" to, or "interchangeable" with, a previously licensed biological product. As part of FDASIA, Congress passed the BsUFA in 2012 to authorize FDA to collect user fees from biosimilar product manufacturers.

Each of these four user fee programs is due to expire at the end of this fiscal year and must be reauthorized through 2022, which the FDA Reauthorization Act of 2017 would do. Throughout conversations and hearings related to the bill, members brought forward additional policies that would improve the regulation of certain medical products. A number of these policies are also included in the bill.

HEARINGS

On March 2, 2017, the Subcommittee on Health held a hearing entitled "Examining FDA's Generic Drug and Biosimilar User Fee Programs" and received testimony from the following witnesses:

- Janet Woodcock, M.D., Director, Center for Drug Evaluation and Research, Food and Drug Administration;
- David Gaugh, Senior Vice President of Sciences and Regulatory Sciences, Association for Accessible Medicines;
- Bruce A. Leicher, Senior Vice President and General Counsel, Momenta Pharmaceuticals, Inc., Chair, The Biosimilars Council, a Division of the Association for Accessible Medicines;

- Juliana Reed, Vice President of Government Affairs, Coherus BioSciences, Immediate Past President, The Biosimilars Forum;
- Kay Holcombe, Senior Vice President of Science Policy, Biotechnology Industry Organization; and,
- Allan Coukell, Senior Director, Health Programs, The Pew Charitable Trusts.

On March 20, 2017, the Subcommittee on Health held a hearing entitled “Examining FDA’s Prescription Drug User Fee Program” and received testimony from the following witnesses:

- Janet Woodcock, M.D., Director, Center for Drug Evaluation and Research, Food and Drug Administration;
- Jeff Allen, President and CEO, Friends of Cancer Research;
- Kay Holcombe, Senior Vice President of Science Policy, Biotechnology Industry Organization; and,
- Anne Pritchett, Vice President of Policy and Research, Pharmaceutical Research and Manufacturers of America.

On March 28, 2017, the Subcommittee on Health held a hearing entitled “Examining FDA’s Medical Device User Fee Program” and received testimony from the following witnesses:

- Jeffrey Shuren, M.D., J.D., Director, Center for Devices and Radiological Health, Food and Drug Administration;
- Cynthia Bens, Vice President of Public Policy, Alliance for Aging Research;
- Robert Kieval, Founder and Chief Development Officer, CVRx;
- Patrick Daly, President and CEO, Cohera Medical; and,
- Diane Wurzbarger, Executive, Regulatory Affairs U.S. and Canada, Global Strategic Policy and Programs, GE Healthcare.

On May 2, 2017, the Subcommittee on Health held a hearing entitled “Examining Improvements to the Regulation of Medical Technologies” and received testimony from the following witnesses:

- Jeffrey Shuren, M.D., J.D., Director, Center for Devices and Radiological Health, Food and Drug Administration;
- Thomas Powers, Ph.D., Powers Consulting, LLC;
- Frank Lin, M.D., Ph.D., Associate Professor of Otolaryngology—Head and Neck Surgery, Geriatric Medicine, Mental Health, and Epidemiology, Johns Hopkins University;
- Joe Robinson, Senior Vice President, Health Systems Solutions, Philips North America;
- Robert Kerwin, General Counsel, International Association of Medical Equipment Remarketers and Servicers; and,
- Patricia Shrader, Vice President, Global Regulatory Affairs, Medtronic.

COMMITTEE CONSIDERATION

On May 18, 2017, the Subcommittee on Health met in open markup session and forwarded H.R. 2430 to the full Committee, as amended, by a voice vote. On June 7, 2017, the full Committee on Energy and Commerce met in open markup session and ordered H.R. 2430 reported to the House, as amended, by a vote of 54 yeas and 0 nays.

COMMITTEE VOTES

Clause 3(b) of rule XIII of the Rules of the House of Representatives requires the Committee to list the record votes on the motion to report legislation and amendments thereto. The following reflects the record votes taken during the Committee consideration:

**COMMITTEE ON ENERGY AND COMMERCE -- 115TH CONGRESS
ROLL CALL VOTE # 33**

BILL: H.R. 2430, FDA Reauthorization Act of 2017

AMENDMENT: A motion by Mr. Walden to order H.R. 2430 favorably reported to the House, as amended.
(Final Passage)

DISPOSITION: **AGREED TO**, by a roll call vote of 54 yeas and 0 nays.

REPRESENTATIVE	YEAS	NAYS	PRESENT	REPRESENTATIVE	YEAS	NAYS	PRESENT
Mr. Walden	X			Mr. Pallone	X		
Mr. Barton	X			Mr. Rush	X		
Mr. Upton	X			Ms. Eshoo	X		
Mr. Shimkus	X			Mr. Engel			
Mr. Murphy	X			Mr. Green	X		
Mr. Burgess	X			Ms. DeGette	X		
Mrs. Blackburn	X			Mr. Doyle	X		
Mr. Scalise	X			Ms. Schakowsky	X		
Mr. Latta	X			Mr. Butterfield	X		
Mrs. McMorris Rodgers	X			Ms. Matsui	X		
Mr. Harper	X			Ms. Castor	X		
Mr. Lance	X			Mr. Sarbanes	X		
Mr. Guthrie	X			Mr. McNerney	X		
Mr. Olson	X			Mr. Welch	X		
Mr. McKinley	X			Mr. Lujan	X		
Mr. Kinzinger	X			Mr. Tonko	X		
Mr. Griffith	X			Ms. Clarke	X		
Mr. Bilirakis	X			Mr. Loeb sack	X		
Mr. Johnson	X			Mr. Schrader	X		
Mr. Long	X			Mr. Kennedy	X		
Mr. Bucshon	X			Mr. Cardenas	X		
Mr. Flores	X			Mr. Ruiz	X		
Mrs. Brooks	X			Mr. Peters	X		
Mr. Mullin	X			Ms. Dingell	X		
Mr. Hudson	X						
Mr. Collins	X						
Mr. Cramer	X						
Mr. Walberg	X						
Mrs. Walters	X						
Mr. Costello	X						
Mr. Carter	X						

06/07/2017

COMMITTEE OVERSIGHT FINDINGS

Pursuant to clause 3(c)(1) of rule XIII of the Rules of the House of Representatives, the Committee held hearings and made findings that are reflected in this report.

STATEMENT OF GENERAL PERFORMANCE GOALS AND OBJECTIVES

The goal of this legislation is to reauthorize four important user fee programs at FDA and to improve the review and regulation of medical products.

NEW BUDGET AUTHORITY, ENTITLEMENT AUTHORITY, AND TAX EXPENDITURES

In compliance with clause 3(c)(2) of rule XIII of the Rules of the House of Representatives, the Committee finds that H.R. 2430, would result in no new or increased budget authority, entitlement authority, or tax expenditures or revenues.

earmark, LIMITED TAX BENEFITS, AND LIMITED TARIFF BENEFITS

In compliance with clause 9(e), 9(f), and 9(g) of rule XXI of the Rules of the House of Representatives, the Committee finds that H.R. 2430 contains no earmarks, limited tax benefits, or limited tariff benefits.

COMMITTEE COST ESTIMATE

The Committee adopts as its own the cost estimate prepared by the Director of the Congressional Budget Office pursuant to section 402 of the Congressional Budget Act of 1974. At the time this report was filed, the estimate was not available.

CONGRESSIONAL BUDGET OFFICE ESTIMATE

Pursuant to clause 3(c)(3) of rule XIII, at the time this report was filed, the cost estimate prepared by the Director of the Congressional Budget Office pursuant to section 402 of the Congressional Budget Act of 1974 was not available.

FEDERAL MANDATES STATEMENT

The Committee adopts as its own the estimate of Federal mandates prepared by the Director of the Congressional Budget Office pursuant to section 423 of the Unfunded Mandates Reform Act.

DUPLICATION OF FEDERAL PROGRAMS

No provision of H.R. 2430 establishes or reauthorizes a program of the Federal Government known to be duplicative of another Federal program, a program that was included in any report from the Government Accountability Office to Congress pursuant to section 21 of Public Law 111-139, or a program related to a program identified in the most recent Catalog of Federal Domestic Assistance.

DISCLOSURE OF DIRECTED RULE MAKINGS

Pursuant to section 3(i) of H. Res. 5, the following directed rule makings are contained in H.R. 2430:

1. Section 603 requires FDA to issue a draft and final guidance document specifying how the agency will implement the process changes for inspecting medical device facilities pursuant to this section.

2. Section 604 requires FDA to issue a draft and final guidance document providing for a process for resolving issues relating to certifications to foreign government for medical devices being exported.

3. Section 613 requires FDA, not later than three years after the date of enactment, to promulgate proposed regulations to establish a category of over-the-counter hearing aids. Not later than 180 days after the date on which the public comment period on the proposed regulations closes, FDA shall issue final regulations.

4. Section 613 also requires FDA to update and finalize a draft guidance document clarifying which products meet the definition of a medical device and which products meet the definition of a personal sound amplification product.

5. Section 701 requires FDA to issue a draft and final guidance document specifying the actions the agency will take to expedite the development and review of certain generic drug applications and, if FDA determines that it is necessary to amend the regulations, the agency shall do so not later than two years after the date of enactment.

ADVISORY COMMITTEE STATEMENT

No advisory committees within the meaning of section 5(b) of the Federal Advisory Committee Act were created by this legislation.

APPLICABILITY TO LEGISLATIVE BRANCH

The Committee finds that the legislation does not relate to the terms and conditions of employment or access to public services or accommodations within the meaning of section 102(b)(3) of the Congressional Accountability Act.

SECTION-BY-SECTION ANALYSIS OF THE LEGISLATION

TITLE I—FEES RELATING TO DRUGS

Section 101. Short title; finding

Section 101 establishes a short title—“Prescription Drug User Fee Amendments of 2017”—and provides that the fees authorized in the title will go toward human prescription drug activities as set forth in the commitment letter submitted to the Congressional Record.

Section 102. Authority to assess and use drug fees

Section 102 reauthorizes FDA’s ability to collect user fees at a higher level, and restructures such fees to reduce administrative burden and make funding more predictable.

The section also modernizes the fee structure and updates the base fee amount. Historically, fees were derived one-third from facility fees, one-third from various application fees, and one-third from product fees. The new structure is derived from 20 percent application fees and 80 percent program fees for approved products.

Supplemental application fees and facility fees are eliminated. In fiscal year (FY) 2018, the base fee amount will be \$878,590,000.

In addition, the section replaces the workload adjustment with a capacity planning adjuster so that fees more accurately reflect the workload and existing staff capacity at FDA.

Section 103. Reauthorization; reporting requirements

Section 103 maintains the existing reauthorization process and reporting requirements. The Secretary of Health and Human Services (HHS) is required to provide recommendations to Congress by January 15, 2022, after an extensive process of public meetings. Performance and financial reports continue to be due to Congress every year.

Section 104. Sunset dates

Section 104 sunsets the authority to collect fees on October 1, 2022, and the requirement to submit performance and financial reports on January 31, 2023.

Section 105. Effective date

Section 105 clarifies that the effective date is October 1, 2017, or date of enactment, whichever is later, and the fee structure and amount in this Act applies to all human drug applications received on or after October 1, 2017, regardless of the date of the enactment of this Act.

Section 106. Savings clause

Section 106 clarifies that submissions made prior to October 1, 2017, will continue to be reviewed and assessed fees based on the agreement for FY 2012 to 2017.

TITLE II—FEES RELATING TO DEVICES

Section 201. Short title; findings

Section 201 establishes a short title—“Medical Device Drug User Fee Amendments of 2017”—and provides that the fees authorized in the title will go toward medical device activities as set forth in the commitment letter submitted to the Congressional Record.

Section 202. Definitions

Section 202 adds the term “de novo classification request” to enable new user fees specifically for review of de novo medical device classification requests.

Section 203. Authority to assess and use device fees

Section 203 adds authority to collect fees for de novo classification request.

The section also updates the target base fee amounts for each year. The FY 2018 base is increased to \$183,280,756, ending at \$213,687,660 in FY 2022.

In addition, the section updates the adjustment for inflation and allows the Secretary of HHS to increase, if necessary, the fees to meet the base target.

Section 203 also reauthorizes the authority to collect, and the availability and crediting, of fees.

Section 204. Reauthorization; reporting requirements

Section 204 maintains the existing reauthorization and reporting requirements. The Secretary of HHS is required to provide recommendations to Congress by January 15, 2022, after an extensive process of public meetings. Performance and financial reports continue to be due to Congress every year.

Section 205. Conformity assessment pilot program

Section 205 establishes a pilot program to provide FDA the authority to audit and certify laboratories who conduct device conformance testing to a recognized standard, and also to withdraw the certification if necessary. FDA is required to evaluate the use of this scheme in at least five device types, or device parts that are found in multiple devices. FDA is also required to obtain public input on the development of the pilot.

The authority for the pilot project sunsets in 2022.

Section 206. Reauthorization of review

Section 206 reauthorizes and provides flexibility for the Secretary of HHS to better target which device types are most appropriate for, third party review.

The section also requires the Secretary of HHS to conduct a public guidance development process to identify the factors the Secretary of HHS will use to determine which devices are eligible for third party review.

Section 207. Electronic format for submissions

FDA currently receives both paper and electronic submissions. Section 207 requires all submissions to be in electronic format by October 1, 2021. The Secretary of HHS has the authority to extend the date as late as April 1, 2023.

Section 208. Savings clause

Section 208 clarifies that submissions made prior to October 1, 2017, will continue to be reviewed and assessed fees based on the agreement for FY 2012 to 2017.

Section 209. Effective date

Section 209 clarifies that the effective date is October 1, 2017, or date of enactment, whichever is later, and the fee structure and amount in this Act applies to all medical device applications received on or after October 1, 2017, regardless of the date of the enactment of this Act.

Section 210. Sunset clause

The authority to collect fees sunsets on October 1, 2022, and the requirement to submit performance and financial reports on January 31, 2023.

TITLE III—FEES RELATING TO GENERIC DRUGS

Section 301. Short title; finding

Section 301 establishes a short title—“Generic Drug User Fee Amendments of 2017”—and provides that the fees authorized in

the title will go toward human generic drug activities, as set forth in the commitment letter submitted to the Congressional Record.

Section 302. Definitions

The definitions are amended to clarify that submissions by a State or Federal Government entity for drugs not intended for sale do not have to pay user fees. A definition for “contract manufacturing organization facility” is also included.

Section 303. Authority to assess and use human generic drug fees

Section 303 updates the fee structure to provide more predictability for FDA and flexibility for small businesses.

The section removes the fees for prior approval supplements and establishes a generic drug applicant program fee.

Thirty-three percent of the total user fee revenue will come from application fees, 20 percent of such revenue will come from generic drug facility fees, seven percent of such revenue will come from active pharmaceutical ingredient facility fees, and 35 percent of such revenue will come from a new generic drug applicant program fee.

The generic drug applicant program fee is determined by how many applications the applicant has approved by the FDA:

- a manufacturer with 20 or more approved applications pays the full fee;
- a manufacturer with six–19 approved applications pays 40 percent of the full fee; and
- a manufacturer with five or fewer approved applications pays 10 percent of the full fee.

The base fee amount is updated to \$493,600,000 in FY 2018.

Section 304. Reauthorization; reporting requirements

Section 304 maintains the existing reauthorization and reporting requirements. The Secretary of HHS is required to provide recommendations to Congress by January 15, 2022, after an extensive process of public meetings. Performance and financial reports continue to be due to Congress every year.

Section 305. Sunset dates

The authority to collect fees sunsets on October 1, 2022, and the requirement to submit performance and financial reports on January 31, 2023.

Section 306. Effective date

Section 306 clarifies that the effective date is October 1, 2017, or date of enactment, whichever is later, and the fee structure and amount in this Act applies to all human generic drug applications received on or after October 1, 2017, regardless of the date of the enactment of this Act.

Section 307. Savings clause

Section 307 clarifies that submissions made prior to October 1, 2017, will continue to be reviewed and assessed fees based on the agreement for FY 2012 to 2017.

TITLE IV—FEES RELATING TO BIOSIMILAR BIOLOGICAL PRODUCTS

Section 401. Short title; finding

Section 401 establishes a short title—“Biosimilar User Fee Amendments of 2017”—and that the fees authorized in the title will go toward biosimilar activities as set forth in the commitment letter submitted to the Congressional Record.

Section 402. Definitions

Technical updates are made to the definitions of “adjustment factor” and “biosimilar biological product to provide clarity.”

Section 403. Authority to assess and use biosimilar fees

Section 403 establishes an independent fee structure for biosimilars for the first time based on the following types of fees:

- Initial Biosimilar Development Fee for the first year once a sponsor begins clinical trials for a new biosimilar;
- Annual Biosimilar Development Fee for subsequent years a sponsor is developing a new biosimilar;
- Biosimilar Program Fee for sponsors of approved biosimilars; and
- Application Fee for new biosimilar applications.

The section eliminates supplement and establishment fees and allows the Secretary of HHS to determine the appropriate percentage that will come from each of the fees, and each fee amount annually. The base fee amount is updated to \$45,000,000.

Section 404. Reauthorization; reporting requirements

Section 404 maintains the existing reauthorization and reporting requirements. The Secretary of HHS is required to provide recommendations to Congress by January 15, 2022, after an extensive process of public meetings. Performance and financial reports continue to be due to Congress every year.

Section 405. Sunset dates

The authority to collect fees sunsets on October 1, 2022, and the requirement to submit performance and financial reports on January 31, 2023.

Section 406. Effective date

Section 406 clarifies that the effective date is October 1, 2017, or date of enactment, whichever is later, and the fee structure and amount in this Act applies to all biosimilar applications received on or after October 1, 2017, regardless of the date of the enactment of this Act.

Section 407. Savings clause

Section 407 clarifies that submissions made prior to October 1, 2017, will continue to be reviewed and assessed fees based on the agreement for FY 2012 to 2017.

TITLE V—REAUTHORIZATIONS AND IMPROVEMENTS RELATED TO
DRUGS

Section 501. Reauthorization of provision relating to exclusivity of certain drugs containing single enantiomers

Section 501 reauthorizes section 505(u), which provides the Secretary of HHS the authority to grant exclusivity for drugs containing single enantiomers, until 2022.

Section 502. Reauthorization of orphan grants program

Section 503 reauthorizes the authority of FDA to issue grants for orphan drug development until 2022.

Section 503. Reauthorization of pediatric study of drugs

Section 503 reauthorizes funding for National Institutes of Health to conduct pediatric trials not being conducted by drug sponsors.

Section 504. Protecting and strengthening the drug supply chain

Section 504 harmonizes the penalties for illegally diverting drugs into the U.S. that were manufactured abroad and intended for foreign markets with the penalties for diverting drugs that were initially manufactured in the U.S.

The section raises the penalties for knowingly making, selling or dispensing, or holding for sale or dispensing, a counterfeit drug to conform with the penalties for illegally diverting drugs.

Section 505. Sense of Congress on lowering the cost of prescription drugs

Section 505 expresses a Sense of Congress that the Secretary of HHS should commit to engaging with Congress on administrative actions and legislative changes to lower the cost of prescription drugs.

TITLE VI—DEVICE INSPECTION AND REGULATORY IMPROVEMENTS

Section 601. Risk-based inspections for devices

Section 601 requires FDA to inspect medical device establishments using a risk-based inspection schedule based on a number of considerations.

Section 602. Recognition of foreign government inspections

Section 602 applies changes made in section 603 to section 809 of the FDCA, recognizing foreign government inspections.

Section 603. Improvements to inspections process for device establishments

Section 603 establishes standards to improve predictability for scheduled (not for-cause) inspections for medical device facilities.

Section 604. Certificates to foreign governments for devices

Section 604 clarifies the process for issuance of foreign export certificates for medical devices. The section also establishes a pathway by which manufacturers denied a certificate can present information and work with FDA to correct any outstanding issue.

Section 605. Facilitating international harmonization

Section 605 allows FDA to recognize auditors used by foreign governments to improve international harmonization of inspection standards and increase FDA access to audit data.

Section 606. Reauthorization of inspection program

Section 606 reauthorizes the authority of FDA to conduct inspections via accredited organizations.

Section 611. Reauthorization of pediatric humanitarian device exceptions

Section 611 reauthorizes rules regarding the development of medical devices for rare pediatric conditions until 2022.

Section 612. Reauthorization of pediatric device consortia

Section 612 reauthorizes the authority of FDA to issue grants to consortia working to develop medical devices for pediatric population at current law authorization levels until 2022.

Section 613. Regulation of over-the-counter hearing aids

Section 613 requires FDA to promulgate regulations to establish a category of over-the-counter (OTC) hearing aids. In doing so, FDA should consult with relevant stakeholders, including hearing aid manufacturers, licensed hearing professionals, patients, and others, during the rulemaking process.

Section 614. Report on ensuring quality, safety, and continued effectiveness of devices that have been serviced

Section 614 requires FDA to issue a report on how the agency intends to ensure the quality, safety, and effectiveness of medical devices that have been serviced, as well as whether FDA's current authority is sufficient to oversee and regulate servicing or whether additional authority is necessary.

Section 615. Device pilot projects to generate reliable and timely safety and active surveillance data

Section 615 creates a new voluntary pilot program for medical device manufacturers who wish to meet FDA reporting or post-market study requirements using active surveillance. Requires FDA to report safety data from the pilot consistent with current reporting.

Section 616. Risk-based classification of accessories

Section 616 clarifies a process by which FDA classifies medical device accessories based on the intended use of the accessory.

TITLE VII—GENERIC DRUG ACCESS AND COMPETITION

Section 701. Competitive Generic Therapies

Section 701 requires FDA to expedite the review and development of generic drugs if there is not more than one approved version of the drug actively being marketed.

Section 702. Enhancing regulatory transparency to enhance generic competition

Section 702 improves communication between FDA and generic drug application sponsors about the categorical status of their applications.

Section 703. Incentivizing competitive generic therapy development

Section 703 provides a period of 180-day market exclusivity to certain generic drug manufacturers that enter the market where there is currently no blocking patents or exclusivities, incentivizing generic drug manufacturers to compete with off-patent drugs.

Section 704. Tropical disease product application

Section 704 clarifies the qualifying criteria for companies receiving a neglected tropical diseases priority review voucher (PRV) to ensure the PRV is awarded to sponsors that conduct new clinical investigations necessary for FDA approval.

Section 705. GAO study of issues regarding first cycle approvals of generic medicines

Section 705 directs the Government Accountability Office (GAO) to issue a report on the rate of generic drug applications that are approved on the first review cycle and related issues.

TITLE VIII—FOSTERING INNOVATION IN MEDICAL IMAGING

Section 801. Approval of applications for certain diagnostic medical imaging devices

Section 801 allows the FDA to approve a medical imaging device with the use of a contrast agent as long as the contrast agent is used at the same dose, in the same patient population, with the same type of imaging technology, and does not pose any additional safety risk.

Section 802. Applications for approval of contrast agents intended for use with certain diagnostic medical imaging devices

Section 802 clarifies that a contrast agent for which an application has been approved may be approved for a new indication or condition of use following the authorization of a premarket submission for an applicable medical imaging device for that use.

TITLE IX—ADDITIONAL PROVISIONS

Section 901. Technical corrections

Section 901 makes technical changes to provisions in 21st Century Cures.

Section 902. Reauthorization of the critical path public-private partnerships

Section 902 reauthorizes the critical path public-private partnership for an additional five years at current law authorization levels.

CHANGES IN EXISTING LAW MADE BY THE BILL, AS REPORTED

In compliance with clause 3(e) of rule XIII of the Rules of the House of Representatives, changes in existing law made by the bill, as reported, are shown as follows (existing law proposed to be omitted is enclosed in black brackets, new matter is printed in italic, and existing law in which no change is proposed is shown in roman):

FEDERAL FOOD, DRUG, AND COSMETIC ACT

* * * * *

CHAPTER III—PROHIBITED ACTS AND PENALTIES

* * * * *

PENALTIES

SEC. 303. (a)(1) Any person who violates a provision of section 301 shall be imprisoned for not more than one year or fined not more than \$1,000, or both.

(2) Notwithstanding the provisions of paragraph (1) of this section, if any person commits such a violation after a conviction of him under this section has become final, or commits such a violation with the intent to defraud or mislead, such person shall be imprisoned for not more than three years or fined not more than \$10,000 or both.

(b)(1) Notwithstanding subsection (a), any person who violates section 301(t) by—

(A) knowingly importing a drug in violation of section 801(d)(1),

(B) knowingly selling, purchasing, or trading a drug or drug sample or knowingly offering to sell, purchase, or trade a drug or drug sample, in violation of section 503(c)(1),

(C) knowingly selling, purchasing, or trading a coupon, knowingly offering to sell, purchase, or trade such a coupon, or knowingly counterfeiting such a coupon, in violation of section 503(c)(2), or

(D) knowingly distributing drugs in violation of section 503(e)(1),

shall be imprisoned for not more than 10 years or fined not more than \$250,000, or both.

(2) Any manufacturer or distributor who distributes drug samples by means other than the mail or common carrier whose representative, during the course of the representative's employment or association with that manufacturer or distributor, violated section 301(t) because of a violation of section 503(c)(1) or violated any State law prohibiting the sale, purchase, or trade of a drug sample subject to section 503(b) or the offer to sell, purchase, or trade such a drug sample shall, upon conviction of the representative for such violation, be subject to the following civil penalties:

(A) A civil penalty of not more than \$50,000 for each of the first two such violations resulting in a conviction of any representative of the manufacturer or distributor in any 10-year period.

(B) A civil penalty of not more than \$1,000,000 for each violation resulting in a conviction of any representative after the second conviction in any 10-year period.

For the purposes of this paragraph, multiple convictions of one or more persons arising out of the same event or transaction, or a related series of events or transactions, shall be considered as one violation.

(3) Any manufacturer or distributor who violates section 301(t) because of a failure to make a report required by section 503(d)(3)(E) shall be subject to a civil penalty of not more than \$100,000.

(4)(A) If a manufacturer or distributor or any representative of such manufacturer or distributor provides information leading to the institution of a criminal proceeding against, and conviction of, any representative of that manufacturer or distributor for a violation of section 301(t) because of a sale, purchase, or trade or offer to purchase, sell, or trade a drug sample in violation of section 503(c)(1) or for a violation of State law prohibiting the sale, purchase, or trade or offer to sell, purchase, or trade a drug sample, the conviction of such representative shall not be considered as a violation for purposes of paragraph (2).

(B) If, in an action brought under paragraph (2) against a manufacturer or distributor relating to the conviction of a representative of such manufacturer or distributor for the sale, purchase, or trade of a drug or the offer to sell, purchase, or trade a drug, it is shown, by clear and convincing evidence—

(i) that the manufacturer or distributor conducted, before the institution of a criminal proceeding against such representative for the violation which resulted in such conviction, an investigation of events or transactions which would have led to the reporting of information leading to the institution of a criminal proceeding against, and conviction of, such representative for such purchase, sale, or trade or offer to purchase, sell, or trade, or

(ii) that, except in the case of the conviction of a representative employed in a supervisory function, despite diligent implementation by the manufacturer or distributor of an independent audit and security system designed to detect such a violation, the manufacturer or distributor could not reasonably have been expected to have detected such violation, the conviction of such representative shall not be considered as a conviction for purposes of paragraph (2).

(5) If a person provides information leading to the institution of a criminal proceeding against, and conviction of, a person for a violation of section 301(t) because of the sale, purchase, or trade of a drug sample or the offer to sell, purchase, or trade a drug sample in violation of section 503(c)(1), such person shall be entitled to one-half of the criminal fine imposed and collected for such violation but not more than \$125,000.

(6) Notwithstanding subsection (a), any person who is a manufacturer or importer of a prescription drug under section 804(b) and knowingly fails to comply with a requirement of section 804(e) that is applicable to such manufacturer or importer, respectively, shall be imprisoned for not more than 10 years or fined not more than \$250,000, or both.

(7) Notwithstanding subsection (a)(2), any person that knowingly and intentionally adulterates a drug such that the drug is adulterated under subsection (a)(1), (b), (c), or (d) of section 501 and has a reasonable probability of causing serious adverse health consequences or death to humans or animals shall be imprisoned for not more than 20 years or fined not more than \$1,000,000, or both.

(8) *Notwithstanding subsection (a), any person who violates section 301(i)(3) by knowingly making, selling or dispensing, or holding for sale or dispensing, a counterfeit drug shall be imprisoned for not more than 10 years or fined in accordance with title 18, United States Code, or both.*

(c) No person shall be subject to the penalties of subsection (a)(1) of this section, (1) for having received in interstate commerce any article and delivered it or proffered delivery of it, if such delivery or proffer was made in good faith, unless he refuses to furnish on request of an officer or employee duly designated by the Secretary the name and address of the person from whom he purchased or received such article and copies of all documents, if any there be, pertaining to the delivery of the article to him; or (2) for having violated section 301(a) or (d), if he establishes a guaranty or undertaking signed by, and containing the name and address of, the person residing in the United States from whom he received in good faith the article, to the effect, in case of an alleged violation of section 301(a), that such article is not adulterated or misbranded, within the meaning of this Act, designating this Act, or to the effect, in case of an alleged violation of section 301(d), that such article is not an article which may not, under the provisions of section 404 or 505, be introduced into interstate commerce; or (3) for having violated section 301(a), where the violation exists because the article is adulterated by reason of containing a color additive not from a batch certified in accordance with regulations promulgated by the Secretary under this Act, if such person establishes a guaranty or undertaking signed by, and containing the name and address of, the manufacturer of the color additive, to the effect that such color additive was from a batch certified in accordance with the applicable regulations promulgated by the Secretary under this Act; or (4) for having violated section 301 (b), (c), or (k) by failure to comply with section 502(f) in respect to an article received in interstate commerce to which neither section 503(a) nor section 503(b)(1) is applicable, if the delivery or proffered delivery was made in good faith and the labeling at the time thereof contained the same directions for use and warning statements as were contained in the labeling at the time of such receipt of such article; or (5) for having violated section 301(i)(2) if such person acted in good faith and had no reason to believe that use of the punch, die, plate, stone, or other thing involved would result in a drug being a counterfeit drug, or for having violated section 301(i)(3) if the person doing the act or causing it to be done acted in good faith and had no reason to believe that the drug was a counterfeit drug.

(d) No person shall be subject to the penalties of subsection (a)(1) of this section for a violation of section 301 involving misbranded food if the violation exists solely because the food is misbranded under section 403(a)(2) because of its advertising.

(e)(1) Except as provided in paragraph (2), whoever knowingly distributes, or possesses with intent to distribute, human growth

hormone for any use in humans other than the treatment of a disease or other recognized medical condition, where such use has been authorized by the Secretary of Health and Human Services under section 505 and pursuant to the order of a physician, is guilty of an offense punishable by not more than 5 years in prison, such fines as are authorized by title 18, United States Code, or both.

(2) Whoever commits any offense set forth in paragraph (1) and such offense involves an individual under 18 years of age is punishable by not more than 10 years imprisonment, such fines as are authorized by title 18, United States Code, or both.

(3) Any conviction for a violation of paragraphs (1) and (2) of this subsection shall be considered a felony violation of the Controlled Substances Act for the purposes of forfeiture under section 413 of such Act.

(4) As used in this subsection the term "human growth hormone" means somatrem, somatropin, or an analogue of either of them.

(5) The Drug Enforcement Administration is authorized to investigate offenses punishable by this subsection.

(f)(1)(A) Except as provided in subparagraph (B), any person who violates a requirement of this Act which relates to devices shall be liable to the United States for a civil penalty in an amount not to exceed \$15,000 for each such violation, and not to exceed \$1,000,000 for all such violations adjudicated in a single proceeding. For purposes of the preceding sentence, a person accredited under paragraph (2) of section 704(g) who is substantially not in compliance with the standards of accreditation under such section, or who poses a threat to public health or fails to act in a manner that is consistent with the purposes of such section, shall be considered to have violated a requirement of this Act that relates to devices.

(B) Subparagraph (A) shall not apply—

(i) to any person who violates the requirements of section 519(a) or 520(f) unless such violation constitutes (I) a significant or knowing departure from such requirements, or (II) a risk to public health,

(ii) to any person who commits minor violations of section 519(e) or 519(g) (only with respect to correction reports) if such person demonstrates substantial compliance with such section, or

(iii) to violations of section 501(a)(2)(A) which involve one or more devices which are not defective.

(2)(A) Any person who introduces into interstate commerce or delivers for introduction into interstate commerce an article of food that is adulterated within the meaning of section 402(a)(2)(B) or any person who does not comply with a recall order under section 423 shall be subject to a civil money penalty of not more than \$50,000 in the case of an individual and \$250,000 in the case of any other person for such introduction or delivery, not to exceed \$500,000 for all such violations adjudicated in a single proceeding.

(B) This paragraph shall not apply to any person who grew the article of food that is adulterated. If the Secretary assesses a civil penalty against any person under this paragraph, the Secretary may not use the criminal authorities under this section to sanction such person for the introduction or delivery for introduction into

interstate commerce of the article of food that is adulterated. If the Secretary assesses a civil penalty against any person under this paragraph, the Secretary may not use the seizure authorities of section 304 or the injunction authorities of section 302 with respect to the article of food that is adulterated.

(C) In a hearing to assess a civil penalty under this paragraph, the presiding officer shall have the same authority with regard to compelling testimony or production of documents as a presiding officer has under section 408(g)(2)(B). The third sentence of paragraph (5)(A) shall not apply to any investigation under this paragraph.

(3)(A) Any person who violates section 301(jj) shall be subject to a civil monetary penalty of not more than \$10,000 for all violations adjudicated in a single proceeding.

(B) If a violation of section 301(jj) is not corrected within the 30-day period following notification under section 402(j)(5)(C)(ii), the person shall, in addition to any penalty under subparagraph (A), be subject to a civil monetary penalty of not more than \$10,000 for each day of the violation after such period until the violation is corrected.

(4)(A) Any responsible person (as such term is used in section 505-1) that violates a requirement of section 505(o), 505(p), or 505-1 shall be subject to a civil monetary penalty of—

(i) not more than \$250,000 per violation, and not to exceed \$1,000,000 for all such violations adjudicated in a single proceeding; or

(ii) in the case of a violation that continues after the Secretary provides written notice to the responsible person, the responsible person shall be subject to a civil monetary penalty of \$250,000 for the first 30-day period (or any portion thereof) that the responsible person continues to be in violation, and such amount shall double for every 30-day period thereafter that the violation continues, not to exceed \$1,000,000 for any 30-day period, and not to exceed \$10,000,000 for all such violations adjudicated in a single proceeding.

(B) In determining the amount of a civil penalty under subparagraph (A)(ii), the Secretary shall take into consideration whether the responsible person is making efforts toward correcting the violation of the requirement of section 505(o), 505(p), or 505-1 for which the responsible person is subject to such civil penalty.

(5)(A) A civil penalty under paragraph (1), (2), (3), (4), or (9) shall be assessed, or a no-tobacco-sale order may be imposed, by the Secretary by an order made on the record after opportunity for a hearing provided in accordance with this subparagraph and section 554 of title 5, United States Code. Before issuing such an order, the Secretary shall give written notice to the person to be assessed a civil penalty, or upon whom a no-tobacco-sale order is to be imposed, under such order of the Secretary's proposal to issue such order and provide such person an opportunity for a hearing on the order. In the course of any investigation, the Secretary may issue subpoenas requiring the attendance and testimony of witnesses and the production of evidence that relates to the matter under investigation.

(B) In determining the amount of a civil penalty, or the period to be covered by a no-tobacco-sale order, the Secretary shall take

into account the nature, circumstances, extent, and gravity of the violation or violations and, with respect to the violator, ability to pay, effect on ability to continue to do business, any history of prior such violations, the degree of culpability, and such other matters as justice may require. A no-tobacco-sale order permanently prohibiting an individual retail outlet from selling tobacco products shall include provisions that allow the outlet, after a specified period of time, to request that the Secretary compromise, modify, or terminate the order.

(C) The Secretary may compromise, modify, or remit, with or without conditions, any civil penalty which may be assessed under paragraph (1), (2), (3), (4), or (9). The amount of such penalty, when finally determined, or the amount agreed upon in compromise, may be deducted from any sums owing by the United States to the person charged.

(D) The Secretary may compromise, modify, or terminate, with or without conditions, any no-tobacco-sale order.

(6) Any person who requested, in accordance with paragraph (5)(A), a hearing respecting the assessment of a civil penalty or the imposition of a no-tobacco-sale order and who is aggrieved by an order assessing a civil penalty or the imposition of a no-tobacco-sale order may file a petition for judicial review of such order with the United States Court of Appeals for the District of Columbia Circuit or for any other circuit in which such person resides or transacts business. Such a petition may only be filed within the 60-day period beginning on the date the order making such assessment was issued, or on which the no-tobacco-sale order was imposed, as the case may be.

(7) If any person fails to pay an assessment of a civil penalty—

(A) after the order making the assessment becomes final, and if such person does not file a petition for judicial review of the order in accordance with paragraph (6), or

(B) after a court in an action brought under paragraph (6) has entered a final judgment in favor of the Secretary,

the Attorney General shall recover the amount assessed (plus interest at currently prevailing rates from the date of the expiration of the 60-day period referred to in paragraph (6) or the date of such final judgment, as the case may be) in an action brought in any appropriate district court of the United States. In such an action, the validity, amount, and appropriateness of such penalty shall not be subject to review.

(8) If the Secretary finds that a person has committed repeated violations of restrictions promulgated under section 906(d) at a particular retail outlet then the Secretary may impose a no-tobacco-sale order on that person prohibiting the sale of tobacco products in that outlet. A no-tobacco-sale order may be imposed with a civil penalty under paragraph (1). Prior to the entry of a no-sale order under this paragraph, a person shall be entitled to a hearing pursuant to the procedures established through regulations of the Food and Drug Administration for assessing civil money penalties, including at a retailer's request a hearing by telephone, or at the nearest regional or field office of the Food and Drug Administration, or at a Federal, State, or county facility within 100 miles from the location of the retail outlet, if such a facility is available.

(9) CIVIL MONETARY PENALTIES FOR VIOLATION OF TOBACCO PRODUCT REQUIREMENTS.—

(A) IN GENERAL.—Subject to subparagraph (B), any person who violates a requirement of this Act which relates to tobacco products shall be liable to the United States for a civil penalty in an amount not to exceed \$15,000 for each such violation, and not to exceed \$1,000,000 for all such violations adjudicated in a single proceeding.

(B) ENHANCED PENALTIES.—

(i) Any person who intentionally violates a requirement of section 902(5), 902(6), 904, 908(c), or 911(a), shall be subject to a civil monetary penalty of—

(I) not to exceed \$250,000 per violation, and not to exceed \$1,000,000 for all such violations adjudicated in a single proceeding; or

(II) in the case of a violation that continues after the Secretary provides written notice to such person, \$250,000 for the first 30-day period (or any portion thereof) that the person continues to be in violation, and such amount shall double for every 30-day period thereafter that the violation continues, not to exceed \$1,000,000 for any 30-day period, and not to exceed \$10,000,000 for all such violations adjudicated in a single proceeding.

(ii) Any person who violates a requirement of section 911(g)(2)(C)(ii) or 911(i)(1), shall be subject to a civil monetary penalty of—

(I) not to exceed \$250,000 per violation, and not to exceed \$1,000,000 for all such violations adjudicated in a single proceeding; or

(II) in the case of a violation that continues after the Secretary provides written notice to such person, \$250,000 for the first 30-day period (or any portion thereof) that the person continues to be in violation, and such amount shall double for every 30-day period thereafter that the violation continues, not to exceed \$1,000,000 for any 30-day period, and not to exceed \$10,000,000 for all such violations adjudicated in a single proceeding.

(iii) In determining the amount of a civil penalty under clause (i)(II) or (ii)(II), the Secretary shall take into consideration whether the person is making efforts toward correcting the violation of the requirements of the section for which such person is subject to such civil penalty.

(g)(1) With respect to a person who is a holder of an approved application under section 505 for a drug subject to section 503(b) or under section 351 of the Public Health Service Act, any such person who disseminates or causes another party to disseminate a direct-to-consumer advertisement that is false or misleading shall be liable to the United States for a civil penalty in an amount not to exceed \$250,000 for the first such violation in any 3-year period, and not to exceed \$500,000 for each subsequent violation in any 3-year period. No other civil monetary penalties in this Act (including the civil penalty in section 303(f)(4)) shall apply to a violation regarding direct-to-consumer advertising. For purposes of this para-

graph: (A) Repeated dissemination of the same or similar advertisement prior to the receipt of the written notice referred to in paragraph (2) for such advertisements shall be considered one violation. (B) On and after the date of the receipt of such a notice, all violations under this paragraph occurring in a single day shall be considered one violation. With respect to advertisements that appear in magazines or other publications that are published less frequently than daily, each issue date (whether weekly or monthly) shall be treated as a single day for the purpose of calculating the number of violations under this paragraph.

(2) A civil penalty under paragraph (1) shall be assessed by the Secretary by an order made on the record after providing written notice to the person to be assessed a civil penalty and an opportunity for a hearing in accordance with this paragraph and section 554 of title 5, United States Code. If upon receipt of the written notice, the person to be assessed a civil penalty objects and requests a hearing, then in the course of any investigation related to such hearing, the Secretary may issue subpoenas requiring the attendance and testimony of witnesses and the production of evidence that relates to the matter under investigation, including information pertaining to the factors described in paragraph (3).

(3) The Secretary, in determining the amount of the civil penalty under paragraph (1), shall take into account the nature, circumstances, extent, and gravity of the violation or violations, including the following factors:

(A) Whether the person submitted the advertisement or a similar advertisement for review under section 736A.

(B) Whether the person submitted the advertisement for review if required under section 503B.

(C) Whether, after submission of the advertisement as described in subparagraph (A) or (B), the person disseminated or caused another party to disseminate the advertisement before the end of the 45-day comment period.

(D) Whether the person incorporated any comments made by the Secretary with regard to the advertisement into the advertisement prior to its dissemination.

(E) Whether the person ceased distribution of the advertisement upon receipt of the written notice referred to in paragraph (2) for such advertisement.

(F) Whether the person had the advertisement reviewed by qualified medical, regulatory, and legal reviewers prior to its dissemination.

(G) Whether the violations were material.

(H) Whether the person who created the advertisement or caused the advertisement to be created acted in good faith.

(I) Whether the person who created the advertisement or caused the advertisement to be created has been assessed a civil penalty under this provision within the previous 1-year period.

(J) The scope and extent of any voluntary, subsequent remedial action by the person.

(K) Such other matters, as justice may require.

(4)(A) Subject to subparagraph (B), no person shall be required to pay a civil penalty under paragraph (1) if the person submitted the advertisement to the Secretary and disseminated or caused an-

other party to disseminate such advertisement after incorporating each comment received from the Secretary.

(B) The Secretary may retract or modify any prior comments the Secretary has provided to an advertisement submitted to the Secretary based on new information or changed circumstances, so long as the Secretary provides written notice to the person of the new views of the Secretary on the advertisement and provides a reasonable time for modification or correction of the advertisement prior to seeking any civil penalty under paragraph (1).

(5) The Secretary may compromise, modify, or remit, with or without conditions, any civil penalty which may be assessed under paragraph (1). The amount of such penalty, when finally determined, or the amount charged upon in compromise, may be deducted from any sums owed by the United States to the person charged.

(6) Any person who requested, in accordance with paragraph (2), a hearing with respect to the assessment of a civil penalty and who is aggrieved by an order assessing a civil penalty, may file a petition for de novo judicial review of such order with the United States Court of Appeals for the District of Columbia Circuit or for any other circuit in which such person resides or transacts business. Such a petition may only be filed within the 60-day period beginning on the date the order making such assessments was issued.

(7) If any person fails to pay an assessment of a civil penalty under paragraph (1)—

(A) after the order making the assessment becomes final, and if such person does not file a petition for judicial review of the order in accordance with paragraph (6), or

(B) after a court in an action brought under paragraph (6) has entered a final judgment in favor of the Secretary, the Attorney General of the United States shall recover the amount assessed (plus interest at currently prevailing rates from the date of the expiration of the 60-day period referred to in paragraph (6) or the date of such final judgment, as the case may be) in an action brought in any appropriate district court of the United States. In such an action, the validity, amount, and appropriateness of such penalty shall not be subject to review.

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CHAPTER V—DRUGS AND DEVICES

SUBCHAPTER A—DRUGS AND DEVICES

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NEW DRUGS

SEC. 505. (a) No person shall introduce or deliver for introduction into interstate commerce any new drug, unless an approval of an application filed pursuant to subsection (b) or (j) is effective with respect to such drug.

(b)(1) Any person may file with the Secretary an application with respect to any drug subject to the provisions of subsection (a). Such persons shall submit to the Secretary as a part of the application (A) full reports of investigations which have been made to show

whether or not such drug is safe for use and whether such drug is effective in use; (B) a full list of the articles used as components of such drug; (C) a full statement of the composition of such drug; (D) a full description of the methods used in, and the facilities and controls used for, the manufacture, processing, and packing of such drug; (E) such samples of such drug and of the articles used as components thereof as the Secretary may require; (F) specimens of the labeling proposed to be used for such drug, and (G) any assessments required under section 505B. The applicant shall file with the application the patent number and the expiration date of any patent which claims the drug for which the applicant submitted the application or which claims a method of using such drug and with respect to which a claim of patent infringement could reasonably be asserted if a person not licensed by the owner engaged in the manufacture use, or sale of the drug. If a application is filed under this subsection for a drug and a patent which claims such drug or a method of using such drug is issued after the filing date but before approval of the application, the applicant shall amend the application to include the information required by the preceding sentence. Upon approval of the application, the Secretary shall publish information submitted under the two preceding sentences. The Secretary shall, in consultation with the Director of the National Institutes of Health and with representatives of the drug manufacturing industry, review and develop guidance, as appropriate, on the inclusion of women and minorities in clinical trials required by clause (A).

(2) An application submitted under paragraph (1) for a drug for which the investigations described in clause (A) of such paragraph and relied upon by the applicant for approval of the application were not conducted by or for the applicant and for which the applicant has not obtained a right of reference or use from the person by or for whom the investigations were conducted shall also include—

(A) a certification, in the opinion of the applicant and to the best of his knowledge, with respect to each patent which claims the drug for which such investigations were conducted or which claims a use for such drug for which the applicant is seeking approval under this subsection and for which information is required to be filed under paragraph (1) or subsection (c)—

(i) that such patent information has not been filed,

(ii) that such patent has expired,

(iii) of the date on which such patent will expire, or

(iv) that such patent is invalid or will not be infringed

by the manufacture, use, or sale of the new drug for which the application is submitted; and

(B) if with respect to the drug for which investigations described in paragraph (1)(A) were conducted information was filed under paragraph (1) or subsection (c) for a method of use patent which does not claim a use for which the applicant is seeking approval under this subsection, a statement that the method of use patent does not claim such a use.

(3) NOTICE OF OPINION THAT PATENT IS INVALID OR WILL NOT BE INFRINGED.—

(A) AGREEMENT TO GIVE NOTICE.—An applicant that makes a certification described in paragraph (2)(A)(iv) shall include in the application a statement that the applicant will give notice as required by this paragraph.

(B) TIMING OF NOTICE.—An applicant that makes a certification described in paragraph (2)(A)(iv) shall give notice as required under this paragraph—

(i) if the certification is in the application, not later than 20 days after the date of the postmark on the notice with which the Secretary informs the applicant that the application has been filed; or

(ii) if the certification is in an amendment or supplement to the application, at the time at which the applicant submits the amendment or supplement, regardless of whether the applicant has already given notice with respect to another such certification contained in the application or in an amendment or supplement to the application.

(C) RECIPIENTS OF NOTICE.—An applicant required under this paragraph to give notice shall give notice to—

(i) each owner of the patent that is the subject of the certification (or a representative of the owner designated to receive such a notice); and

(ii) the holder of the approved application under this subsection for the drug that is claimed by the patent or a use of which is claimed by the patent (or a representative of the holder designated to receive such a notice).

(D) CONTENTS OF NOTICE.—A notice required under this paragraph shall—

(i) state that an application that contains data from bioavailability or bioequivalence studies has been submitted under this subsection for the drug with respect to which the certification is made to obtain approval to engage in the commercial manufacture, use, or sale of the drug before the expiration of the patent referred to in the certification; and

(ii) include a detailed statement of the factual and legal basis of the opinion of the applicant that the patent is invalid or will not be infringed.

(4)(A) An applicant may not amend or supplement an application referred to in paragraph (2) to seek approval of a drug that is a different drug than the drug identified in the application as submitted to the Secretary.

(B) With respect to the drug for which such an application is submitted, nothing in this subsection or subsection (c)(3) prohibits an applicant from amending or supplementing the application to seek approval of a different strength.

(5)(A) The Secretary shall issue guidance for the individuals who review applications submitted under paragraph (1) or under section 351 of the Public Health Service Act, which shall relate to promptness in conducting the review, technical excellence, lack of bias and conflict of interest, and knowledge of regulatory and scientific standards, and which shall apply equally to all individuals who review such applications.

(B) The Secretary shall meet with a sponsor of an investigation or an applicant for approval for a drug under this subsection or sec-

tion 351 of the Public Health Service Act if the sponsor or applicant makes a reasonable written request for a meeting for the purpose of reaching agreement on the design and size—

(i)(I) of clinical trials intended to form the primary basis of an effectiveness claim; or

(II) in the case where human efficacy studies are not ethical or feasible, of animal and any associated clinical trials which, in combination, are intended to form the primary basis of an effectiveness claim; or

(ii) with respect to an application for approval of a biological product under section 351(k) of the Public Health Service Act, of any necessary clinical study or studies.

The sponsor or applicant shall provide information necessary for discussion and agreement on the design and size of the clinical trials. Minutes of any such meeting shall be prepared by the Secretary and made available to the sponsor or applicant upon request.

(C) Any agreement regarding the parameters of the design and size of clinical trials of a new drug under this paragraph that is reached between the Secretary and a sponsor or applicant shall be reduced to writing and made part of the administrative record by the Secretary. Such agreement shall not be changed after the testing begins, except—

(i) with the written agreement of the sponsor or applicant;

or

(ii) pursuant to a decision, made in accordance with subparagraph (D) by the director of the reviewing division, that a substantial scientific issue essential to determining the safety or effectiveness of the drug has been identified after the testing has begun.

(D) A decision under subparagraph (C)(ii) by the director shall be in writing and the Secretary shall provide to the sponsor or applicant an opportunity for a meeting at which the director and the sponsor or applicant will be present and at which the director will document the scientific issue involved.

(E) The written decisions of the reviewing division shall be binding upon, and may not directly or indirectly be changed by, the field or compliance division personnel unless such field or compliance division personnel demonstrate to the reviewing division why such decision should be modified.

(F) No action by the reviewing division may be delayed because of the unavailability of information from or action by field personnel unless the reviewing division determines that a delay is necessary to assure the marketing of a safe and effective drug.

(G) For purposes of this paragraph, the reviewing division is the division responsible for the review of an application for approval of a drug under this subsection or section 351 of the Public Health Service Act (including all scientific and medical matters, chemistry, manufacturing, and controls).

(6) An application submitted under this subsection shall be accompanied by the certification required under section 402(j)(5)(B) of the Public Health Service Act. Such certification shall not be considered an element of such application.

(c)(1) Within one hundred and eighty days after the filing of an application under subsection (b), or such additional period as may

be agreed upon by the Secretary and the applicant, the Secretary shall either—

(A) approve the application if he then finds that none of the grounds for denying approval specified in subsection (d) applies, or

(B) give the applicant notice of an opportunity for a hearing before the Secretary under subsection (d) on the question whether such application is approvable. If the applicant elects to accept the opportunity for hearing by written request within thirty days after such notice, such hearing shall commence not more than ninety days after the expiration of such thirty days unless the Secretary and the applicant otherwise agree. Any such hearing shall thereafter be conducted on an expedited basis and the Secretary's order thereon shall be issued within ninety days after the date fixed by the Secretary for filing final briefs.

(2) If the patent information described in subsection (b) could not be filed with the submission of an application under subsection (b) because the application was filed before the patent information was required under subsection (b) or a patent was issued after the application was approved under such subsection, the holder of an approved application shall file with the Secretary, the patent number and the expiration date of any patent which claims the drug for which the application was submitted or which claims a method of using such drug and with respect to which a claim of patent infringement could reasonably be asserted if a person not licensed by the owner engaged in the manufacture, use, or sale of the drug. If the holder of an approved application could not file patent information under subsection (b) because it was not required at the time the application was approved, the holder shall file such information under this subsection not later than thirty days after the date of the enactment of this sentence, and if the holder of an approved application could not file patent information under subsection (b) because no patent had been issued when an application was filed or approved, the holder shall file such information under this subsection not later than thirty days after after the date the patent involved is issued. Upon the submission of patent information under this subsection, the Secretary shall publish it.

(3) The approval of an application filed under subsection (b) which contains a certification required by paragraph (2) of such subsection shall be made effective on the last applicable date determined by applying the following to each certification made under subsection (b)(2)(A):

(A) If the applicant only made a certification described in clause (i) or (ii) of subsection (b)(2)(A) or in both such clauses, the approval may be made effective immediately.

(B) If the applicant made a certification described in clause (iii) of subsection (b)(2)(A), the approval may be made effective on the date certified under clause (iii).

(C) If the applicant made a certification described in clause (iv) of subsection (b)(2)(A), the approval shall be made effective immediately unless, before the expiration of 45 days after the date on which the notice described in subsection (b)(3) is received, an action is brought for infringement of the patent that is the subject of the certification and for which information was

submitted to the Secretary under paragraph (2) or subsection (b)(1) before the date on which the application (excluding an amendment or supplement to the application) was submitted. If such an action is brought before the expiration of such days, the approval may be made effective upon the expiration of the thirty-month period beginning on the date of the receipt of the notice provided under subsection (b)(3) or such shorter or longer period as the court may order because either party to the action failed to reasonably cooperate in expediting the action, except that—

- (i) if before the expiration of such period the district court decides that the patent is invalid or not infringed (including any substantive determination that there is no cause of action for patent infringement or invalidity), the approval shall be made effective on—
 - (I) the date on which the court enters judgment reflecting the decision; or
 - (II) the date of a settlement order or consent decree signed and entered by the court stating that the patent that is the subject of the certification is invalid or not infringed;
 - (ii) if before the expiration of such period the district court decides that the patent has been infringed—
 - (I) if the judgment of the district court is appealed, the approval shall be made effective on—
 - (aa) the date on which the court of appeals decides that the patent is invalid or not infringed (including any substantive determination that there is no cause of action for patent infringement or invalidity); or
 - (bb) the date of a settlement order or consent decree signed and entered by the court of appeals stating that the patent that is the subject of the certification is invalid or not infringed; or
 - (II) if the judgment of the district court is not appealed or is affirmed, the approval shall be made effective on the date specified by the district court in a court order under section 271(e)(4)(A) of title 35, United States Code;
 - (iii) if before the expiration of such period the court grants a preliminary injunction prohibiting the applicant from engaging in the commercial manufacture or sale of the drug until the court decides the issues of patent validity and infringement and if the court decides that such patent is invalid or not infringed, the approval shall be made effective as provided in clause (i); or
 - (iv) if before the expiration of such period the court grants a preliminary injunction prohibiting the applicant from engaging in the commercial manufacture or sale of the drug until the court decides the issues of patent validity and infringement and if the court decides that such patent has been infringed, the approval shall be made effective as provided in clause (ii).
- In such an action, each of the parties shall reasonably cooperate in expediting the action.

(D) CIVIL ACTION TO OBTAIN PATENT CERTAINTY.—

(i) DECLARATORY JUDGMENT ABSENT INFRINGEMENT ACTION.—

(I) IN GENERAL.—No action may be brought under section 2201 of title 28, United States Code, by an applicant referred to in subsection (b)(2) for a declaratory judgment with respect to a patent which is the subject of the certification referred to in subparagraph (C) unless—

(aa) the 45-day period referred to in such subparagraph has expired;

(bb) neither the owner of such patent nor the holder of the approved application under subsection (b) for the drug that is claimed by the patent or a use of which is claimed by the patent brought a civil action against the applicant for infringement of the patent before the expiration of such period; and

(cc) in any case in which the notice provided under paragraph (2)(B) relates to noninfringement, the notice was accompanied by a document described in subclause (III).

(II) FILING OF CIVIL ACTION.—If the conditions described in items (aa), (bb), and as applicable, (cc) of subclause (I) have been met, the applicant referred to in such subclause may, in accordance with section 2201 of title 28, United States Code, bring a civil action under such section against the owner or holder referred to in such subclause (but not against any owner or holder that has brought such a civil action against the applicant, unless that civil action was dismissed without prejudice) for a declaratory judgment that the patent is invalid or will not be infringed by the drug for which the applicant seeks approval, except that such civil action may be brought for a declaratory judgment that the patent will not be infringed only in a case in which the condition described in subclause (I)(cc) is applicable. A civil action referred to in this subclause shall be brought in the judicial district where the defendant has its principal place of business or a regular and established place of business.

(III) OFFER OF CONFIDENTIAL ACCESS TO APPLICATION.—For purposes of subclause (I)(cc), the document described in this subclause is a document providing an offer of confidential access to the application that is in the custody of the applicant referred to in subsection (b)(2) for the purpose of determining whether an action referred to in subparagraph (C) should be brought. The document providing the offer of confidential access shall contain such restrictions as to persons entitled to access, and on the use and disposition of any information accessed, as would apply had a protective order been entered for the purpose of protecting trade secrets and other confidential business information. A request for access to an application

under an offer of confidential access shall be considered acceptance of the offer of confidential access with the restrictions as to persons entitled to access, and on the use and disposition of any information accessed, contained in the offer of confidential access, and those restrictions and other terms of the offer of confidential access shall be considered terms of an enforceable contract. Any person provided an offer of confidential access shall review the application for the sole and limited purpose of evaluating possible infringement of the patent that is the subject of the certification under subsection (b)(2)(A)(iv) and for no other purpose, and may not disclose information of no relevance to any issue of patent infringement to any person other than a person provided an offer of confidential access. Further, the application may be redacted by the applicant to remove any information of no relevance to any issue of patent infringement.

(ii) COUNTERCLAIM TO INFRINGEMENT ACTION.—

(I) IN GENERAL.—If an owner of the patent or the holder of the approved application under subsection (b) for the drug that is claimed by the patent or a use of which is claimed by the patent brings a patent infringement action against the applicant, the applicant may assert a counterclaim seeking an order requiring the holder to correct or delete the patent information submitted by the holder under subsection (b) or this subsection on the ground that the patent does not claim either—

(aa) the drug for which the application was approved; or

(bb) an approved method of using the drug.

(II) NO INDEPENDENT CAUSE OF ACTION.—Subclause (I) does not authorize the assertion of a claim described in subclause (I) in any civil action or proceeding other than a counterclaim described in subclause (I).

(iii) NO DAMAGES.—An applicant shall not be entitled to damages in a civil action under clause (i) or a counterclaim under clause (ii).

(E)(i) If an application (other than an abbreviated new drug application) submitted under subsection (b) for a drug, no active ingredient (including any ester or salt of the active ingredient) of which has been approved in any other application under subsection (b), was approved during the period beginning January 1, 1982, and ending on the date of the enactment of this subsection, the Secretary may not make the approval of another application for a drug for which the investigations described in clause (A) of subsection (b)(1) and relied upon by the applicant for approval of the application were not conducted by or for the applicant and for which the applicant has not obtained a right of reference or use from the person by or for whom the investigations were conducted effective before the expiration of ten years from the date of the approval of the application previously approved under subsection (b).

(ii) If an application submitted under subsection (b) for a drug, no active ingredient (including any ester or salt of the active ingredient) of which has been approved in any other application under subsection (b), is approved after the date of the enactment of this clause, no application which refers to the drug for which the subsection (b) application was submitted and for which the investigations described in clause (A) of subsection (b)(1) and relied upon by the applicant for approval of the application were not conducted by or for the applicant and for which the applicant has not obtained a right of reference or use from the person by or for whom the investigations were conducted may be submitted under subsection (b) before the expiration of five years from the date of the approval of the application under subsection (b), except that such an application may be submitted under subsection (b) after the expiration of four years from the date of the approval of the subsection (b) application if it contains a certification of patent invalidity or noninfringement described in clause (iv) of subsection (b)(2)(A). The approval of such an application shall be made effective in accordance with this paragraph except that, if an action for patent infringement is commenced during the one-year period beginning forty-eight months after the date of the approval of the subsection (b) application, the thirty-month period referred to in subparagraph (C) shall be extended by such amount of time (if any) which is required for seven and one-half years to have elapsed from the date of approval of the subsection (b) application.

(iii) If an application submitted under subsection (b) for a drug, which includes an active ingredient (including any ester or salt of the active ingredient) that has been approved in another application approved under subsection (b), is approved after the date of the enactment of this clause and if such application contains reports of new clinical investigations (other than bioavailability studies) essential to the approval of the application and conducted or sponsored by the applicant, the Secretary may not make the approval of an application submitted under subsection (b) for the conditions of approval of such drug in the approved subsection (b) application effective before the expiration of three years from the date of the approval of the application under subsection (b) if the investigations described in clause (A) of subsection (b)(1) and relied upon by the applicant for approval of the application were not conducted by or for the applicant and if the applicant has not obtained a right of reference or use from the person by or for whom the investigations were conducted.

(iv) If a supplement to an application approved under subsection (b) is approved after the date of enactment of this clause and the supplement contains reports of new clinical investigations (other than bioavailability studies) essential to the approval of the supplement and conducted or sponsored by the person submitting the supplement, the Secretary may not make the approval of an application submitted under subsection (b) for a change approved in the supplement effective before the expiration of three years from the date of the approval of the supplement under subsection (b) if the investiga-

tions described in clause (A) of subsection (b)(1) and relied upon by the applicant for approval of the application were not conducted by or for the applicant and if the applicant has not obtained a right of reference or use from the person by or for whom the investigations were conducted.

(v) If an application (or supplement to an application) submitted under subsection (b) for a drug, which includes an active ingredient (including any ester or salt of the active ingredient) that has been approved in another application under subsection (b), was approved during the period beginning January 1, 1982, and ending on the date of the enactment of this clause, the Secretary may not make the approval of an application submitted under this subsection and for which the investigations described in clause (A) of subsection (b)(1) and relied upon by the applicant for approval of the application were not conducted by or for the applicant and for which the applicant has not obtained a right of reference or use from the person by or for whom the investigations were conducted and which refers to the drug for which the subsection (b) application was submitted effective before the expiration of two years from the date of enactment of this clause.

(4) A drug manufactured in a pilot or other small facility may be used to demonstrate the safety and effectiveness of the drug and to obtain approval for the drug prior to manufacture of the drug in a larger facility, unless the Secretary makes a determination that a full scale production facility is necessary to ensure the safety or effectiveness of the drug.

(5)(A) The Secretary may rely upon qualified data summaries to support the approval of a supplemental application, with respect to a qualified indication for a drug, submitted under subsection (b), if such supplemental application complies with subparagraph (B).

(B) A supplemental application is eligible for review as described in subparagraph (A) only if—

(i) there is existing data available and acceptable to the Secretary demonstrating the safety of the drug; and

(ii) all data used to develop the qualified data summaries are submitted to the Secretary as part of the supplemental application.

(C) The Secretary shall post on the Internet website of the Food and Drug Administration and update annually—

(i) the number of applications reviewed solely under subparagraph (A) or section 351(a)(2)(E) of the Public Health Service Act;

(ii) the average time for completion of review under subparagraph (A) or section 351(a)(2)(E) of the Public Health Service Act;

(iii) the average time for review of supplemental applications where the Secretary did not use review flexibility under subparagraph (A) or section 351(a)(2)(E) of the Public Health Service Act; and

(iv) the number of applications reviewed under subparagraph (A) or section 351(a)(2)(E) of the Public Health Service Act for which the Secretary made use of full data sets in addition to the qualified data summary.

(D) In this paragraph—

(i) the term “qualified indication” means an indication for a drug that the Secretary determines to be appropriate for summary level review under this paragraph; and

(ii) the term “qualified data summary” means a summary of clinical data that demonstrates the safety and effectiveness of a drug with respect to a qualified indication.

(d) If the Secretary finds, after due notice to the applicant in accordance with subsection (c) and giving him an opportunity for a hearing, in accordance with said subsection, that (1) the investigations, reports of which are required to be submitted to the Secretary pursuant to subsection (b), do not include adequate tests by all methods reasonably applicable to show whether or not such drug is safe for use under the conditions prescribed, recommended, or suggested in the proposed labeling thereof; (2) the results of such tests show that such drug is unsafe for use under such conditions or do not show that such drug is safe for use under such conditions; (3) the methods used in, and the facilities and controls used for, the manufacture, processing, and packing of such drug are inadequate to preserve its identity, strength, quality, and purity; (4) upon the basis of the information submitted to him as part of the application, or upon the basis of any other information before him with respect to such drug, he has insufficient information to determine whether such drug is safe for use under such conditions; or (5) evaluated on the basis of the information submitted to him as part of the application and any other information before him with respect to such drug, there is a lack of substantial evidence that the drug will have the effect it purports or is represented to have under the conditions of use prescribed, recommended, or suggested in the proposed labeling thereof; or (6) the application failed to contain the patent information prescribed by subsection (b); or (7) based on a fair evaluation of all material facts, such labeling is false or misleading in any particular; he shall issue an order refusing to approve the application. If, after such notice and opportunity for hearing, the Secretary finds that clauses (1) through (6) do not apply, he shall issue an order approving the application. As used in this subsection and subsection (e), the term “substantial evidence” means evidence consisting of adequate and well-controlled investigations, including clinical investigations, by experts qualified by scientific training and experience to evaluate the effectiveness of the drug involved, on the basis of which it could fairly and responsibly be concluded by such experts that the drug will have the effect it purports or is represented to have under the conditions of use prescribed, recommended, or suggested in the labeling or proposed labeling thereof. If the Secretary determines, based on relevant science, that data from one adequate and well-controlled clinical investigation and confirmatory evidence (obtained prior to or after such investigation) are sufficient to establish effectiveness, the Secretary may consider such data and evidence to constitute substantial evidence for purposes of the preceding sentence. The Secretary shall implement a structured risk-benefit assessment framework in the new drug approval process to facilitate the balanced consideration of benefits and risks, a consistent and systematic approach to the discussion and regulatory decisionmaking, and the communication of the benefits and risks of new drugs. Nothing

in the preceding sentence shall alter the criteria for evaluating an application for marketing approval of a drug.

(e) The Secretary shall, after due notice and opportunity for hearing to the applicant, withdraw approval of an application with respect to any drug under this section if the Secretary finds (1) that clinical or other experience, tests, or other scientific data show that such drug is unsafe for use under the conditions of use upon the basis of which the application was approved; (2) that new evidence of clinical experience, not contained in such application or not available to the Secretary until after such application was approved, or tests by new methods, or tests by methods not deemed reasonably applicable when such application was approved, evaluated together with the evidence available to the Secretary when the application was approved, shows that such drug is not shown to be safe for use under the conditions of use upon the basis of which the application was approved; or (3) on the basis of new information before him with respect to such drug, evaluated together with the evidence available to him when the application was approved, that there is a lack of substantial evidence that the drug will have the effect it purports or is represented to have under the conditions of use prescribed, recommended, or suggested in the labeling thereof; or (4) the patent information prescribed by subsection (c) was not filed within thirty days after the receipt of written notice from the Secretary specifying the failure to file such information; or (5) that the application contains any untrue statement of a material fact: *Provided*, That if the Secretary (or in his absence the officer acting as Secretary) finds that there is an imminent hazard to the public health, he may suspend the approval of such application immediately, and give the applicant prompt notice of his action and afford the applicant the opportunity for an expedited hearing under this subsection; but the authority conferred by this proviso to suspend the approval of an application shall not be delegated. The Secretary may also, after due notice and opportunity for hearing to the applicant, withdraw the approval of an application submitted under subsection (b) or (j) with respect to any drug under this section if the Secretary finds (1) that the applicant has failed to establish a system for maintaining required records, or has repeatedly or deliberately failed to maintain such records or to make required reports, in accordance with a regulation or order under subsection (k) or to comply with the notice requirements of section 510(k)(2), or the applicant has refused to permit access to, or copying or verification of, such records as required by paragraph (2) of such subsection; or (2) that on the basis of new information before him, evaluated together with the evidence before him when the application was approved, the methods used in, or the facilities and controls used for, the manufacture, processing, and packing of such drug are inadequate to assure and preserve its identity, strength, quality, and purity and were not made adequate within a reasonable time after receipt of written notice from the Secretary specifying the matter complained of; or (3) that on the basis of new information before him, evaluated together with the evidence before him when the application was approved, the labeling of such drug, based on a fair evaluation of all material facts, is false or misleading in any particular and was not corrected within a reasonable time after receipt of written notice from the Secretary speci-

fyng the matter complained of. Any order under this subsection shall state the findings upon which it is based. The Secretary may withdraw the approval of an application submitted under this section, or suspend the approval of such an application, as provided under this subsection, without first ordering the applicant to submit an assessment of the approved risk evaluation and mitigation strategy for the drug under section 505-1(g)(2)(D).

(f) Whenever the Secretary finds that the facts so require, he shall revoke any previous order under subsection (d) or (e) refusing, withdrawing, or suspending approval of an application and shall approve such application or reinstate such approval, as may be appropriate.

(g) Orders of the Secretary issued under this section shall be served (1) in person by any officer or employee of the Department designated by the Secretary or (2) by mailing the order by registered mail or by certified mail addressed to the applicant or respondent at his last-known address in the records of the Secretary.

(h) An appeal may be taken by the applicant from an order of the Secretary refusing or withdrawing approval of an application under this section. Such appeal shall be taken by filing in the United States court of appeals for the circuit wherein such applicant resides or has his principal place of business, or in the United States Court of Appeals for the District of Columbia Circuit, within sixty days after the entry of such order, a written petition praying that the order of the Secretary be set aside. A copy of such petition shall be forthwith transmitted by the clerk of the court to the Secretary, or any officer designated by him for that purpose, and thereupon the Secretary shall certify and file in the court the record upon which the order complained of was entered, as provided in section 2112 of title 28, United States Code. Upon the filing of such petition such court shall have exclusive jurisdiction to affirm or set aside such order, except that until the filing of the record the Secretary may modify or set aside his order. No objection to the order of the Secretary shall be considered by the court unless such objection shall have been urged before the Secretary or unless there were reasonable grounds for failure so to do. The finding of the Secretary as to the facts, if supported by substantial evidence, shall be conclusive. If any person shall apply to the court for leave to adduce additional evidence, and shall show to the satisfaction of the court that such additional evidence is material and that there were reasonable grounds for failure to adduce such evidence in the proceeding before the Secretary, the court may order such additional evidence to be taken before the Secretary and to be adduced upon the hearing in such manner and upon such terms and conditions as to the court may seem proper. The Secretary may modify his findings as to the facts by reason of the additional evidence so taken, and he shall file with the court such modified findings which, if supported by substantial evidence, shall be conclusive, and his recommendation, if any, for the setting aside of the original order. The judgment of the court affirming or setting aside any such order of the Secretary shall be final, subject to review by the Supreme Court of the United States upon certiorari or certification as provided in section 1254 of title 28 of the United States Code. The commencement of proceedings under this subsection

shall not, unless specifically ordered by the court to the contrary, operate as a stay of the Secretary's order.

(i)(1) The Secretary shall promulgate regulations for exempting from the operation of the foregoing subsections of this section drugs intended solely for investigational use by experts qualified by scientific training and experience to investigate the safety and effectiveness of drugs. Such regulations may, within the discretion of the Secretary, among other conditions relating to the protection of the public health, provide for conditioning such exemption upon—

(A) the submission to the Secretary, before any clinical testing of a new drug is undertaken, of reports, by the manufacturer or the sponsor of the investigation of such drug, or pre-clinical tests (including tests on animals) of such drug adequate to justify the proposed clinical testing;

(B) the manufacturer or the sponsor of the investigation of a new drug proposed to be distributed to investigators for clinical testing obtaining a signed agreement from each of such investigators that patients to whom the drug is administered will be under his personal supervision, or under the supervision of investigators responsible to him, and that he will not supply such drug to any other investigator, or to clinics, for administration to human beings;

(C) the establishment and maintenance of such records, and the making of such reports to the Secretary, by the manufacturer or the sponsor of the investigation of such drug, of data (including but not limited to analytical reports by investigators) obtained as the result of such investigational use of such drug, as the Secretary finds will enable him to evaluate the safety and effectiveness of such drug in the event of the filing of an application pursuant to subsection (b); and

(D) the submission to the Secretary by the manufacturer or the sponsor of the investigation of a new drug of a statement of intent regarding whether the manufacturer or sponsor has plans for assessing pediatric safety and efficacy.

(2) Subject to paragraph (3), a clinical investigation of a new drug may begin 30 days after the Secretary has received from the manufacturer or sponsor of the investigation a submission containing such information about the drug and the clinical investigation, including—

(A) information on design of the investigation and adequate reports of basic information, certified by the applicant to be accurate reports, necessary to assess the safety of the drug for use in clinical investigation; and

(B) adequate information on the chemistry and manufacturing of the drug, controls available for the drug, and primary data tabulations from animal or human studies.

(3)(A) At any time, the Secretary may prohibit the sponsor of an investigation from conducting the investigation (referred to in this paragraph as a "clinical hold") if the Secretary makes a determination described in subparagraph (B). The Secretary shall specify the basis for the clinical hold, including the specific information available to the Secretary which served as the basis for such clinical hold, and confirm such determination in writing.

(B) For purposes of subparagraph (A), a determination described in this subparagraph with respect to a clinical hold is that—

(i) the drug involved represents an unreasonable risk to the safety of the persons who are the subjects of the clinical investigation, taking into account the qualifications of the clinical investigators, information about the drug, the design of the clinical investigation, the condition for which the drug is to be investigated, and the health status of the subjects involved; or

(ii) the clinical hold should be issued for such other reasons as the Secretary may by regulation establish (including reasons established by regulation before the date of the enactment of the Food and Drug Administration Modernization Act of 1997).

(C) Any written request to the Secretary from the sponsor of an investigation that a clinical hold be removed shall receive a decision, in writing and specifying the reasons therefor, within 30 days after receipt of such request. Any such request shall include sufficient information to support the removal of such clinical hold.

(4) Regulations under paragraph (1) shall provide that such exemption shall be conditioned upon the manufacturer, or the sponsor of the investigation, requiring that experts using such drugs for investigational purposes certify to such manufacturer or sponsor that they will inform any human beings to whom such drugs, or any controls used in connection therewith, are being administered, or their representatives, that such drugs are being used for investigational purposes and will obtain the consent of such human beings or their representatives, except where it is not feasible, it is contrary to the best interests of such human beings, or the proposed clinical testing poses no more than minimal risk to such human beings and includes appropriate safeguards as prescribed to protect the rights, safety, and welfare of such human beings. Nothing in this subsection shall be construed to require any clinical investigator to submit directly to the Secretary reports on the investigational use of drugs. The Secretary shall update such regulations to require inclusion in the informed consent documents and process a statement that clinical trial information for such clinical investigation has been or will be submitted for inclusion in the registry data bank pursuant to subsection (j) of section 402 of the Public Health Service Act.

(j)(1) Any person may file with the Secretary an abbreviated application for the approval of a new drug.

(2)(A) An abbreviated application for a new drug shall contain—

(i) information to show that the conditions of use prescribed, recommended, or suggested in the labeling proposed for the new drug have been previously approved for a drug listed under paragraph (7) (hereinafter in this subsection referred to as a “listed drug”);

(ii)(I) if the listed drug referred to in clause (i) has only one active ingredient, information to show that the active ingredient of the new drug is the same as that of the listed drug;

(II) if the listed drug referred to in clause (i) has more than one active ingredient, information to show that the active ingredients of the new drug are the same as those of the listed drug, or

(III) if the listed drug referred to in clause (i) has more than one active ingredient and if one of the active ingredients of the new drug is different and the application is filed pursuant to the approval of a petition filed under subparagraph (C), information to show that the other active ingredients of the new drug are the same as the active ingredients of the listed drug, information to show that the different active ingredient is an active ingredient of a listed drug or of a drug which does not meet the requirements of section 201(p), and such other information respecting the different active ingredient with respect to which the petition was filed as the Secretary may require;

(iii) information to show that the route of administration, the dosage form, and the strength of the new drug are the same as those of the listed drug referred to in clause (i) or, if the route of administration, the dosage form, or the strength of the new drug is different and the application is filed pursuant to the approval of a petition filed under subparagraph (C), such information respecting the route of administration, dosage form, or strength with respect to which the petition was filed as the Secretary may require;

(iv) information to show that the new drug is bioequivalent to the listed drug referred to in clause (i), except that if the application is filed pursuant to the approval of a petition filed under subparagraph (C), information to show that the active ingredients of the new drug are of the same pharmacological or therapeutic class as those of the listed drug referred to in clause (i) and the new drug can be expected to have the same therapeutic effect as the listed drug when administered to patients for a condition of use referred to in clause (i);

(v) information to show that the labeling proposed for the new drug is the same as the labeling approved for the listed drug referred to in clause (i) except for changes required because of differences approved under a petition filed under subparagraph (C) or because the new drug and the listed drug are produced or distributed by different manufacturers;

(vi) the items specified in clauses (B) through (F) of subsection (b)(1);

(vii) a certification, in the opinion of the applicant and to the best of his knowledge, with respect to each patent which claims the listed drug referred to in clause (i) or which claims a use for such listed drug for which the applicant is seeking approval under this subsection and for which information is required to be filed under subsection (b) or (c)—

(I) that such patent information has not been filed,

(II) that such patent has expired,

(III) of the date on which such patent will expire, or

(IV) that such patent is invalid or will not be infringed

by the manufacture, use, or sale of the new drug for which the application is submitted; and

(viii) if with respect to the listed drug referred to in clause (i) information was filed under subsection (b) or (c) for a method of use patent which does not claim a use for which the applicant is seeking approval under this subsection, a statement that the method of use patent does not claim such a use.

The Secretary may not require that an abbreviated application contain information in addition to that required by clauses (i) through (viii).

(B) NOTICE OF OPINION THAT PATENT IS INVALID OR WILL NOT BE INFRINGED.—

(i) AGREEMENT TO GIVE NOTICE.—An applicant that makes a certification described in subparagraph (A)(vii)(IV) shall include in the application a statement that the applicant will give notice as required by this subparagraph.

(ii) TIMING OF NOTICE.—An applicant that makes a certification described in subparagraph (A)(vii)(IV) shall give notice as required under this subparagraph—

(I) if the certification is in the application, not later than 20 days after the date of the postmark on the notice with which the Secretary informs the applicant that the application has been filed; or

(II) if the certification is in an amendment or supplement to the application, at the time at which the applicant submits the amendment or supplement, regardless of whether the applicant has already given notice with respect to another such certification contained in the application or in an amendment or supplement to the application.

(iii) RECIPIENTS OF NOTICE.—An applicant required under this subparagraph to give notice shall give notice to—

(I) each owner of the patent that is the subject of the certification (or a representative of the owner designated to receive such a notice); and

(II) the holder of the approved application under subsection (b) for the drug that is claimed by the patent or a use of which is claimed by the patent (or a representative of the holder designated to receive such a notice).

(iv) CONTENTS OF NOTICE.—A notice required under this subparagraph shall—

(I) state that an application that contains data from bioavailability or bioequivalence studies has been submitted under this subsection for the drug with respect to which the certification is made to obtain approval to engage in the commercial manufacture, use, or sale of the drug before the expiration of the patent referred to in the certification; and

(II) include a detailed statement of the factual and legal basis of the opinion of the applicant that the patent is invalid or will not be infringed.

(C) If a person wants to submit an abbreviated application for a new drug which has a different active ingredient or whose route of administration, dosage form, or strength differ from that of a listed drug, such person shall submit a petition to the Secretary seeking permission to file such an application. The Secretary shall approve or disapprove a petition submitted under this subparagraph within ninety days of the date the petition is submitted. The Secretary shall approve such a petition unless the Secretary finds—

(i) that investigations must be conducted to show the safety and effectiveness of the drug or of any of its active ingredients, the route of administration, the dosage form, or strength which differ from the listed drug; or

(ii) that any drug with a different active ingredient may not be adequately evaluated for approval as safe and effective on the basis of the information required to be submitted in an abbreviated application.

(D)(i) An applicant may not amend or supplement an application to seek approval of a drug referring to a different listed drug from the listed drug identified in the application as submitted to the Secretary.

(ii) With respect to the drug for which an application is submitted, nothing in this subsection prohibits an applicant from amending or supplementing the application to seek approval of a different strength.

(iii) Within 60 days after the date of the enactment of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003, the Secretary shall issue guidance defining the term "listed drug" for purposes of this subparagraph.

(3)(A) The Secretary shall issue guidance for the individuals who review applications submitted under paragraph (1), which shall relate to promptness in conducting the review, technical excellence, lack of bias and conflict of interest, and knowledge of regulatory and scientific standards, and which shall apply equally to all individuals who review such applications.

(B) The Secretary shall meet with a sponsor of an investigation or an applicant for approval for a drug under this subsection if the sponsor or applicant makes a reasonable written request for a meeting for the purpose of reaching agreement on the design and size of bioavailability and bioequivalence studies needed for approval of such application. The sponsor or applicant shall provide information necessary for discussion and agreement on the design and size of such studies. Minutes of any such meeting shall be prepared by the Secretary and made available to the sponsor or applicant.

(C) Any agreement regarding the parameters of design and size of bioavailability and bioequivalence studies of a drug under this paragraph that is reached between the Secretary and a sponsor or applicant shall be reduced to writing and made part of the administrative record by the Secretary. Such agreement shall not be changed after the testing begins, except—

(i) with the written agreement of the sponsor or applicant;

or

(ii) pursuant to a decision, made in accordance with subparagraph (D) by the director of the reviewing division, that a substantial scientific issue essential to determining the safety or effectiveness of the drug has been identified after the testing has begun.

(D) A decision under subparagraph (C)(ii) by the director shall be in writing and the Secretary shall provide to the sponsor or applicant an opportunity for a meeting at which the director and the sponsor or applicant will be present and at which the director will document the scientific issue involved.

(E) The written decisions of the reviewing division shall be binding upon, and may not directly or indirectly be changed by, the field or compliance office personnel unless such field or compliance office personnel demonstrate to the reviewing division why such decision should be modified.

(F) No action by the reviewing division may be delayed because of the unavailability of information from or action by field personnel unless the reviewing division determines that a delay is necessary to assure the marketing of a safe and effective drug.

(G) For purposes of this paragraph, the reviewing division is the division responsible for the review of an application for approval of a drug under this subsection (including scientific matters, chemistry, manufacturing, and controls).

(4) Subject to paragraph (5), the Secretary shall approve an application for a drug unless the Secretary finds—

(A) the methods used in, or the facilities and controls used for, the manufacture, processing, and packing of the drug are inadequate to assure and preserve its identity, strength, quality, and purity;

(B) information submitted with the application is insufficient to show that each of the proposed conditions of use have been previously approved for the listed drug referred to in the application;

(C)(i) if the listed drug has only one active ingredient, information submitted with the application is insufficient to show that the active ingredient is the same as that of the listed drug;

(ii) if the listed drug has more than one active ingredient, information submitted with the application is insufficient to show that the active ingredients are the same as the active ingredients of the listed drug, or

(iii) if the listed drug has more than one active ingredient and if the application is for a drug which has an active ingredient different from the listed drug, information submitted with the application is insufficient to show—

(I) that the other active ingredients are the same as the active ingredients of the listed drug, or

(II) that the different active ingredient is an active ingredient of a listed drug or a drug which does not meet the requirements of section 201(p),

or no petition to file an application for the drug with the different ingredient was approved under paragraph (2)(C);

(D)(i) if the application is for a drug whose route of administration, dosage form, or strength of the drug is the same as the route of administration, dosage form, or strength of the listed drug referred to in the application, information submitted in the application is insufficient to show that the route of administration, dosage form, or strength is the same as that of the listed drug, or

(ii) if the application is for a drug whose route of administration, dosage form, or strength of the drug is different from that of the listed drug referred to in the application, no petition to file an application for the drug with the different route of administration, dosage form, or strength was approved under paragraph (2)(C);

(E) if the application was filed pursuant to the approval of a petition under paragraph (2)(C), the application did not contain the information required by the Secretary respecting the active ingredient, route of administration, dosage form, or strength which is not the same;

(F) information submitted in the application is insufficient to show that the drug is bioequivalent to the listed drug referred to in the application or, if the application was filed pursuant to a petition approved under paragraph (2)(C), information submitted in the application is insufficient to show that the active ingredients of the new drug are of the same pharmacological or therapeutic class as those of the listed drug referred to in paragraph (2)(A)(i) and that the new drug can be expected to have the same therapeutic effect as the listed drug when administered to patients for a condition of use referred to in such paragraph;

(G) information submitted in the application is insufficient to show that the labeling proposed for the drug is the same as the labeling approved for the listed drug referred to in the application except for changes required because of differences approved under a petition filed under paragraph (2)(C) or because the drug and the listed drug are produced or distributed by different manufacturers;

(H) information submitted in the application or any other information available to the Secretary shows that (i) the inactive ingredients of the drug are unsafe for use under the conditions prescribed, recommended, or suggested in the labeling proposed for the drug, or (ii) the composition of the drug is unsafe under such conditions because of the type or quantity of inactive ingredients included or the manner in which the inactive ingredients are included;

(I) the approval under subsection (c) of the listed drug referred to in the application under this subsection has been withdrawn or suspended for grounds described in the first sentence of subsection (e), the Secretary has published a notice of opportunity for hearing to withdraw approval of the listed drug under subsection (c) for grounds described in the first sentence of subsection (e), the approval under this subsection of the listed drug referred to in the application under this subsection has been withdrawn or suspended under paragraph (6), or the Secretary has determined that the listed drug has been withdrawn from sale for safety or effectiveness reasons;

(J) the application does not meet any other requirement of paragraph (2)(A); or

(K) the application contains an untrue statement of material fact.

(5)(A) Within one hundred and eighty days of the initial receipt of an application under paragraph (2) or within such additional period as may be agreed upon by the Secretary and the applicant, the Secretary shall approve or disapprove the application.

(B) The approval of an application submitted under paragraph (2) shall be made effective on the last applicable date determined by applying the following to each certification made under paragraph (2)(A)(vii):

(i) If the applicant only made a certification described in subclause (I) or (II) of paragraph (2)(A)(vii) or in both such subclauses, the approval may be made effective immediately.

(ii) If the applicant made a certification described in subclause (III) of paragraph (2)(A)(vii), the approval may be made effective on the date certified under subclause (III).

(iii) If the applicant made a certification described in subclause (IV) of paragraph (2)(A)(vii), the approval shall be made effective immediately unless, before the expiration of 45 days after the date on which the notice described in paragraph (2)(B) is received, an action is brought for infringement of the patent that is the subject of the certification and for which information was submitted to the Secretary under subsection (b)(1) or (c)(2) before the date on which the application (excluding an amendment or supplement to the application), which the Secretary later determines to be substantially complete, was submitted. If such an action is brought before the expiration of such days, the approval shall be made effective upon the expiration of the thirty-month period beginning on the date of the receipt of the notice provided under paragraph (2)(B)(i) or such shorter or longer period as the court may order because either party to the action failed to reasonably cooperate in expediting the action, except that—

(I) if before the expiration of such period the district court decides that the patent is invalid or not infringed (including any substantive determination that there is no cause of action for patent infringement or invalidity), the approval shall be made effective on—

(aa) the date on which the court enters judgment reflecting the decision; or

(bb) the date of a settlement order or consent decree signed and entered by the court stating that the patent that is the subject of the certification is invalid or not infringed;

(II) if before the expiration of such period the district court decides that the patent has been infringed—

(aa) if the judgment of the district court is appealed, the approval shall be made effective on—

(AA) the date on which the court of appeals decides that the patent is invalid or not infringed (including any substantive determination that there is no cause of action for patent infringement or invalidity); or

(BB) the date of a settlement order or consent decree signed and entered by the court of appeals stating that the patent that is the subject of the certification is invalid or not infringed; or

(bb) if the judgment of the district court is not appealed or is affirmed, the approval shall be made effective on the date specified by the district court in a court order under section 271(e)(4)(A) of title 35, United States Code;

(III) if before the expiration of such period the court grants a preliminary injunction prohibiting the applicant from engaging in the commercial manufacture or sale of the drug until the court decides the issues of patent validity and infringement and if the court decides that such patent is invalid or not infringed, the approval shall be made effective as provided in subclause (I); or

(IV) if before the expiration of such period the court grants a preliminary injunction prohibiting the applicant

from engaging in the commercial manufacture or sale of the drug until the court decides the issues of patent validity and infringement and if the court decides that such patent has been infringed, the approval shall be made effective as provided in subclause (II).

In such an action, each of the parties shall reasonably cooperate in expediting the action.

(iv) 180-DAY EXCLUSIVITY PERIOD.—

(I) EFFECTIVENESS OF APPLICATION.—Subject to subparagraph (D), if the application contains a certification described in paragraph (2)(A)(vii)(IV) and is for a drug for which a first applicant has submitted an application containing such a certification, the application shall be made effective on the date that is 180 days after the date of the first commercial marketing of the drug (including the commercial marketing of the listed drug) by any first applicant.

(II) DEFINITIONS.—In this paragraph:

(aa) 180-DAY EXCLUSIVITY PERIOD.—The term “180-day exclusivity period” means the 180-day period ending on the day before the date on which an application submitted by an applicant other than a first applicant could become effective under this clause.

(bb) FIRST APPLICANT.—As used in this subsection, the term “first applicant” means an applicant that, on the first day on which a substantially complete application containing a certification described in paragraph (2)(A)(vii)(IV) is submitted for approval of a drug, submits a substantially complete application that contains and lawfully maintains a certification described in paragraph (2)(A)(vii)(IV) for the drug.

(cc) SUBSTANTIALLY COMPLETE APPLICATION.—As used in this subsection, the term “substantially complete application” means an application under this subsection that on its face is sufficiently complete to permit a substantive review and contains all the information required by paragraph (2)(A).

(dd) TENTATIVE APPROVAL.—

(AA) IN GENERAL.—The term “tentative approval” means notification to an applicant by the Secretary that an application under this subsection meets the requirements of paragraph (2)(A), but cannot receive effective approval because the application does not meet the requirements of this subparagraph, there is a period of exclusivity for the listed drug under subparagraph (F) or section 505A, or there is a 7-year period of exclusivity for the listed drug under section 527.

(BB) LIMITATION.—A drug that is granted tentative approval by the Secretary is not an approved drug and shall not have an effective approval until the Secretary issues an approval after any necessary additional review of the application.

(v) 180-DAY EXCLUSIVITY PERIOD FOR COMPETITIVE GENERIC THERAPIES.—

(I) *EFFECTIVENESS OF APPLICATION.*—Subject to subparagraph (D)(iv), if the application is for a drug that is the same as a competitive generic therapy for which any first approved applicant has commenced commercial marketing, the application shall be made effective on the date that is 180 days after the date of the first commercial marketing of the competitive generic therapy (including the commercial marketing of the listed drug) by any first approved applicant.

(II) *LIMITATION.*—The exclusivity period under subclause (I) shall not apply with respect to a competitive generic therapy that has previously received an exclusivity period under subclause (I).

(III) *DEFINITIONS.*—In this clause and subparagraph (D)(iv):

(aa) The term “competitive generic therapy” means a drug—

(AA) that is designated as a competitive generic therapy under section 506H; and

(BB) for which there are no unexpired patents or blocking exclusivities on the list of products described in section 505(j)(7)(A) at the time of approval.

(bb) The term “first approved applicant” means any applicant that has submitted an application that—

(AA) is for a competitive generic therapy that is approved on the first day on which any application for such competitive generic therapy is approved;

(BB) is not eligible for a 180-day exclusivity period under clause (iv) for the drug that is the subject of the application for the competitive generic therapy; and

(CC) is not for a drug for which all drug versions have forfeited eligibility for a 180-day exclusivity period under clause (iv) pursuant to subparagraph (D).

(C) *CIVIL ACTION TO OBTAIN PATENT CERTAINTY.*—

(i) *DECLARATORY JUDGMENT ABSENT INFRINGEMENT ACTION.*—

(I) *IN GENERAL.*—No action may be brought under section 2201 of title 28, United States Code, by an applicant under paragraph (2) for a declaratory judgment with respect to a patent which is the subject of the certification referred to in subparagraph (B)(iii) unless—

(aa) the 45-day period referred to in such subparagraph has expired;

(bb) neither the owner of such patent nor the holder of the approved application under subsection (b) for the drug that is claimed by the patent or a use of which is claimed by the patent brought a civil action against the applicant for infringement of the patent before the expiration of such period; and

(cc) in any case in which the notice provided under paragraph (2)(B) relates to noninfringement, the notice was accompanied by a document described in subclause (III).

(II) FILING OF CIVIL ACTION.—If the conditions described in items (aa), (bb), and as applicable, (cc) of subclause (I) have been met, the applicant referred to in such subclause may, in accordance with section 2201 of title 28, United States Code, bring a civil action under such section against the owner or holder referred to in such subclause (but not against any owner or holder that has brought such a civil action against the applicant, unless that civil action was dismissed without prejudice) for a declaratory judgment that the patent is invalid or will not be infringed by the drug for which the applicant seeks approval, except that such civil action may be brought for a declaratory judgment that the patent will not be infringed only in a case in which the condition described in subclause (I)(cc) is applicable. A civil action referred to in this subclause shall be brought in the judicial district where the defendant has its principal place of business or a regular and established place of business.

(III) OFFER OF CONFIDENTIAL ACCESS TO APPLICATION.—For purposes of subclause (I)(cc), the document described in this subclause is a document providing an offer of confidential access to the application that is in the custody of the applicant under paragraph (2) for the purpose of determining whether an action referred to in subparagraph (B)(iii) should be brought. The document providing the offer of confidential access shall contain such restrictions as to persons entitled to access, and on the use and disposition of any information accessed, as would apply had a protective order been entered for the purpose of protecting trade secrets and other confidential business information. A request for access to an application under an offer of confidential access shall be considered acceptance of the offer of confidential access with the restrictions as to persons entitled to access, and on the use and disposition of any information accessed, contained in the offer of confidential access, and those restrictions and other terms of the offer of confidential access shall be considered terms of an enforceable contract. Any person provided an offer of confidential access shall review the application for the sole and limited purpose of evaluating possible infringement of the patent that is the subject of the certification under paragraph (2)(A)(vii)(IV) and for no other purpose, and may not disclose information of no relevance to any issue of patent infringement to any person other than a person provided an offer of confidential access. Further, the application may be redacted by the applicant to remove any information of no relevance to any issue of patent infringement.

(ii) COUNTERCLAIM TO INFRINGEMENT ACTION.—

(I) IN GENERAL.—If an owner of the patent or the holder of the approved application under subsection (b) for the drug that is claimed by the patent or a use of which is claimed by the patent brings a patent infringement action against the applicant, the applicant may assert a counterclaim seeking an order requiring the holder to correct or delete the patent information submitted by the holder under subsection (b) or (c) on the ground that the patent does not claim either—

(aa) the drug for which the application was approved; or

(bb) an approved method of using the drug.

(II) NO INDEPENDENT CAUSE OF ACTION.—Subclause (I) does not authorize the assertion of a claim described in subclause (I) in any civil action or proceeding other than a counterclaim described in subclause (I).

(iii) NO DAMAGES.—An applicant shall not be entitled to damages in a civil action under clause (i) or a counterclaim under clause (ii).

(D) FORFEITURE OF 180-DAY EXCLUSIVITY PERIOD.—

(i) DEFINITION OF FORFEITURE EVENT.—In this subparagraph, the term “forfeiture event”, with respect to an application under this subsection, means the occurrence of any of the following:

(I) FAILURE TO MARKET.—The first applicant fails to market the drug by the later of—

(aa) the earlier of the date that is—

(AA) 75 days after the date on which the approval of the application of the first applicant is made effective under subparagraph (B)(iii); or

(BB) 30 months after the date of submission of the application of the first applicant; or

(bb) with respect to the first applicant or any other applicant (which other applicant has received tentative approval), the date that is 75 days after the date as of which, as to each of the patents with respect to which the first applicant submitted and lawfully maintained a certification qualifying the first applicant for the 180-day exclusivity period under subparagraph (B)(iv), at least 1 of the following has occurred:

(AA) In an infringement action brought against that applicant with respect to the patent or in a declaratory judgment action brought by that applicant with respect to the patent, a court enters a final decision from which no appeal (other than a petition to the Supreme Court for a writ of certiorari) has been or can be taken that the patent is invalid or not infringed.

(BB) In an infringement action or a declaratory judgment action described in subitem (AA), a court signs a settlement order or con-

sent decree that enters a final judgment that includes a finding that the patent is invalid or not infringed.

(CC) The patent information submitted under subsection (b) or (c) is withdrawn as the holder of the application approved under subsection (b).

(II) WITHDRAWAL OF APPLICATION.—The first applicant withdraws the application or the Secretary considers the application to have been withdrawn as a result of a determination by the Secretary that the application does not meet the requirements for approval under paragraph (4).

(III) AMENDMENT OF CERTIFICATION.—The first applicant amends or withdraws the certification for all of the patents with respect to which that applicant submitted a certification qualifying the applicant for the 180-day exclusivity period.

(IV) FAILURE TO OBTAIN TENTATIVE APPROVAL.—The first applicant fails to obtain tentative approval of the application within 30 months after the date on which the application is filed, unless the failure is caused by a change in or a review of the requirements for approval of the application imposed after the date on which the application is filed.

(V) AGREEMENT WITH ANOTHER APPLICANT, THE LISTED DRUG APPLICATION HOLDER, OR A PATENT OWNER.—The first applicant enters into an agreement with another applicant under this subsection for the drug, the holder of the application for the listed drug, or an owner of the patent that is the subject of the certification under paragraph (2)(A)(vii)(IV), the Federal Trade Commission or the Attorney General files a complaint, and there is a final decision of the Federal Trade Commission or the court with regard to the complaint from which no appeal (other than a petition to the Supreme Court for a writ of certiorari) has been or can be taken that the agreement has violated the antitrust laws (as defined in section 1 of the Clayton Act (15 U.S.C. 12), except that the term includes section 5 of the Federal Trade Commission Act (15 U.S.C. 45) to the extent that that section applies to unfair methods of competition).

(VI) EXPIRATION OF ALL PATENTS.—All of the patents as to which the applicant submitted a certification qualifying it for the 180-day exclusivity period have expired.

(ii) FORFEITURE.—The 180-day exclusivity period described in subparagraph (B)(iv) shall be forfeited by a first applicant if a forfeiture event occurs with respect to that first applicant.

(iii) SUBSEQUENT APPLICANT.—If all first applicants forfeit the 180-day exclusivity period under clause (ii)—

(I) approval of any application containing a certification described in paragraph (2)(A)(vii)(IV) shall be

made effective in accordance with subparagraph (B)(iii); and

(II) no applicant shall be eligible for a 180-day exclusivity period.

(iv) SPECIAL FORFEITURE RULE FOR COMPETITIVE GENERIC THERAPY.—The 180-day exclusivity period described in subparagraph (B)(v) shall be forfeited by a first approved applicant if the applicant fails to market the competitive generic therapy within 75 days after the date on which the approval of the first approved applicant's application for the competitive generic therapy is made effective.

(E) If the Secretary decides to disapprove an application, the Secretary shall give the applicant notice of an opportunity for a hearing before the Secretary on the question of whether such application is approvable. If the applicant elects to accept the opportunity for hearing by written request within thirty days after such notice, such hearing shall commence not more than ninety days after the expiration of such thirty days unless the Secretary and the applicant otherwise agree. Any such hearing shall thereafter be conducted on an expedited basis and the Secretary's order thereon shall be issued within ninety days after the date fixed by the Secretary for filing final briefs.

(F)(i) If an application (other than an abbreviated new drug application) submitted under subsection (b) for a drug, no active ingredient (including any ester or salt of the active ingredient) of which has been approved in any other application under subsection (b), was approved during the period beginning January 1, 1982, and ending on the date of the enactment of this subsection, the Secretary may not make the approval of an application submitted under this subsection which refers to the drug for which the subsection (b) application was submitted effective before the expiration of ten years from the date of the approval of the application under subsection (b).

(ii) If an application submitted under subsection (b) for a drug, no active ingredient (including any ester or salt of the active ingredient) of which has been approved in any other application under subsection (b), is approved after the date of the enactment of this subsection, no application may be submitted under this subsection which refers to the drug for which the subsection (b) application was submitted before the expiration of five years from the date of the approval of the application under subsection (b), except that such an application may be submitted under this subsection after the expiration of four years from the date of the approval of the subsection (b) application if it contains a certification of patent invalidity or noninfringement described in subclause (IV) of paragraph (2)(A)(vii). The approval of such an application shall be made effective in accordance with subparagraph (B) except that, if an action for patent infringement is commenced during the one-year period beginning forty-eight months after the date of the approval of the subsection (b) application, the thirty-month period referred to in subparagraph (B)(iii) shall be extended by such amount of time (if any) which is required for seven and one-half years to have elapsed from the date of approval of the subsection (b) application.

(iii) If an application submitted under subsection (b) for a drug, which includes an active ingredient (including any ester or salt of

the active ingredient) that has been approved in another application approved under subsection (b), is approved after the date of enactment of this subsection and if such application contains reports of new clinical investigations (other than bioavailability studies) essential to the approval of the application and conducted or sponsored by the applicant, the Secretary may not make the approval of an application submitted under this subsection for the conditions of approval of such drug in the subsection (b) application effective before the expiration of three years from the date of the approval of the application under subsection (b) for such drug.

(iv) If a supplement to an application approved under subsection (b) is approved after the date of enactment of this subsection and the supplement contains reports of new clinical investigations (other than bioavailability studies) essential to the approval of the supplement and conducted or sponsored by the person submitting the supplement, the Secretary may not make the approval of an application submitted under this subsection for a change approved in the supplement effective before the expiration of three years from the date of the approval of the supplement under subsection (b).

(v) If an application (or supplement to an application) submitted under subsection (b) for a drug, which includes an active ingredient (including any ester or salt of the active ingredient) that has been approved in another application under subsection (b), was approved during the period beginning January 1, 1982, and ending on the date of the enactment of this subsection, the Secretary may not make the approval of an application submitted under this subsection which refers to the drug for which the subsection (b) application was submitted or which refers to a change approved in a supplement to the subsection (b) application effective before the expiration of two years from the date of enactment of this subsection.

(6) If a drug approved under this subsection refers in its approved application to a drug the approval of which was withdrawn or suspended for grounds described in the first sentence of subsection (e) or was withdrawn or suspended under this paragraph or which, as determined by the Secretary, has been withdrawn from sale for safety or effectiveness reasons, the approval of the drug under this subsection shall be withdrawn or suspended—

(A) for the same period as the withdrawal or suspension under subsection (e) or this paragraph, or

(B) if the listed drug has been withdrawn from sale, for the period of withdrawal from sale or, if earlier, the period ending on the date the Secretary determines that the withdrawal from sale is not for safety or effectiveness reasons.

(7)(A)(i) Within sixty days of the date of the enactment of this subsection, the Secretary shall publish and make available to the public—

(I) a list in alphabetical order of the official and proprietary name of each drug which has been approved for safety and effectiveness under subsection (c) before the date of the enactment of this subsection;

(II) the date of approval if the drug is approved after 1981 and the number of the application which was approved; and

(III) whether in vitro or in vivo bioequivalence studies, or both such studies, are required for applications filed under this subsection which will refer to the drug published.

(ii) Every thirty days after the publication of the first list under clause (i) the Secretary shall revise the list to include each drug which has been approved for safety and effectiveness under subsection (c) or approved under this subsection during the thirty-day period.

(iii) When patent information submitted under subsection (b) or (c) respecting a drug included on the list is to be published by the Secretary, the Secretary shall, in revisions made under clause (ii), include such information for such drug.

(B) A drug approved for safety and effectiveness under subsection (c) or approved under this subsection shall, for purposes of this subsection, be considered to have been published under subparagraph (A) on the date of its approval or the date of enactment, whichever is later.

(C) If the approval of a drug was withdrawn or suspended for grounds described in the first sentence of subsection (e) or was withdrawn or suspended under paragraph (6) or if the Secretary determines that a drug has been withdrawn from sale for safety or effectiveness reasons, it may not be published in the list under subparagraph (A) or, if the withdrawal or suspension occurred after its publication in such list, it shall be immediately removed from such list—

(i) for the same period as the withdrawal or suspension under subsection (e) or paragraph (6), or

(ii) if the listed drug has been withdrawn from sale, for the period of withdrawal from sale or, if earlier, the period ending on the date the Secretary determines that the withdrawal from sale is not for safety or effectiveness reasons.

A notice of the removal shall be published in the Federal Register.

(8) For purposes of this subsection:

(A)(i) The term “bioavailability” means the rate and extent to which the active ingredient or therapeutic ingredient is absorbed from a drug and becomes available at the site of drug action.

(ii) For a drug that is not intended to be absorbed into the bloodstream, the Secretary may assess bioavailability by scientifically valid measurements intended to reflect the rate and extent to which the active ingredient or therapeutic ingredient becomes available at the site of drug action.

(B) A drug shall be considered to be bioequivalent to a listed drug if—

(i) the rate and extent of absorption of the drug do not show a significant difference from the rate and extent of absorption of the listed drug when administered at the same molar dose of the therapeutic ingredient under similar experimental conditions in either a single dose or multiple doses; or

(ii) the extent of absorption of the drug does not show a significant difference from the extent of absorption of the listed drug when administered at the same molar dose of the therapeutic ingredient under similar experimental conditions in either a single dose or multiple doses and the

difference from the listed drug in the rate of absorption of the drug is intentional, is reflected in its proposed labeling, is not essential to the attainment of effective body drug concentrations on chronic use, and is considered medically insignificant for the drug.

(C) For a drug that is not intended to be absorbed into the bloodstream, the Secretary may establish alternative, scientifically valid methods to show bioequivalence if the alternative methods are expected to detect a significant difference between the drug and the listed drug in safety and therapeutic effect.

(9) The Secretary shall, with respect to each application submitted under this subsection, maintain a record of—

(A) the name of the applicant,

(B) the name of the drug covered by the application,

(C) the name of each person to whom the review of the chemistry of the application was assigned and the date of such assignment, and

(D) the name of each person to whom the bioequivalence review for such application was assigned and the date of such assignment.

The information the Secretary is required to maintain under this paragraph with respect to an application submitted under this subsection shall be made available to the public after the approval of such application.

(10)(A) If the proposed labeling of a drug that is the subject of an application under this subsection differs from the listed drug due to a labeling revision described under clause (i), the drug that is the subject of such application shall, notwithstanding any other provision of this Act, be eligible for approval and shall not be considered misbranded under section 502 if—

(i) the application is otherwise eligible for approval under this subsection but for expiration of patent, an exclusivity period, or of a delay in approval described in paragraph (5)(B)(iii), and a revision to the labeling of the listed drug has been approved by the Secretary within 60 days of such expiration;

(ii) the labeling revision described under clause (i) does not include a change to the “Warnings” section of the labeling;

(iii) the sponsor of the application under this subsection agrees to submit revised labeling of the drug that is the subject of such application not later than 60 days after the notification of any changes to such labeling required by the Secretary; and

(iv) such application otherwise meets the applicable requirements for approval under this subsection.

(B) If, after a labeling revision described in subparagraph (A)(i), the Secretary determines that the continued presence in interstate commerce of the labeling of the listed drug (as in effect before the revision described in subparagraph (A)(i)) adversely impacts the safe use of the drug, no application under this subsection shall be eligible for approval with such labeling.

(11) *Upon the request of an applicant regarding one or more specified pending applications under this subsection, the Secretary shall—*

(A) *by telephone or electronic mail, provide review status updates; and*

(B) indicate in such updates the categorical status of the applications by each relevant review discipline.

(k)(1) In the case of any drug for which an approval of an application filed under subsection (b) or (j) is in effect, the applicant shall establish and maintain such records, and make such reports to the Secretary, of data relating to clinical experience and other data or information, received or otherwise obtained by such applicant with respect to such drug, as the Secretary may by general regulation, or by order with respect to such application, prescribe on the basis of a finding that such records and reports are necessary in order to enable the Secretary to determine, or facilitate a determination, whether there is or may be ground for invoking subsection (e) of this section. Regulations and orders issued under this subsection and under subsection (i) shall have due regard for the professional ethics of the medical profession and the interests of patients and shall provide, where the Secretary deems it to be appropriate, for the examination, upon request, by the persons to whom such regulations or orders are applicable, of similar information received or otherwise obtained by the Secretary.

(2) Every person required under this section to maintain records, and every person in charge or custody thereof, shall, upon request of an officer or employee designated by the Secretary, permit such officer or employee at all reasonable times to have access to and copy and verify such records.

(3) ACTIVE POSTMARKET RISK IDENTIFICATION.—

(A) DEFINITION.—In this paragraph, the term “data” refers to information with respect to a drug approved under this section or under section 351 of the Public Health Service Act, including claims data, patient survey data, standardized analytic files that allow for the pooling and analysis of data from disparate data environments, and any other data deemed appropriate by the Secretary.

(B) DEVELOPMENT OF POSTMARKET RISK IDENTIFICATION AND ANALYSIS METHODS.—The Secretary shall, not later than 2 years after the date of the enactment of the Food and Drug Administration Amendments Act of 2007, in collaboration with public, academic, and private entities—

(i) develop methods to obtain access to disparate data sources including the data sources specified in subparagraph (C);

(ii) develop validated methods for the establishment of a postmarket risk identification and analysis system to link and analyze safety data from multiple sources, with the goals of including, in aggregate—

(I) at least 25,000,000 patients by July 1, 2010;

and

(II) at least 100,000,000 patients by July 1, 2012; and

(iii) convene a committee of experts, including individuals who are recognized in the field of protecting data privacy and security, to make recommendations to the Secretary on the development of tools and methods for the ethical and scientific uses for, and communication of, postmarketing data specified under subparagraph (C), including recommendations on the de-

velopment of effective research methods for the study of drug safety questions.

(C) ESTABLISHMENT OF THE POSTMARKET RISK IDENTIFICATION AND ANALYSIS SYSTEM.—

(i) IN GENERAL.—The Secretary shall, not later than 1 year after the development of the risk identification and analysis methods under subparagraph (B), establish and maintain procedures—

(I) for risk identification and analysis based on electronic health data, in compliance with the regulations promulgated under section 264(c) of the Health Insurance Portability and Accountability Act of 1996, and in a manner that does not disclose individually identifiable health information in violation of paragraph (4)(B);

(II) for the reporting (in a standardized form) of data on all serious adverse drug experiences (as defined in section 505–1(b)) submitted to the Secretary under paragraph (1), and those adverse events submitted by patients, providers, and drug sponsors, when appropriate;

(III) to provide for active adverse event surveillance using the following data sources, as available:

(aa) Federal health-related electronic data (such as data from the Medicare program and the health systems of the Department of Veterans Affairs);

(bb) private sector health-related electronic data (such as pharmaceutical purchase data and health insurance claims data); and

(cc) other data as the Secretary deems necessary to create a robust system to identify adverse events and potential drug safety signals;

(IV) to identify certain trends and patterns with respect to data accessed by the system;

(V) to provide regular reports to the Secretary concerning adverse event trends, adverse event patterns, incidence and prevalence of adverse events, and other information the Secretary determines appropriate, which may include data on comparative national adverse event trends; and

(VI) to enable the program to export data in a form appropriate for further aggregation, statistical analysis, and reporting.

(ii) TIMELINESS OF REPORTING.—The procedures established under clause (i) shall ensure that such data are accessed, analyzed, and reported in a timely, routine, and systematic manner, taking into consideration the need for data completeness, coding, cleansing, and standardized analysis and transmission.

(iii) PRIVATE SECTOR RESOURCES.—To ensure the establishment of the active postmarket risk identification and analysis system under this subsection not

later than 1 year after the development of the risk identification and analysis methods under subparagraph (B), as required under clause (i), the Secretary may, on a temporary or permanent basis, implement systems or products developed by private entities.

(iv) **COMPLEMENTARY APPROACHES.**—To the extent the active postmarket risk identification and analysis system under this subsection is not sufficient to gather data and information relevant to a priority drug safety question, the Secretary shall develop, support, and participate in complementary approaches to gather and analyze such data and information, including—

(I) approaches that are complementary with respect to assessing the safety of use of a drug in domestic populations not included, or underrepresented, in the trials used to approve the drug (such as older people, people with comorbidities, pregnant women, or children); and

(II) existing approaches such as the Vaccine Adverse Event Reporting System and the Vaccine Safety Datalink or successor databases.

(v) **AUTHORITY FOR CONTRACTS.**—The Secretary may enter into contracts with public and private entities to fulfill the requirements of this subparagraph.

(4) **ADVANCED ANALYSIS OF DRUG SAFETY DATA.**—

(A) **PURPOSE.**—The Secretary shall establish collaborations with public, academic, and private entities, which may include the Centers for Education and Research on Therapeutics under section 912 of the Public Health Service Act, to provide for advanced analysis of drug safety data described in paragraph (3)(C) and other information that is publicly available or is provided by the Secretary, in order to—

(i) improve the quality and efficiency of postmarket drug safety risk-benefit analysis;

(ii) provide the Secretary with routine access to outside expertise to study advanced drug safety questions; and

(iii) enhance the ability of the Secretary to make timely assessments based on drug safety data.

(B) **PRIVACY.**—Such analysis shall not disclose individually identifiable health information when presenting such drug safety signals and trends or when responding to inquiries regarding such drug safety signals and trends.

(C) **PUBLIC PROCESS FOR PRIORITY QUESTIONS.**—At least biannually, the Secretary shall seek recommendations from the Drug Safety and Risk Management Advisory Committee (or any successor committee) and from other advisory committees, as appropriate, to the Food and Drug Administration on—

(i) priority drug safety questions; and

(ii) mechanisms for answering such questions, including through—

(I) active risk identification under paragraph (3); and

(II) when such risk identification is not sufficient, postapproval studies and clinical trials under subsection (o)(3).

(D) PROCEDURES FOR THE DEVELOPMENT OF DRUG SAFETY COLLABORATIONS.—

(i) IN GENERAL.—Not later than 180 days after the date of the establishment of the active postmarket risk identification and analysis system under this subsection, the Secretary shall establish and implement procedures under which the Secretary may routinely contract with one or more qualified entities to—

(I) classify, analyze, or aggregate data described in paragraph (3)(C) and information that is publicly available or is provided by the Secretary;

(II) allow for prompt investigation of priority drug safety questions, including—

(aa) unresolved safety questions for drugs or classes of drugs; and

(bb) for a newly-approved drugs, safety signals from clinical trials used to approve the drug and other preapproval trials; rare, serious drug side effects; and the safety of use in domestic populations not included, or underrepresented, in the trials used to approve the drug (such as older people, people with comorbidities, pregnant women, or children);

(III) perform advanced research and analysis on identified drug safety risks;

(IV) focus postapproval studies and clinical trials under subsection (o)(3) more effectively on cases for which reports under paragraph (1) and other safety signal detection is not sufficient to resolve whether there is an elevated risk of a serious adverse event associated with the use of a drug; and

(V) carry out other activities as the Secretary deems necessary to carry out the purposes of this paragraph.

(ii) REQUEST FOR SPECIFIC METHODOLOGY.—The procedures described in clause (i) shall permit the Secretary to request that a specific methodology be used by the qualified entity. The qualified entity shall work with the Secretary to finalize the methodology to be used.

(E) USE OF ANALYSES.—The Secretary shall provide the analyses described in this paragraph, including the methods and results of such analyses, about a drug to the sponsor or sponsors of such drug.

(F) QUALIFIED ENTITIES.—

(i) IN GENERAL.—The Secretary shall enter into contracts with a sufficient number of qualified entities to develop and provide information to the Secretary in a timely manner.

(ii) QUALIFICATION.—The Secretary shall enter into a contract with an entity under clause (i) only if the

Secretary determines that the entity has a significant presence in the United States and has one or more of the following qualifications:

(I) The research, statistical, epidemiologic, or clinical capability and expertise to conduct and complete the activities under this paragraph, including the capability and expertise to provide the Secretary de-identified data consistent with the requirements of this subsection.

(II) An information technology infrastructure in place to support electronic data and operational standards to provide security for such data.

(III) Experience with, and expertise on, the development of drug safety and effectiveness research using electronic population data.

(IV) An understanding of drug development or risk/benefit balancing in a clinical setting.

(V) Other expertise which the Secretary deems necessary to fulfill the activities under this paragraph.

(G) CONTRACT REQUIREMENTS.—Each contract with a qualified entity under subparagraph (F)(i) shall contain the following requirements:

(i) ENSURING PRIVACY.—The qualified entity shall ensure that the entity will not use data under this subsection in a manner that—

(I) violates the regulations promulgated under section 264(c) of the Health Insurance Portability and Accountability Act of 1996;

(II) violates sections 552 or 552a of title 5, United States Code, with regard to the privacy of individually-identifiable beneficiary health information; or

(III) discloses individually identifiable health information when presenting drug safety signals and trends or when responding to inquiries regarding drug safety signals and trends.

Nothing in this clause prohibits lawful disclosure for other purposes.

(ii) COMPONENT OF ANOTHER ORGANIZATION.—If a qualified entity is a component of another organization—

(I) the qualified entity shall establish appropriate security measures to maintain the confidentiality and privacy of such data; and

(II) the entity shall not make an unauthorized disclosure of such data to the other components of the organization in breach of such confidentiality and privacy requirement.

(iii) TERMINATION OR NONRENEWAL.—If a contract with a qualified entity under this subparagraph is terminated or not renewed, the following requirements shall apply:

(I) CONFIDENTIALITY AND PRIVACY PROTECTIONS.—The entity shall continue to comply with

the confidentiality and privacy requirements under this paragraph with respect to all data disclosed to the entity.

(II) DISPOSITION OF DATA.—The entity shall return any data disclosed to such entity under this subsection to which it would not otherwise have access or, if returning the data is not practicable, destroy the data.

(H) COMPETITIVE PROCEDURES.—The Secretary shall use competitive procedures (as defined in section 4(5) of the Federal Procurement Policy Act) to enter into contracts under subparagraph (G).

(I) REVIEW OF CONTRACT IN THE EVENT OF A MERGER OR ACQUISITION.—The Secretary shall review the contract with a qualified entity under this paragraph in the event of a merger or acquisition of the entity in order to ensure that the requirements under this paragraph will continue to be met.

(J) COORDINATION.—In carrying out this paragraph, the Secretary shall provide for appropriate communications to the public, scientific, public health, and medical communities, and other key stakeholders, and to the extent practicable shall coordinate with the activities of private entities, professional associations, or other entities that may have sources of drug safety data.

(5) The Secretary shall—

(A) conduct regular screenings of the Adverse Event Reporting System database and post a quarterly report on the Adverse Event Reporting System Web site of any new safety information or potential signal of a serious risk identified by Adverse Event Reporting System within the last quarter; and

(B) on an annual basis, review the entire backlog of postmarket safety commitments to determine which commitments require revision or should be eliminated, report to the Congress on these determinations, and assign start dates and estimated completion dates for such commitments; and

(C) make available on the Internet website of the Food and Drug Administration—

(i) guidelines, developed with input from experts qualified by scientific training and experience to evaluate the safety and effectiveness of drugs, that detail best practices for drug safety surveillance using the Adverse Event Reporting System; and

(ii) criteria for public posting of adverse event signals.

(1)(1) Safety and effectiveness data and information which has been submitted in an application under subsection (b) for a drug and which has not previously been disclosed to the public shall be made available to the public, upon request, unless extraordinary circumstances are shown—

(A) if no work is being or will be undertaken to have the application approved,

(B) if the Secretary has determined that the application is not approvable and all legal appeals have been exhausted,

(C) if approval of the application under subsection (c) is withdrawn and all legal appeals have been exhausted,

(D) if the Secretary has determined that such drug is not a new drug, or

(E) upon the effective date of the approval of the first application under subsection (j) which refers to such drug or upon the date upon which the approval of an application under subsection (j) which refers to such drug could be made effective if such an application had been submitted.

(2) ACTION PACKAGE FOR APPROVAL.—

(A) ACTION PACKAGE.—The Secretary shall publish the action package for approval of an application under subsection (b) or section 351 of the Public Health Service Act on the Internet Web site of the Food and Drug Administration—

(i) not later than 30 days after the date of approval of such application for a drug no active ingredient (including any ester or salt of the active ingredient) of which has been approved in any other application under this section or section 351 of the Public Health Service Act; and

(ii) not later than 30 days after the third request for such action package for approval received under section 552 of title 5, United States Code, for any other drug.

(B) IMMEDIATE PUBLICATION OF SUMMARY REVIEW.—Notwithstanding subparagraph (A), the Secretary shall publish, on the Internet Web site of the Food and Drug Administration, the materials described in subparagraph (C)(iv) not later than 48 hours after the date of approval of the drug, except where such materials require redaction by the Secretary.

(C) CONTENTS.—An action package for approval of an application under subparagraph (A) shall be dated and shall include the following:

(i) Documents generated by the Food and Drug Administration related to review of the application.

(ii) Documents pertaining to the format and content of the application generated during drug development.

(iii) Labeling submitted by the applicant.

(iv) A summary review that documents conclusions from all reviewing disciplines about the drug, noting any critical issues and disagreements with the applicant and within the review team and how they were resolved, recommendations for action, and an explanation of any nonconurrence with review conclusions.

(v) The Division Director and Office Director's decision document which includes—

(I) a brief statement of concurrence with the summary review;

(II) a separate review or addendum to the review if disagreeing with the summary review; and

(III) a separate review or addendum to the review to add further analysis.

(vi) Identification by name of each officer or employee of the Food and Drug Administration who—

(I) participated in the decision to approve the application; and

(II) consents to have his or her name included in the package.

(D) REVIEW.—A scientific review of an application is considered the work of the reviewer and shall not be altered by management or the reviewer once final.

(E) CONFIDENTIAL INFORMATION.—This paragraph does not authorize the disclosure of any trade secret, confidential commercial or financial information, or other matter listed in section 552(b) of title 5, United States Code.

(m) For purposes of this section, the term “patent” means a patent issued by the United States Patent and Trademark Office.

(n)(1) For the purpose of providing expert scientific advice and recommendations to the Secretary regarding a clinical investigation of a drug or the approval for marketing of a drug under section 505 or section 351 of the Public Health Service Act, the Secretary shall establish panels of experts or use panels of experts established before the date of enactment of the Food and Drug Administration Modernization Act of 1997, or both.

(2) The Secretary may delegate the appointment and oversight authority granted under section 1004 to a director of a center or successor entity within the Food and Drug Administration.

(3) The Secretary shall make appointments to each panel established under paragraph (1) so that each panel shall consist of—

(A) members who are qualified by training and experience to evaluate the safety and effectiveness of the drugs to be referred to the panel and who, to the extent feasible, possess skill and experience in the development, manufacture, or utilization of such drugs;

(B) members with diverse expertise in such fields as clinical and administrative medicine, pharmacy, pharmacology, pharmacoeconomics, biological and physical sciences, and other related professions;

(C) a representative of consumer interests, and a representative of interests of the drug manufacturing industry not directly affected by the matter to be brought before the panel; and

(D) two or more members who are specialists or have other expertise in the particular disease or condition for which the drug under review is proposed to be indicated.

Scientific, trade, and consumer organizations shall be afforded an opportunity to nominate individuals for appointment to the panels. No individual who is in the regular full-time employ of the United States and engaged in the administration of this Act may be a voting member of any panel. The Secretary shall designate one of the members of each panel to serve as chairman thereof.

(4) The Secretary shall, as appropriate, provide education and training to each new panel member before such member participates in a panel’s activities, including education regarding requirements under this Act and related regulations of the Secretary, and the administrative processes and procedures related to panel meetings.

(5) Panel members (other than officers or employees of the United States), while attending meetings or conferences of a panel or otherwise engaged in its business, shall be entitled to receive compensation for each day so engaged, including traveltime, at

rates to be fixed by the Secretary, but not to exceed the daily equivalent of the rate in effect for positions classified above grade GS-15 of the General Schedule. While serving away from their homes or regular places of business, panel members may be allowed travel expenses (including per diem in lieu of subsistence) as authorized by section 5703 of title 5, United States Code, for persons in the Government service employed intermittently.

(6) The Secretary shall ensure that scientific advisory panels meet regularly and at appropriate intervals so that any matter to be reviewed by such a panel can be presented to the panel not more than 60 days after the matter is ready for such review. Meetings of the panel may be held using electronic communication to convene the meetings.

(7) Within 90 days after a scientific advisory panel makes recommendations on any matter under its review, the Food and Drug Administration official responsible for the matter shall review the conclusions and recommendations of the panel, and notify the affected persons of the final decision on the matter, or of the reasons that no such decision has been reached. Each such final decision shall be documented including the rationale for the decision.

(o) POSTMARKET STUDIES AND CLINICAL TRIALS; LABELING.—

(1) IN GENERAL.—A responsible person may not introduce or deliver for introduction into interstate commerce the new drug involved if the person is in violation of a requirement established under paragraph (3) or (4) with respect to the drug.

(2) DEFINITIONS.—For purposes of this subsection:

(A) RESPONSIBLE PERSON.—The term “responsible person” means a person who—

(i) has submitted to the Secretary a covered application that is pending; or

(ii) is the holder of an approved covered application.

(B) COVERED APPLICATION.—The term “covered application” means—

(i) an application under subsection (b) for a drug that is subject to section 503(b); and

(ii) an application under section 351 of the Public Health Service Act.

(C) NEW SAFETY INFORMATION; SERIOUS RISK.—The terms “new safety information”, “serious risk”, and “signal of a serious risk” have the meanings given such terms in section 505-1(b).

(3) STUDIES AND CLINICAL TRIALS.—

(A) IN GENERAL.—For any or all of the purposes specified in subparagraph (B), the Secretary may, subject to subparagraph (D), require a responsible person for a drug to conduct a postapproval study or studies of the drug, or a postapproval clinical trial or trials of the drug, on the basis of scientific data deemed appropriate by the Secretary, including information regarding chemically-related or pharmacologically-related drugs.

(B) PURPOSES OF STUDY OR CLINICAL TRIAL.—The purposes referred to in this subparagraph with respect to a postapproval study or postapproval clinical trial are the following:

(i) To assess a known serious risk related to the use of the drug involved.

(ii) To assess signals of serious risk related to the use of the drug.

(iii) To identify an unexpected serious risk when available data indicates the potential for a serious risk.

(C) ESTABLISHMENT OF REQUIREMENT AFTER APPROVAL OF COVERED APPLICATION.—The Secretary may require a postapproval study or studies or postapproval clinical trial or trials for a drug for which an approved covered application is in effect as of the date on which the Secretary seeks to establish such requirement only if the Secretary becomes aware of new safety information.

(D) DETERMINATION BY SECRETARY.—

(i) POSTAPPROVAL STUDIES.—The Secretary may not require the responsible person to conduct a study under this paragraph, unless the Secretary makes a determination that the reports under subsection (k)(1) and the active postmarket risk identification and analysis system as available under subsection (k)(3) will not be sufficient to meet the purposes set forth in subparagraph (B).

(ii) POSTAPPROVAL CLINICAL TRIALS.—The Secretary may not require the responsible person to conduct a clinical trial under this paragraph, unless the Secretary makes a determination that a postapproval study or studies will not be sufficient to meet the purposes set forth in subparagraph (B).

(E) NOTIFICATION; TIMETABLES; PERIODIC REPORTS.—

(i) NOTIFICATION.—The Secretary shall notify the responsible person regarding a requirement under this paragraph to conduct a postapproval study or clinical trial by the target dates for communication of feedback from the review team to the responsible person regarding proposed labeling and postmarketing study commitments as set forth in the letters described in section 101(c) of the Food and Drug Administration Amendments Act of 2007.

(ii) TIMETABLE; PERIODIC REPORTS.—For each study or clinical trial required to be conducted under this paragraph, the Secretary shall require that the responsible person submit a timetable for completion of the study or clinical trial. With respect to each study required to be conducted under this paragraph or otherwise undertaken by the responsible person to investigate a safety issue, the Secretary shall require the responsible person to periodically report to the Secretary on the status of such study including whether any difficulties in completing the study have been encountered. With respect to each clinical trial required to be conducted under this paragraph or otherwise undertaken by the responsible person to investigate a safety issue, the Secretary shall require the responsible person to periodically report to the Secretary on

the status of such clinical trial including whether enrollment has begun, the number of participants enrolled, the expected completion date, whether any difficulties completing the clinical trial have been encountered, and registration information with respect to the requirements under section 402(j) of the Public Health Service Act. If the responsible person fails to comply with such timetable or violates any other requirement of this subparagraph, the responsible person shall be considered in violation of this subsection, unless the responsible person demonstrates good cause for such noncompliance or such other violation. The Secretary shall determine what constitutes good cause under the preceding sentence.

(F) DISPUTE RESOLUTION.—The responsible person may appeal a requirement to conduct a study or clinical trial under this paragraph using dispute resolution procedures established by the Secretary in regulation and guidance.

(4) SAFETY LABELING CHANGES REQUESTED BY SECRETARY.—

(A) NEW SAFETY INFORMATION.—If the Secretary becomes aware of new safety information that the Secretary believes should be included in the labeling of the drug, the Secretary shall promptly notify the responsible person or, if the same drug approved under section 505(b) is not currently marketed, the holder of an approved application under 505(j).

(B) RESPONSE TO NOTIFICATION.—Following notification pursuant to subparagraph (A), the responsible person or the holder of the approved application under section 505(j) shall within 30 days—

(i) submit a supplement proposing changes to the approved labeling to reflect the new safety information, including changes to boxed warnings, contraindications, warnings, precautions, or adverse reactions; or

(ii) notify the Secretary that the responsible person or the holder of the approved application under section 505(j) does not believe a labeling change is warranted and submit a statement detailing the reasons why such a change is not warranted.

(C) REVIEW.—Upon receipt of such supplement, the Secretary shall promptly review and act upon such supplement. If the Secretary disagrees with the proposed changes in the supplement or with the statement setting forth the reasons why no labeling change is necessary, the Secretary shall initiate discussions to reach agreement on whether the labeling for the drug should be modified to reflect the new safety information, and if so, the contents of such labeling changes.

(D) DISCUSSIONS.—Such discussions shall not extend for more than 30 days after the response to the notification under subparagraph (B), unless the Secretary determines an extension of such discussion period is warranted.

(E) ORDER.—Within 15 days of the conclusion of the discussions under subparagraph (D), the Secretary may issue

an order directing the responsible person or the holder of the approved application under section 505(j) to make such a labeling change as the Secretary deems appropriate to address the new safety information. Within 15 days of such an order, the responsible person or the holder of the approved application under section 505(j) shall submit a supplement containing the labeling change.

(F) DISPUTE RESOLUTION.—Within 5 days of receiving an order under subparagraph (E), the responsible person or the holder of the approved application under section 505(j) may appeal using dispute resolution procedures established by the Secretary in regulation and guidance.

(G) VIOLATION.—If the responsible person or the holder of the approved application under section 505(j) has not submitted a supplement within 15 days of the date of such order under subparagraph (E), and there is no appeal or dispute resolution proceeding pending, the responsible person or holder shall be considered to be in violation of this subsection. If at the conclusion of any dispute resolution procedures the Secretary determines that a supplement must be submitted and such a supplement is not submitted within 15 days of the date of that determination, the responsible person or holder shall be in violation of this subsection.

(H) PUBLIC HEALTH THREAT.—Notwithstanding subparagraphs (A) through (F), if the Secretary concludes that such a labeling change is necessary to protect the public health, the Secretary may accelerate the timelines in such subparagraphs.

(I) RULE OF CONSTRUCTION.—This paragraph shall not be construed to affect the responsibility of the responsible person or the holder of the approved application under section 505(j) to maintain its label in accordance with existing requirements, including subpart B of part 201 and sections 314.70 and 601.12 of title 21, Code of Federal Regulations (or any successor regulations).

(5) NON-DELEGATION.—Determinations by the Secretary under this subsection for a drug shall be made by individuals at or above the level of individuals empowered to approve a drug (such as division directors within the Center for Drug Evaluation and Research).

(p) RISK EVALUATION AND MITIGATION STRATEGY.—

(1) IN GENERAL.—A person may not introduce or deliver for introduction into interstate commerce a new drug if—

(A)(i) the application for such drug is approved under subsection (b) or (j) and is subject to section 503(b); or

(ii) the application for such drug is approved under section 351 of the Public Health Service Act; and

(B) a risk evaluation and mitigation strategy is required under section 505–1 with respect to the drug and the person fails to maintain compliance with the requirements of the approved strategy or with other requirements under section 505–1, including requirements regarding assessments of approved strategies.

(2) CERTAIN POSTMARKET STUDIES.—The failure to conduct a postmarket study under section 506, subpart H of part 314, or subpart E of part 601 of title 21, Code of Federal Regulations (or any successor regulations), is deemed to be a violation of paragraph (1).

(q) PETITIONS AND CIVIL ACTIONS REGARDING APPROVAL OF CERTAIN APPLICATIONS.—

(1) IN GENERAL.—

(A) DETERMINATION.—The Secretary shall not delay approval of a pending application submitted under subsection (b)(2) or (j) of this section or section 351(k) of the Public Health Service Act because of any request to take any form of action relating to the application, either before or during consideration of the request, unless—

(i) the request is in writing and is a petition submitted to the Secretary pursuant to section 10.30 or 10.35 of title 21, Code of Federal Regulations (or any successor regulations); and

(ii) the Secretary determines, upon reviewing the petition, that a delay is necessary to protect the public health.

Consideration of the petition shall be separate and apart from review and approval of any application.

(B) NOTIFICATION.—If the Secretary determines under subparagraph (A) that a delay is necessary with respect to an application, the Secretary shall provide to the applicant, not later than 30 days after making such determination, the following information:

(i) Notification of the fact that a determination under subparagraph (A) has been made.

(ii) If applicable, any clarification or additional data that the applicant should submit to the docket on the petition to allow the Secretary to review the petition promptly.

(iii) A brief summary of the specific substantive issues raised in the petition which form the basis of the determination.

(C) FORMAT.—The information described in subparagraph (B) shall be conveyed via either, at the discretion of the Secretary—

(i) a document; or

(ii) a meeting with the applicant involved.

(D) PUBLIC DISCLOSURE.—Any information conveyed by the Secretary under subparagraph (C) shall be considered part of the application and shall be subject to the disclosure requirements applicable to information in such application.

(E) DENIAL BASED ON INTENT TO DELAY.—If the Secretary determines that a petition or a supplement to the petition was submitted with the primary purpose of delaying the approval of an application and the petition does not on its face raise valid scientific or regulatory issues, the Secretary may deny the petition at any point based on such determination. The Secretary may issue guidance to describe the factors that will be used to determine under

this subparagraph whether a petition is submitted with the primary purpose of delaying the approval of an application.

(F) FINAL AGENCY ACTION.—The Secretary shall take final agency action on a petition not later than 150 days after the date on which the petition is submitted. The Secretary shall not extend such period for any reason, including—

- (i) any determination made under subparagraph (A);
- (ii) the submission of comments relating to the petition or supplemental information supplied by the petitioner; or
- (iii) the consent of the petitioner.

(G) EXTENSION OF 30-MONTH PERIOD.—If the filing of an application resulted in first-applicant status under subsection (j)(5)(D)(i)(IV) and approval of the application was delayed because of a petition, the 30-month period under such subsection is deemed to be extended by a period of time equal to the period beginning on the date on which the Secretary received the petition and ending on the date of final agency action on the petition (inclusive of such beginning and ending dates), without regard to whether the Secretary grants, in whole or in part, or denies, in whole or in part, the petition.

(H) CERTIFICATION.—The Secretary shall not consider a petition for review unless the party submitting such petition does so in written form and the subject document is signed and contains the following certification: “I certify that, to my best knowledge and belief: (a) this petition includes all information and views upon which the petition relies; (b) this petition includes representative data and/or information known to the petitioner which are unfavorable to the petition; and (c) I have taken reasonable steps to ensure that any representative data and/or information which are unfavorable to the petition were disclosed to me. I further certify that the information upon which I have based the action requested herein first became known to the party on whose behalf this petition is submitted on or about the following date: _____ . If I received or expect to receive payments, including cash and other forms of consideration, to file this information or its contents, I received or expect to receive those payments from the following persons or organizations: _____ . I verify under penalty of perjury that the foregoing is true and correct as of the date of the submission of this petition.”, with the date on which such information first became known to such party and the names of such persons or organizations inserted in the first and second blank space, respectively.

(I) VERIFICATION.—The Secretary shall not accept for review any supplemental information or comments on a petition unless the party submitting such information or comments does so in written form and the subject document is signed and contains the following verification: “I certify that, to my best knowledge and belief: (a) I have not inten-

tionally delayed submission of this document or its contents; and (b) the information upon which I have based the action requested herein first became known to me on or about _____. If I received or expect to receive payments, including cash and other forms of consideration, to file this information or its contents, I received or expect to receive those payments from the following persons or organizations: _____. I verify under penalty of perjury that the foregoing is true and correct as of the date of the submission of this petition.”, with the date on which such information first became known to the party and the names of such persons or organizations inserted in the first and second blank space, respectively.

(2) EXHAUSTION OF ADMINISTRATIVE REMEDIES.—

(A) FINAL AGENCY ACTION WITHIN 150 DAYS.—The Secretary shall be considered to have taken final agency action on a petition if—

(i) during the 150-day period referred to in paragraph (1)(F), the Secretary makes a final decision within the meaning of section 10.45(d) of title 21, Code of Federal Regulations (or any successor regulation); or

(ii) such period expires without the Secretary having made such a final decision.

(B) DISMISSAL OF CERTAIN CIVIL ACTIONS.—If a civil action is filed against the Secretary with respect to any issue raised in the petition before the Secretary has taken final agency action on the petition within the meaning of subparagraph (A), the court shall dismiss without prejudice the action for failure to exhaust administrative remedies.

(C) ADMINISTRATIVE RECORD.—For purposes of judicial review related to the approval of an application for which a petition under paragraph (1) was submitted, the administrative record regarding any issue raised by the petition shall include—

(i) the petition filed under paragraph (1) and any supplements and comments thereto;

(ii) the Secretary’s response to such petition, if issued; and

(iii) other information, as designated by the Secretary, related to the Secretary’s determinations regarding the issues raised in such petition, as long as the information was considered by the agency no later than the date of final agency action as defined under subparagraph (2)(A), and regardless of whether the Secretary responded to the petition at or before the approval of the application at issue in the petition.

(3) ANNUAL REPORT ON DELAYS IN APPROVALS PER PETITIONS.—The Secretary shall annually submit to the Congress a report that specifies—

(A) the number of applications that were approved during the preceding 12-month period;

(B) the number of such applications whose effective dates were delayed by petitions referred to in paragraph (1) during such period;

(C) the number of days by which such applications were so delayed; and

(D) the number of such petitions that were submitted during such period.

(4) EXCEPTIONS.—

(A) This subsection does not apply to—

(i) a petition that relates solely to the timing of the approval of an application pursuant to subsection (j)(5)(B)(iv); or

(ii) a petition that is made by the sponsor of an application and that seeks only to have the Secretary take or refrain from taking any form of action with respect to that application.

(B) Paragraph (2) does not apply to a petition addressing issues concerning an application submitted pursuant to section 351(k) of the Public Health Service Act.

(5) DEFINITIONS.—

(A) APPLICATION.—For purposes of this subsection, the term “application” means an application submitted under subsection (b)(2) or (j) of this section or section 351(k) of the Public Health Service Act.

(B) PETITION.—For purposes of this subsection, other than paragraph (1)(A)(i), the term “petition” means a request described in paragraph (1)(A)(i).

(r) POSTMARKET DRUG SAFETY INFORMATION FOR PATIENTS AND PROVIDERS.—

(1) ESTABLISHMENT.—Not later than 1 year after the date of the enactment of the Food and Drug Administration Amendments Act of 2007, the Secretary shall improve the transparency of information about drugs and allow patients and health care providers better access to information about drugs by developing and maintaining an Internet Web site that—

(A) provides links to drug safety information listed in paragraph (2) for prescription drugs that are approved under this section or licensed under section 351 of the Public Health Service Act; and

(B) improves communication of drug safety information to patients and providers.

(2) INTERNET WEB SITE.—The Secretary shall carry out paragraph (1) by—

(A) developing and maintaining an accessible, consolidated Internet Web site with easily searchable drug safety information, including the information found on United States Government Internet Web sites, such as the United States National Library of Medicine’s Daily Med and Medline Plus Web sites, in addition to other such Web sites maintained by the Secretary;

(B) ensuring that the information provided on the Internet Web site is comprehensive and includes, when available and appropriate—

(i) patient labeling and patient packaging inserts;

(ii) a link to a list of each drug, whether approved under this section or licensed under such section 351, for which a Medication Guide, as provided for under

part 208 of title 21, Code of Federal Regulations (or any successor regulations), is required;

(iii) a link to the registry and results data bank provided for under subsections (i) and (j) of section 402 of the Public Health Service Act;

(iv) the most recent safety information and alerts issued by the Food and Drug Administration for drugs approved by the Secretary under this section, such as product recalls, warning letters, and import alerts;

(v) publicly available information about implemented RiskMAPs and risk evaluation and mitigation strategies under subsection (o);

(vi) guidance documents and regulations related to drug safety; and

(vii) other material determined appropriate by the Secretary;

(C) providing access to summaries of the assessed and aggregated data collected from the active surveillance infrastructure under subsection (k)(3) to provide information of known and serious side-effects for drugs approved under this section or licensed under such section 351;

(D) preparing and making publicly available on the Internet website established under paragraph (1) best practices for drug safety surveillance activities for drugs approved under this section or section 351 of the Public Health Service Act;

(E) enabling patients, providers, and drug sponsors to submit adverse event reports through the Internet Web site;

(F) providing educational materials for patients and providers about the appropriate means of disposing of expired, damaged, or unusable medications; and

(G) supporting initiatives that the Secretary determines to be useful to fulfill the purposes of the Internet Web site.

(3) POSTING OF DRUG LABELING.—The Secretary shall post on the Internet Web site established under paragraph (1) the approved professional labeling and any required patient labeling of a drug approved under this section or licensed under such section 351 not later than 21 days after the date the drug is approved or licensed, including in a supplemental application with respect to a labeling change.

(4) PRIVATE SECTOR RESOURCES.—To ensure development of the Internet Web site by the date described in paragraph (1), the Secretary may, on a temporary or permanent basis, implement systems or products developed by private entities.

(5) AUTHORITY FOR CONTRACTS.—The Secretary may enter into contracts with public and private entities to fulfill the requirements of this subsection.

(6) REVIEW.—The Advisory Committee on Risk Communication under section 567 shall, on a regular basis, perform a comprehensive review and evaluation of the types of risk communication information provided on the Internet Web site established under paragraph (1) and, through other means, shall identify, clarify, and define the purposes and types of information available to facilitate the efficient flow of information to

patients and providers, and shall recommend ways for the Food and Drug Administration to work with outside entities to help facilitate the dispensing of risk communication information to patients and providers.

(s) REFERRAL TO ADVISORY COMMITTEE.—Prior to the approval of a drug no active ingredient (including any ester or salt of the active ingredient) of which has been approved in any other application under this section or section 351 of the Public Health Service Act, the Secretary shall—

(1) refer such drug to a Food and Drug Administration advisory committee for review at a meeting of such advisory committee; or

(2) if the Secretary does not refer such a drug to a Food and Drug Administration advisory committee prior to the approval of the drug, provide in the action letter on the application for the drug a summary of the reasons why the Secretary did not refer the drug to an advisory committee prior to approval.

(t) DATABASE FOR AUTHORIZED GENERIC DRUGS.—

(1) IN GENERAL.—

(A) PUBLICATION.—The Commissioner shall—

(i) not later than 9 months after the date of the enactment of the Food and Drug Administration Amendments Act of 2007, publish a complete list on the Internet Web site of the Food and Drug Administration of all authorized generic drugs (including drug trade name, brand company manufacturer, and the date the authorized generic drug entered the market); and

(ii) update the list quarterly to include each authorized generic drug included in an annual report submitted to the Secretary by the sponsor of a listed drug during the preceding 3-month period.

(B) NOTIFICATION.—The Commissioner shall notify relevant Federal agencies, including the Centers for Medicare & Medicaid Services and the Federal Trade Commission, when the Commissioner first publishes the information described in subparagraph (A) that the information has been published and that the information will be updated quarterly.

(2) INCLUSION.—The Commissioner shall include in the list described in paragraph (1) each authorized generic drug included in an annual report submitted to the Secretary by the sponsor of a listed drug after January 1, 1999.

(3) AUTHORIZED GENERIC DRUG.—In this section, the term “authorized generic drug” means a listed drug (as that term is used in subsection (j)) that—

(A) has been approved under subsection (c); and

(B) is marketed, sold, or distributed directly or indirectly to retail class of trade under a different labeling, packaging (other than repackaging as the listed drug in blister packs, unit doses, or similar packaging for use in institutions), product code, labeler code, trade name, or trade mark than the listed drug.

(u) CERTAIN DRUGS CONTAINING SINGLE ENANTIOMERS.—

(1) IN GENERAL.—For purposes of subsections (c)(3)(E)(ii) and (j)(5)(F)(ii), if an application is submitted under subsection (b) for a non-racemic drug containing as an active ingredient (including any ester or salt of the active ingredient) a single enantiomer that is contained in a racemic drug approved in another application under subsection (b), the applicant may, in the application for such non-racemic drug, elect to have the single enantiomer not be considered the same active ingredient as that contained in the approved racemic drug, if—

(A)(i) the single enantiomer has not been previously approved except in the approved racemic drug; and

(ii) the application submitted under subsection (b) for such non-racemic drug—

(I) includes full reports of new clinical investigations (other than bioavailability studies)—

(aa) necessary for the approval of the application under subsections (c) and (d); and

(bb) conducted or sponsored by the applicant; and

(II) does not rely on any clinical investigations that are part of an application submitted under subsection (b) for approval of the approved racemic drug; and

(B) the application submitted under subsection (b) for such non-racemic drug is not submitted for approval of a condition of use—

(i) in a therapeutic category in which the approved racemic drug has been approved; or

(ii) for which any other enantiomer of the racemic drug has been approved.

(2) LIMITATION.—

(A) NO APPROVAL IN CERTAIN THERAPEUTIC CATEGORIES.—Until the date that is 10 years after the date of approval of a non-racemic drug described in paragraph (1) and with respect to which the applicant has made the election provided for by such paragraph, the Secretary shall not approve such non-racemic drug for any condition of use in the therapeutic category in which the racemic drug has been approved.

(B) LABELING.—If applicable, the labeling of a non-racemic drug described in paragraph (1) and with respect to which the applicant has made the election provided for by such paragraph shall include a statement that the non-racemic drug is not approved, and has not been shown to be safe and effective, for any condition of use of the racemic drug.

(3) DEFINITION.—

(A) IN GENERAL.—For purposes of this subsection, the term “therapeutic category” means a therapeutic category identified in the list developed by the United States Pharmacopeia pursuant to section 1860D–4(b)(3)(C)(ii) of the Social Security Act and as in effect on the date of the enactment of this subsection.

(B) PUBLICATION BY SECRETARY.—The Secretary shall publish the list described in subparagraph (A) and may amend such list by regulation.

(4) AVAILABILITY.—The election referred to in paragraph (1) may be made only in an application that is submitted to the Secretary after the date of the enactment of this subsection and before October 1, ~~2017~~ 2022.

(v) ANTIBIOTIC DRUGS SUBMITTED BEFORE NOVEMBER 21, 1997.—

(1) ANTIBIOTIC DRUGS APPROVED BEFORE NOVEMBER 21, 1997.—

(A) IN GENERAL.—Notwithstanding any provision of the Food and Drug Administration Modernization Act of 1997 or any other provision of law, a sponsor of a drug that is the subject of an application described in subparagraph (B)(i) shall be eligible for, with respect to the drug, the 3-year exclusivity period referred to under clauses (iii) and (iv) of subsection (c)(3)(E) and under clauses (iii) and (iv) of subsection (j)(5)(F), subject to the requirements of such clauses, as applicable.

(B) APPLICATION; ANTIBIOTIC DRUG DESCRIBED.—

(i) APPLICATION.—An application described in this clause is an application for marketing submitted under this section after the date of the enactment of this subsection in which the drug that is the subject of the application contains an antibiotic drug described in clause (ii).

(ii) ANTIBIOTIC DRUG.—An antibiotic drug described in this clause is an antibiotic drug that was the subject of an application approved by the Secretary under section 507 of this Act (as in effect before November 21, 1997).

(2) ANTIBIOTIC DRUGS SUBMITTED BEFORE NOVEMBER 21, 1997, BUT NOT APPROVED.—

(A) IN GENERAL.—Notwithstanding any provision of the Food and Drug Administration Modernization Act of 1997 or any other provision of law, a sponsor of a drug that is the subject of an application described in subparagraph (B)(i) may elect to be eligible for, with respect to the drug—

(i)(I) the 3-year exclusivity period referred to under clauses (iii) and (iv) of subsection (c)(3)(E) and under clauses (iii) and (iv) of subsection (j)(5)(F), subject to the requirements of such clauses, as applicable; and

(II) the 5-year exclusivity period referred to under clause (ii) of subsection (c)(3)(E) and under clause (ii) of subsection (j)(5)(F), subject to the requirements of such clauses, as applicable; or

(ii) a patent term extension under section 156 of title 35, United States Code, subject to the requirements of such section.

(B) APPLICATION; ANTIBIOTIC DRUG DESCRIBED.—

(i) APPLICATION.—An application described in this clause is an application for marketing submitted under this section after the date of the enactment of this subsection in which the drug that is the subject of the application contains an antibiotic drug described in clause (ii).

(ii) ANTIBIOTIC DRUG.—An antibiotic drug described in this clause is an antibiotic drug that was the subject of 1 or more applications received by the Secretary under section 507 of this Act (as in effect before November 21, 1997), none of which was approved by the Secretary under such section.

(3) LIMITATIONS.—

(A) EXCLUSIVITIES AND EXTENSIONS.—Paragraphs (1)(A) and (2)(A) shall not be construed to entitle a drug that is the subject of an approved application described in subparagraphs (1)(B)(i) or (2)(B)(i), as applicable, to any market exclusivities or patent extensions other than those exclusivities or extensions described in paragraph (1)(A) or (2)(A).

(B) CONDITIONS OF USE.—Paragraphs (1)(A) and (2)(A)(i) shall not apply to any condition of use for which the drug referred to in subparagraph (1)(B)(i) or (2)(B)(i), as applicable, was approved before the date of the enactment of this subsection.

(4) APPLICATION OF CERTAIN PROVISIONS.—Notwithstanding section 125, or any other provision, of the Food and Drug Administration Modernization Act of 1997, or any other provision of law, and subject to the limitations in paragraphs (1), (2), and (3), the provisions of the Drug Price Competition and Patent Term Restoration Act of 1984 shall apply to any drug subject to paragraph (1) or any drug with respect to which an election is made under paragraph (2)(A).

(w) DEADLINE FOR DETERMINATION ON CERTAIN PETITIONS.—The Secretary shall issue a final, substantive determination on a petition submitted pursuant to subsection (b) of section 314.161 of title 21, Code of Federal Regulations (or any successor regulations), no later than 270 days after the date the petition is submitted.

(x) DATE OF APPROVAL IN THE CASE OF RECOMMENDED CONTROLS UNDER THE CSA.—

(1) IN GENERAL.—In the case of an application under subsection (b) with respect to a drug for which the Secretary provides notice to the sponsor that the Secretary intends to issue a scientific and medical evaluation and recommend controls under the Controlled Substances Act, approval of such application shall not take effect until the interim final rule controlling the drug is issued in accordance with section 201(j) of the Controlled Substances Act.

(2) DATE OF APPROVAL.—For purposes of this section, with respect to an application described in paragraph (1), the term “date of approval” shall mean the later of—

(A) the date an application under subsection (b) is approved under subsection (c); or

(B) the date of issuance of the interim final rule controlling the drug.

(y) CONTRAST AGENTS INTENDED FOR USE WITH APPLICABLE MEDICAL IMAGING DEVICES.—

(1) *The sponsor of a contrast agent for which an application has been approved under this section may submit a supplement to the application seeking approval for the use of the contrast agent for a new indication and conditions of use following the*

authorization of a premarket submission for an applicable medical imaging device for that use with the contrast agent pursuant to section 520(q)(1).

(2) In reviewing a supplement submitted under this subsection, the agency center charged with the premarket review of drugs may—

(A) consult with the center charged with the premarket review of devices; and

(B) review information and data submitted to the Secretary by the sponsor of an applicable medical imaging device pursuant to section 515, 510(k), or 513(f)(2) so long as the sponsor of such applicable medical imaging device has provided to the sponsor of the contrast agent a right of reference.

(3) For purposes of this subsection—

(A) the term “new indication” means a use of a contrast agent that is described in the approved labeling of an applicable medical imaging device described in section 520(q), but that is not described in the approved labeling of the contrast agent; and

(B) the term “applicable medical imaging device” and “contrast agent” have the meanings given such terms in section 520(q).

* * * * *

SEC. 505F. UTILIZING REAL WORLD EVIDENCE.

(a) **IN GENERAL.**—The Secretary shall establish a program to evaluate the potential use of real world evidence—

(1) to help to support the approval of a new indication for a drug approved under section 505(c); and

(2) to help to support or satisfy postapproval study requirements.

(b) **REAL WORLD EVIDENCE DEFINED.**—In this section, the term “real world evidence” means data regarding the usage, or the potential benefits or risks, of a drug derived from sources other than **[randomized]** *traditional* clinical trials.

(c) **PROGRAM FRAMEWORK.**—

(1) **IN GENERAL.**—Not later than 2 years after the date of enactment of the 21st Century Cures Act, the Secretary shall establish a draft framework for implementation of the program under this section.

(2) **CONTENTS OF FRAMEWORK.**—The framework shall include information describing—

(A) the sources of real world evidence, including ongoing safety surveillance, observational studies, registries, claims, and patient-centered outcomes research activities;

(B) the gaps in data collection activities;

(C) the standards and methodologies for collection and analysis of real world evidence; and

(D) the priority areas, remaining challenges, and potential pilot opportunities that the program established under this section will address.

(3) **CONSULTATION.**—

(A) **IN GENERAL.**—In developing the program framework under this subsection, the Secretary shall consult with reg-

ulated industry, academia, medical professional organizations, representatives of patient advocacy organizations, consumer organizations, disease research foundations, and other interested parties.

(B) PROCESS.—The consultation under subparagraph (A) may be carried out through approaches such as—

(i) a public-private partnership with the entities described in such subparagraph in which the Secretary may participate;

(ii) a contract, grant, or other arrangement, as the Secretary determines appropriate, with such a partnership or an independent research organization; or

(iii) public workshops with the entities described in such subparagraph.

(d) PROGRAM IMPLEMENTATION.—The Secretary shall, not later than **[2]** 3 years after the date of enactment of the 21st Century Cures Act and in accordance with the framework established under subsection (c), implement the program to evaluate the potential use of real world evidence.

(e) GUIDANCE FOR INDUSTRY.—The Secretary shall—

(1) utilize the program established under subsection (a), its activities, and any subsequent pilots or written reports, to inform a guidance for industry on—

(A) the circumstances under which sponsors of drugs and the Secretary may rely on real world evidence for the purposes described in paragraphs (1) and (2) of subsection (a); and

(B) the appropriate standards and methodologies for collection and analysis of real world evidence submitted for such purposes;

(2) not later than 5 years after the date of enactment of the 21st Century Cures Act, issue draft guidance for industry as described in paragraph (1); and

(3) not later than 18 months after the close of the public comment period for the draft guidance described in paragraph (2), issue revised draft guidance or final guidance.

(f) RULE OF CONSTRUCTION.—

(1) IN GENERAL.—Subject to paragraph (2), nothing in this section prohibits the Secretary from using real world evidence for purposes not specified in this section, provided the Secretary determines that sufficient basis exists for any such non-specified use.

(2) STANDARDS OF EVIDENCE AND SECRETARY'S AUTHORITY.—This section shall not be construed to alter—

(A) the standards of evidence under—

(i) subsection (c) or (d) of section 505, including the substantial evidence standard in such subsection (d); or

(ii) section 351(a) of the Public Health Service Act; or

(B) the Secretary's authority to require postapproval studies or clinical trials, or the standards of evidence under which studies or trials are evaluated.

* * * * *

SEC. 506G. STANDARDS FOR REGENERATIVE MEDICINE AND REGENERATIVE ADVANCED THERAPIES.

(a) **IN GENERAL.**—Not later than 2 years after the date of enactment of the 21st Century Cures Act, the Secretary, in consultation with the National Institute of Standards and Technology and stakeholders (including regenerative medicine and advanced therapies manufacturers and clinical trial sponsors, contract manufacturers, academic institutions, practicing clinicians, regenerative medicine and advanced therapies industry organizations, and standard setting organizations), shall facilitate an effort to coordinate and prioritize the development of standards and consensus definition of terms, through a public process, to support, through regulatory predictability, the development, evaluation, and review of regenerative medicine therapies and regenerative advanced therapies, including with respect to the manufacturing processes and controls of such products.

(b) **ACTIVITIES.**—

(1) **IN GENERAL.**—In carrying out this section, the Secretary shall continue to—

(A) **[identity]** *identify* opportunities to help advance the development of regenerative medicine therapies and regenerative advanced therapies;

(B) identify opportunities for the development of laboratory regulatory science research and documentary standards that the Secretary determines would help support the development, evaluation, and review of regenerative medicine therapies and regenerative advanced therapies through regulatory predictability; and

(C) work with stakeholders, such as those described in subsection (a), as appropriate, in the development of such standards.

(2) **REGULATIONS AND GUIDANCE.**—Not later than 1 year after the development of standards as described in subsection (a), the Secretary shall review relevant regulations and guidance and, through a public process, update such regulations and guidance as the Secretary determines appropriate.

(c) **DEFINITIONS.**—For purposes of this section, the terms “regenerative medicine therapy” and “regenerative advanced therapy” have the meanings given such terms in section 506(g).

SEC. 506H. COMPETITIVE GENERIC THERAPIES.

(a) **IN GENERAL.**—*The Secretary shall, at the request of the sponsor of a drug that is designated as a competitive generic therapy pursuant to subsection (b), expedite the development and review of such drug pursuant to section 505(j).*

(b) **DESIGNATION PROCESS.**—

(1) **REQUEST.**—*The sponsor of a drug may request the Secretary to designate the drug as a competitive generic therapy.*

(2) **TIMING.**—*A request under paragraph (1) may be made concurrently with, or at any time prior to, the submission of an abbreviated new drug application for the drug under section 505(j).*

(3) **CRITERIA.**—*A drug is eligible for designation as a competitive generic therapy under this section if the Secretary determines that there is inadequate generic competition.*

(4) *DESIGNATION.*—Not later than 60 calendar days after the receipt of a request under paragraph (1), the Secretary shall—

(A) determine whether the drug that is the subject of the request meets the criteria described in paragraph (3); and

(B) if the Secretary finds that the drug meets such criteria, designate the drug as a competitive generic therapy.

(c) *ACTIONS.*—In expediting the development and review of a drug under subsection (a), the Secretary shall, as requested by the sponsor, take actions including the following:

(1) Hold meetings with the sponsor and the review team throughout the development of the drug prior to submission of the application for such drug under section 505(j).

(2) Provide timely advice to, and interactive communication with, the sponsor regarding the development of the drug to ensure that the development program to gather the data necessary for approval is as efficient as practicable.

(3) Involve senior managers and experienced review staff, as appropriate, in a collaborative, coordinated review, including with respect to drug-device combination products and other complex products.

(4) Assign a cross-disciplinary project lead for the Food and Drug Administration review team—

(A) to facilitate an efficient review of the development program and application, including manufacturing inspections; and

(B) to serve as a scientific liaison between the review team and the sponsor.

(d) *DEFINITIONS.*—In this section:

(1) The term “generic drug” means a drug that is approved pursuant to section 505(j).

(2) The term “inadequate generic competition” means, with respect to a product, there is not more than one approved drug product on the list of products described in section 505(j)(7)(A) (not including products on the discontinued section of such list) that is—

(A) the reference listed drug; or

(B) a generic drug with the same reference listed drug as the drug for which designation as a competitive generic therapy is sought.

(3) The term “reference listed drug” means the listed drug (as such term is used in section 505(j)) for the drug involved.

* * * * *

SEC. 510. (a) As used in this section—

(1) the term “manufacture, preparation, propagation, compounding, or processing” shall include repackaging or otherwise changing the container, wrapper, or labeling of any drug package or device package in furtherance of the distribution of the drug or device from the original place of manufacture to the person who makes final delivery or sale to the ultimate consumer or user; and

(2) the term “name” shall include in the case of a partnership the name of each partner and, in the case of a corporation, the name of each corporate officer and director, and the State of incorporation.

(b)(1) During the period beginning on October 1 and ending on December 31 of each year, every person who owns or operates any establishment in any State engaged in the manufacture, preparation, propagation, compounding, or processing of a drug or drugs shall register with the Secretary the name of such person, places of business of such person, all such establishments, the unique facility identifier of each such establishment, and a point of contact e-mail address.

(2) During the period beginning on October 1 and ending on December 31 of each year, every person who owns or operates any establishment in any State engaged in the manufacture, preparation, propagation, compounding, or processing of a device or devices shall register with the Secretary his name, places of business, and all such establishments.

(3) The Secretary shall specify the unique facility identifier system that shall be used by registrants under paragraph (1). The requirement to include a unique facility identifier in a registration under paragraph (1) shall not apply until the date that the identifier system is specified by the Secretary under the preceding sentence.

(c) Every person upon first engaging in the manufacture, preparation, propagation, compounding, or processing of a drug or drugs or a device or devices in any establishment which he owns or operates in any State shall immediately register with the Secretary—

(1) with respect to drugs, the information described under subsection (b)(1); and

(2) with respect to devices, the information described under subsection (b)(2)..

(d) Every person duly registered in accordance with the foregoing subsections of this section shall immediately register with the Secretary any additional establishment which he owns or operates in any State and in which he begins the manufacture, preparation, propagation, compounding, or processing of a drug or drugs or a device or devices.

(e) The Secretary may assign a registration number to any person or any establishment registered in accordance with this section. The Secretary may also assign a listing number to each drug or class of drugs listed under subsection (j). Any number assigned pursuant to the preceding sentence shall be the same as that assigned pursuant to the National Drug Code. The Secretary may by regulation prescribe a uniform system for the identification of devices intended for human use and may require that persons who are required to list such devices pursuant to subsection (j) shall list such devices in accordance with such system.

(f) The Secretary shall make available for inspection, to any person so requesting, any registration filed pursuant to this section; except that any list submitted pursuant to paragraph (3) of subsection (j) and the information accompanying any list or notice filed under paragraph (1) or (2) of that subsection shall be exempt from such inspection unless the Secretary finds that such an exemption would be inconsistent with protection of the public health.

(g) The foregoing subsections of this section shall not apply to—

(1) pharmacies which maintain establishments in conformance with any applicable local laws regulating the practice of pharmacy and medicine and which are regularly engaged in

dispensing prescription drugs or devices, upon prescriptions of practitioners licensed to administer such drugs or devices to patients under the care of such practitioners in the course of their professional practice, and which do not manufacture, prepare, propagate, compound, or process drugs or devices for sale other than in the regular course of their business of dispensing or selling drugs or devices at retail;

(2) practitioners licensed by law to prescribe or administer drugs or devices and who manufacture, prepare, propagate, compound, or process drugs or devices solely for use in the course of their professional practice;

(3) persons who manufacture, prepare, propagate, compound, or process drugs or devices solely for use in research, teaching, or chemical analysis and not for sale;

(4) any distributor who acts as a wholesale distributor of devices, and who does not manufacture, repackage, process, or relabel a device; or

(5) such other classes of persons as the Secretary may by regulation exempt from the application of this section upon a finding that registration by such classes of persons in accordance with this section is not necessary for the protection of the public health.

In this subsection, the term “wholesale distributor” means any person (other than the manufacturer or the initial importer) who distributes a device from the original place of manufacture to the person who makes the final delivery or sale of the device to the ultimate consumer or user.

(h) INSPECTIONS.—

(1) IN GENERAL.—Every establishment that is required to be registered with the Secretary under this section shall be subject to inspection pursuant to section 704.

[(2) BIENNIAL INSPECTIONS FOR DEVICES.—Every establishment described in paragraph (1), in any State, that is engaged in the manufacture, propagation, compounding, or processing of a device or devices classified in class II or III shall be so inspected by one or more officers or employees duly designated by the Secretary, or by persons accredited to conduct inspections under section 704(g), at least once in the 2-year period beginning with the date of registration of such establishment pursuant to this section and at least once in every successive 2-year period thereafter.]

(2) RISK-BASED SCHEDULE FOR DEVICES.—

(A) IN GENERAL.—*The Secretary, acting through one or more officers or employees duly designated by the Secretary, shall inspect establishments described in paragraph (1) that are engaged in the manufacture, propagation, compounding, or processing of a device or devices (referred to in this subsection as “device establishments”) in accordance with a risk-based schedule established by the Secretary.*

(B) FACTORS AND CONSIDERATIONS.—*In establishing the risk-based schedule under subparagraph (A), the Secretary shall—*

(i) apply, to the extent applicable for device establishments, the factors identified in paragraph (4); and

(ii) *consider the participation of the device establishment, as applicable, in international device audit programs in which the United States participates or which the United States recognizes for purposes of inspecting device establishments.*

(3) RISK-BASED SCHEDULE FOR DRUGS.—The Secretary, acting through one or more officers or employees duly designated by the Secretary, shall inspect establishments described in paragraph (1) that are engaged in the manufacture, preparation, propagation, compounding, or processing of a drug or drugs (referred to in this subsection as “drug establishments”) in accordance with a risk-based schedule established by the Secretary.

(4) RISK FACTORS.—In establishing a risk-based schedule under paragraph (3), the Secretary shall inspect establishments according to the known safety risks of such establishments, which shall be based on the following factors:

(A) The compliance history of the establishment.

(B) The record, history, and nature of recalls linked to the establishment.

(C) The inherent risk of the drug manufactured, prepared, propagated, compounded, or processed at the establishment.

(D) The inspection frequency and history of the establishment, including whether the establishment has been inspected pursuant to section 704 within the last 4 years.

(E) Whether the establishment has been inspected by a foreign government or an agency of a foreign government recognized under section 809.

(F) Any other criteria deemed necessary and appropriate by the Secretary for purposes of allocating inspection resources.

(5) EFFECT OF STATUS.—In determining the risk associated with an establishment for purposes of establishing a risk-based schedule under paragraph (3), the Secretary shall not consider whether the drugs manufactured, prepared, propagated, compounded, or processed by such establishment are drugs described in section 503(b).

(6) ANNUAL REPORT ON INSPECTIONS OF ESTABLISHMENTS.—Beginning in 2014, not later than February 1 of each year, the Secretary shall make available on the Internet Web site of the Food and Drug Administration a report regarding—

(A)(i) the number of domestic and foreign establishments registered pursuant to this section in the previous calendar year; and

(ii) the number of such domestic establishments and the number of such foreign establishments that the Secretary inspected in the previous calendar year;

(B) with respect to establishments that manufacture, prepare, propagate, compound, or process an active ingredient of a drug or a finished drug product, the number of each such type of establishment; and

(C) the percentage of the budget of the Food and Drug Administration used to fund the inspections described under subparagraph (A).

(i)(1) Every person who owns or operates any establishment with in any foreign country engaged in the manufacture, preparation, propagation, compounding, or processing of a drug or device that is imported or offered for import into the United States shall, through electronic means in accordance with the criteria of the Secretary—

(A) upon first engaging in any such activity, immediately submit a registration to the Secretary that includes—

(i) with respect to drugs, the name and place of business of such person, all such establishments, the unique facility identifier of each such establishment, a point of contact e-mail address, the name of the United States agent of each such establishment, the name of each importer of such drug in the United States that is known to the establishment, and the name of each person who imports or offers for import such drug to the United States for purposes of importation; and

(ii) with respect to devices, the name and place of business of the establishment, the name of the United States agent for the establishment, the name of each importer of such device in the United States that is known to the establishment, and the name of each person who imports or offers for import such device to the United States for purposes of importation; and

(B) each establishment subject to the requirements of subparagraph (A) shall thereafter register with the Secretary during the period beginning on October 1 and ending on December 31 of each year.

(2) The establishment shall also provide the information required by subsection (j).

(3) The Secretary is authorized to enter into cooperative arrangements with officials of foreign countries to ensure that adequate and effective means are available for purposes of determining, from time to time, whether drugs or devices manufactured, prepared, propagated, compounded, or processed by an establishment described in paragraph (1), if imported or offered for import into the United States, shall be refused admission on any of the grounds set forth in section 801(a).

(4) The Secretary shall specify the unique facility identifier system that shall be used by registrants under paragraph (1) with respect to drugs. The requirement to include a unique facility identifier in a registration under paragraph (1) with respect to drugs shall not apply until the date that the identifier system is specified by the Secretary under the preceding sentence.

(j)(1) Every person who registers with the Secretary under subsection (b), (c), (d), or (i) shall, at the time of registration under any such subsection, file with the Secretary a list of all drugs and a list of all devices and a brief statement of the basis for believing that each device included in the list is a device rather than a drug (with each drug and device in each list listed by its established name (as defined in section 502(e)) and by any proprietary name) which are being manufactured, prepared, propagated, compounded, or processed by him for commercial distribution and which he has not included in any list of drugs or devices filed by him with the Secretary under this paragraph or paragraph (2) before such time of

registration. Such list shall be prepared in such form and manner as the Secretary may prescribe and shall be accompanied by—

(A) in the case of a drug contained in the applicable list and subject to section 505 or 512, or a device intended for human use contained in the applicable list with respect to which a performance standard has been established under section 514 or which is subject to section 515, a reference to the authority for the marketing of such drug or device and a copy of all labeling for such drug or device;

(B) in the case of any other drug or device contained in an applicable list—

(i) which drug is subject to section 503(b)(1), or which device is a restricted device, a copy of all labeling for such drug or device, a representative sampling of advertisements for such drug or device, and, upon request made by the Secretary for good cause, a copy of all advertisements for a particular drug product or device, or

(ii) which drug is not subject to section 503(b)(1) or which device is not a restricted device, the label and package insert for such drug or device and a representative sampling of any other labeling for such drug or device;

(C) in the case of any drug contained in an applicable list which is described in subparagraph (B), a quantitative listing of its active ingredient or ingredients, except that with respect to a particular drug product the Secretary may require the submission of a quantitative listing of all ingredients if he finds that such submission is necessary to carry out the purposes of this Act;

(D) if the registrant filing a list has determined that a particular drug product or device contained in such list is not subject to section 505 or 512, or the particular device contained in such list is not subject to a performance standard established under section 514 or to section 515 or is not a restricted device, a brief statement of the basis upon which the registrant made such determination if the Secretary requests such a statement with respect to that particular drug product or device; and

(E) in the case of a drug contained in the applicable list, the name and place of business of each manufacturer of an excipient of the listed drug with which the person listing the drug conducts business, including all establishments used in the production of such excipient, the unique facility identifier of each such establishment, and a point of contact e-mail address for each such excipient manufacturer.

(2) Each person who registers with the Secretary under this section shall report to the Secretary, with regard to drugs once during the month of June of each year and once during the month of December of each year, and with regard to devices once each year during the period beginning on October 1 and ending on December 31, the following information:

(A) A list of each drug or device introduced by the registrant for commercial distribution which has not been included in any list previously filed by him with the Secretary under this subparagraph or paragraph (1) of this subsection. A list under this subparagraph shall list a drug or device by its established name (as defined in section 502(e)) and by any proprietary

name it may have and shall be accompanied by the other information required by paragraph (1).

(B) If since the date the registrant last made a report under this paragraph (or if he has not made a report under this paragraph, since the effective date of this subsection) he has discontinued the manufacture, preparation, propagation, compounding, or processing for commercial distribution of a drug or device included in a list filed by him under subparagraph (A) or paragraph (1); notice of such discontinuance, the date of such discontinuance, and the identity (by established name (as defined in section 502(e)) and by any proprietary name) of such drug or device.

(C) If since the date the registrant reported pursuant to subparagraph (B) a notice of discontinuance he has resumed the manufacture, preparation, propagation, compounding, or processing for commercial distribution of the drug or device with respect to which such notice of discontinuance was reported; notice of such resumption, the date of such resumption, the identity of such drug or device (by established name (as defined in section 502(e)) and by any proprietary name), and the other information required by paragraph (1), unless the registrant has previously reported such resumption to the Secretary pursuant to this subparagraph.

(D) Any material change in any information previously submitted pursuant to this paragraph or paragraph (1).

(3) The Secretary may also require each registrant under this section to submit a list of each drug product which (A) the registrant is manufacturing, preparing, propagating, compounding, or processing for commercial distribution, and (B) contains a particular ingredient. The Secretary may not require the submission of such a list unless he has made a finding that the submission of such a list is necessary to carry out the purposes of this Act.

(4) The Secretary shall require persons subject to this subsection to use, for purposes of this subsection, the unique facility identifier systems specified under subsections (b)(3) and (i)(4) with respect to drugs. Such requirement shall not apply until the date that the identifier system under subsection (b)(3) or (i)(4), as applicable, is specified by the Secretary.

(k) Each person who is required to register under this section and who proposes to begin the introduction or delivery for introduction into interstate commerce for commercial distribution of a device intended for human use shall, at least ninety days before making such introduction or delivery, report to the Secretary or person who is accredited under section 523(a) (in such form and manner as the Secretary shall by regulation prescribe)—

(1) the class in which the device is classified under section 513 or if such person determines that the device is not classified under such section, a statement of that determination and the basis for such person's determination that the device is or is not so classified, and

(2) action taken by such person to comply with requirements under section 514 or 515 which are applicable to the device.

A notification submitted under this subsection that contains clinical trial data for an applicable device clinical trial (as defined in section 402(j)(1) of the Public Health Service Act) shall be accom-

panied by the certification required under section 402(j)(5)(B) of such Act. Such certification shall not be considered an element of such notification.

(1)(1) A report under subsection (k) is not required for a device intended for human use that is exempted from the requirements of this subsection under subsection (m) or is within a type that has been classified into class I under section 513. The exception established in the preceding sentence does not apply to any class I device that is intended for a use which is of substantial importance in preventing impairment of human health, or to any class I device that presents a potential unreasonable risk of illness or injury.

(2) Not later than 120 calendar days after the date of enactment of the 21st Century Cures Act and at least once every 5 years thereafter, as the Secretary determines appropriate, the Secretary shall identify, through publication in the Federal Register, any type of class I device that the Secretary determines no longer requires a report under subsection (k) to provide reasonable assurance of safety and effectiveness. Upon such publication—

(A) each type of class I device so identified shall be exempt from the requirement for a report under subsection (k); and

(B) the classification regulation applicable to each such type of device shall be deemed amended to incorporate such exemption.

(m)(1) The Secretary shall—

(A) not later than 90 days after the date of enactment of the 21st Century Cures Act and at least once every 5 years thereafter, as the Secretary determines appropriate—

(i) publish in the Federal Register a notice that contains a list of each type of class II device that the Secretary determines no longer requires a report under subsection (k) to provide reasonable assurance of safety and effectiveness; and

(ii) provide for a period of not less than 60 calendar days for public comment beginning on the date of the publication of such notice; and

(B) not later than 210 calendar days after the date of enactment of the 21st Century Cures Act, publish in the Federal Register a list representing the Secretary's final determination with respect to the devices contained in the list published under subparagraph (A).

(2) Beginning on the date that is 1 calendar day after the date of publication of the final list under paragraph (1)(B), the Secretary may exempt a class II device from the requirement to submit a report under subsection (k), upon the Secretary's own initiative or a petition of an interested person, if the Secretary determines that such report is not necessary to assure the safety and effectiveness of the device. The Secretary shall publish in the Federal Register notice of the intent of the Secretary to exempt the device, or of the petition, and provide a 60-calendar-day period for public comment. Within 120 days after the issuance of the notice in the Federal Register, the Secretary shall publish an order in the Federal Register that sets forth the final determination of the Secretary regarding the exemption of the device that was the subject of the no-

tice. If the Secretary fails to respond to a petition within 180 days of receiving it, the petition shall be deemed to be granted.

(3) Upon the publication of the final list under paragraph (1)(B)—

(A) each type of class II device so listed shall be exempt from the requirement for a report under subsection (k); and

(B) the classification regulation applicable to each such type of device shall be deemed amended to incorporate such exemption.

(n)(1) The Secretary shall review the report required in subsection (k) and make a determination under section 513(f)(1) not later than 90 days after receiving the report.

(2)(A) Not later than 18 months after the date of enactment of this paragraph, the Secretary shall submit to the Committee on Energy and Commerce of the House of Representatives and the Committee on Health, Education, Labor, and Pensions of the Senate a report regarding when a premarket notification under subsection (k) should be submitted for a modification or change to a legally marketed device. The report shall include the Secretary's interpretation of the following terms: "could significantly affect the safety or effectiveness of the device", "a significant change or modification in design, material, chemical composition, energy source, or manufacturing process", and "major change or modification in the intended use of the device". The report also shall discuss possible processes for industry to use to determine whether a new submission under subsection (k) is required and shall analyze how to leverage existing quality system requirements to reduce premarket burden, facilitate continual device improvement, and provide reasonable assurance of safety and effectiveness of modified devices. In developing such report, the Secretary shall consider the input of interested stakeholders.

(B) The Secretary shall withdraw the Food and Drug Administration draft guidance entitled "Guidance for Industry and FDA Staff—510(k) Device Modifications: Deciding When to Submit a 510(k) for a Change to an Existing Device", dated July 27, 2011, and shall not use this draft guidance as part of, or for the basis of, any premarket review or any compliance or enforcement decisions or actions. The Secretary shall not issue—

(i) any draft guidance or proposed regulation that addresses when to submit a premarket notification submission for changes and modifications made to a manufacturer's previously cleared device before the receipt by the Committee on Energy and Commerce of the House of Representatives and the Committee on Health, Education, Labor, and Pensions of the Senate of the report required in subparagraph (A); and

(ii) any final guidance or regulation on that topic for one year after date of receipt of such report by the Committee on Energy and Commerce of the House of Representatives and the Committee on Health, Education, Labor, and Pensions of the Senate.

(C) The Food and Drug Administration guidance entitled "Deciding When to Submit a 510(k) for a Change to an Exist-

ing Device”, dated January 10, 1997, shall be in effect until the subsequent issuance of guidance or promulgation, if appropriate, of a regulation described in subparagraph (B), and the Secretary shall interpret such guidance in a manner that is consistent with the manner in which the Secretary has interpreted such guidance since 1997.

(o)(1) With respect to reprocessed single-use devices for which reports are required under subsection (k):

(A) The Secretary shall identify such devices or types of devices for which reports under such subsection must, in order to ensure that the device is substantially equivalent to a predicate device, include validation data, the types of which shall be specified by the Secretary, regarding cleaning and sterilization, and functional performance demonstrating that the single-use device will remain substantially equivalent to its predicate device after the maximum number of times the device is reprocessed as intended by the person submitting the premarket notification. Within six months after enactment of this subsection, the Secretary shall publish in the Federal Register a list of the types so identified, and shall revise the list as appropriate. Reports under subsection (k) for devices or types of devices within a type included on the list are, upon publication of the list, required to include such validation data.

(B) In the case of each report under subsection (k) that was submitted to the Secretary before the publication of the initial list under subparagraph (A), or any revision thereof, and was for a device or type of device included on such list, the person who submitted the report under subsection (k) shall submit validation data as described in subparagraph (A) to the Secretary not later than nine months after the publication of the list. During such nine-month period, the Secretary may not take any action under this Act against such device solely on the basis that the validation data for the device have not been submitted to the Secretary. After the submission of the validation data to the Secretary, the Secretary may not determine that the device is misbranded under section 502(o) or adulterated under section 501(f)(1)(B), or take action against the device under section 301(p) for failure to provide any information required by subsection (k) until (i) the review is terminated by withdrawal of the submission of the report under subsection (k); (ii) the Secretary finds the data to be acceptable and issues a letter; or (iii) the Secretary determines that the device is not substantially equivalent to a predicate device. Upon a determination that a device is not substantially equivalent to a predicate device, or if such submission is withdrawn, the device can no longer be legally marketed.

(C) In the case of a report under subsection (k) for a device identified under subparagraph (A) that is of a type for which the Secretary has not previously received a report under such subsection, the Secretary may, in advance of revising the list under subparagraph (A) to include such type, require that the report include the validation data specified in subparagraph (A).

(D) Section 502(o) applies with respect to the failure of a report under subsection (k) to include validation data required under subparagraph (A).

(2) With respect to critical or semi-critical reprocessed single-use devices that, under subsection (l) or (m), are exempt from the requirement of submitting reports under subsection (k):

(A) The Secretary shall identify such devices or types of devices for which such exemptions should be terminated in order to provide a reasonable assurance of the safety and effectiveness of the devices. The Secretary shall publish in the Federal Register a list of the devices or types of devices so identified, and shall revise the list as appropriate. The exemption for each device or type included on the list is terminated upon the publication of the list. For each report under subsection (k) submitted pursuant to this subparagraph the Secretary shall require the validation data described in paragraph (1)(A).

(B) For each device or type of device included on the list under subparagraph (A), a report under subsection (k) shall be submitted to the Secretary not later than 15 months after the publication of the initial list, or a revision of the list, whichever terminates the exemption for the device. During such 15-month period, the Secretary may not take any action under this Act against such device solely on the basis that such report has not been submitted to the Secretary. After the submission of the report to the Secretary the Secretary may not determine that the device is misbranded under section 502(o) or adulterated under section 501(f)(1)(B), or take action against the device under section 301(p) for failure to provide any information required by subsection (k) until (i) the review is terminated by withdrawal of the submission; (ii) the Secretary determines by order that the device is substantially equivalent to a predicate device; or (iii) the Secretary determines by order that the device is not substantially equivalent to a predicate device. Upon a determination that a device is not substantially equivalent to a predicate device, the device can no longer be legally marketed.

(C) In the case of semi-critical devices, the initial list under subparagraph (A) shall be published not later than 18 months after the effective date of this subsection. In the case of critical devices, the initial list under such subparagraph shall be published not later than six months after such effective date.

(D) Section 502(o) applies with respect to the failure to submit a report under subsection (k) that is required pursuant to subparagraph (A), including a failure of the report to include validation data required in such subparagraph.

(E) The termination under subparagraph (A) of an exemption under subsection (l) or (m) for a critical or semi-critical reprocessed single-use device does not terminate the exemption under subsection (l) or (m) for the original device.

(p) ELECTRONIC REGISTRATION AND LISTING.—

(1) IN GENERAL.—Registrations and listings under this section (including the submission of updated information) shall be submitted to the Secretary by electronic means unless the Secretary grants a request for waiver of such requirement because

use of electronic means is not reasonable for the person requesting such waiver.

(2) ELECTRONIC DATABASE.—Not later than 2 years after the Secretary specifies a unique facility identifier system under subsections (b) and (i), the Secretary shall maintain an electronic database, which shall not be subject to inspection under subsection (f), populated with the information submitted as described under paragraph (1) that—

(A) enables personnel of the Food and Drug Administration to search the database by any field of information submitted in a registration described under paragraph (1), or combination of such fields; and

(B) uses the unique facility identifier system to link with other relevant databases within the Food and Drug Administration, including the database for submission of information under section 801(r).

(3) RISK-BASED INFORMATION AND COORDINATION.—The Secretary shall ensure the accuracy and coordination of relevant Food and Drug Administration databases in order to identify and inform risk-based inspections under section 510(h).

(q) REUSABLE MEDICAL DEVICES.—

(1) IN GENERAL.—Not later than 180 days after the date of enactment of the 21st Century Cures Act, the Secretary shall identify and publish a list of reusable device types for which reports under subsection (k) are required to include—

(A) instructions for use, which have been validated in a manner specified by the Secretary; and

(B) validation data, the types of which shall be specified by the Secretary; regarding cleaning, disinfection, and sterilization, and for which a substantial equivalence determination may be based.

(2) REVISION OF LIST.—The Secretary shall revise the list under paragraph (2), as the Secretary determines appropriate, with notice in the Federal Register.

(3) CONTENT OF REPORTS.—Reports under subsection (k) that are submitted after the publication of the list described in paragraph (1), for devices or types of devices included on such list, shall include such instructions for use and validation data.

* * * * *

CLASSIFICATION OF DEVICES INTENDED FOR HUMAN USE

Device Classes

SEC. 513. (a)(1) There are established the following classes of devices intended for human use:

(A) CLASS I, GENERAL CONTROLS.—

(i) A device for which the controls authorized by or under section 501, 502, 510, 516, 518, 519, or 520 or any combination of such sections are sufficient to provide reasonable assurance of the safety and effectiveness of the device.

(ii) A device for which insufficient information exists to determine that the controls referred to in clause (i) are sufficient to provide reasonable assurance of the safety and

effectiveness of the device or to establish special controls to provide such assurance, but because it—

(I) is not purported or represented to be for a use in supporting or sustaining human life or for a use which is of substantial importance in preventing impairment of human health, and

(II) does not present a potential unreasonable risk of illness or injury,

is to be regulated by the controls referred to in clause (i).

(B) CLASS II, SPECIAL CONTROLS.—A device which cannot be classified as a class I device because the general controls by themselves are insufficient to provide reasonable assurance of the safety and effectiveness of the device, and for which there is sufficient information to establish special controls to provide such assurance, including the promulgation of performance standards, postmarket surveillance, patient registries, development and dissemination of guidelines (including guidelines for the submission of clinical data in premarket notification submissions in accordance with section 510(k)), recommendations, and other appropriate actions as the Secretary deems necessary to provide such assurance. For a device that is purported or represented to be for a use in supporting or sustaining human life, the Secretary shall examine and identify the special controls, if any, that are necessary to provide adequate assurance of safety and effectiveness and describe how such controls provide such assurance.

(C) CLASS III, PREMARKET APPROVAL.—A device which because—

(i) it (I) cannot be classified as a class I device because insufficient information exists to determine that the application of general controls are sufficient to provide reasonable assurance of the safety and effectiveness of the device, and (II) cannot be classified as a class II device because insufficient information exists to determine that the special controls described in subparagraph (B) would provide reasonable assurance of its safety and effectiveness, and

(ii)(I) is purported or represented to be for a use in supporting or sustaining human life or for a use which is of substantial importance in preventing impairment of human health, or

(II) presents a potential unreasonable risk of illness or injury,

is to be subject, in accordance with section 515, to premarket approval to provide reasonable assurance of its safety and effectiveness.

If there is not sufficient information to establish a performance standard for a device to provide reasonable assurance of its safety and effectiveness, the Secretary may conduct such activities as may be necessary to develop or obtain such information.

(2) For purposes of this section and sections 514 and 515, the safety and effectiveness of a device are to be determined—

(A) with respect to the persons for whose use the device is represented or intended,

(B) with respect to the conditions of use prescribed, recommended, or suggested in the labeling of the device, and

(C) weighing any probable benefit to health from the use of the device against any probable risk of injury or illness from such use.

(3)(A) Except as authorized by subparagraph (B), the effectiveness of a device is, for purposes of this section and sections 514 and 515, to be determined, in accordance with regulations promulgated by the Secretary, on the basis of well-controlled investigations, including 1 or more clinical investigations where appropriate, by experts qualified by training and experience to evaluate the effectiveness of the device, from which investigations it can fairly and responsibly be concluded by qualified experts that the device will have the effect it purports or is represented to have under the conditions of use prescribed, recommended, or suggested in the labeling of the device.

(B) If the Secretary determines that there exists valid scientific evidence (other than evidence derived from investigations described in subparagraph (A))—

(i) which is sufficient to determine the effectiveness of a device, and

(ii) from which it can fairly and responsibly be concluded by qualified experts that the device will have the effect it purports or is represented to have under the conditions of use prescribed, recommended, or suggested in the labeling of the device,

then, for purposes of this section and sections 514 and 515, the Secretary may authorize the effectiveness of the device to be determined on the basis of such evidence.

(C) In making a determination of a reasonable assurance of the effectiveness of a device for which an application under section 515 has been submitted, the Secretary shall consider whether the extent of data that otherwise would be required for approval of the application with respect to effectiveness can be reduced through reliance on postmarket controls.

(D)(i) The Secretary, upon the written request of any person intending to submit an application under section 515, shall meet with such person to determine the type of valid scientific evidence (within the meaning of subparagraphs (A) and (B)) that will be necessary to demonstrate for purposes of approval of an application the effectiveness of a device for the conditions of use proposed by such person. The written request shall include a detailed description of the device, a detailed description of the proposed conditions of use of the device, a proposed plan for determining whether there is a reasonable assurance of effectiveness, and, if available, information regarding the expected performance from the device. Within 30 days after such meeting, the Secretary shall specify in writing the type of valid scientific evidence that will provide a reasonable assurance that a device is effective under the conditions of use proposed by such person.

(ii) Any clinical data, including one or more well-controlled investigations, specified in writing by the Secretary for demonstrating a reasonable assurance of device effectiveness shall be specified as result of a determination by the Secretary that such data are necessary to establish device effectiveness. The Secretary shall consider, in consultation with the applicant, the least burdensome ap-

propriate means of evaluating device effectiveness that would have a reasonable likelihood of resulting in approval.

(iii) For purposes of clause (ii), the term “necessary” means the minimum required information that would support a determination by the Secretary that an application provides reasonable assurance of the effectiveness of the device.

(iv) Nothing in this subparagraph shall alter the criteria for evaluating an application for premarket approval of a device.

(v) The determination of the Secretary with respect to the specification of valid scientific evidence under clauses (i) and (ii) shall be binding upon the Secretary, unless such determination by the Secretary could be contrary to the public health.

Classification; Classification Panels

(b)(1) For purposes of—

(A) determining which devices intended for human use should be subject to the requirements of general controls, performance standards, or premarket approval, and

(B) providing notice to the manufacturers and importers of such devices to enable them to prepare for the application of such requirements to devices manufactured or imported by them,

the Secretary shall classify all such devices (other than devices classified by subsection (f)) into the classes established by subsection (a). For the purpose of securing recommendations with respect to the classification of devices, the Secretary shall establish panels of experts or use panels of experts established before the date of the enactment of this section, or both. Section 14 of the Federal Advisory Committee Act shall not apply to the duration of a panel established under this paragraph.

(2) The Secretary shall appoint to each panel established under paragraph (1) persons who are qualified by training and experience to evaluate the safety and effectiveness of the devices to be referred to the panel and who, to the extent feasible, possess skill in the use of, or experience in the development, manufacture, or utilization of, such devices. The Secretary shall make appointments to each panel so that each panel shall consist of members with adequately diversified expertise in such fields as clinical and administrative medicine, engineering, biological and physical sciences, and other related professions. In addition, each panel shall include as non-voting members a representative of consumer interests and a representative of interests of the device manufacturing industry. Scientific, trade, and consumer organizations shall be afforded an opportunity to nominate individuals for appointment to the panels. No individual who is in the regular full-time employ of the United States and engaged in the administration of this Act may be a member of any panel. The Secretary shall designate one of the members of each panel to serve as chairman thereof.

(3) Panel members (other than officers or employees of the United States), while attending meetings or conferences of a panel or otherwise engaged in its business, shall be entitled to receive compensation at rates to be fixed by the Secretary, but not at rates exceeding the daily equivalent of the rate in effect for grade GS-18 of the General Schedule, for each day so engaged, including traveltime; and while so serving away from their homes or regular

places of business each member may be allowed travel expenses (including per diem in lieu of subsistence) as authorized by section 5703 of title 5, United States Code, for persons in the Government service employed intermittently.

(4) The Secretary shall furnish each panel with adequate clerical and other necessary assistance.

(5)(A) Classification panels covering each type of device shall be scheduled to meet at such times as may be appropriate for the Secretary to meet applicable statutory deadlines.

(B) When a device is specifically the subject of review by a classification panel, the Secretary shall—

(i) ensure that adequate expertise is represented on the classification panel to assess—

(I) the disease or condition which the device is intended to cure, treat, mitigate, prevent, or diagnose; and

(II) the technology of the device; and

(ii) provide an opportunity for the person whose device is specifically the subject of panel review to provide recommendations on the expertise needed among the voting members of the panel.

(C) For purposes of subparagraph (B)(i), the term “adequate expertise” means that the membership of the classification panel includes—

(i) two or more voting members, with a specialty or other expertise clinically relevant to the device under review; and

(ii) at least one voting member who is knowledgeable about the technology of the device.

(D) The Secretary shall provide an annual opportunity for patients, representatives of patients, and sponsors of [medical device submissions] *medical devices that may be specifically the subject of a review by a classification panel* to provide recommendations for individuals with appropriate expertise to fill voting member positions on classification panels.

(6)(A) Any person whose device is specifically the subject of review by a classification panel shall have—

(i) the same access to data and information submitted to a classification panel (except for data and information that are not available for public disclosure under section 552 of title 5, United States Code) as the Secretary;

(ii) the opportunity to submit, for review by a classification panel, information that is based on the data or information provided in the application submitted under section 515 by the person, which information shall be submitted to the Secretary for prompt transmittal to the classification panel; and

(iii) the same opportunity as the Secretary to participate in meetings of the panel, including, subject to the discretion of the panel chairperson, by designating a representative who will be provided a time during the panel meeting to address the panel for the purpose of correcting misstatements of fact or providing clarifying information, and permitting the person or representative to call on experts within the person’s organization to address such specific issues in the time provided.

(B)(i) Any meeting of a classification panel with respect to the review of a device shall—

- (I) provide adequate time for initial presentations by the person whose device is specifically the subject of such review and by the Secretary; and
 - (II) encourage free and open participation by all interested persons.
- (ii) Following the initial presentations described in clause (i), the panel may—
- (I) pose questions to a designated representative described in subparagraph (A)(iii); and
 - (II) consider the responses to such questions in the panel's review of the device.
- (7) After receiving from a classification panel the conclusions and recommendations of the panel on a matter that the panel has reviewed, the Secretary shall review the conclusions and recommendations, shall make a final decision on the matter in accordance with section 515(d)(2), and shall notify the affected persons of the decision in writing and, if the decision differs from the conclusions and recommendations of the panel, shall include the reasons for the difference.
- (8) A classification panel under this subsection shall not be subject to the annual chartering and annual report requirements of the Federal Advisory Committee Act.
- 【(9) The Secretary shall classify an accessory under this section based on the intended use of the accessory, notwithstanding the classification of any other device with which such accessory is intended to be used.】

Classification Panel Organization and Operation

(c)(1) The Secretary shall organize the panels according to the various fields of clinical medicine and fundamental sciences in which devices intended for human use are used. The Secretary shall refer a device to be classified under this section to an appropriate panel established or authorized to be used under subsection (b) for its review and for its recommendation respecting the classification of the device. The Secretary shall by regulation prescribe the procedure to be followed by the panels in making their reviews and recommendations. In making their reviews of devices, the panels, to the maximum extent practicable, shall provide an opportunity for interested persons to submit data and views on the classification of the devices.

(2)(A) Upon completion of a panel's review of a device referred to it under paragraph (1), the panel shall, subject to subparagraphs (B) and (C), submit to the Secretary its recommendation for the classification of the device. Any such recommendation shall (i) contain (I) a summary of the reasons for the recommendation, (II) a summary of the data upon which the recommendation is based, and (III) an identification of the risks to health (if any) presented by the device with respect to which the recommendation is made, and (ii) to the extent practicable, include a recommendation for the assignment of a priority for the application of the requirements of section 514 or 515 to a device recommended to be classified in class II or class III.

(B) A recommendation of a panel for the classification of a device in class I shall include a recommendation as to whether the device

should be exempted from the requirements of section 510, 519, or 520(f).

(C) In the case of a device which has been referred under paragraph (1) to a panel, and which—

(i) is intended to be implanted in the human body or is purported or represented to be for a use in supporting or sustaining human life, and

(ii)(I) has been introduced or delivered for introduction into interstate commerce for commercial distribution before the date of enactment of this section, or

(II) is within a type of device which was so introduced or delivered before such date and is substantially equivalent to another device within that type,

such panel shall recommend to the Secretary that the device be classified in class III unless the panel determines that classification of the device in such class is not necessary to provide reasonable assurance of its safety and effectiveness. If a panel does not recommend that such a device be classified in class III, it shall in its recommendation to the Secretary for the classification of the device set forth the reasons for not recommending classification of the device in such class.

(3) The panels shall submit to the Secretary within one year of the date funds are first appropriated for the implementation of this section their recommendations respecting all devices of a type introduced or delivered for introduction into interstate commerce for commercial distribution before the date of the enactment of this section.

Classification

(d)(1) Upon receipt of a recommendation from a panel respecting a device, the Secretary shall publish in the Federal Register the panel's recommendation and a proposed regulation classifying such device and shall provide interested persons an opportunity to submit comments on such recommendation and the proposed regulation. After reviewing such comments, the Secretary shall, subject to paragraph (2), by regulation classify such device.

(2)(A) A regulation under paragraph (1) classifying a device in class I shall prescribe which, if any, of the requirements of section 510, 519 or 520(f) shall not apply to the device. A regulation which makes a requirement of section 510, 519, or 520(f) inapplicable to a device shall be accompanied by a statement of the reasons of the Secretary for making such requirement inapplicable.

(B) A device described in subsection (c)(2)(C) shall be classified in class III unless the Secretary determines that classification of the device in such class is not necessary to provide reasonable assurance of its safety and effectiveness. A proposed regulation under paragraph (1) classifying such a device in a class other than class III shall be accompanied by a full statement of the reasons of the Secretary (and supporting documentation and data) for not classifying such device in such class and an identification of the risks to health (if any) presented by such device.

(3) In the case of devices classified in class II and devices classified under this subsection in class III and described in section 515(b)(1) the Secretary may establish priorities which, in his dis-

cretion, shall be used in applying sections 514 and 515, as appropriate, to such devices.

Classification Changes

(e)(1)(A)(i) Based on new information respecting a device, the Secretary may, upon the initiative of the Secretary or upon petition of an interested person, change the classification of such device, and revoke, on account of the change in classification, any regulation or requirement in effect under section 514 or 515 with respect to such device, by administrative order published in the Federal Register following publication of a proposed reclassification order in the Federal Register, a meeting of a device classification panel described in subsection (b), and consideration of comments to a public docket, notwithstanding subchapter II of chapter 5 of title 5, United States Code. The proposed reclassification order published in the Federal Register shall set forth the proposed reclassification, and a substantive summary of the valid scientific evidence concerning the proposed reclassification, including—

(I) the public health benefit of the use of the device, and the nature and, if known, incidence of the risk of the device;

(II) in the case of a reclassification from class II to class III, why general controls pursuant to subsection (a)(1)(A) and special controls pursuant to subsection (a)(1)(B) together are not sufficient to provide a reasonable assurance of safety and effectiveness for such device; and

(III) in the case of reclassification from class III to class II, why general controls pursuant to subsection (a)(1)(A) and special controls pursuant to subsection (a)(1)(B) together are sufficient to provide a reasonable assurance of safety and effectiveness for such device.

(ii) An order under this subsection changing the classification of a device from class III to class II may provide that such classification shall not take effect until the effective date of a performance standard established under section 514 for such device.

(B) Authority to issue such administrative order shall not be delegated below the Director of the Center for Devices and Radiological Health, acting in consultation with the Commissioner.

(2) By an order issued under paragraph (1), the Secretary may change the classification of a device from class III—

(A) to class II if the Secretary determines that special controls would provide reasonable assurance of the safety and effectiveness of the device and that general controls would not provide reasonable assurance of the safety and effectiveness of the device, or

(B) to class I if the Secretary determines that general controls would provide reasonable assurance of the safety and effectiveness of the device.

Initial Classification and Reclassification of Certain Devices

(f)(1) Any device intended for human use which was not introduced or delivered for introduction into interstate commerce for commercial distribution before the date of the enactment of this section is classified in class III unless—

(A) the device—

(i) is within a type of device (I) which was introduced or delivered for introduction into interstate commerce for commercial distribution before such date and which is to be classified pursuant to subsection (b), or (II) which was not so introduced or delivered before such date and has been classified in class I or II, and

(ii) is substantially equivalent to another device within such type;

(B) the Secretary in response to a petition submitted under paragraph (3) has classified such device in class I or II; or

(C) the device is classified pursuant to a request submitted under paragraph (2).

A device classified in class III under this paragraph shall be classified in that class until the effective date of an order of the Secretary under paragraph (2) or (3) classifying the device in class I or II.

(2)(A)(i) Any person who submits a report under section 510(k) for a type of device that has not been previously classified under this Act, and that is classified into class III under paragraph (1), may request, after receiving written notice of such a classification, the Secretary to classify the device.

(ii) In lieu of submitting a report under section 510(k) and submitting a request for classification under clause (i) for a device, if a person determines there is no legally marketed device upon which to base a determination of substantial equivalence (as defined in subsection (i)), a person may submit a request under this clause for the Secretary to classify the device.

(iii) Upon receipt of a request under clause (i) or (ii), the Secretary shall classify the device subject to the request under the criteria set forth in subparagraphs (A) through (C) of subsection (a)(1) within 120 days.

(iv) Notwithstanding clause (iii), the Secretary may decline to undertake a classification request submitted under clause (ii) if the Secretary identifies a legally marketed device that could provide a reasonable basis for review of substantial equivalence under paragraph (1), or when the Secretary determines that the device submitted is not of low to moderate risk or that general controls would be inadequate to control the risks and special controls to mitigate the risks cannot be developed.

(v) The person submitting the request for classification under this subparagraph may recommend to the Secretary a classification for the device and shall, if recommending classification in class II, include in the request an initial draft proposal for applicable special controls, as described in subsection (a)(1)(B), that are necessary, in conjunction with general controls, to provide reasonable assurance of safety and effectiveness and a description of how the special controls provide such assurance. Any such request shall describe the device and provide detailed information and reasons for the recommended classification.

(B)(i) The Secretary shall by written order classify the device involved. Such classification shall be the initial classification of the device for purposes of paragraph (1) and any device classified under this paragraph shall be a predicate device for determining substantial equivalence under paragraph (1).

(ii) A device that remains in class III under this subparagraph shall be deemed to be adulterated within the meaning of section 501(f)(1)(B) until approved under section 515 or exempted from such approval under section 520(g).

(C) Within 30 days after the issuance of an order classifying a device under this paragraph, the Secretary shall publish a notice in the Federal Register announcing such classification.

(3)(A) The Secretary may initiate the reclassification of a device classified into class III under paragraph (1) of this subsection or the manufacturer or importer of a device classified under paragraph (1) may petition the Secretary (in such form and manner as he shall prescribe) for the issuance of an order classifying the device in class I or class II. Within thirty days of the filing of such a petition, the Secretary shall notify the petitioner of any deficiencies in the petition which prevent the Secretary from making a decision on the petition.

(B)(i) Upon determining that a petition does not contain any deficiency which prevents the Secretary from making a decision on the petition, the Secretary may for good cause shown refer the petition to an appropriate panel established or authorized to be used under subsection (b). A panel to which such a petition has been referred shall not later than ninety days after the referral of the petition make a recommendation to the Secretary respecting approval or denial of the petition. Any such recommendation shall contain (I) a summary of the reasons for the recommendation, (II) a summary of the data upon which the recommendation is based, and (III) an identification of the risks to health (if any) presented by the device with respect to which the petition was filed. In the case of a petition for a device which is intended to be implanted in the human body or which is purported or represented to be for a use in supporting or sustaining human life, the panel shall recommend that the petition be denied unless the panel determines that the classification in class III of the device is not necessary to provide reasonable assurance of its safety and effectiveness. If the panel recommends that such petition be approved, it shall in its recommendation to the Secretary set forth its reasons for such recommendation.

(ii) The requirements of paragraphs (1) and (2) of subsection (c) (relating to opportunities for submission of data and views and recommendations respecting priorities and exemptions from sections 510, 519, and 520(f)) shall apply with respect to consideration by panels of petitions submitted under subparagraph (A).

(C)(i) Within ninety days from the date the Secretary receives the recommendation of a panel respecting a petition (but not later than 210 days after the filing of such petition) the Secretary shall by order deny or approve the petition. If the Secretary approves the petition, the Secretary shall order the classification of the device into class I or class II in accordance with the criteria prescribed by subsection (a)(1)(A) or (a)(1)(B). In the case of a petition for a device which is intended to be implanted in the human body or which is purported or represented to be for a use in supporting or sustaining human life, the Secretary shall deny the petition unless the Secretary determines that the classification in class III of the device is not necessary to provide reasonable assurance of its safety and effectiveness. An order approving such petition shall be accom-

panied by a full statement of the reasons of the Secretary (and supporting documentation and data) for approving the petition and an identification of the risks to health (if any) presented by the device to which such order applies.

(ii) The requirements of paragraphs (1) and (2)(A) of subsection (d) (relating to publication of recommendations, opportunity for submission of comments, and exemption from sections 510, 519, and 520(f)) shall apply with respect to action by the Secretary on petitions submitted under subparagraph (A).

(4) If a manufacturer reports to the Secretary under section 510(k) that a device is substantially equivalent to another device—

(A) which the Secretary has classified as a class III device under subsection (b),

(B) which was introduced or delivered for introduction into interstate commerce for commercial distribution before December 1, 1990, and

(C) for which no final regulation requiring premarket approval has been promulgated under section 515(b),

the manufacturer shall certify to the Secretary that the manufacturer has conducted a reasonable search of all information known or otherwise available to the manufacturer respecting such other device and has included in the report under section 510(k) a summary of and a citation to all adverse safety and effectiveness data respecting such other device and respecting the device for which the section 510(k) report is being made and which has not been submitted to the Secretary under section 519. The Secretary may require the manufacturer to submit the adverse safety and effectiveness data described in the report.

(5) The Secretary may not withhold a determination of the initial classification of a device under paragraph (1) because of a failure to comply with any provision of this Act unrelated to a substantial equivalence decision, including a finding that the facility in which the device is manufactured is not in compliance with good manufacturing requirements as set forth in regulations of the Secretary under section 520(f) (other than a finding that there is a substantial likelihood that the failure to comply with such regulations will potentially present a serious risk to human health).

(6)(A) *Subject to the succeeding subparagraphs of this paragraph, the Secretary shall, by written order, classify an accessory under this section based on the risks of the accessory when used as intended and the level of regulatory controls necessary to provide a reasonable assurance of safety and effectiveness of the accessory, notwithstanding the classification of any other device with which such accessory is intended to be used.*

(B) *The classification of any accessory distinct from another device by regulation or written order issued prior to December 13, 2016, shall continue to apply unless and until the accessory is reclassified by the Secretary, notwithstanding the classification of any other device with which such accessory is intended to be used. Nothing in this section shall preclude the Secretary's ability to initiate the classification of an accessory through regulation or written order, as appropriate.*

(C)(i) *In the case of an accessory that has been granted marketing authorization as part of a submission under section 515(c), 510(k), or paragraph (2) of this subsection with another device with which*

such accessory is intended to be used, and with respect to which the Secretary has issued a written order classifying such accessory type distinct from another device in accordance with subparagraph (A), the manufacturer or importer of such accessory may, in lieu of submitting a request for classification of such accessory, submit a written request to the Secretary identifying such classification. A request under this clause shall include such information to support the request as may be specified by the Secretary.

(ii) A request under clause (i) shall include a recommendation for the proper classification of the accessory pursuant to subparagraph (A), and shall include such information as may be necessary for the Secretary to evaluate, based on the least burdensome approach, the appropriate class for the accessory under subsection (a).

(iii) The Secretary shall respond to a request under clause (i) within 90 calendar days by granting or denying the request for reclassification of the accessory.

(iv) Within 30 calendar days after granting a request submitted under clause (i), the Secretary shall publish a notice in the Federal Register announcing such response.

(v) A written notification that the Secretary disagrees with the classification recommended in a request pursuant to clause (ii) shall include a detailed description and justification for the determination to disagree.

(D)(i) In the case of a device intended to be used with an accessory, where the accessory has been included in an application for premarket approval of such device under section 515 or a report under section 510(k) for clearance of such device and the Secretary has not classified such accessory distinctly from another device in accordance with subparagraph (A), the person filing the application or report (as applicable) at the time such application or report is filed—

(I) may include a written request for the proper classification of the accessory pursuant to subparagraph (A);

(II) shall include in any such request such information as may be necessary for the Secretary to evaluate, based on the least burdensome approach, the appropriate class for the accessory under subsection (a); and

(III) shall, if the request under subclause (I) is requesting classification of the accessory in class II, include in the application an initial draft proposal for special controls, if special controls would be required pursuant to subsection (a)(1)(B).

(ii) The Secretary's response under section 515(d) or section 510(n) (as applicable) to an application or report described in clause (i) shall also contain the Secretary's granting or denial of the request for classification of the accessory involved.

(iii) The Secretary's evaluation of an accessory under clause (i) shall constitute an order establishing a new classification for such accessory for the specified intended use or uses of such accessory and for any accessory with the same intended use or uses as such accessory.

(E) For accessories that have been granted marketing authorization as part of a submission for another device with which the accessory involved is intended to be used, through an application for such other device under section 515(c), a report under section 510(k), or a request for classification under paragraph (2) of this

subsection, and that have not been classified by the Secretary based on the risks and appropriate level of regulatory controls in accordance with subparagraph (A):

(i) Not later than the date that is one year after the date of enactment of the FDA Reauthorization Act of 2017 and at least once every 5 years thereafter, and as the Secretary otherwise deems appropriate, pursuant to this paragraph, the Secretary shall publish in the Federal Register a notice proposing a list of such accessories that the Secretary believes may be suitable for a distinct classification in class I and the proposed regulations for such classifications. In developing such lists, the Secretary shall consider recommendations from sponsors of device submissions and other stakeholders for accessories to be included on such lists. The notices shall provide for a period of not less than 60 calendar days for public comment. Within 180 days after the end of the comment period, the Secretary shall publish in the Federal Register a final action classifying such suitable accessories into class I.

(ii) A manufacturer or importer of an accessory that has been granted such marketing authorization may submit to the Secretary a written request for the appropriate classification of the accessory based on the risks and appropriate level of regulatory controls as described in subparagraph (A) or (C), and shall, if the request is requesting classification of the accessory in class II, include in the submission an initial draft proposal for special controls, if special controls would be required pursuant to subsection (a)(1)(B). Such request shall include such information as may be necessary for the Secretary to evaluate, based on the least burdensome approach, the appropriate class for the accessory under subsection (a). The Secretary shall provide an opportunity for a manufacturer or importer to meet with appropriate personnel of the Food and Drug Administration to discuss the appropriate classification of such accessory prior to submitting a written request under this clause for classification of the accessory.

(iii) The Secretary shall respond to a request made under clause (ii) not later than 90 calendar days after receiving such submission by granting or denying the request for classification of the accessory, and the Secretary shall by written order classify such accessory or deny the request. If the Secretary does not agree with the recommendation for classification submitted by the manufacturer or importer, the response shall include a detailed description and justification for such determination. Within 30 calendar days after granting such a request, the Secretary shall publish a notice in the Federal Register announcing such response.

(F) Nothing in this paragraph may be construed as precluding a manufacturer of an accessory of a new type from using the classification process described in subsection (f)(2) to obtain classification of such accessory in accordance with the criteria and requirements set forth in that subsection.

Information

(g) Within sixty days of the receipt of a written request of any person for information respecting the class in which a device has

been classified or the requirements applicable to a device under this Act, the Secretary shall provide such person a written statement of the classification (if any) of such device and the requirements of this Act applicable to the device.

Definitions

(h) For purposes of this section and sections 501, 510, 514, 515, 516, 519, and 520—

(1) a reference to “general controls” is a reference to the controls authorized by or under sections 501, 502, 510, 516, 518, 519, and 520,

(2) a reference to “class I,” “class II,” or “class III” is a reference to a class of medical devices described in subparagraph (A), (B), or (C) of subsection (a)(1), and

(3) a reference to a “panel under section 513” is a reference to a panel established or authorized to be used under this section.

Substantial Equivalence

(i)(1)(A) For purposes of determinations of substantial equivalence under subsection (f) and section 520(l), the term “substantially equivalent” or “substantial equivalence” means, with respect to a device being compared to a predicate device, that the device has the same intended use as the predicate device and that the Secretary by order has found that the device—

(i) has the same technological characteristics as the predicate device, or

(ii)(I) has different technological characteristics and the information submitted that the device is substantially equivalent to the predicate device contains information, including appropriate clinical or scientific data if deemed necessary by the Secretary or a person accredited under section 523, that demonstrates that the device is as safe and effective as a legally marketed device, and (II) does not raise different questions of safety and effectiveness than the predicate device.

(B) For purposes of subparagraph (A), the term “different technological characteristics” means, with respect to a device being compared to a predicate device, that there is a significant change in the materials, design, energy source, or other features of the device from those of the predicate device.

(C) To facilitate reviews of reports submitted to the Secretary under section 510(k), the Secretary shall consider the extent to which reliance on postmarket controls may expedite the classification of devices under subsection (f)(1) of this section.

(D)(i) Whenever the Secretary requests information to demonstrate that devices with differing technological characteristics are substantially equivalent, the Secretary shall only request information that is necessary to making substantial equivalence determinations. In making such request, the Secretary shall consider the least burdensome means of demonstrating substantial equivalence and request information accordingly.

(ii) For purposes of clause (i), the term “necessary” means the minimum required information that would support a determination

of substantial equivalence between a new device and a predicate device.

(iii) Nothing in this subparagraph shall alter the standard for determining substantial equivalence between a new device and a predicate device.

(E)(i) Any determination by the Secretary of the intended use of a device shall be based upon the proposed labeling submitted in a report for the device under section 510(k). However, when determining that a device can be found substantially equivalent to a legally marketed device, the director of the organizational unit responsible for regulating devices (in this subparagraph referred to as the “Director”) may require a statement in labeling that provides appropriate information regarding a use of the device not identified in the proposed labeling if, after providing an opportunity for consultation with the person who submitted such report, the Director determines and states in writing—

(I) that there is a reasonable likelihood that the device will be used for an intended use not identified in the proposed labeling for the device; and

(II) that such use could cause harm.

(ii) Such determination shall—

(I) be provided to the person who submitted the report within 10 days from the date of the notification of the Director’s concerns regarding the proposed labeling;

(II) specify the limitations on the use of the device not included in the proposed labeling; and

(III) find the device substantially equivalent if the requirements of subparagraph (A) are met and if the labeling for such device conforms to the limitations specified in subclause (II).

(iii) The responsibilities of the Director under this subparagraph may not be delegated.

(F) Not later than 270 days after the date of the enactment of the Food and Drug Administration Modernization Act of 1997, the Secretary shall issue guidance specifying the general principles that the Secretary will consider in determining when a specific intended use of a device is not reasonably included within a general use of such device for purposes of a determination of substantial equivalence under subsection (f) or section 520(l).

(2) A device may not be found to be substantially equivalent to a predicate device that has been removed from the market at the initiative of the Secretary or that has been determined to be misbranded or adulterated by a judicial order.

(3)(A) As part of a submission under section 510(k) respecting a device, the person required to file a premarket notification under such section shall provide an adequate summary of any information respecting safety and effectiveness or state that such information will be made available upon request by any person.

(B) Any summary under subparagraph (A) respecting a device shall contain detailed information regarding data concerning adverse health effects and shall be made available to the public by the Secretary within 30 days of the issuance of a determination that such device is substantially equivalent to another device.

(j) TRAINING AND OVERSIGHT OF LEAST BURDENSOME REQUIREMENTS.—

(1) The Secretary shall—

(A) ensure that each employee of the Food and Drug Administration who is involved in the review of premarket submissions, including supervisors, receives training regarding the meaning and implementation of the least burdensome requirements under subsections (a)(3)(D) and (i)(1)(D) of this section and section 515(c)(5); and

(B) periodically assess the implementation of the least burdensome requirements, including the employee training under subparagraph (A), to ensure that the least burdensome requirements are fully and consistently applied.

(2) Not later than 18 months after the date of enactment of the 21st Century Cures Act, the ombudsman for any organizational unit of the Food and Drug Administration responsible for the premarket review of devices shall—

(A) conduct an audit of the training described in paragraph (1)(A), including the effectiveness of such training in implementing the least burdensome requirements;

(B) include in such audit interviews of persons who are representatives of the device industry regarding their experiences in the device premarket review process, including with respect to the application of least burdensome concepts to premarket review and decisionmaking;

(C) include in such audit a list of the measurement tools the Secretary uses to assess the implementation of the least burdensome requirements, including under paragraph (1)(B) and section 517A(a)(3), and may also provide feedback on the effectiveness of such tools in the implementation of the least burdensome requirements;

(D) summarize the findings of such audit in a final audit report; and

(E) within 30 calendar days of completion of such final audit report, make such final audit report available—

(i) to the Committee on Health, Education, Labor, and Pensions of the Senate and the Committee on Energy and Commerce of the House of Representatives; and

(ii) on the Internet website of the Food and Drug Administration.

PERFORMANCE STANDARDS

Provisions of Standards

SEC. 514. (a)(1) The special controls required by section 513(a)(1)(B) shall include performance standards for a class II device if the Secretary determines that a performance standard is necessary to provide reasonable assurance of the safety and effectiveness of the device. A class III device may also be considered a class II device for purposes of establishing a standard for the device under subsection (b) if the device has been reclassified as a class II device under an administrative order under section 513(e) (or a regulation promulgated under such section prior to the date of enactment of the Food and Drug Administration Safety and Innovation Act) but such order (or regulation) provides that the reclassification is not to take effect until the effective date of such a standard for the device.

(2) A performance standard established under subsection (b) for a device—

(A) shall include provisions to provide reasonable assurance of its safe and effective performance;

(B) shall, where necessary to provide reasonable assurance of its safe and effective performance, include—

(i) provisions respecting the construction, components, ingredients, and properties of the device and its compatibility with power systems and connections to such systems,

(ii) provisions for the testing (on a sample basis or, if necessary, on an individual basis) of the device or, if it is determined that no other more practicable means are available to the Secretary to assure the conformity of the device to the standard, provisions for the testing (on a sample basis or, if necessary, on an individual basis) by the Secretary or by another person at the direction of the Secretary,

(iii) provisions for the measurement of the performance characteristics of the device,

(iv) provisions requiring that the results of each or of certain of the tests of the device required to be made under clause (ii) show that the device is in conformity with the portions of the standard for which the test or tests were required, and

(v) a provision requiring that the sale and distribution of the device be restricted but only to the extent that the sale and distribution of a device may be restricted under a regulation under section 520(e); and

(C) shall, where appropriate, require the use and prescribe the form and content of labeling for the proper installation, maintenance, operation, and use of the device.

(3) The Secretary shall provide for periodic evaluation of performance standards established under subsection (b) to determine if such standards should be changed to reflect new medical, scientific, or other technological data.

(4) In carrying out his duties under this subsection and subsection (b), the Secretary shall, to the maximum extent practicable—

(A) use personnel, facilities, and other technical support available in other Federal agencies,

(B) consult with other Federal agencies concerned with standard-setting and other nationally or internationally recognized standard-setting entities, and

(C) invite appropriate participation, through joint or other conferences, workshops, or other means, by informed persons representative of scientific, professional, industry, or consumer organizations who in his judgment can make a significant contribution.

Establishment of a Standard

(b)(1)(A) The Secretary shall publish in the Federal Register a notice of proposed rulemaking for the establishment, amendment, or revocation of any performance standard for a device.

(B) A notice of proposed rulemaking for the establishment or amendment of a performance standard for a device shall—

(i) set forth a finding with supporting justification that the performance standard is appropriate and necessary to provide reasonable assurance of the safety and effectiveness of the device,

(ii) set forth proposed findings with respect to the risk of illness or injury that the performance standard is intended to reduce or eliminate,

(iii) invite interested persons to submit to the Secretary, within 30 days of the publication of the notice, requests for changes in the classification of the device pursuant to section 513(e) based on new information relevant to the classification, and

(iv) invite interested persons to submit an existing performance standard for the device, including a draft or proposed performance standard, for consideration by the Secretary.

(C) A notice of proposed rulemaking for the revocation of a performance standard shall set forth a finding with supporting justification that the performance standard is no longer necessary to provide reasonable assurance of the safety and effectiveness of a device.

(D) The Secretary shall provide for a comment period of not less than 60 days.

(2) If, after publication of a notice in accordance with paragraph (1), the Secretary receives a request for a change in the classification of the device, the Secretary shall, within 60 days of the publication of the notice, after consultation with the appropriate panel under section 513, either deny the request or give notice of an intent to initiate such change under section 513(e).

(3)(A) After the expiration of the period for comment on a notice of proposed rulemaking published under paragraph (1) respecting a performance standard and after consideration of such comments and any report from an advisory committee under paragraph (5), the Secretary shall (i) promulgate a regulation establishing a performance standard and publish in the Federal Register findings on the matters referred to in paragraph (1), or (ii) publish a notice terminating the proceeding for the development of the standard together with the reasons for such termination. If a notice of termination is published, the Secretary shall (unless such notice is issued because the device is a banned device under section 516) initiate a proceeding under section 513(e) to reclassify the device subject to the proceeding terminated by such notice.

(B) A regulation establishing a performance standard shall set forth the date or dates upon which the standard shall take effect, but no such regulation may take effect before one year after the date of its publication unless (i) the Secretary determines that an earlier effective date is necessary for the protection of the public health and safety, or (ii) such standard has been established for a device which, effective upon the effective date of the standard, has been reclassified from class III to class II. Such date or dates shall be established so as to minimize, consistent with the public health and safety, economic loss to, and disruption or dislocation of, domestic and international trade.

(4)(A) The Secretary, upon his own initiative or upon petition of an interested person may by regulation, promulgated in accordance with the requirements of paragraphs (1), (2), and (3)(B) of this subsection, amend or revoke a performance standard.

(B) The Secretary may declare a proposed amendment of a performance standard to be effective on and after its publication in the Federal Register and until the effective date of any final action taken on such amendment if he determines that making it so effective is in the public interest. A proposed amendment of a performance standard made so effective under the preceding sentence may not prohibit, during the period in which it is so effective, the introduction or delivery for introduction into interstate commerce of a device which conforms to such standard without the change or changes provided by such proposed amendment.

(5)(A) The Secretary—

(i) may on his own initiative refer a proposed regulation for the establishment, amendment, or revocation of a performance standard, or

(ii) shall, upon the request of an interested person which demonstrates good cause for referral and which is made before the expiration of the period for submission of comments on such proposed regulation refer such proposed regulation, to an advisory committee of experts, established pursuant to subparagraph (B) for a report and recommendation with respect to any matter involved in the proposed regulation which requires the exercise of scientific judgment. If a proposed regulation is referred under this subparagraph to an advisory committee, the Secretary shall provide the advisory committee with the data and information on which such proposed regulation is based. The advisory committee shall, within sixty days of the referral of a proposed regulation and after independent study of the data and information furnished to it by the Secretary and other data and information before it, submit to the Secretary a report and recommendation respecting such regulation, together with all underlying data and information and a statement of the reason or basis for the recommendation. A copy of such report and recommendation shall be made public by the Secretary.

(B) The Secretary shall establish advisory committees (which may not be panels under section 513) to receive referrals under subparagraph (A). The Secretary shall appoint as members of any such advisory committee persons qualified in the subject matter to be referred to the committee and of appropriately diversified professional background, except that the Secretary may not appoint to such a committee any individual who is in the regular full-time employ of the United States and engaged in the administration of this Act. Each such committee shall include as nonvoting members a representative of consumer interests and a representative of interests of the device manufacturing industry. Members of an advisory committee who are not officers or employees of the United States, while attending conferences or meetings of their committee or otherwise serving at the request of the Secretary, shall be entitled to receive compensation at rates to be fixed by the Secretary, which rates may not exceed the daily equivalent of the rate in effect for grade GS-18 of the General Schedule, for each day (including traveltime) they are so engaged; and while so serving away from their

homes or regular places of business each member may be allowed travel expenses, including per diem in lieu of subsistence, as authorized by section 5703 of title 5 of the United States Code for persons in the Government service employed intermittently. The Secretary shall designate one of the members of each advisory committee to serve as chairman thereof. The Secretary shall furnish each advisory committee with clerical and other assistance, and shall by regulation prescribe the procedures to be followed by each such committee in acting on referrals made under subparagraph (A).

Recognition of a Standard

(c)(1)(A) In addition to establishing a performance standard under this section, the Secretary shall, by publication in the Federal Register (or, with respect to a susceptibility test interpretive criteria standard under section 511A, by posting on the Interpretive Criteria Website in accordance with such section), recognize all or part of an appropriate standard established by a nationally or internationally recognized standard development organization for which a person may submit a declaration of conformity in order to meet a premarket submission requirement or other requirement under this Act to which such standard is applicable.

(B) If a person elects to use a standard recognized by the Secretary under subparagraph (A) to meet the requirements described in such subparagraph, the person shall provide a declaration of conformity to the Secretary that certifies that the device is in conformity with such standard. A person may elect to use data, or information, other than data required by a standard recognized under subparagraph (A) to meet any requirement regarding devices under this Act.

(C)(i) Any person may submit a request for recognition under subparagraph (A) of all or part of an appropriate standard established by a nationally or internationally recognized standard organization.

(ii) Not later than 60 calendar days after the Secretary receives such a request, the Secretary shall—

(I) make a determination to recognize all, part, or none of the standard that is the subject of the request; and

(II) issue to the person who submitted such request a response in writing that states the Secretary's rationale for that determination, including the scientific, technical, regulatory, or other basis for such determination.

(iii) The Secretary shall make a response issued under clause (ii)(II) publicly available, in such a manner as the Secretary determines appropriate.

(iv) The Secretary shall take such actions as may be necessary to implement all or part of a standard recognized under clause (ii)(I), in accordance with subparagraph (A).

(D) The Secretary shall make publicly available, in such manner as the Secretary determines appropriate, the rationale for recognition under subparagraph (A) of all, part, or none of a standard, including the scientific, technical, regulatory, or other basis for the decision regarding such recognition.

(2) The Secretary may withdraw such recognition of a standard through publication of a notice in the Federal Register if the Sec-

retary determines that the standard is no longer appropriate for meeting a requirement regarding devices under this Act.

(3)(A) Subject to subparagraph (B), the Secretary shall accept a declaration of conformity that a device is in conformity with a standard recognized under paragraph (1) unless the Secretary finds—

(i) that the data or information submitted to support such declaration does not demonstrate that the device is in conformity with the standard identified in the declaration of conformity; or

(ii) that the standard identified in the declaration of conformity is not applicable to the particular device under review.

(B) The Secretary may request, at any time, the data or information relied on by the person to make a declaration of conformity with respect to a standard recognized under paragraph (1).

(C) A person making a declaration of conformity with respect to a standard recognized under paragraph (1) shall maintain the data and information demonstrating conformity of the device to the standard for a period of two years after the date of the classification or approval of the device by the Secretary or a period equal to the expected design life of the device, whichever is longer.

(4) The Secretary shall provide to all employees of the Food and Drug Administration who review premarket submissions for devices periodic training on the concept and use of recognized standards for purposes of meeting a premarket submission requirement or other applicable requirement under this Act, including standards relevant to an employee's area of device review.

(d) *PILOT ACCREDITATION SCHEME FOR CONFORMITY ASSESSMENT.*—

(1) *IN GENERAL.*—*The Secretary shall establish a pilot program under which—*

(A) testing laboratories may be accredited, by accreditation bodies meeting criteria specified by the Secretary, to assess the conformance of a device with certain standards recognized under this section; and

(B) subject to paragraph (2), determinations by testing laboratories so accredited that a device conforms with such standard or standards shall be accepted by the Secretary for purposes of demonstrating such conformity under this section unless the Secretary finds that a particular such determination shall not be so accepted.

(2) *SECRETARIAL REVIEW OF ACCREDITED LABORATORY DETERMINATIONS.*—*The Secretary may—*

(A) review determinations by testing laboratories accredited pursuant to this subsection, including by conducting periodic audits of such determinations or processes of accredited bodies or testing laboratories and, following such review, taking additional measures under this Act, such as suspension or withdrawal of accreditation of such testing laboratory under paragraph (1)(A) or requesting additional information with respect to such device, as the Secretary determines appropriate; and

(B) if the Secretary becomes aware of information materially bearing on safety or effectiveness of a device assessed for conformity by a testing laboratory so accredited, take

such additional measures under this Act as the Secretary determines appropriate, such as suspension or withdrawal of accreditation of such testing laboratory under paragraph (1)(A), or requesting additional information with regard to such device.

(3) IMPLEMENTATION AND REPORTING.—

(A) PUBLIC MEETING.—*The Secretary shall publish in the Federal Register a notice of a public meeting to be held no later than September 30, 2018, to discuss and obtain input and recommendations from stakeholders regarding the goals and scope of, and a suitable framework and procedures and requirements for, the pilot program under this subsection.*

(B) PILOT PROGRAM GUIDANCE.—*The Secretary shall—*

(i) not later than September 30, 2019, issue draft guidance regarding the goals and implementation of the pilot program under this subsection; and

(ii) not later than September 30, 2021, issue final guidance with respect to the implementation of such program.

(C) PILOT PROGRAM INITIATION.—*Not later than September 30, 2020, the Secretary shall initiate the pilot program under this subsection.*

(D) REPORT.—*The Secretary shall make available on the website of the Food and Drug Administration an annual report on the progress of the pilot program under this subsection.*

(4) SUNSET.—As of October 1, 2022—

(A) *the authority for accreditation bodies to accredit testing laboratories pursuant to paragraph (1)(A) shall cease to have force or effect;*

(B) *the Secretary—*

(i) may not accept a determination pursuant to paragraph (1)(B) made by a testing laboratory after such date; and

(ii) may accept such a determination made prior to such date;

(C) *except for purposes of accepting a determination described in subparagraph (B)(ii), the Secretary shall not continue to recognize the accreditation of testing laboratories accredited under paragraph (1)(A); and*

(D) *the Secretary may take actions in accordance with paragraph (2) with respect to the determinations made prior to such date and recognition of the accreditation of testing laboratories pursuant to determinations made prior to such date.*

PREMARKET APPROVAL

General Requirement

SEC. 515. (a) A class III device—

- (1) which is subject to an order issued under subsection (b) (or a regulation promulgated under such subsection prior to the date of enactment of the Food and Drug Administration Safety and Innovation Act); or

(2) which is a class III device because of section 513(f), is required to have, unless exempt under section 520(g), an approval under this section of an application for premarket approval or, as applicable, an approval under subsection (c)(2) of a report seeking premarket approval.

Order To Require Premarket Approval

(b)(1) In the case of a class III device which—

(A) was introduced or delivered for introduction into interstate commerce for commercial distribution before the date of enactment of this section; or

(B) is (i) of a type so introduced or delivered, and (ii) is substantially equivalent to another device within that type;

the Secretary shall by administrative order following publication of a proposed order in the Federal Register, a meeting of a device classification panel described in section 513(b), and consideration of comments from all affected stakeholders, including patients, payors, and providers, notwithstanding subchapter II of chapter 5 of title 5, United States Code, require that such device have an approval under this section of an application for premarket approval. Authority to issue such administrative order shall not be delegated below the Director of the Center for Devices and Radiological Health, acting in consultation with the Commissioner.

(2) A proposed order required under paragraph (1) shall contain—

(A) the proposed order;

(B) proposed findings with respect to the degree of risk of illness or injury designed to be eliminated or reduced by requiring the device to have an approved application for premarket approval and the benefit to the public from use of the device;

(C) opportunity for the submission of comments on the proposed order and the proposed findings; and

(D) opportunity to request a change in the classification of the device based on new information relevant to the classification of the device.

(3) After the expiration of the period for comment on a proposed order and proposed findings published under paragraph (2), consideration of comments submitted on such proposed order and findings, and a meeting of a device classification panel described in section 513(b), the Secretary shall (A) issue an administrative order under paragraph (1) and publish in the Federal Register findings on the matters referred to in paragraph (2)(B), or (B) publish a notice terminating the proceeding for the issuance of the administrative order together with the reasons for such termination. If a notice of termination is published, the Secretary shall (unless such notice is issued because the device is a banned device under section 516) initiate a proceeding under section 513(e) to reclassify the device subject to the proceeding terminated by such notice.

Application for Premarket Approval

(c)(1) Any person may file with the Secretary an application for premarket approval for a class III device. Such an application for a device shall contain—

(A) full reports of all information, published or known to or which should reasonably be known to the applicant, concerning investigations which have been made to show whether or not such device is safe and effective;

(B) a full statement of the components, ingredients, and properties and of the principle or principles of operation, of such device;

(C) a full description of the methods used in, and the facilities and controls used for, the manufacture, processing, and, when relevant, packing and installation of, such device;

(D) an identifying reference to any performance standard under section 514 which would be applicable to any aspect of such device if it were a class II device, and either adequate information to show that such aspect of such device fully meets such performance standard or adequate information to justify any deviation from such standard;

(E) such samples of such device and of components thereof as the Secretary may reasonably require, except that where the submission of such samples is impracticable or unduly burdensome, the requirement of this subparagraph may be met by the submission of complete information concerning the location of one or more such devices readily available for examination and testing;

(F) specimens of the labeling proposed to be used for such device;

(G) the certification required under section 402(j)(5)(B) of the Public Health Service Act (which shall not be considered an element of such application); and

(H) such other information relevant to the subject matter of the application as the Secretary, with the concurrence of the appropriate panel under section 513, may require.

(2)(A) Any person may file with the Secretary a report seeking premarket approval for a class III device referred to in subsection (a) that is a reprocessed single-use device. Such a report shall contain the following:

(i) The device name, including both the trade or proprietary name and the common or usual name.

(ii) The establishment registration number of the owner or operator submitting the report.

(iii) Actions taken to comply with performance standards under section 514.

(iv) Proposed labels, labeling, and advertising sufficient to describe the device, its intended use, and directions for use.

(v) Full reports of all information, published or known to or which should be reasonably known to the applicant, concerning investigations which have been made to show whether or not the device is safe or effective.

(vi) A description of the device's components, ingredients, and properties.

(vii) A full description of the methods used in, and the facilities and controls used for, the reprocessing and packing of the device.

(viii) Such samples of the device that the Secretary may reasonably require.

(ix) A financial certification or disclosure statement or both, as required by part 54 of title 21, Code of Federal Regulations.

(x) A statement that the applicant believes to the best of the applicant's knowledge that all data and information submitted to the Secretary are truthful and accurate and that no material fact has been omitted in the report.

(xi) Any additional data and information, including information of the type required in paragraph (1) for an application under such paragraph, that the Secretary determines is necessary to determine whether there is reasonable assurance of safety and effectiveness for the reprocessed device.

(xii) Validation data described in section 510(o)(1)(A) that demonstrates that the reasonable assurance of the safety or effectiveness of the device will remain after the maximum number of times the device is reprocessed as intended by the person submitting such report.

(B) In the case of a class III device referred to in subsection (a) that is a reprocessed single-use device:

(i) Subparagraph (A) of this paragraph applies in lieu of paragraph (1).

(ii) Subject to clause (i), the provisions of this section apply to a report under subparagraph (A) to the same extent and in the same manner as such provisions apply to an application under paragraph (1).

(iii) Each reference in other sections of this Act to an application under this section, other than such a reference in section 737 or 738, shall be considered to be a reference to a report under subparagraph (A).

(iv) Each reference in other sections of this Act to a device for which an application under this section has been approved, or has been denied, suspended, or withdrawn, other than such a reference in section 737 or 738, shall be considered to be a reference to a device for which a report under subparagraph (A) has been approved, or has been denied, suspended, or withdrawn, respectively.

(3) Upon receipt of an application meeting the requirements set forth in paragraph (1), the Secretary—

(A) may on the Secretary's own initiative, or

(B) shall, upon the request of an applicant unless the Secretary finds that the information in the application which would be reviewed by a panel substantially duplicates information which has previously been reviewed by a panel appointed under section 513,

refer such application to the appropriate panel under section 513 for study and for submission (within such period as he may establish) of a report and recommendation respecting approval of the application, together with all underlying data and the reasons or basis for the recommendation. Where appropriate, the Secretary shall ensure that such panel includes, or consults with, one or more pediatric experts.

(4)(A) Prior to the submission of an application under this subsection, the Secretary shall accept and review any portion of the application that the applicant and the Secretary agree is complete, ready, and appropriate for review, except that such requirement does not apply, and the Secretary has discretion whether to accept

and review such portion, during any period in which, under section **[738(h)] 738(g)**, the Secretary does not have the authority to collect fees under section 738(a).

(B) Each portion of a submission reviewed under subparagraph (A) and found acceptable by the Secretary shall not be further reviewed after receipt of an application that satisfies the requirements of paragraph (1), unless a significant issue of safety or effectiveness provides the Secretary reason to review such accepted portion.

(C) Whenever the Secretary determines that a portion of a submission under subparagraph (A) is unacceptable, the Secretary shall, in writing, provide to the applicant a description of any deficiencies in such portion and identify the information that is required to correct these deficiencies, unless the applicant is no longer pursuing the application.

(5)(A) In requesting additional information with respect to an application under this section, the Secretary shall consider the least burdensome appropriate means necessary to demonstrate a reasonable assurance of device safety and effectiveness.

(B) For purposes of subparagraph (A), the term “necessary” means the minimum required information that would support a determination by the Secretary that an application provides a reasonable assurance of the safety and effectiveness of the device.

(C) For purposes of this paragraph, the Secretary shall consider the role of postmarket information in determining the least burdensome means of demonstrating a reasonable assurance of device safety and effectiveness.

(D) Nothing in this paragraph alters the standards for premarket approval of a device.

Action on an Application for Premarket Approval

(d)(1)(A) As promptly as possible, but in no event later than one hundred and eighty days after the receipt of an application under subsection (c) (except as provided in section 520(l)(3)(D)(ii) or unless, in accordance with subparagraph (B)(i), an additional period as agreed upon by the Secretary and the applicant), the Secretary, after considering the report and recommendation submitted under paragraph (2) of such subsection, shall—

(i) issue an order approving the application if he finds that none of the grounds for denying approval specified in paragraph (2) of this subsection applies; or

(ii) deny approval of the application if he finds (and sets forth the basis for such finding as part of or accompanying such denial) that one or more grounds for denial specified in paragraph (2) of this subsection apply.

In making the determination whether to approve or deny the application, the Secretary shall rely on the conditions of use included in the proposed labeling as the basis for determining whether or not there is a reasonable assurance of safety and effectiveness, if the proposed labeling is neither false nor misleading. In determining whether or not such labeling is false or misleading, the Secretary shall fairly evaluate all material facts pertinent to the proposed labeling.

(B)(i) The Secretary may not enter into an agreement to extend the period in which to take action with respect to an application

submitted for a device subject to a regulation promulgated under subsection (b) unless he finds that the continued availability of the device is necessary for the public health.

(ii) An order approving an application for a device may require as a condition to such approval that the sale and distribution of the device be restricted but only to the extent that the sale and distribution of a device may be restricted under a regulation under section 520(e).

(iii) The Secretary shall accept and review statistically valid and reliable data and any other information from investigations conducted under the authority of regulations required by section 520(g) to make a determination of whether there is a reasonable assurance of safety and effectiveness of a device subject to a pending application under this section if—

(I) the data or information is derived from investigations of an earlier version of the device, the device has been modified during or after the investigations (but prior to submission of an application under subsection (c)) and such a modification of the device does not constitute a significant change in the design or in the basic principles of operation of the device that would invalidate the data or information; or

(II) the data or information relates to a device approved under this section, is available for use under this Act, and is relevant to the design and intended use of the device for which the application is pending.

(2) The Secretary shall deny approval of an application for a device if, upon the basis of the information submitted to the Secretary as part of the application and any other information before him with respect to such device, the Secretary finds that—

(A) there is a lack of a showing of reasonable assurance that such device is safe under the conditions of use prescribed, recommended, or suggested in the proposed labeling thereof;

(B) there is a lack of a showing of reasonable assurance that the device is effective under the conditions of use prescribed, recommended, or suggested in the proposed labeling thereof;

(C) the methods used in, or the facilities or controls used for, the manufacture, processing, packing, or installation of such device do not conform to the requirements of section 520(f);

(D) based on a fair evaluation of all material facts, the proposed labeling is false or misleading in any particular; or

(E) such device is not shown to conform in all respects to a performance standard in effect under section 514 compliance with which is a condition to approval of the application and there is a lack of adequate information to justify the deviation from such standard.

Any denial of an application shall, insofar as the Secretary determines to be practicable, be accompanied by a statement informing the applicant of the measures required to place such application in approvable form (which measures may include further research by the applicant in accordance with one or more protocols prescribed by the Secretary).

(3)(A)(i) The Secretary shall, upon the written request of an applicant, meet with the applicant, not later than 100 days after the receipt of an application that has been filed as complete under subsection (c), to discuss the review status of the application.

(ii) The Secretary shall, in writing and prior to the meeting, provide to the applicant a description of any deficiencies in the application that, at that point, have been identified by the Secretary based on an interim review of the entire application and identify the information that is required to correct those deficiencies.

(iii) The Secretary shall notify the applicant promptly of—

(I) any additional deficiency identified in the application, or

(II) any additional information required to achieve completion of the review and final action on the application,

that was not described as a deficiency in the written description provided by the Secretary under clause (ii).

(B) The Secretary and the applicant may, by mutual consent, establish a different schedule for a meeting required under this paragraph.

(4) An applicant whose application has been denied approval may, by petition filed on or before the thirtieth day after the date upon which he receives notice of such denial, obtain review thereof in accordance with either paragraph (1) or (2) of subsection (g), and any interested person may obtain review, in accordance with paragraph (1) or (2) of subsection (g), of an order of the Secretary approving an application.

(5)(A)(i) A supplemental application shall be required for any change to a device subject to an approved application under this subsection that affects safety or effectiveness, unless such change is a modification in a manufacturing procedure or method of manufacturing and the holder of the approved application submits a written notice to the Secretary that describes in detail the change, summarizes the data or information supporting the change, and informs the Secretary that the change has been made under the requirements of section 520(f).

(ii) The holder of an approved application who submits a notice under clause (i) with respect to a manufacturing change of a device may distribute the device 30 days after the date on which the Secretary receives the notice, unless the Secretary within such 30-day period notifies the holder that the notice is not adequate and describes such further information or action that is required for acceptance of such change. If the Secretary notifies the holder that a supplemental application is required, the Secretary shall review the supplement within 135 days after the receipt of the supplement. The time used by the Secretary to review the notice of the manufacturing change shall be deducted from the 135-day review period if the notice meets appropriate content requirements for pre-market approval supplements.

(B)(i) Subject to clause (ii), in reviewing a supplement to an approved application, for an incremental change to the design of a device that affects safety or effectiveness, the Secretary shall approve such supplement if—

(I) nonclinical data demonstrate that the design modification creates the intended additional capacity, function, or performance of the device; and

(II) clinical data from the approved application and any supplement to the approved application provide a reasonable assurance of safety and effectiveness for the changed device.

(ii) The Secretary may require, when necessary, additional clinical data to evaluate the design modification of the device to provide a reasonable assurance of safety and effectiveness.

Withdrawal and Temporary Suspension of Approval of Application

(e)(1) The Secretary shall, upon obtaining, where appropriate, advice on scientific matters from a panel or panels under section 513, and after due notice and opportunity for informal hearing to the holder of an approved application for a device, issue an order withdrawing approval of the application if the Secretary finds—

(A) that such device is unsafe or ineffective under the conditions of use prescribed, recommended, or suggested in the labeling thereof;

(B) on the basis of new information before him with respect to such device, evaluated together with the evidence available to him when the application was approved, that there is a lack of a showing of reasonable assurance that the device is safe or effective under the conditions of use prescribed, recommended, or suggested in the labeling thereof;

(C) that the application contained or was accompanied by an untrue statement of a material fact;

(D) that the applicant (i) has failed to establish a system for maintaining records, or has repeatedly or deliberately failed to maintain records or to make reports, required by an applicable regulation under section 519(a), (ii) has refused to permit access to, or copying or verification of, such records as required by section 704, or (iii) has not complied with the requirements of section 510;

(E) on the basis of new information before him with respect to such device, evaluated together with the evidence before him when the application was approved, that the methods used in, or the facilities and controls used for, the manufacture, processing, packing, or installation of such device do not conform with the requirements of section 520(f) and were not brought into conformity with such requirements within a reasonable time after receipt of written notice from the Secretary of non-conformity;

(F) on the basis of new information before him, evaluated together with the evidence before him when the application was approved, that the labeling of such device, based on a fair evaluation of all material facts, is false or misleading in any particular and was not corrected within a reasonable time after receipt of written notice from the Secretary of such fact; or

(G) on the basis of new information before him, evaluated together with the evidence before him when the application was approved, that such device is not shown to conform in all respects to a performance standard which is in effect under section 514 compliance with which was a condition to approval of the application and that there is a lack of adequate information to justify the deviation from such standard.

(2) The holder of an application subject to an order issued under paragraph (1) withdrawing approval of the application may, by petition filed on or before the thirtieth day after the date upon which he receives notice of such withdrawal, obtain review thereof in accordance with either paragraph (1) or (2) of subsection (g).

(3) If, after providing an opportunity for an informal hearing, the Secretary determines there is reasonable probability that the continuation of distribution of a device under an approved application would cause serious, adverse health consequences or death, the Secretary shall by order temporarily suspend the approval of the application approved under this section. If the Secretary issues such an order, the Secretary shall proceed expeditiously under paragraph (1) to withdraw such application.

Product Development Protocol

(f)(1) In the case of a class III device which is required to have an approval of an application submitted under subsection (c), such device shall be considered as having such an approval if a notice of completion of testing conducted in accordance with a product development protocol approved under paragraph (4) has been declared completed under paragraph (6).

(2) Any person may submit to the Secretary a proposed product development protocol with respect to a device. Such a protocol shall be accompanied by data supporting it. If, within thirty days of the receipt of such a protocol, the Secretary determines that it appears to be appropriate to apply the requirements of this subsection to the device with respect to which the protocol is submitted, the Secretary—

(A) may, at the initiative of the Secretary, refer the proposed protocol to the appropriate panel under section 513 for its recommendation respecting approval of the protocol; or

(B) shall so refer such protocol upon the request of the submitter, unless the Secretary finds that the proposed protocol and accompanying data which would be reviewed by such panel substantially duplicate a product development protocol and accompanying data which have previously been reviewed by such a panel.

(3) A proposed product development protocol for a device may be approved only if—

(A) the Secretary determines that it is appropriate to apply the requirements of this subsection to the device in lieu of the requirement of approval of an application submitted under subsection (c); and

(B) the Secretary determines that the proposed protocol provides—

(i) a description of the device and the changes which may be made in the device,

(ii) a description of the preclinical trials (if any) of the device and a specification of (I) the results from such trials to be required before the commencement of clinical trials of the device, and (II) any permissible variations in preclinical trials and the results therefrom,

(iii) a description of the clinical trials (if any) of the device and a specification of (I) the results from such trials to be required before the filing of a notice of completion of the requirements of the protocol, and (II) any permissible variations in such trials and the results therefrom,

(iv) a description of the methods to be used in, and the facilities and controls to be used for, the manufacture,

processing, and when relevant, packing and installation of the device,

(v) an identifying reference to any performance standard under section 514 to be applicable to any aspect of such device,

(vi) if appropriate, specimens of the labeling proposed to be used for such device,

(vii) such other information relevant to the subject matter of the protocol as the Secretary, with the concurrence of the appropriate panel or panels under section 513, may require, and

(viii) a requirement for submission of progress reports and, when completed, records of the trials conducted under the protocol which records are adequate to show compliance with the protocol.

(4) The Secretary shall approve or disapprove a proposed product development protocol submitted under paragraph (2) within one hundred and twenty days of its receipt unless an additional period is agreed upon by the Secretary and the person who submitted the protocol. Approval of a protocol or denial of approval of a protocol is final agency action subject to judicial review under chapter 7 of title 5, United States Code.

(5) At any time after a product development protocol for a device has been approved pursuant to paragraph (4), the person for whom the protocol was approved may submit a notice of completion—

(A) stating (i) his determination that the requirements of the protocol have been fulfilled and that, to the best of his knowledge, there is no reason bearing on safety or effectiveness why the notice of completion should not become effective, and (ii) the data and other information upon which such determination was made, and

(B) setting forth the results of the trials required by the protocol and all the information required by subsection (c)(1).

(6)(A) The Secretary may, after providing the person who has an approved protocol an opportunity for an informal hearing and at any time prior to receipt of notice of completion of such protocol, issue a final order to revoke such protocol if he finds that—

(i) such person has failed substantially to comply with the requirements of the protocol,

(ii) the results of the trials obtained under the protocol differ so substantially from the results required by the protocol that further trials cannot be justified, or

(iii) the results of the trials conducted under the protocol or available new information do not demonstrate that the device tested under the protocol does not present an unreasonable risk to health and safety.

(B) After the receipt of a notice of completion of an approved protocol the Secretary shall, within the ninety-day period beginning on the date such notice is received, by order either declare the protocol completed or declare it not completed. An order declaring a protocol not completed may take effect only after the Secretary has provided the person who has the protocol opportunity for an informal hearing on the order. Such an order may be issued only if the Secretary finds—

(i) such person has failed substantially to comply with the requirements of the protocol,

(ii) the results of the trials obtained under the protocol differ substantially from the results required by the protocol, or

(iii) there is a lack of a showing of reasonable assurance of the safety and effectiveness of the device under the conditions of use prescribed, recommended, or suggested in the proposed labeling thereof.

(C) A final order issued under subparagraph (A) or (B) shall be in writing and shall contain the reasons to support the conclusions thereof.

(7) At any time after a notice of completion has become effective, the Secretary may issue an order (after due notice and opportunity for an informal hearing to the person for whom the notice is effective) revoking the approval of a device provided by a notice of completion which has become effective as provided in subparagraph (B) if he finds that any of the grounds listed in subparagraphs (A) through (G) of subsection (e)(1) of this section apply. Each reference in such subparagraphs to an application shall be considered for purposes of this paragraph as a reference to a protocol and the notice of completion of such protocol, and each reference to the time when an application was approved shall be considered for purposes of this paragraph as a reference to the time when a notice of completion took effect.

(8) A person who has an approved protocol subject to an order issued under paragraph (6)(A) revoking such protocol, a person who has an approved protocol with respect to which an order under paragraph (6)(B) was issued declaring that the protocol had not been completed, or a person subject to an order issued under paragraph (7) revoking the approval of a device may, by petition filed on or before the thirtieth day after the date upon which he receives notice of such order, obtain review thereof in accordance with either paragraph (1) or (2) of subsection (g).

Review

(g)(1) Upon petition for review of—

(A) an order under subsection (d) approving or denying approval of an application or an order under subsection (e) withdrawing approval of an application, or

(B) an order under subsection (f)(6)(A) revoking an approved protocol, under subsection (f)(6)(B) declaring that an approved protocol has not been completed, or under subsection (f)(7) revoking the approval of a device,

the Secretary shall, unless he finds the petition to be without good cause or unless a petition for review of such order has been submitted under paragraph (2), hold a hearing, in accordance with section 554 of title 5 of the United States Code, on the order. The panel or panels which considered the application, protocol, or device subject to such order shall designate a member to appear and testify at any such hearing upon request of the Secretary, the petitioner, or the officer conducting the hearing, but this requirement does not preclude any other member of the panel or panels from appearing and testifying at any such hearing. Upon completion of such hearing and after considering the record established in such hearing, the Secretary shall issue an order either affirming the

order subject to the hearing or reversing such order and, as appropriate, approving or denying approval of the application, reinstating the application's approval, approving the protocol, or placing in effect a notice of completion.

(2)(A) Upon petition for review of—

(i) an order under subsection (d) approving or denying approval of an application or an order under subsection (e) withdrawing approval of an application, or

(ii) an order under subsection (f)(6)(A) revoking an approved protocol, under subsection (f)(6)(B) declaring that an approved protocol has not been completed, or under subsection (f)(7) revoking the approval of a device,

the Secretary shall refer the application or protocol subject to the order and the basis for the order to an advisory committee of experts established pursuant to subparagraph (B) for a report and recommendation with respect to the order. The advisory committee shall, after independent study of the data and information furnished to it by the Secretary and other data and information before it, submit to the Secretary a report and recommendation, together with all underlying data and information and a statement of the reasons or basis for the recommendation. A copy of such report shall be promptly supplied by the Secretary to any person who petitioned for such referral to the advisory committee.

(B) The Secretary shall establish advisory committees (which may not be panels under section 513) to receive referrals under subparagraph (A). The Secretary shall appoint as members of any such advisory committee persons qualified in the subject matter to be referred to the committee and of appropriately diversified professional backgrounds, except that the Secretary may not appoint to such a committee any individual who is in the regular full-time employ of the United States and engaged in the administration of this Act. Members of an advisory committee (other than officers or employees of the United States), while attending conferences or meetings of their committee or otherwise serving at the request of the Secretary, shall be entitled to receive compensation at rates to be fixed by the Secretary which rates may not exceed the daily equivalent for grade GS-18 of the General Schedule for each day (including traveltime) they are so engaged; and while so serving away from their homes or regular places of business each member may be allowed travel expenses, including per diem in lieu of subsistence, as authorized by section 5703 of title 5 of the United States Code for persons in the Government service employed intermittently. The Secretary shall designate the chairman of an advisory committee from its members. The Secretary shall furnish each advisory committee with clerical and other assistance, and shall by regulation prescribe the procedures to be followed by each such committee in acting on referrals made under subparagraph (A).

(C) The Secretary shall make public the report and recommendation made by an advisory committee with respect to an application and shall by order, stating the reasons therefor, either affirm the order referred to the advisory committee or reverse such order and, if appropriate, approve or deny approval of the application, reinstate the application's approval, approve the protocol, or place in effect a notice of completion.

Service of Orders

(h) Orders of the Secretary under this section shall be served (1) in person by any officer or employee of the department designated by the Secretary, or (2) by mailing the order by registered mail or certified mail addressed to the applicant at his last known address in the records of the Secretary.

Revision

(i)(1) Before December 1, 1995, the Secretary shall by order require manufacturers of devices, which were introduced or delivered for introduction into interstate commerce for commercial distribution before May 28, 1976, and which are subject to revision of classification under paragraph (2), to submit to the Secretary a summary of and citation to any information known or otherwise available to the manufacturer respecting such devices, including adverse safety or effectiveness information which has not been submitted under section 519. The Secretary may require the manufacturer to submit the adverse safety or effectiveness data for which a summary and citation were submitted, if such data are available to the manufacturer.

(2) After the issuance of an order under paragraph (1) but before the date that is 2 years after the date of enactment of the Food and Drug Administration Safety and Innovation Act, the Secretary shall issue an administrative order following publication of a proposed order in the Federal Register, a meeting of a device classification panel described in section 513(b), and consideration of comments from all affected stakeholders, including patients, payors, and providers, notwithstanding subchapter II of chapter 5 of title 5, United States Code, for each device—

(A) which the Secretary has classified as a class III device, and

(B) for which no administrative order has been issued under subsection (b) (or no regulation has been promulgated under such subsection prior to the date of enactment of the Food and Drug Administration Safety and Innovation Act),

revising the classification of the device so that the device is classified into class I or class II, unless the administrative order issued under this paragraph requires the device to remain in class III. In determining whether to revise the classification of a device or to require a device to remain in class III, the Secretary shall apply the criteria set forth in section 513(a).

(3) The Secretary shall, as promptly as is reasonably achievable, but not later than 12 months after the effective date of the order requiring a device to remain in class III, establish a schedule for the issuance of an administrative order under subsection (b) for each device which is subject to the order requiring the device to remain in class III.

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SEC. [515C.] 515B. BREAKTHROUGH DEVICES.

(a) **PURPOSE.**—The purpose of this section is to encourage the Secretary, and provide the Secretary with sufficient authority, to apply efficient and flexible approaches to expedite the development

of, and prioritize the Food and Drug Administration's review of, devices that represent breakthrough technologies.

(b) ESTABLISHMENT OF PROGRAM.—The Secretary shall establish a program to expedite the development of, and provide for the priority review for, devices, as determined by the Secretary—

(1) that provide for more effective treatment or diagnosis of life-threatening or irreversibly debilitating human disease or conditions; and

(2)(A) that represent breakthrough technologies;

(B) for which no approved or cleared alternatives exist;

(C) that offer significant advantages over existing approved or cleared alternatives, including the potential, compared to existing approved alternatives, to reduce or eliminate the need for hospitalization, improve patient quality of life, facilitate patients' ability to manage their own care (such as through self-directed personal assistance), or establish long-term clinical efficiencies; or

(D) the availability of which is in the best interest of patients.

(c) REQUEST FOR DESIGNATION.—A sponsor of a device may request that the Secretary designate such device for expedited development and priority review under this section. Any such request for designation may be made at any time prior to the submission of an application under section 515(c), a notification under section 510(k), or a petition for classification under section 513(f)(2).

(d) DESIGNATION PROCESS.—

(1) IN GENERAL.—Not later than 60 calendar days after the receipt of a request under subsection (c), the Secretary shall determine whether the device that is the subject of the request meets the criteria described in subsection (b). If the Secretary determines that the device meets the criteria, the Secretary shall designate the device for expedited development and priority review.

(2) REVIEW.—Review of a request under subsection (c) shall be undertaken by a team that is composed of experienced staff and senior managers of the Food and Drug Administration.

(3) WITHDRAWAL.—The Secretary may not withdraw a designation granted under this section on the basis of the criteria under subsection (b) no longer applying because of the subsequent clearance or approval of another device that—

(A) was designated under this section; or

(B) was given priority review under section 515(d)(5), as in effect prior to the date of enactment of the 21st Century Cures Act.

(e) EXPEDITED DEVELOPMENT AND PRIORITY REVIEW.—

(1) ACTIONS.—For purposes of expediting the development and review of devices designated under subsection (d) the Secretary shall—

(A) assign a team of staff, including a team leader with appropriate subject matter expertise and experience, for each device for which a request is submitted under subsection (c);

(B) provide for oversight of the team by senior agency personnel to facilitate the efficient development of the de-

vice and the efficient review of any submission described in subsection (c) for the device;

(C) adopt an efficient process for timely dispute resolution;

(D) provide for interactive and timely communication with the sponsor of the device during the development program and review process;

(E) expedite the Secretary's review of manufacturing and quality systems compliance, as applicable;

(F) disclose to the sponsor, not less than 5 business days in advance, the topics of any consultation the Secretary intends to undertake with external experts or an advisory committee concerning the sponsor's device and provide the sponsor the opportunity to recommend such external experts;

(G) provide for advisory committee input, as the Secretary determines appropriate (including in response to the request of the sponsor) for applications submitted under section 515(c); and

(H) assign staff to be available within a reasonable time to address questions by institutional review committees concerning the conditions and clinical testing requirements applicable to the investigational use of the device pursuant to an exemption under section 520(g).

(2) ADDITIONAL ACTIONS.—In addition to the actions described in paragraph (1), for purposes of expediting the development and review of devices designated under subsection (d), the Secretary, in collaboration with the device sponsor, may, as appropriate—

(A) coordinate with the sponsor regarding early agreement on a data development plan;

(B) take steps to ensure that the design of clinical trials is as efficient and flexible as practicable, when scientifically appropriate;

(C) facilitate, when scientifically appropriate, expedited and efficient development and review of the device through utilization of timely postmarket data collection with regard to application for approval under section 515(c); and

(D) agree in writing to clinical protocols that the Secretary will consider binding on the Secretary and the sponsor, subject to—

(i) changes to such protocols agreed to in writing by the sponsor and the Secretary; or

(ii) a decision, made by the director of the office responsible for reviewing the device submission, that a substantial scientific issue essential to determining the safety or effectiveness of such device exists, provided that such decision is in writing, and is made only after the Secretary provides to the device sponsor or applicant an opportunity for a meeting at which the director and the sponsor or applicant are present and at which the director documents the substantial scientific issue.

(f) PRIORITY REVIEW GUIDANCE.—

(1) CONTENT.—Not later than 1 year after the date of enactment of the 21st Century Cures Act, the Secretary shall issue guidance on the implementation of this section. Such guidance shall—

(A) set forth the process by which a person may seek a designation under subsection (d);

(B) provide a template for requests under subsection (c);

(C) identify the criteria the Secretary will use in evaluating a request for designation under this section; and

(D) identify the criteria and processes the Secretary will use to assign a team of staff, including team leaders, to review devices designated for expedited development and priority review, including any training required for such personnel to ensure effective and efficient review.

(2) PROCESS.—Prior to finalizing the guidance under paragraph (1), the Secretary shall seek public comment on [a proposed guidance] *a draft version of that guidance*.

(g) RULE OF CONSTRUCTION.—Nothing in this section shall be construed to affect—

(1) the criteria and standards for evaluating an application pursuant to section 515(c), a report and request for classification under section 513(f)(2), or a report under section 510(k), including the recognition of valid scientific evidence as described in section 513(a)(3)(B) and consideration and application of the least burdensome means of evaluating device effectiveness or demonstrating substantial equivalence between devices with differing technological characteristics, as applicable;

(2) the authority of the Secretary with respect to clinical holds under section 520(g)(8)(A);

(3) the authority of the Secretary to act on an application pursuant to section 515(d) before completion of an establishment inspection, as the Secretary determines appropriate; or

(4) the authority of the Secretary with respect to postmarket surveillance under sections 519(h) and 522.

* * * * *

RECORDS AND REPORTS ON DEVICES

General Rule

SEC. 519. (a) Every person who is a manufacturer or importer of a device intended for human use shall establish and maintain such records, make such reports, and provide such information, as the Secretary may by regulation reasonably require to assure that such device is not adulterated or misbranded and to otherwise assure its safety and effectiveness. Regulations prescribed under the preceding sentence—

(1) shall require a device manufacturer or importer to report to the Secretary whenever the manufacturer or importer receives or otherwise becomes aware of information that reasonably suggests that one of its marketed devices—

(A) may have caused or contributed to a death or serious injury, or

(B) has malfunctioned and that such device or a similar device marketed by the manufacturer or importer would be

likely to cause or contribute to a death or serious injury if the malfunction were to recur, which report under this subparagraph—

(i) shall be submitted in accordance with part 803 of title 21, Code of Federal Regulations (or successor regulations), unless the Secretary grants an exemption or variance from, or an alternative to, a requirement under such regulations pursuant to section 803.19 of such part, if the device involved is—

(I) a class III device;

(II) a class II device that is permanently implantable, is life supporting, or is life sustaining; or

(III) a type of device which the Secretary has, by notice published in the Federal Register or letter to the person who is the manufacturer or importer of the device, indicated should be subject to such part 803 in order to protect the public health;

(ii) shall, if the device is not subject to clause (i), be submitted in accordance with criteria established by the Secretary for reports made pursuant to this clause, which criteria shall require the reports to be in summary form and made on a quarterly basis; or

(iii) shall, if the device is imported into the United States and for which part 803 of title 21, Code of Federal Regulations (or successor regulations) requires an importer to submit a report to the manufacturer, be submitted by the importer to the manufacturer in accordance with part 803 of title 21, Code of Federal Regulations (or successor regulations)

(2) shall define the term “serious injury” to mean an injury that—

(A) is life threatening,

(B) results in permanent impairment of a body function or permanent damage to a body structure, or

(C) necessitates medical or surgical intervention to preclude permanent impairment of a body function or permanent damage to a body structure;

(3) shall require reporting of other significant adverse device experiences as determined by the Secretary to be necessary to be reported;

(4) shall not impose requirements unduly burdensome to a device manufacturer or importer taking into account his cost of complying with such requirements and the need for the protection of the public health and the implementation of this Act;

(5) which prescribe the procedure for making requests for reports or information shall require that each request made under such regulations for submission of a report or information to the Secretary state the reason or purpose for such request and identify to the fullest extent practicable such report or information;

(6) which require submission of a report or information to the Secretary shall state the reason or purpose for the submis-

sion of such report or information and identify to the fullest extent practicable such report or information;

(7) may not require that the identity of any patient be disclosed in records, reports, or information required under this subsection unless required for the medical welfare of an individual, to determine the safety or effectiveness of a device, or to verify a record, report, or information submitted under this Act; and

(8) may not require a manufacturer or importer of a class I device to—

(A) maintain for such a device records respecting information not in the possession of the manufacturer or importer, or

(B) to submit for such a device to the Secretary any report or information—

(i) not in the possession of the manufacturer or importer, or

(ii) on a periodic basis,

unless such report or information is necessary to determine if the device should be reclassified or if the device is adulterated or misbranded. and

In prescribing such regulations, the Secretary shall have due regard for the professional ethics of the medical profession and the interests of patients. The prohibitions of paragraph (7) of this subsection continue to apply to records, reports, and information concerning any individual who has been a patient, irrespective of whether or when he ceases to be a patient. The Secretary shall by regulation require distributors to keep records and make such records available to the Secretary upon request. Paragraphs (4) and (8) apply to distributors to the same extent and in the same manner as such paragraphs apply to manufacturers and importers.

User Reports

(b)(1)(A) Whenever a device user facility receives or otherwise becomes aware of information that reasonably suggests that a device has or may have caused or contributed to the death of a patient of the facility, the facility shall, as soon as practicable but not later than 10 working days after becoming aware of the information, report the information to the Secretary and, if the identity of the manufacturer is known, to the manufacturer of the device. In the case of deaths, the Secretary may by regulation prescribe a shorter period for the reporting of such information.

(B) Whenever a device user facility receives or otherwise becomes aware of—

(i) information that reasonably suggests that a device has or may have caused or contributed to the serious illness of, or serious injury to, a patient of the facility, or

(ii) other significant adverse device experiences as determined by the Secretary by regulation to be necessary to be reported,

shall, as soon as practicable but not later than 10 working days after becoming aware of the information, report the information to the manufacturer of the device or to the Secretary if the identity of the manufacturer is not known.

(C) Each device user facility shall submit to the Secretary on an annual basis a summary of the reports made under subparagraphs (A) and (B). Such summary shall be submitted on January 1 of each year. The summary shall be in such form and contain such information from such reports as the Secretary may require and shall include—

- (i) sufficient information to identify the facility which made the reports for which the summary is submitted,
- (ii) in the case of any product which was the subject of a report, the product name, serial number, and model number,
- (iii) the name and the address of the manufacturer of such device, and
- (iv) a brief description of the event reported to the manufacturer.

(D) For purposes of subparagraphs (A), (B), and (C), a device user facility shall be treated as having received or otherwise become aware of information with respect to a device of that facility when medical personnel who are employed by or otherwise formally affiliated with the facility receive or otherwise become aware of information with respect to that device in the course of their duties.

(2) The Secretary may not disclose the identity of a device user facility which makes a report under paragraph (1) except in connection with—

- (A) an action brought to enforce section 301(q), or
- (B) a communication to a manufacturer of a device which is the subject of a report under paragraph (1).

This paragraph does not prohibit the Secretary from disclosing the identity of a device user facility making a report under paragraph (1) or any information in such a report to employees of the Department of Health and Human Services, to the Department of Justice, or to the duly authorized committees and subcommittees of the Congress.

(3) No report made under paragraph (1) by—

- (A) a device user facility,
- (B) an individual who is employed by or otherwise formally affiliated with such a facility, or
- (C) a physician who is not required to make such a report, shall be admissible into evidence or otherwise used in any civil action involving private parties unless the facility, individual, or physician who made the report had knowledge of the falsity of the information contained in the report.

(4) A report made under paragraph (1) does not affect any obligation of a manufacturer who receives the report to file a report as required under subsection (a).

(5) With respect to device user facilities:

(A) The Secretary shall by regulation plan and implement a program under which the Secretary limits user reporting under paragraphs (1) through (4) to a subset of user facilities that constitutes a representative profile of user reports for device deaths and serious illnesses or serious injuries.

(B) During the period of planning the program under subparagraph (A), paragraphs (1) through (4) continue to apply.

(C) During the period in which the Secretary is providing for a transition to the full implementation of the program, para-

graphs (1) through (4) apply except to the extent that the Secretary determines otherwise.

(D) On and after the date on which the program is fully implemented, paragraphs (1) through (4) do not apply to a user facility unless the facility is included in the subset referred to in subparagraph (A).

(E) Not later than 2 years after the date of the enactment of the Food and Drug Administration Modernization Act of 1997, the Secretary shall submit to the Committee on Commerce of the House of Representatives, and to the Committee on Labor and Human Resources of the Senate, a report describing the plan developed by the Secretary under subparagraph (A) and the progress that has been made toward the implementation of the plan.

(6) For purposes of this subsection:

(A) The term “device user facility” means a hospital, ambulatory surgical facility, nursing home, or outpatient treatment facility which is not a physician’s office. The Secretary may by regulation include an outpatient diagnostic facility which is not a physician’s office in such term.

(B) The terms “serious illness” and “serious injury” mean illness or injury, respectively, that—

(i) is life threatening,

(ii) results in permanent impairment of a body function or permanent damage to a body structure, or

(iii) necessitates medical or surgical intervention to preclude permanent impairment of a body function or permanent damage to a body structure.

Persons Exempt

(c) Subsection (a) shall not apply to—

(1) any practitioner who is licensed by law to prescribe or administer devices intended for use in humans and who manufactures or imports devices solely for use in the course of his professional practice;

(2) any person who manufactures or imports devices intended for use in humans solely for such person’s use in research or teaching and not for sale (including any person who uses a device under an exemption granted under section 520(g)); and

(3) any other class of persons as the Secretary may by regulation exempt from subsection (a) upon a finding that compliance with the requirements of such subsection by such class with respect to a device is not necessary to (A) assure that a device is not adulterated or misbranded or (B) otherwise to assure its safety and effectiveness.

Device Tracking

(e)(1) The Secretary may by order require a manufacturer to adopt a method of tracking a class II or class III device—

(A) the failure of which would be reasonably likely to have serious adverse health consequences; or

(B) which is—

- (i) intended to be implanted in the human body for more than one year, or
 - (ii) a life sustaining or life supporting device used outside a device user facility.
- (2) Any patient receiving a device subject to tracking under paragraph (1) may refuse to release, or refuse permission to release, the patient's name, address, social security number, or other identifying information for the purpose of tracking.

Unique Device Identification System

(f) Not later than December 31, 2012, the Secretary shall issue proposed regulations establishing a unique device identification system for medical devices requiring the label of devices to bear a unique identifier, unless the Secretary requires an alternative placement or provides an exception for a particular device or type of device. The unique identifier shall adequately identify the device through distribution and use, and may include information on the lot or serial number. The Secretary shall finalize the proposed regulations not later than 6 months after the close of the comment period and shall implement the final regulations with respect to devices that are implantable, life-saving, or life sustaining not later than 2 years after the regulations are finalized, taking into account patient access to medical devices and therapies.

Reports of Removals and Corrections

(g)(1) Except as provided in paragraph (2), the Secretary shall by regulation require a manufacturer or importer of a device to report promptly to the Secretary any correction or removal of a device undertaken by such manufacturer or importer if the removal or correction was undertaken—

(A) to reduce a risk to health posed by the device, or

(B) to remedy a violation of this Act caused by the device which may present a risk to health.

A manufacturer or importer of a device who undertakes a correction or removal of a device which is not required to be reported under this paragraph shall keep a record of such correction or removal.

(2) No report of the corrective action or removal of a device may be required under paragraph (1) if a report of the corrective action or removal is required and has been submitted under subsection (a).

(3) For purposes of paragraphs (1) and (2), the terms "correction" and "removal" do not include routine servicing.

(h) INCLUSION OF DEVICES IN THE POSTMARKET RISK IDENTIFICATION AND ANALYSIS SYSTEM.—

(1) IN GENERAL.—

(A) APPLICATION TO DEVICES.—The Secretary shall amend the procedures established and maintained under clauses (i), (ii), (iii), and (v) of section 505(k)(3)(C) in order to expand the postmarket risk identification and analysis system established under such section to include and apply to devices.

(B) EXCEPTION.—Subclause (II) of clause (i) of section 505(k)(3)(C) shall not apply to devices.

(C) CLARIFICATION.—With respect to devices, the private sector health-related electronic data provided under section 505(k)(3)(C)(i)(III)(bb) may include medical device utilization data, health insurance claims data, and procedure and device registries.

(2) DATA.—In expanding the system as described in paragraph (1)(A), the Secretary shall use relevant data with respect to devices cleared under section 510(k) or approved under section 515, including claims data, patient survey data, and any other data deemed appropriate by the Secretary.

(3) STAKEHOLDER INPUT.—To help ensure effective implementation of the system as described in paragraph (1) with respect to devices, the Secretary shall engage outside stakeholders in development of the system, and gather information from outside stakeholders regarding the content of an effective sentinel program, through a public hearing, advisory committee meeting, maintenance of a public docket, or other similar public measures.

(4) VOLUNTARY SURVEYS.—Chapter 35 of title 44, United States Code, shall not apply to the collection of voluntary information from health care providers, such as voluntary surveys or questionnaires, initiated by the Secretary for purposes of postmarket risk identification, mitigation, and analysis for devices.

(i) *PILOT PROJECTS TO GENERATE RELIABLE AND TIMELY SAFETY AND ACTIVE SURVEILLANCE DATA.*—

(1) *IN GENERAL.*—*The Secretary shall, not later than one year after the date of the enactment of the FDA Reauthorization Act of 2017, initiate one or more pilot projects relating to providing timely and reliable information on the safety and effectiveness of devices approved under section 515, cleared under section 510(k), or classified under section 513(f)(2), in which a manufacturer or manufacturers of a device or device type voluntarily participate. Any such project shall meet each of the following criteria:*

(A) *The project is designed to efficiently generate reliable and timely safety and active surveillance data for use by the Secretary or manufacturers of the devices that are involved in the pilot project.*

(B) *The project informs, to the extent applicable, the development of methods, systems, data criteria, and programs that could be used to support safety and active surveillance activities for any device.*

(C) *The project shall be designed and conducted in coordination with a comprehensive system for evaluating device technology that operates under a governing board with appropriate representation of stakeholders, including patient groups and device manufacturers.*

(D) *The project uses electronic health data including, as appropriate, claims data, patient survey data, and any other data, as the Secretary determines appropriate.*

(E) *The project prioritizes devices and device types that meet one or more of the following criteria:*

(i) *Devices and device types for which the collection and analysis of real world evidence regarding a de-*

vice's safety and effectiveness is likely to advance public health.

(ii) Devices and device types that are widely used.

(iii) Devices and device types, the failure of which has significant health consequences.

(iv) Devices and device types for which the Secretary—

(I) has received public recommendations in accordance with paragraph (2)(B); and

(II) has determined to meet one of the criteria under clause (i), (ii), or (iii) and is appropriate for such a pilot project.

(2) *PARTICIPATION.*—The Secretary shall establish the conditions and processes—

(A) under which a manufacturer of a device may voluntarily participate in a pilot project described in paragraph (1); and

(B) for facilitating public recommendations for devices to be prioritized under such a pilot project, including requirements for the data necessary to support such a recommendation.

(3) *CONTINUATION OF ONGOING PROJECTS.*—The Secretary may continue or expand projects, with respect to providing timely and reliable information on the safety and effectiveness of devices approved under section 515, cleared under section 510(k), or classified under section 513(f)(2), that are being carried out as of the date of the enactment of the FDA Reauthorization Act of 2017. The Secretary shall, beginning on such date of enactment, take such steps as may be necessary—

(A) to ensure such projects meet the requirements of subparagraphs (A) through (E) of paragraph (1); and

(B) to increase the voluntary participation in such projects of manufacturers of devices and facilitate public recommendations for any devices prioritized under such a project.

(4) *IMPLEMENTATION.*—

(A) *CONTRACTING AUTHORITY.*—The Secretary may carry out a pilot project meeting the criteria specified in subparagraphs (A) through (E) of paragraph (1) or a project continued or expanded under paragraph (3) by entering into contracts, cooperative agreements, grants, or other appropriate agreements with public or private entities that have a significant presence in the United States and meet the following conditions:

(i) If such an entity is a component of another organization, the entity and the organization have established an agreement under which appropriate security measures are implemented to maintain the confidentiality and privacy of the data described in paragraph (1)(D) and such agreement ensures that the entity will not make an unauthorized disclosure of such data to the other components of the organization in breach of requirements with respect to confidentiality and privacy of such data established under such security measures.

(ii) *In the case of the termination or nonrenewal of such a contract, cooperative agreement, grant, or other appropriate agreement, the entity or entities involved shall comply with each of the following:*

(I) *The entity or entities shall continue to comply with the requirements with respect to confidentiality and privacy referred to in clause (i) under this subparagraph with respect to all data disclosed to the entity under such an agreement.*

(II) *The entity or entities shall return any data disclosed to such entity pursuant to this subsection and to which it would not otherwise have access or, if returning such data is not practicable, destroy the data.*

(iii) *The entity or entities shall have one or more qualifications with respect to—*

(I) *research, statistical, epidemiologic, or clinical capability and expertise to conduct and complete the activities under this subsection, including the capability and expertise to provide the Secretary access to de-identified data consistent with the requirements of this subsection;*

(II) *an information technology infrastructure to support electronic data and operational standards to provide security for such data, as appropriate;*

(III) *experience with, and expertise on, the development of research on, and surveillance of, device safety and effectiveness using electronic health data; or*

(IV) *such other expertise which the Secretary determines necessary to carry out such a project.*

(B) *REVIEW OF CONTRACT IN THE EVENT OF A MERGER OR ACQUISITION.—The Secretary shall review any contract, cooperative agreement, grant, or other appropriate agreement entered into under this paragraph with an entity meeting the conditions specified in subparagraph (A) in the event of a merger or acquisition of the entity in order to ensure that the requirements specified in this subsection will continue to be met.*

(5) *COMPLIANCE WITH REQUIREMENTS FOR RECORDS OR REPORTS ON DEVICES.—The participation of a manufacturer in pilot projects under this subsection shall not affect the eligibility of such manufacturer to participate in any quarterly reporting program with respect to devices carried out under section 519 or 522. The Secretary may determine that, for a specified time period to be determined by the Secretary, a manufacturer's participation in a pilot project under this subsection or a project continued or expanded under paragraph (3) may meet the applicable requirements of section 519 or 522, if—*

(A) *the project has demonstrated success in capturing relevant adverse event information; and*

(B) *the Secretary has established procedures for making adverse event and safety information collected from such project public, to the extent possible.*

(6) *PRIVACY REQUIREMENTS.*—With respect to the disclosure of any health information collected through a project conducted under this subsection—

(A) *individually identifiable health information so collected shall not be disclosed when presenting any information from such project; and*

(B) *any such disclosure shall be made in compliance with regulations issued pursuant to section 264(c) of the Health Insurance Portability and Accountability Act of 1996 (42 U.S.C. 1320d–2 note) and sections 552 and 552a of title 5, United States Code.*

(7) *LIMITATIONS.*—

(A) *IN GENERAL.*—No pilot project under this subsection undertaken in coordination with the comprehensive system described in paragraph (1)(C), shall allow for an entity participating in such program, other than the Secretary or the Secretary’s designee, to make determinations of safety or effectiveness, or substantial equivalence, for purposes of the Act.

(B) *NO USE OF FEES.*—Pilot projects initiated under this subsection may not primarily utilize funds collected pursuant to the Medical Device User Fee Amendments of 2017.

(8) *OTHER PROJECTS REQUIRED TO COMPLY.*—Paragraphs (1)(B), (4)(A)(i), (4)(A)(ii), (5), and (6) shall apply with respect to any pilot program undertaken in coordination with the comprehensive system described in paragraph (1)(C) that relates to the use of real world evidence for devices in the same manner and to the same extent as such paragraphs apply with respect to pilot projects conducted under this subsection.

(9) *REPORT TO CONGRESS.*—Not later than 18 months after the date of enactment of this Act, and annually thereafter, the Secretary shall submit to the Committee on Energy and Commerce of the House of Representatives and the Committee on Health, Education, Labor and Pensions of the Senate a report containing a description of the pilot projects being conducted under this subsection and projects continued or expanded pursuant to paragraph (3), including for each such project—

(A) *how the project is being implemented in accordance with paragraph (4), including how such project is being implemented through a contract, cooperative agreement, grant, or other appropriate agreement, if applicable;*

(B) *the number of manufacturers that have agreed to participate in such project;*

(C) *the data sources used to conduct such project;*

(D) *the devices or device categories involved in such project;*

(E) *the number of patients involved in such project; and*

(F) *the findings of the project in relation to device safety, including adverse events, malfunctions, and other safety information.*

(10) *SUNSET.*—The Secretary may not carry out a pilot project initiated by the Secretary under this subsection after October 1, 2022.

GENERAL PROVISIONS RESPECTING CONTROL OF DEVICES INTENDED
FOR HUMAN USE

General Rule

SEC. 520. (a) Any requirement authorized by or under section 501, 502, 510, or 519 applicable to a device intended for human use shall apply to such device until the applicability of the requirement to the device has been changed by action taken under section 513, 514, or 515 or under subsection (g) of this section, and any requirement established by or under section 501, 502, 510, or 519 which is inconsistent with a requirement imposed on such device under section 514 or 515 or under subsection (g) of this section shall not apply to such device.

(b) CUSTOM DEVICES.—

(1) IN GENERAL.—The requirements of sections 514 and 515 shall not apply to a device that—

(A) is created or modified in order to comply with the order of an individual physician or dentist (or any other specially qualified person designated under regulations promulgated by the Secretary after an opportunity for an oral hearing);

(B) in order to comply with an order described in subparagraph (A), necessarily deviates from an otherwise applicable performance standard under section 514 or requirement under section 515;

(C) is not generally available in the United States in finished form through labeling or advertising by the manufacturer, importer, or distributor for commercial distribution;

(D) is designed to treat a unique pathology or physiological condition that no other device is domestically available to treat;

(E)(i) is intended to meet the special needs of such physician or dentist (or other specially qualified person so designated) in the course of the professional practice of such physician or dentist (or other specially qualified person so designated); or

(ii) is intended for use by an individual patient named in such order of such physician or dentist (or other specially qualified person so designated);

(F) is assembled from components or manufactured and finished on a case-by-case basis to accommodate the unique needs of individuals described in clause (i) or (ii) of subparagraph (E); and

(G) may have common, standardized design characteristics, chemical and material compositions, and manufacturing processes as commercially distributed devices.

(2) LIMITATIONS.—Paragraph (1) shall apply to a device only if—

(A) such device is for the purpose of treating a sufficiently rare condition, such that conducting clinical investigations on such device would be impractical;

(B) production of such device under paragraph (1) is limited to no more than 5 units per year of a particular device type, provided that such replication otherwise complies with this section; and

(C) the manufacturer of such device notifies the Secretary on an annual basis, in a manner prescribed by the Secretary, of the manufacture of such device.

(3) GUIDANCE.—Not later than 2 years after the date of enactment of this section, the Secretary shall issue final guidance on replication of multiple devices described in paragraph (2)(B).

Trade Secrets

(c) Any information reported to or otherwise obtained by the Secretary or his representative under section 513, 514, 515, 516, 518, 519, or 704 or under subsection (f) or (g) of this section which is exempt from disclosure pursuant to subsection (a) of section 552 of title 5, United States Code, by reason of subsection (b)(4) of such section shall be considered confidential and shall not be disclosed and may not be used by the Secretary as the basis for the reclassification of a device from class III to class II or class I or as the basis for the establishment or amendment of a performance standard under section 514 for a device reclassified from class III to class II, except (1) in accordance with subsection (h), and (2) that such information may be disclosed to other officers or employees concerned with carrying out this Act or when relevant in any proceeding under this Act (other than section 513 or 514 thereof).

Notices and Findings

(d) Each notice of proposed rulemaking under section 513, 514, 515, 516, 518, or 519, or under this section, any other notice which is published in the Federal Register with respect to any other action taken under any such section and which states the reasons for such action, and each publication of findings required to be made in connection with rulemaking under any such section shall set forth—

(1) the manner in which interested persons may examine data and other information on which the notice or findings is based, and

(2) the period within which interested persons may present their comments on the notice or findings (including the need therefor) orally or in writing, which period shall be at least sixty days but may not exceed ninety days unless the time is extended by the Secretary by a notice published in the Federal Register stating good cause therefor.

Restricted Devices

(e)(1) The Secretary may by regulation require that a device be restricted to sale, distribution, or use—

(A) only upon the written or oral authorization of a practitioner licensed by law to administer or use such device, or

(B) upon such other conditions as the Secretary may prescribe in such regulation,

if, because of its potentiality for harmful effect or the collateral measures necessary to its use, the Secretary determines that there cannot otherwise be reasonable assurance of its safety and effectiveness. No condition prescribed under subparagraph (B) may restrict the use of a device to persons with specific training or experi-

ence in its use or to persons for use in certain facilities unless the Secretary determines that such a restriction is required for the safe and effective use of the device. No such condition may exclude a person from using a device solely because the person does not have the training or experience to make him eligible for certification by a certifying board recognized by the American Board of Medical Specialties or has not been certified by such a Board. A device subject to a regulation under this subsection is a restricted device.

(2) The label of a restricted device shall bear such appropriate statements of the restrictions required by a regulation under paragraph (1) as the Secretary may in such regulation prescribe.

Good Manufacturing Practice Requirements

(f)(1)(A) The Secretary may, in accordance with subparagraph (B), prescribe regulations requiring that the methods used in, and the facilities and controls used for, the manufacture, pre-production design validation (including a process to assess the performance of a device but not including an evaluation of the safety or effectiveness of a device), packing, storage, and installation of a device conform to current good manufacturing practice, as prescribed in such regulations, to assure that the device will be safe and effective and otherwise in compliance with this Act.

(B) Before the Secretary may promulgate any regulation under subparagraph (A) he shall—

- (i) afford the advisory committee established under paragraph (3) an opportunity to submit recommendations to him with respect to the regulation proposed to be promulgated;
- (ii) afford opportunity for an oral hearing; and
- (iii) ensure that such regulation conforms, to the extent practicable, with internationally recognized standards defining quality systems, or parts of the standards, for medical devices.

The Secretary shall provide the advisory committee a reasonable time to make its recommendation with respect to proposed regulations under subparagraph (A).

(2)(A) Any person subject to any requirement prescribed by regulations under paragraph (1) may petition the Secretary for an exemption or variance from such requirement. Such a petition shall be submitted to the Secretary in such form and manner as he shall prescribe and shall—

- (i) in the case of a petition for an exemption from a requirement, set forth the basis for the petitioner's determination that compliance with the requirement is not required to assure that the device will be safe and effective and otherwise in compliance with this Act,
- (ii) in the case of a petition for a variance from a requirement, set forth the methods proposed to be used in, and the facilities and controls proposed to be used for, the manufacture, packing, storage, and installation of the device in lieu of the methods, facilities, and controls prescribed by the requirement, and
- (iii) contain such other information as the Secretary shall prescribe.

(B) The Secretary may refer to the advisory committee established under paragraph (3) any petition submitted under subparagraph (A). The advisory committee shall report its recommenda-

tions to the Secretary with respect to a petition referred to it within sixty days of the date of the petition's referral. Within sixty days after—

(i) the date the petition was submitted to the Secretary under subparagraph (A), or

(ii) if the petition was referred to an advisory committee, the expiration of the sixty-day period beginning on the date the petition was referred to the advisory committee,

whichever occurs later, the Secretary shall by order either deny the petition or approve it.

(C) The Secretary may approve—

(i) a petition for an exemption for a device from a requirement if he determines that compliance with such requirement is not required to assure that the device will be safe and effective and otherwise in compliance with this Act, and

(ii) a petition for a variance for a device from a requirement if he determines that the methods to be used in, and the facilities and controls to be used for, the manufacture, packing, storage, and installation of the device in lieu of the methods, controls, and facilities prescribed by the requirement are sufficient to assure that the device will be safe and effective and otherwise in compliance with this Act.

An order of the Secretary approving a petition for a variance shall prescribe such conditions respecting the methods used in, and the facilities and controls used for, the manufacture, packing, storage, and installation of the device to be granted the variance under the petition as may be necessary to assure that the device will be safe and effective and otherwise in compliance with this Act.

(D) After the issuance of an order under subparagraph (B) respecting a petition, the petitioner shall have an opportunity for an informal hearing on such order.

(3) The Secretary shall establish an advisory committee for the purpose of advising and making recommendations to him with respect to regulations proposed to be promulgated under paragraph (1)(A) and the approval or disapproval of petitions submitted under paragraph (2). The advisory committee shall be composed of nine members as follows:

(A) Three of the members shall be appointed from persons who are officers or employees of any State or local government or of the Federal Government.

(B) Two of the members shall be appointed from persons who are representative of interests of the device manufacturing industry; two of the members shall be appointed from persons who are representative of the interests of physicians and other health professionals; and two of the members shall be representative of the interests of the general public.

Members of the advisory committee who are not officers or employees of the United States, while attending conferences or meetings of the committee or otherwise engaged in its business, shall be entitled to receive compensation at rates to be fixed by the Secretary, which rates may not exceed the daily equivalent of the rate in effect for grade GS-18 of the General Schedule, for each day (including traveltime) they are so engaged; and while so serving away from their homes or regular places of business each member may be allowed travel expenses, including per diem in lieu of subsist-

ence, as authorized by section 5703 of title 5 of the United States Code for persons in the Government service employed intermittently. The Secretary shall designate one of the members of the advisory committee to serve as its chairman. The Secretary shall furnish the advisory committee with clerical and other assistance. Section 14 of the Federal Advisory Committee Act shall not apply with respect to the duration of the advisory committee established under this paragraph.

Exemption for Devices for Investigational Use

(g)(1) It is the purpose of this subsection to encourage to the extent consistent with the protection of the public health and safety and with ethical standards, the discovery and development of useful devices intended for human use and to that end to maintain optimum freedom for scientific investigators in their pursuit of that purpose.

(2)(A) The Secretary shall, within the one hundred and twenty-day period beginning on the date of the enactment of this section, by regulation prescribe procedures and conditions under which devices intended for human use may upon application be granted an exemption from the requirements of section 502, 510, 514, 515, 516, 519, or 721 or subsection (e) or (f) of this section or from any combination of such requirements to permit the investigational use of such devices by experts qualified by scientific training and experience to investigate the safety and effectiveness of such devices.

(B) The conditions prescribed pursuant to subparagraph (A) shall include the following:

(i) A requirement that an application be submitted to the Secretary before an exemption may be granted and that the application be submitted in such form and manner as the Secretary shall specify.

(ii) A requirement that the person applying for an exemption for a device assure the establishment and maintenance of such records, and the making of such reports to the Secretary of safety or effectiveness data obtained as a result of the investigational use of the device during the exemption, as the Secretary determines will enable him to assure compliance with such conditions, review the progress of the investigation, and evaluate the safety and effectiveness of the device.

(iii) Such other requirements as the Secretary may determine to be necessary for the protection of the public health and safety.

(C) Procedures and conditions prescribed pursuant to subparagraph (A) for an exemption may appropriately vary depending on (i) the scope and duration of clinical testing to be conducted under such exemption, (ii) the number of human subjects that are to be involved in such testing, (iii) the need to permit changes to be made in the device subject to the exemption during testing conducted in accordance with a clinical testing plan required under paragraph (3)(A), and (iv) whether the clinical testing of such device is for the purpose of developing data to obtain approval for the commercial distribution of such device.

(3) Procedures and conditions prescribed pursuant to paragraph (2)(A) shall require, as a condition to the exemption of any device

to be the subject of testing involving human subjects, that the person applying for the exemption—

(A) submit a plan for any proposed clinical testing of the device and a report of prior investigations of the device (including, where appropriate, tests on animals) adequate to justify the proposed clinical testing—

(i) to the institutional review committee established in accordance with regulations of the Secretary to supervise clinical testing of devices in the facilities where the proposed clinical testing is to be conducted, or

(ii) to the Secretary, if—

(I) no such committee exists, or

(II) the Secretary finds that the process of review by such committee is inadequate (whether or not the plan for such testing has been approved by such committee),

for review for adequacy to justify the commencement of such testing; and, unless the plan and report are submitted to the Secretary, submit to the Secretary a summary of the plan and a report of prior investigations of the device (including, where appropriate, tests on animals);

(B) promptly notify the Secretary (under such circumstances and in such manner as the Secretary prescribes) of approval by an institutional review committee of any clinical testing plan submitted to it in accordance with subparagraph (A);

(C) in the case of a device to be distributed to investigators for testing, obtain signed agreements from each of such investigators that any testing of the device involving human subjects will be under such investigator's supervision and in accordance with subparagraph (D) and submit such agreements to the Secretary; and

(D) assure that informed consent will be obtained from each human subject (or his representative) of proposed clinical testing involving such device, except where, subject to such conditions as the Secretary may prescribe—

(i) the proposed clinical testing poses no more than minimal risk to the human subject and includes appropriate safeguards to protect the rights, safety, and welfare of the human subject; or

(ii) the investigator conducting or supervising the proposed clinical testing of the device determines in writing that there exists a life threatening situation involving the human subject of such testing which necessitates the use of such device and it is not feasible to obtain informed consent from the subject and there is not sufficient time to obtain such consent from his representative.

The determination required by subparagraph (D)(ii) shall be concurred in by a licensed physician who is not involved in the testing of the human subject with respect to which such determination is made unless immediate use of the device is required to save the life of the human subject of such testing and there is not sufficient time to obtain such concurrence.

(4)(A) An application, submitted in accordance with the procedures prescribed by regulations under paragraph (2), for an exemption for a device (other than an exemption from section 516) shall

be deemed approved on the thirtieth day after the submission of the application to the Secretary unless on or before such day the Secretary by order disapproves the application and notifies the applicant of the disapproval of the application.

(B) The Secretary may disapprove an application only if he finds that the investigation with respect to which the application is submitted does not conform to procedures and conditions prescribed under regulations under paragraph (2). Such a notification shall contain the order of disapproval and a complete statement of the reasons for the Secretary's disapproval of the application and afford the applicant opportunity for an informal hearing on the disapproval order.

(C) Consistent with paragraph (1), the Secretary shall not disapprove an application under this subsection because the Secretary determines that—

(i) the investigation may not support a substantial equivalence or de novo classification determination or approval of the device;

(ii) the investigation may not meet a requirement, including a data requirement, relating to the approval or clearance of a device; or

(iii) an additional or different investigation may be necessary to support clearance or approval of the device.

(5) The Secretary may by order withdraw an exemption granted under this subsection for a device if the Secretary determines that the conditions applicable to the device under this subsection for such exemption are not met. Such an order may be issued only after opportunity for an informal hearing, except that such an order may be issued before the provision of an opportunity for an informal hearing if the Secretary determines that the continuation of testing under the exemption with respect to which the order is to be issued will result in an unreasonable risk to the public health.

(6)(A) Not later than 1 year after the date of the enactment of the Food and Drug Administration Modernization Act of 1997, the Secretary shall by regulation establish, with respect to a device for which an exemption under this subsection is in effect, procedures and conditions that, without requiring an additional approval of an application for an exemption or the approval of a supplement to such an application, permit—

(i) developmental changes in the device (including manufacturing changes) that do not constitute a significant change in design or in basic principles of operation and that are made in response to information gathered during the course of an investigation; and

(ii) changes or modifications to clinical protocols that do not affect—

(I) the validity of data or information resulting from the completion of an approved protocol, or the relationship of likely patient risk to benefit relied upon to approve a protocol;

(II) the scientific soundness of an investigational plan submitted under paragraph (3)(A); or

(III) the rights, safety, or welfare of the human subjects involved in the investigation.

(B) Regulations under subparagraph (A) shall provide that a change or modification described in such subparagraph may be made if—

(i) the sponsor of the investigation determines, on the basis of credible information (as defined by the Secretary) that the applicable conditions under subparagraph (A) are met; and

(ii) the sponsor submits to the Secretary, not later than 5 days after making the change or modification, a notice of the change or modification.

(7)(A) In the case of a person intending to investigate the safety or effectiveness of a class III device or any implantable device, the Secretary shall ensure that the person has an opportunity, prior to submitting an application to the Secretary or to an institutional review committee, to submit to the Secretary, for review, an investigational plan (including a clinical protocol). If the applicant submits a written request for a meeting with the Secretary regarding such review, the Secretary shall, not later than 30 days after receiving the request, meet with the applicant for the purpose of reaching agreement regarding the investigational plan (including a clinical protocol). The written request shall include a detailed description of the device, a detailed description of the proposed conditions of use of the device, a proposed plan (including a clinical protocol) for determining whether there is a reasonable assurance of effectiveness, and, if available, information regarding the expected performance from the device.

(B) Any agreement regarding the parameters of an investigational plan (including a clinical protocol) that is reached between the Secretary and a sponsor or applicant shall be reduced to writing and made part of the administrative record by the Secretary. Any such agreement shall not be changed, except—

(i) with the written agreement of the sponsor or applicant;

or

(ii) pursuant to a decision, made in accordance with subparagraph (C) by the director of the office in which the device involved is reviewed, that a substantial scientific issue essential to determining the safety or effectiveness of the device involved has been identified.

(C) A decision under subparagraph (B)(ii) by the director shall be in writing, and may be made only after the Secretary has provided to the sponsor or applicant an opportunity for a meeting at which the director and the sponsor or applicant are present and at which the director documents the scientific issue involved.

(8)(A) At any time, the Secretary may prohibit the sponsor of an investigation from conducting the investigation (referred to in this paragraph as a “clinical hold”) if the Secretary makes a determination described in subparagraph (B). The Secretary shall specify the basis for the clinical hold, including the specific information available to the Secretary which served as the basis for such clinical hold, and confirm such determination in writing.

(B) For purposes of subparagraph (A), a determination described in this subparagraph with respect to a clinical hold is a determination that—

(i) the device involved represents an unreasonable risk to the safety of the persons who are the subjects of the clinical investigation, taking into account the qualifications of the clinical

investigators, information about the device, the design of the clinical investigation, the condition for which the device is to be investigated, and the health status of the subjects involved; or

(ii) the clinical hold should be issued for such other reasons as the Secretary may by regulation establish.

(C) Any written request to the Secretary from the sponsor of an investigation that a clinical hold be removed shall receive a decision, in writing and specifying the reasons therefor, within 30 days after receipt of such request. Any such request shall include sufficient information to support the removal of such clinical hold.

Release of Safety and Effectiveness Information

(h)(1) The Secretary shall promulgate regulations under which a detailed summary of information respecting the safety and effectiveness of a device which information was submitted to the Secretary and which was the basis for—

(A) an order under section 515(d)(1)(A) approving an application for premarket approval for the device or denying approval of such an application or an order under section 515(e) withdrawing approval of such an application for the device,

(B) an order under section 515(f)(6)(A) revoking an approved protocol for the device, an order under section 515(f)(6)(B) declaring a protocol for the device completed or not completed, or an order under section 515(f)(7) revoking the approval of the device, or

(C) an order approving an application under subsection (g) for an exemption for the device from section 516 or an order disapproving, or withdrawing approval of, an application for an exemption under such subsection for the device,

shall be made available to the public upon issuance of the order. Summaries of information made available pursuant to this paragraph respecting a device shall include information respecting any adverse effects on health of the device.

(2) The Secretary shall promulgate regulations under which each advisory committee established under section 515(g)(2)(B) shall make available to the public a detailed summary of information respecting the safety and effectiveness of a device which information was submitted to the advisory committee and which was the basis for its recommendation to the Secretary pursuant to section 515(g)(2)(A). A summary of information upon which such a recommendation is based shall be made available pursuant to this paragraph only after the issuance of the order with respect to which the recommendation was made and each summary shall include information respecting any adverse effect on health of the device subject to such order.

(3) Except as provided in paragraph (4), any information respecting a device which is made available pursuant to paragraph (1) or (2) of this subsection (A) may not be used to establish the safety or effectiveness of another device for purposes of this Act by any person other than the person who submitted the information so made available, and (B) shall be made available subject to subsection (c) of this section.

(4)(A) Subject to subparagraph (C), any information contained in an application for premarket approval filed with the Secretary pur-

suant to section 515(c) (including information from clinical and pre-clinical tests or studies that demonstrate the safety and effectiveness of a device, but excluding descriptions of methods of manufacture and product composition and other trade secrets) shall be available, 6 years after the application has been approved by the Secretary, for use by the Secretary in—

- (i) approving another device;
- (ii) determining whether a product development protocol has been completed, under section 515 for another device;
- (iii) establishing a performance standard or special control under this Act; or
- (iv) classifying or reclassifying another device under section 513 and subsection (1)(2).

(B) The publicly available detailed summaries of information respecting the safety and effectiveness of devices required by paragraph (1)(A) shall be available for use by the Secretary as the evidentiary basis for the agency actions described in subparagraph (A).

(C) No information contained in an application for premarket approval filed with the Secretary pursuant to section 515(c) may be used to approve or clear any application submitted under section 515 or 510(k) or to classify a product under section 513(f)(2) for a combination product containing as a constituent part an approved drug (as defined in section 503(g)(5)(B)) unless—

- (i) the application includes the certification or statement referenced in section 503(g)(5)(A);
- (ii) the applicant provides notice as described in section 503(g)(5)(A); and
- (iii) the Secretary's approval of such application is subject to the provisions in section 503(g)(5)(C).

Proceedings of Advisory Panels and Committees

(i) Each panel under section 513 and each advisory committee established under section 514(b)(5)(B) or 515(g) or under subsection (f) of this section shall make and maintain a transcript of any proceeding of the panel or committee. Each such panel and committee shall delete from any transcript made pursuant to this subsection information which under subsection (c) of this section is to be considered confidential.

Traceability Requirements

(j) Except as provided in section 519(e), no regulation under this Act may impose on a type or class of device requirements for the traceability of such type or class of device unless such requirements are necessary to assure the protection of the public health.

Research and Development

(k) The Secretary may enter into contracts for research, testing, and demonstrations respecting devices and may obtain devices for research, testing, and demonstration purposes without regard to sections 3648 and 3709 of the Revised Statutes (31 U.S.C. 529, 41 U.S.C. 5).

Transitional Provisions for Devices Considered as New Drugs

(1)(1) Any device intended for human use—

(A) for which on the date of enactment of the Medical Device Amendments of 1976 (hereinafter in this subsection referred to as the “enactment date”) an approval of an application submitted under section 505(b) was in effect;

(B) for which such an application was filed on or before the enactment date and with respect to which application no order of approval or refusing to approve had been issued on such date under subsection (c) or (d) of such section;

(C) for which on the enactment date an exemption under subsection (i) of such section was in effect;

(D) which is within a type of device described in subparagraph (A), (B), or (C) and is substantially equivalent to another device within that type;

(E) which the Secretary in a notice published in the Federal Register before the enactment date has declared to be a new drug subject to section 505; or

(F) with respect to which on the enactment date an action is pending in a United States court under section 302, 303, or 304 for an alleged violation of a provision of section 301 which enforces a requirement of section 505 or for an alleged violation of section 505(a),

is classified in class III unless the Secretary in response to a petition submitted under paragraph (2) has classified such device in class I or II.

(2) The Secretary may initiate the reclassification of a device classified into class III under paragraph (1) of this subsection or the manufacturer or importer of a device classified under paragraph (1) may petition the Secretary (in such form and manner as he shall prescribe) for the issuance of an order classifying the device in class I or class II. Within thirty days of the filing of such a petition, the Secretary shall notify the petitioner of any deficiencies in the petition which prevent the Secretary from making a decision on the petition. Except as provided in paragraph (3)(D)(ii), within one hundred and eighty days after the filing of a petition under this paragraph, the Secretary shall, after consultation with the appropriate panel under section 513, by order either deny the petition or order the classification, in accordance with the criteria prescribed by section 513(a)(1)(A) or 513(a)(1)(B), of the device in class I or class II.

(3)(A) In the case of a device which is described in paragraph (1)(A) and which is in class III—

(i) such device shall on the enactment date be considered a device with an approved application under section 515, and

(ii) the requirements applicable to such device before the enactment date under section 505 shall continue to apply to such device until changed by the Secretary as authorized by this Act.

(B) In the case of a device which is described in paragraph (1)(B) and which is in class III, an application for such device shall be considered as having been filed under section 515 on the enactment date. The period in which the Secretary shall act on such application in accordance with section 515(d)(1) shall be one hundred and

eighty days from the enactment date (or such greater period as the Secretary and the applicant may agree upon after the Secretary has made the finding required by section 515(d)(1)(B)(i)) less the number of days in the period beginning on the date an application for such device was filed under section 505 and ending on the enactment date. After the expiration of such period such device is required, unless exempt under subsection (g), to have in effect an approved application under section 515.

(C) A device which is described in paragraph (1)(C) and which is in class III shall be considered a new drug until the expiration of the ninety-day period beginning on the date of the promulgation of regulations under subsection (g) of this section. After the expiration of such period such device is required, unless exempt under subsection (g), to have in effect an approved application under section 515.

(D)(i) Except as provided in clauses (ii) and (iii), a device which is described in subparagraph (D), (E), or (F) of paragraph (1) and which is in class III is required, unless exempt under subsection (g) of this section, to have on and after sixty days after the enactment date in effect an approved application under section 515.

(ii) If—

(I) a petition is filed under paragraph (2) for a device described in subparagraph (D), (E), or (F) of paragraph (1), or

(II) an application for premarket approval is filed under section 515 for such a device,

within the sixty-day period beginning on the enactment date (or within such greater period as the Secretary, after making the finding required under section 515(d)(1)(B), and the petitioner or applicant may agree upon), the Secretary shall act on such petition or application in accordance with paragraph (2) or section 515 except that the period within which the Secretary must act on the petition or application shall be within the one hundred and twenty-day period beginning on the date the petition or application is filed. If such a petition or application is filed within such sixty-day (or greater) period, clause (i) of this subparagraph shall not apply to such device before the expiration of such one hundred and twenty-day period, or if such petition is denied or such application is denied approval, before the date of such denial, whichever occurs first.

(iii) In the case of a device which is described in subparagraph (E) of paragraph (1), which the Secretary in a notice published in the Federal Register after March 31, 1976, declared to be a new drug subject to section 505, and which is in class III—

(I) the device shall, after eighteen months after the enactment date, have in effect an approved application under section 515 unless exempt under subsection (g) of this section, and

(II) the Secretary may, during the period beginning one hundred and eighty days after the enactment date and ending eighteen months after such date, restrict the use of the device to investigational use by experts qualified by scientific training and experience to investigate the safety and effectiveness of such device, and to investigational use in accordance with the requirements applicable under regulations under subsection (g) of this section to investigational use of devices granted an exemption under such subsection.

If the requirements under subsection (g) of this section are made applicable to the investigational use of such a device, they shall be made applicable in such a manner that the device shall be made reasonably available to physicians meeting appropriate qualifications prescribed by the Secretary.

(5)(A) Before December 1, 1991, the Secretary shall by order require manufacturers of devices described in paragraph (1), which are subject to revision of classification under subparagraph (B), to submit to the Secretary a summary of and citation to any information known or otherwise available to the manufacturers respecting the devices, including adverse safety or effectiveness information which has not been submitted under section 519. The Secretary may require a manufacturer to submit the adverse safety or effectiveness data for which a summary and citation were submitted, if such data are available to the manufacturer.

(B) Except as provided in subparagraph (C), after the issuance of an order under subparagraph (A) but before December 1, 1992, the Secretary shall publish a regulation in the Federal Register for each device which is classified in class III under paragraph (1) revising the classification of the device so that the device is classified into class I or class II, unless the regulation requires the device to remain in class III. In determining whether to revise the classification of a device or to require a device to remain in class III, the Secretary shall apply the criteria set forth in section 513(a). Before the publication of a regulation requiring a device to remain in class III or revising its classification, the Secretary shall publish a proposed regulation respecting the classification of a device under this subparagraph and provide an opportunity for the submission of comments on any such regulation. No regulation under this subparagraph requiring a device to remain in class III or revising its classification may take effect before the expiration of 90 days from the date of the publication in the Federal Register of the proposed regulation.

(C) The Secretary may by notice published in the Federal Register extend the period prescribed by subparagraph (B) for a device for an additional period not to exceed 1 year.

Humanitarian Device Exemption

(m)(1) To the extent consistent with the protection of the public health and safety and with ethical standards, it is the purpose of this subsection to encourage the discovery and use of devices intended to benefit patients in the treatment and diagnosis of diseases or conditions that affect not more than 8,000 individuals in the United States.

(2) The Secretary may grant a request for an exemption from the effectiveness requirements of sections 514 and 515 for a device for which the Secretary finds that—

(A) the device is designed to treat or diagnose a disease or condition that affects not more than 8,000 individuals in the United States,

(B) the device would not be available to a person with a disease or condition referred to in subparagraph (A) unless the Secretary grants such an exemption and there is no comparable device, other than under this exemption, available to treat or diagnose such disease or condition, and

(C) the device will not expose patients to an unreasonable or significant risk of illness or injury and the probable benefit to health from the use of the device outweighs the risk of injury or illness from its use, taking into account the probable risks and benefits of currently available device or alternative forms of treatment.

The request shall be in the form of an application submitted to the Secretary and such application shall include the certification required under section 402(j)(5)(B) of the Public Health Service Act (which shall not be considered an element of such application). Not later than 75 days after the date of the receipt of the application, the Secretary shall issue an order approving or denying the application.

(3) Except as provided in paragraph (6), no person granted an exemption under paragraph (2) with respect to a device may sell the device for an amount that exceeds the costs of research and development, fabrication, and distribution of the device.

(4) Devices granted an exemption under paragraph (2) may only be used—

(A) in facilities in which clinical testing of devices is supervised by an institutional review committee established in accordance with the regulations of the Secretary; and

(B) if, before the use of a device, an institutional review committee approves the use in the treatment or diagnosis of a disease or condition referred to in paragraph (2)(A), unless a physician determines in an emergency situation that approval from an institutional review committee can not be obtained in time to prevent serious harm or death to a patient.

In a case described in subparagraph (B) in which a physician uses a device without an approval from an institutional review committee, the physician shall, after the use of the device, notify the chairperson of the institutional review committee of such use. Such notification shall include the identification of the patient involved, the date on which the device was used, and the reason for the use.

(5) The Secretary may require a person granted an exemption under paragraph (2) to demonstrate continued compliance with the requirements of this subsection if the Secretary believes such demonstration to be necessary to protect the public health, if the Secretary has reason to believe that the requirements of paragraph (6) are no longer met, or if the Secretary has reason to believe that the criteria for the exemption are no longer met. If the person granted an exemption under paragraph (2) fails to demonstrate continued compliance with the requirements of this subsection, the Secretary may suspend or withdraw the exemption from the effectiveness requirements of sections 514 and 515 for a humanitarian device only after providing notice and an opportunity for an informal hearing.

(6)(A) Except as provided in subparagraph (D), the prohibition in paragraph (3) shall not apply with respect to a person granted an exemption under paragraph (2) if each of the following conditions apply:

(i) The device with respect to which the exemption is granted—

(I) is intended for the treatment or diagnosis of a disease or condition that occurs in pediatric patients or in a pediatric subpopulation, and such device is labeled for use in

pediatric patients or in a pediatric subpopulation in which the disease or condition occurs; or

(II) is intended for the treatment or diagnosis of a disease or condition that does not occur in pediatric patients or that occurs in pediatric patients in such numbers that the development of the device for such patients is impossible, highly impracticable, or unsafe.

(ii) During any calendar year, the number of such devices distributed during that year under each exemption granted under this subsection does not exceed the annual distribution number for such device. In this paragraph, the term “annual distribution number” means the number of such devices reasonably needed to treat, diagnose, or cure a population of 8,000 individuals in the United States. The Secretary shall determine the annual distribution number when the Secretary grants such exemption.

(iii) Such person immediately notifies the Secretary if the number of such devices distributed during any calendar year exceeds the annual distribution number referred to in clause (ii).

(iv) The request for such exemption is submitted on or before October 1, [2017] 2022.

(B) The Secretary may inspect the records relating to the number of devices distributed during any calendar year of a person granted an exemption under paragraph (2) for which the prohibition in paragraph (3) does not apply.

(C) A person may petition the Secretary to modify the annual distribution number determined by the Secretary under subparagraph (A)(ii) with respect to a device if additional information arises, and the Secretary may modify such annual distribution number.

(D) If a person notifies the Secretary, or the Secretary determines through an inspection under subparagraph (B), that the number of devices distributed during any calendar year exceeds the annual distribution number, as required under subparagraph (A)(iii), and modified under subparagraph (C), if applicable, then the prohibition in paragraph (3) shall apply with respect to such person for such device for any sales of such device after such notification.

(E)(i) In this subsection, the term “pediatric patients” means patients who are 21 years of age or younger at the time of the diagnosis or treatment.

(ii) In this subsection, the term “pediatric subpopulation” means 1 of the following populations:

- (I) Neonates.
- (II) Infants.
- (III) Children.
- (IV) Adolescents.

(7) The Secretary shall refer any report of an adverse event regarding a device described in paragraph (6)(A)(i)(I) for which the prohibition under paragraph (3) does not apply pursuant to paragraph (6)(A) that the Secretary receives to the Office of Pediatric Therapeutics, established under section 6 of the Best Pharmaceuticals for Children Act (Public Law 107–109). In considering the report, the Director of the Office of Pediatric Therapeutics, in con-

sultation with experts in the Center for Devices and Radiological Health, shall provide for periodic review of the report by the Pediatric Advisory Committee, including obtaining any recommendations of such committee regarding whether the Secretary should take action under this Act in response to the report.

(8) The Secretary, acting through the Office of Pediatric Therapeutics and the Center for Devices and Radiological Health, shall provide for an annual review by the Pediatric Advisory Committee of all devices described in paragraph (6)(A)(i)(I) to ensure that the exemption under paragraph (2) remains appropriate for the pediatric populations for which it is granted.

Regulation of Contact Lens as Devices

(n)(1) All contact lenses shall be deemed to be devices under section 201(h).

(2) Paragraph (1) shall not be construed as bearing on or being relevant to the question of whether any product other than a contact lens is a device as defined by section 201(h) or a drug as defined by section 201(g).

(o) REGULATION OF MEDICAL AND CERTAIN DECISIONS SUPPORT SOFTWARE.—

(1) The term device, as defined in section 201(h), shall not include a software function that is intended—

(A) for administrative support of a health care facility, including the processing and maintenance of financial records, claims or billing information, appointment schedules, business analytics, information about patient populations, admissions, practice and inventory management, analysis of historical claims data to predict future utilization or cost-effectiveness, determination of health benefit eligibility, population health management, and laboratory workflow;

(B) for maintaining or encouraging a healthy lifestyle and is unrelated to the diagnosis, cure, mitigation, prevention, or treatment of a disease or condition;

(C) to serve as electronic patient records, including patient-provided information, to the extent that such records are intended to transfer, store, convert formats, or display the equivalent of a paper medical chart, so long as—

(i) such records were created, stored, transferred, or reviewed by health care professionals, or by individuals working under supervision of such professionals;

(ii) such records are part of health information technology that is certified under section 3001(c)(5) of the Public Health Service Act; and

(iii) such function is not intended to interpret or analyze patient records, including medical image data, for the purpose of the diagnosis, cure, mitigation, prevention, or treatment of a disease or condition;

(D) for transferring, storing, converting formats, or displaying clinical laboratory test or other device data and results, findings by a health care professional with respect to such data and results, general information about such findings, and general background information about such laboratory test or other device, unless such function is in-

tended to interpret or analyze clinical laboratory test or other device data, results, and findings; or

(E) unless the function is intended to acquire, process, or analyze a medical image or a signal from an in vitro diagnostic device or a pattern or signal from a signal acquisition system, for the purpose of—

(i) displaying, analyzing, or printing medical information about a patient or other medical information (such as peer-reviewed clinical studies and clinical practice guidelines);

(ii) supporting or providing recommendations to a health care professional about prevention, diagnosis, or treatment of a disease or condition; and

(iii) enabling such health care professional to independently review the basis for such recommendations that such software presents so that it is not the intent that such health care professional rely primarily on any of such recommendations to make a clinical diagnosis or treatment decision regarding an individual patient.

(2) In the case of a product with multiple functions that contains—

(A) at least one software function that meets the criteria under paragraph (1) or that otherwise does not meet the definition of device under section 201(h); and

(B) at least one function that does not meet the criteria under paragraph (1) and that otherwise meets the definition of a device under section 201(h),

the Secretary shall not regulate the software function of such product described in subparagraph (A) as a device. Notwithstanding the preceding sentence, when assessing the safety and effectiveness of the device function or functions of such product described in subparagraph (B), the Secretary may assess the impact that the software function or functions described in subparagraph (A) have on such device function or functions.

(3)(A) Notwithstanding paragraph (1), a software function described in subparagraph (C), (D), or (E) of paragraph (1) shall not be excluded from the definition of device under section 201(h) if—

(i) the Secretary makes a finding that use of such software function would be reasonably likely to have serious adverse health consequences; and

(ii) the software function has been identified in a final order issued by the Secretary under subparagraph (B).

(B) Subparagraph (A) shall apply only if the Secretary—

(i) publishes a notification and proposed order in the Federal Register;

(ii) includes in such notification the Secretary's finding, including the rationale and identification of the evidence on which such finding was based, as described in subparagraph (A)(i); and

(iii) provides for a period of not less than 30 calendar days for public comment before issuing a final order or withdrawing such proposed order.

(C) In making a finding under subparagraph (A)(i) with respect to a software function, the Secretary shall consider—

(i) the likelihood and severity of patient harm if the software function were to not perform as intended;

(ii) the extent to which the software function is intended to support the clinical judgment of a health care professional;

(iii) whether there is a reasonable opportunity for a health care professional to review the basis of the information or treatment recommendation provided by the software function; and

(iv) the intended user and user environment, such as whether a health care professional will use a software function of a type described in subparagraph (E) of paragraph (1).

(4) Nothing in this subsection shall be construed as limiting the authority of the Secretary to—

(A) exercise enforcement discretion as to any device subject to regulation under this Act;

(B) regulate software used in the manufacture and transfusion of blood and blood components to assist in the prevention of disease in humans; or

(C) regulate software as a device under this Act if such software meets the criteria under section 513(a)(1)(C).

(p) *REGULATION OF OVER-THE-COUNTER HEARING AIDS.—*

(1) *DEFINITION.—*

(A) *In this subsection, the term “over-the-counter hearing aid” means a device—*

(i) *that uses the same fundamental scientific technology as air conduction hearing aids (as defined in section 874.3300 of title 21, Code of Federal Regulations) (or any successor regulation) or wireless air conduction hearing aids (as defined in section 874.3305 of title 21, Code of Federal Regulations) (or any successor regulation);*

(ii) *that is intended to be used by adults over the age of 18 to compensate for perceived mild to moderate hearing impairment;*

(iii) *that, through tools, tests, or software, allows the user to control the over-the-counter hearing aid and customize it to the user’s hearing needs;*

(iv) *that may—*

(I) *use wireless technology; or*

(II) *include tests for self-assessment of hearing loss; and*

(v) *that is available over-the-counter, without the supervision, prescription, or other order, involvement, or intervention of a licensed person, to consumers through in-person transactions, by mail, or online.*

(B) *Such term does not include a personal sound amplification product intended to amplify sound for nonhearing impaired consumers in situations including hunting and bird-watching.*

(2) *REGULATION.—An over-the-counter hearing aid shall be subject to the regulations promulgated in accordance with sec-*

tion 613(b) of the FDA Reauthorization Act of 2017 and shall be exempt from sections 801.420 and 801.421 of title 21, Code of Federal Regulations (or any successor regulations).

(q) **DIAGNOSTIC IMAGING DEVICES INTENDED FOR USE WITH CONTRAST AGENTS.**—

(1) *The Secretary may, subject to the succeeding provisions of this subsection, approve an application (or a supplement to such an application) submitted under section 515 with respect to an applicable medical imaging device, or, in the case of an applicable medical imaging device for which a notification is submitted under section 510(k), may make a substantial equivalence determination with respect to an applicable medical imaging device, or may grant a request submitted under section 513(f)(2) for an applicable medical imaging device, if the indications and conditions of use proposed in such application, notification, or request involve the use of a contrast agent that is not—*

(A) in a concentration, rate of administration, or route of administration that is different from those described in the approved labeling of the contrast agent, except that the Secretary may approve such application, make such substantial equivalence determination, or grant such request if the Secretary determines that such differences in concentration, rate of administration, or route of administration exist but do not adversely affect the safety and effectiveness of the contrast agent when used with the device;

(B) in a region, organ, or system of the body that is different from those described in the approved labeling of the contrast agent, except that the Secretary may approve such application, make such substantial equivalence determination, or grant such request if the Secretary determines that such differences in region, organ, or system of the body exist but do not adversely affect the safety and effectiveness of the contrast agent when used with the device;

(C) in a patient population that is different from those described in the approved labeling of the contrast agent, except that the Secretary may approve such application, make such substantial equivalence determination, or grant such request if the Secretary determines such differences in patient population exist but do not adversely affect the safety and effectiveness of the contrast agent when used with the device; or

(D) in an imaging modality (such as an ultrasound, an x-ray, diagnostic radiopharmaceutical-based technologies, fluorescent imaging technology, or magnetic resonance) that is different from those described in the approved labeling of the contrast agent.

(2) *The agency center charged with premarket review of devices shall have primary jurisdiction with respect to the review of an application, notification, or request described in paragraph (1). In conducting such review, such agency center may—*

(A) consult with the agency center charged with the premarket review of drugs or biological products; and

(B) review information and data provided to the Secretary by the sponsor of a contrast agent in an application

submitted under section 505 of this Act or section 351 of the Public Health Service Act, so long as the sponsor of such contrast agent has provided to the sponsor of the applicable medical imaging device that is the subject of such review a right of reference and the application is submitted in accordance with this subsection.

(3) An application submitted under section 515, a notification submitted under section 510(k), or a request submitted under section 513(f)(2), as described in paragraph (1), with respect to an applicable medical imaging device shall be subject to the requirements of such respective section. Such application, notification, or request shall only be subject to the requirements of this Act applicable to devices.

(4) For purposes of this subsection and section 505(y)—

(A) the term “applicable medical imaging device” means a device intended to be used in conjunction with a contrast agent (or class of contrast agents) for an imaging use that is not described in the approved labeling of such contrast agent (or the approved labeling of any contrast agent in the same class as such contrast agent); and

(B) the term “contrast agent” means a drug that is approved under section 505 or licensed under section 351 of the Public Health Service Act, is intended for use in conjunction with an applicable medical imaging device, and—

(i) is a diagnostic radiopharmaceutical, as defined in section 315.2 and 601.31 of title 21, Code of Federal Regulations (or any successor regulations); or

(ii) is a diagnostic agent that improves the visualization of structure or function within the body by increasing the relative difference in signal intensity within the target tissue, structure, or fluid.

* * * * *

SEC. 523. ACCREDITED PERSONS.

(a) IN GENERAL.—

(1) REVIEW AND CLASSIFICATION OF DEVICES.—Not later than 1 year after the date of the enactment of the Food and Drug Administration Modernization Act of 1997, the Secretary shall, subject to paragraph (3), accredit persons for the purpose of reviewing reports submitted under section 510(k) and making recommendations to the Secretary regarding the initial classification of devices under section 513(f)(1).

(2) REQUIREMENTS REGARDING REVIEW.—

(A) IN GENERAL.—In making a recommendation to the Secretary under paragraph (1), an accredited person shall notify the Secretary in writing of the reasons for the recommendation.

(B) TIME PERIOD FOR REVIEW.—Not later than 30 days after the date on which the Secretary is notified under subparagraph (A) by an accredited person with respect to a recommendation of an initial classification of a device, the Secretary shall make a determination with respect to the initial classification.

(C) SPECIAL RULE.—The Secretary may change the initial classification under section 513(f)(1) that is rec-

ommended under paragraph (1) by an accredited person, and in such case shall provide to such person, and the person who submitted the report under section 510(k) for the device, a statement explaining in detail the reasons for the change.

(3) CERTAIN DEVICES.—

(A) IN GENERAL.—An accredited person may not be used to perform a review of—

(i) a class III device;

[(ii) a class II device which is intended to be permanently implantable or life sustaining or life supporting; or

[(iii) a class II device which requires clinical data in the report submitted under section 510(k) for the device, except that the number of class II devices to which the Secretary applies this clause for a year, less the number of such reports to which clauses (i) and (ii) apply, may not exceed 6 percent of the number that is equal to the total number of reports submitted to the Secretary under such section for such year less the number of such reports to which such clauses apply for such year.]

(ii) a device classified under section 513(f)(2) or designated under section 515C(d); or

(iii) a device that is of a type, or subset of a type, listed as not eligible for review under subparagraph (B)(iii).

[(B) ADJUSTMENT.—In determining for a year the ratio described in subparagraph (A)(iii), the Secretary shall not include in the numerator class III devices that the Secretary reclassified into class II, and the Secretary shall include in the denominator class II devices for which reports under section 510(k) were not required to be submitted by reason of the operation of section 510(m).]

(B) DESIGNATION FOR REVIEW.—*The Secretary shall—*

(i) issue draft guidance on the factors the Secretary will use in determining whether a class I or class II device type, or subset of such device types, is eligible for review by an accredited person, including—

(I) the risk of the device type, or subset of such device type; and

(II) whether the device type, or subset of such device type, is permanently implantable, life sustaining, or life supporting;

(ii) not later than 24 months after the date on which the Secretary issues such draft guidance, finalize such guidance; and

(iii) beginning on the date such guidance is finalized, designate and post on the internet website of the Food and Drug Administration, an updated list of class I and class II device types, or subsets of such device types, and the Secretary's determination with respect to whether each such device type, or subset of a device type, is eligible or not eligible for review by an accred-

ited person under this section based on the factors described in clause (i).

(C) INTERIM RULE.—Until the date on which the updated list is designated and posted in accordance with subparagraph (B)(iii), the list in effect on the date of enactment the Medical Device User Fee Amendments of 2017 shall be in effect.

(b) ACCREDITATION.—

(1) PROGRAMS.—The Secretary shall provide for such accreditation through programs administered by the Food and Drug Administration, other government agencies, or by other qualified nongovernment organizations.

(2) ACCREDITATION.—

(A) IN GENERAL.—Not later than 180 days after the date of the enactment of the Food and Drug Administration Modernization Act of 1997, the Secretary shall establish and publish in the Federal Register criteria to accredit or deny accreditation to persons who request to perform the duties specified in subsection (a). The Secretary shall respond to a request for accreditation within 60 days of the receipt of the request. The accreditation of such person shall specify the particular activities under subsection (a) for which such person is accredited.

(B) WITHDRAWAL OF ACCREDITATION.—The Secretary may suspend or withdraw accreditation of any person accredited under this paragraph, after providing notice and an opportunity for an informal hearing, when such person is substantially not in compliance with the requirements of this section or poses a threat to public health or fails to act in a manner that is consistent with the purposes of this section.

(C) PERFORMANCE AUDITING.—To ensure that persons accredited under this section will continue to meet the standards of accreditation, the Secretary shall—

(i) make onsite visits on a periodic basis to each accredited person to audit the performance of such person; and

(ii) take such additional measures as the Secretary determines to be appropriate.

[(D) ANNUAL REPORT.—The Secretary shall include in the annual report required under section 1003(g) the names of all accredited persons and the particular activities under subsection (a) for which each such person is accredited and the name of each accredited person whose accreditation has been withdrawn during the year.]

[(E)] (D) PERIODIC REACCREDITATION.—

(i) PERIOD.—Subject to suspension or withdrawal under subparagraph (B), any accreditation under this section shall be valid for a period of 3 years after its issuance.

(ii) RESPONSE TO REACCREDITATION REQUEST.—Upon the submission of a request by an accredited person for reaccreditation under this section, the Secretary shall approve or deny such request not later than 60 days after receipt of the request.

(iii) CRITERIA.—Not later than 120 days after the date of the enactment of this subparagraph, the Secretary shall establish and publish in the Federal Register criteria to reaccredit or deny reaccreditation to persons under this section. The reaccreditation of persons under this section shall specify the particular activities under subsection (a), and the devices, for which such persons are reaccredited.

(3) QUALIFICATIONS.—An accredited person shall, at a minimum, meet the following requirements:

(A) Such person may not be an employee of the Federal Government.

(B) Such person shall be an independent organization which is not owned or controlled by a manufacturer, supplier, or vendor of devices and which has no organizational, material, or financial affiliation with such a manufacturer, supplier, or vendor.

(C) Such person shall be a legally constituted entity permitted to conduct the activities for which it seeks accreditation.

(D) Such person shall not engage in the design, manufacture, promotion, or sale of devices.

(E) *The operations of such person shall be in accordance with generally accepted professional and ethical business practices.*

[(E)] (F) [The operations of such person shall be in accordance with generally accepted professional and ethical business practices and shall agree in writing that as a minimum it will—] Such person shall agree, at a minimum, to include in its request for accreditation a commitment to, at the time of accreditation, and at any time it is performing any review pursuant to this section—

(i) certify that reported information accurately reflects data reviewed;

(ii) limit work to that for which competence and capacity are available;

(iii) treat information received, records, reports, and recommendations as proprietary information;

(iv) promptly respond and attempt to resolve complaints regarding its activities for which it is accredited; and

(v) protect against the use, in carrying out subsection (a) with respect to a device, of any officer or employee of the person who has a financial conflict of interest regarding the device, and annually make available to the public disclosures of the extent to which the person, and the officers and employees of the person, have maintained compliance with requirements under this clause relating to financial conflicts of interest.

(4) SELECTION OF ACCREDITED PERSONS.—The Secretary shall provide each person who chooses to use an accredited person to receive a section 510(k) report a panel of at least two or more accredited persons from which the regulated person may select one for a specific regulatory function.

(5) COMPENSATION OF ACCREDITED PERSONS.—Compensation for an accredited person shall be determined by agreement between the accredited person and the person who engages the services of the accredited person, and shall be paid by the person who engages such services.

(c) DURATION.—The authority provided by this section terminates October 1, [2017] 2022.

SEC. 524. PRIORITY REVIEW TO ENCOURAGE TREATMENTS FOR TROPICAL DISEASES.

(a) DEFINITIONS.—In this section:

(1) PRIORITY REVIEW.—The term “priority review”, with respect to a human drug application as defined in section 735(1), means review and action by the Secretary on such application not later than 6 months after receipt by the Secretary of such application, as described in the Manual of Policies and Procedures of the Food and Drug Administration and goals identified in the letters described in section 101(c) of the Food and Drug Administration Amendments Act of 2007.

(2) PRIORITY REVIEW VOUCHER.—The term “priority review voucher” means a voucher issued by the Secretary to the sponsor of a tropical disease product application that entitles the holder of such voucher to priority review of a single human drug application submitted under section 505(b)(1) or section 351 of the Public Health Service Act after the date of approval of the tropical disease product application.

(3) TROPICAL DISEASE.—The term “tropical disease” means any of the following:

- (A) Tuberculosis.
- (B) Malaria.
- (C) Blinding trachoma.
- (D) Buruli Ulcer.
- (E) Cholera.
- (F) Dengue/dengue haemorrhagic fever.
- (G) Dracunculiasis (guinea-worm disease).
- (H) Fascioliasis.
- (I) Human African trypanosomiasis.
- (J) Leishmaniasis.
- (K) Leprosy.
- (L) Lymphatic filariasis.
- (M) Onchocerciasis.
- (N) Schistosomiasis.
- (O) Soil transmitted helminthiasis.
- (P) Yaws.
- (Q) Filovirus Diseases.
- (R) Zika Virus Disease.
- (S) Any other infectious disease for which there is no significant market in developed nations and that disproportionately affects poor and marginalized populations, designated by order of the Secretary.

(4) TROPICAL DISEASE PRODUCT APPLICATION.—The term “tropical disease product application” means an application that—

- (A) is a human drug application as defined in section 735(1)—

(i) for prevention or treatment of a tropical disease;
[and]

(ii) the Secretary deems eligible for priority review;
(iii) that contains reports of one or more new clinical investigations (other than bioavailability studies) that are essential to the approval of the application and conducted or sponsored by the sponsor of such application; and

(iv) that contains an attestation from the sponsor of the application that such reports were not submitted as part of an application for marketing approval or licensure by a regulatory authority in India, Brazil, Thailand, or any country that is a member of the Pharmaceutical Inspection Convention or the Pharmaceutical Inspection Cooperation Scheme prior to September 27, 2007.

(B) is approved after the date of the enactment of the Food and Drug Administration Amendments Act of 2007, by the Secretary for use in the prevention, detection, or treatment of a tropical disease; and

(C) is for a human drug, no active ingredient (including any ester or salt of the active ingredient) of which has been approved in any other application under section 505(b)(1) or section 351 of the Public Health Service Act.

(b) PRIORITY REVIEW VOUCHER.—

(1) IN GENERAL.—The Secretary shall award a priority review voucher to the sponsor of a tropical disease product application upon approval by the Secretary of such tropical disease product application.

(2) TRANSFERABILITY.—The sponsor of a tropical disease product that receives a priority review voucher under this section may transfer (including by sale) the entitlement to such voucher to a sponsor of a human drug for which an application under section 505(b)(1) or section 351 of the Public Health Service Act will be submitted after the date of the approval of the tropical disease product application. There is no limit on the number of times a priority review voucher may be transferred before such voucher is used.

(3) LIMITATION.—

(A) NO AWARD FOR PRIOR APPROVED APPLICATION.—A sponsor of a tropical disease product may not receive a priority review voucher under this section if the tropical disease product application was submitted to the Secretary prior to the date of the enactment of this section.

(B) ONE-YEAR WAITING PERIOD.—The Secretary shall issue a priority review voucher to the sponsor of a tropical disease product no earlier than the date that is 1 year after the date of the enactment of the Food and Drug Administration Amendments Act of 2007.

(4) NOTIFICATION.—The sponsor of a human drug application shall notify the Secretary not later than 90 days prior to submission of the human drug application that is the subject of a priority review voucher of an intent to submit the human drug application, including the date on which the sponsor intends to submit the application. Such notification shall be a legally

binding commitment to pay for the user fee to be assessed in accordance with this section.

(c) PRIORITY REVIEW USER FEE.—

(1) IN GENERAL.—The Secretary shall establish a user fee program under which a sponsor of a human drug application that is the subject of a priority review voucher shall pay to the Secretary a fee determined under paragraph (2). Such fee shall be in addition to any fee required to be submitted by the sponsor under chapter VII.

(2) FEE AMOUNT.—The amount of the priority review user fee shall be determined each fiscal year by the Secretary and based on the average cost incurred by the agency in the review of a human drug application subject to priority review in the previous fiscal year.

(3) ANNUAL FEE SETTING.—The Secretary shall establish, before the beginning of each fiscal year beginning after September 30, 2007, for that fiscal year, the amount of the priority review user fee.

(4) PAYMENT.—

(A) IN GENERAL.—The priority review user fee required by this subsection shall be due upon the submission of a human drug application under section 505(b)(1) or section 351 of the Public Health Service Act for which the priority review voucher is used.

(B) COMPLETE APPLICATION.—An application described under subparagraph (A) for which the sponsor requests the use of a priority review voucher shall be considered incomplete if the fee required by this subsection and all other applicable user fees are not paid in accordance with the Secretary’s procedures for paying such fees.

(C) NO WAIVERS, EXEMPTIONS, REDUCTIONS, OR REFUNDS.—The Secretary may not grant a waiver, exemption, reduction, or refund of any fees due and payable under this section.

(5) OFFSETTING COLLECTIONS.—Fees collected pursuant to this subsection for any fiscal year—

(A) shall be deposited and credited as offsetting collections to the account providing appropriations to the Food and Drug Administration; and

(B) shall not be collected for any fiscal year except to the extent provided in advance in appropriation Acts.

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SUBCHAPTER E—GENERAL PROVISIONS RELATING TO DRUGS AND DEVICES

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SEC. 566. CRITICAL PATH PUBLIC-PRIVATE PARTNERSHIPS.

(a) ESTABLISHMENT.—The Secretary, acting through the Commissioner of Food and Drugs, may enter into collaborative agreements, to be known as Critical Path Public-Private Partnerships, with one or more eligible entities to implement the Critical Path Initiative of the Food and Drug Administration by developing innovative, collaborative projects in research, education, and outreach for the purpose of fostering medical product innovation, enabling the accelera-

tion of medical product development, manufacturing, and translational therapeutics, and enhancing medical product safety.

(b) **ELIGIBLE ENTITY.**—In this section, the term “eligible entity” means an entity that meets each of the following:

(1) The entity is—

(A) an institution of higher education (as such term is defined in section 101 of the Higher Education Act of 1965) or a consortium of such institutions; or

(B) an organization described in section 501(c)(3) of the Internal Revenue Code of 1986 and exempt from tax under section 501(a) of such Code.

(2) The entity has experienced personnel and clinical and other technical expertise in the biomedical sciences, which may include graduate training programs in areas relevant to priorities of the Critical Path Initiative.

(3) The entity demonstrates to the Secretary’s satisfaction that the entity is capable of—

(A) developing and critically evaluating tools, methods, and processes—

(i) to increase efficiency, predictability, and productivity of medical product development; and

(ii) to more accurately identify the benefits and risks of new and existing medical products;

(B) establishing partnerships, consortia, and collaborations with health care practitioners and other providers of health care goods or services; pharmacists; pharmacy benefit managers and purchasers; health maintenance organizations and other managed health care organizations; health care insurers; government agencies; patients and consumers; manufacturers of prescription drugs, biological products, diagnostic technologies, and devices; and academic scientists; and

(C) securing funding for the projects of a Critical Path Public-Private Partnership from Federal and nonfederal governmental sources, foundations, and private individuals.

(c) **FUNDING.**—The Secretary may not enter into a collaborative agreement under subsection (a) unless the eligible entity involved provides an assurance that the entity will not accept funding for a Critical Path Public-Private Partnership project from any organization that manufactures or distributes products regulated by the Food and Drug Administration unless the entity provides assurances in its agreement with the Food and Drug Administration that the results of the Critical Path Public-Private Partnership project will not be influenced by any source of funding.

(d) **ANNUAL REPORT.**—Not later than 18 months after the date of the enactment of this section, and annually thereafter, the Secretary, in collaboration with the parties to each Critical Path Public-Private Partnership, shall submit a report to the Committee on Health, Education, Labor, and Pensions of the Senate and the Committee on Energy and Commerce of the House of Representatives—

(1) reviewing the operations and activities of the Partnerships in the previous year; and

(2) addressing such other issues relating to this section as the Secretary determines to be appropriate.

(e) DEFINITION.—In this section, the term “medical product” includes a drug, a biological product as defined in section 351 of the Public Health Service Act, a device, and any combination of such products.

(f) AUTHORIZATION OF APPROPRIATIONS.—To carry out this section, there is authorized to be appropriated \$6,000,000 for each of fiscal years **[2013 through 2017]** *2018 through 2022*.

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CHAPTER VII—GENERAL AUTHORITY

SUBCHAPTER A—GENERAL ADMINISTRATIVE PROVISIONS

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FACTORY INSPECTION

SEC. 704. (a)(1) For purposes of enforcement of this Act, officers or employees duly designated by the Secretary, upon presenting appropriate credentials and a written notice to the owner, operator, or agent in charge, are authorized (A) to enter, at reasonable times, any factory, warehouse, or establishment in which food, drugs, devices, tobacco products, or cosmetics are manufactured, processed, packed, or held, for introduction into interstate commerce or after such introduction, or to enter any vehicle, being used to transport or hold such food, drugs, devices, tobacco products, or cosmetics in interstate commerce; and (B) to inspect, at reasonable times and within reasonable limits and in a reasonable manner, such factory, warehouse, establishment, or vehicle and all pertinent equipment, finished and unfinished materials, containers, and labeling therein. In the case of any person (excluding farms and restaurants) who manufactures, processes, packs, transports, distributes, holds, or imports foods, the inspection shall extend to all records and other information described in section 414, when the standard for records inspection under paragraph (1) or (2) of section 414(a) applies, subject to the limitations established in section 414(d). In the case of any factory, warehouse, establishment, or consulting laboratory in which prescription drugs, nonprescription drugs intended for human use, restricted devices, or tobacco products are manufactured, processed, packed, or held, inspection shall extend to all things therein (including records, files, papers, processes, controls, and facilities) bearing on whether prescription drugs, nonprescription drugs intended for human use, restricted devices, or tobacco products which are adulterated or misbranded within the meaning of this Act, or which may not be manufactured, introduced into interstate commerce, or sold, or offered for sale by reason of any provision of this Act, have been or are being manufactured, processed, packed, transported, or held in any such place, or otherwise bearing on violation of this Act. No inspection authorized by the preceding sentence or by paragraph (3) shall extend to financial data, sales data other than shipment data, pricing data, personnel data (other than data as to qualifications of technical and professional personnel performing functions subject to this Act), and research data (other than data relating to new drugs, antibiotic

drugs, devices, and tobacco products and subject to reporting and inspection under regulations lawfully issued pursuant to section 505 (i) or (k), section 519, section 520(g), or chapter IX and data relating to other drugs, devices, or tobacco products which in the case of a new drug would be subject to reporting or inspection under lawful regulations issued pursuant to section 505(j)). A separate notice shall be given for each such inspection, but a notice shall not be required for each entry made during the period covered by the inspection. Each such inspection shall be commenced and completed with reasonable promptness.

(2) The provisions of the third sentence of paragraph (1) shall not apply to—

(A) pharmacies which maintain establishments in conformance with any applicable local laws regulating the practice of pharmacy and medicine and which are regularly engaged in dispensing prescription drugs or devices, upon prescriptions of practitioners licensed to administer such drugs or devices to patients under the care of such practitioners in the course of their professional practice, and which do not, either through a subsidiary or otherwise, manufacture, prepare, propagate, compound, or process drugs or devices for sale other than in the regular course of their business of dispensing or selling drugs or devices at retail;

(B) practitioners licensed by law to prescribe or administer drugs, or prescribe or use devices, as the case may be, and who manufacture, prepare, propagate, compound, or process drugs, or manufacture or process devices solely for use in the course of their professional practice;

(C) persons who manufacture, prepare, propagate, compound, or process drugs, or manufacture or process devices solely for use in research, teaching, or chemical analysis and not for sale;

(D) such other classes of persons as the Secretary may by regulation exempt from the application of this section upon a finding that inspection as applied to such classes of persons in accordance with this section is not necessary for the protection of the public health.

(3) An officer or employee making an inspection under paragraph (1) for purposes of enforcing the requirements of section 412 applicable to infant formulas shall be permitted, at all reasonable times, to have access to and to copy and verify any records—

(A) bearing on whether the infant formula manufactured or held in the facility inspected meets the requirements of section 412, or

(B) required to be maintained under section 412.

(4)(A) Any records or other information that the Secretary may inspect under this section from a person that owns or operates an establishment that is engaged in the manufacture, preparation, propagation, compounding, or processing of a drug shall, upon the request of the Secretary, be provided to the Secretary by such person, in advance of or in lieu of an inspection, within a reasonable timeframe, within reasonable limits, and in a reasonable manner, and in either electronic or physical form, at the expense of such person. The Secretary's request shall include a sufficient description of the records requested.

(B) Upon receipt of the records requested under subparagraph (A), the Secretary shall provide to the person confirmation of receipt.

(C) Nothing in this paragraph supplants the authority of the Secretary to conduct inspections otherwise permitted under this Act in order to ensure compliance with this Act.

(b) Upon completion of any such inspection of a factory, warehouse, consulting laboratory, or other establishment, and prior to leaving the premises, the officer or employee making the inspection shall give to the owner, operator, or agent in charge a report in writing setting forth any conditions or practices observed by him which, in his judgment, indicate that any food, drug, device, tobacco product, or cosmetic in such establishment (1) consists in whole or in part of any filthy, putrid, or decomposed substance, or (2) has been prepared, packed, or held under insanitary conditions whereby it may have become contaminated with filth, or whereby it may have been rendered injurious to health. A copy of such report shall be sent promptly to the Secretary.

(c) If the officer or employee making any such inspection of a factory, warehouse, or other establishment has obtained any sample in the course of the inspection, upon completion of the inspection and prior to leaving the premises he shall give to the owner, operator, or agent in charge a receipt describing the samples obtained.

(d) Whenever in the course of any such inspection of a factory or other establishment where food is manufactured, processed, or packed, the officer or employee making the inspection obtains a sample of any such food, and an analysis is made of such sample for the purpose of ascertaining whether such food consists in whole or in part of any filthy, putrid, or decomposed substance, or is otherwise unfit for food, a copy of the results of such analysis shall be furnished promptly to the owner, operator, or agent in charge.

(e) Every person required under section 519 or 520(g) to maintain records and every person who is in charge or custody of such records shall, upon request of an officer or employee designated by the Secretary, permit such officer or employee at all reasonable times to have access to, and to copy and verify, such records.

(f)(1) An accredited person described in paragraph (3) shall maintain records documenting the training qualifications of the person and the employees of the person, the procedures used by the person for handling confidential information, the compensation arrangements made by the person, and the procedures used by the person to identify and avoid conflicts of interest. Upon the request of an officer or employee designated by the Secretary, the person shall permit the officer or employee, at all reasonable times, to have access to, to copy, and to verify, the records.

(2) Within 15 days after the receipt of a written request from the Secretary to an accredited person described in paragraph (3) for copies of records described in paragraph (1), the person shall produce the copies of the records at the place designated by the Secretary.

(3) For purposes of paragraphs (1) and (2), an accredited person described in this paragraph is a person who—

- (A) is accredited under subsection (g); or
- (B) is accredited under section 523.

(g)(1) The Secretary shall, subject to the provisions of this subsection, accredit persons for the purpose of conducting inspections of establishments that manufacture, prepare, propagate, compound, or process class II or class III devices, which inspections are required under section 510(h) or are inspections of such establishments required to register under section 510(i). The owner or operator of such an establishment that is eligible under paragraph (6) may, from the list published under paragraph (4), select an accredited person to conduct such inspections.

(2) The Secretary shall publish in the Federal Register criteria to accredit or deny accreditation to persons who request to perform the duties specified in paragraph (1). Thereafter, the Secretary shall inform those requesting accreditation, within 60 days after the receipt of such request, whether the request for accreditation is adequate for review, and the Secretary shall promptly act on the request for accreditation. Any resulting accreditation shall state that such person is accredited to conduct inspections at device establishments identified in paragraph (1). The accreditation of such person shall specify the particular activities under this subsection for which such person is accredited.

(3) An accredited person shall, at a minimum, meet the following requirements:

(A) Such person may not be an employee of the Federal Government.

(B) Such person shall be an independent organization which is not owned or controlled by a manufacturer, supplier, or vendor of articles regulated under this Act and which has no organizational, material, or financial affiliation (including a consultative affiliation) with such a manufacturer, supplier, or vendor.

(C) Such person shall be a legally constituted entity permitted to conduct the activities for which it seeks accreditation.

(D) Such person shall not engage in the design, manufacture, promotion, or sale of articles regulated under this Act.

(E) The operations of such person shall be in accordance with generally accepted professional and ethical business practices, and such person shall agree in writing that at a minimum the person will—

(i) certify that reported information accurately reflects data reviewed, inspection observations made, other matters that relate to or may influence compliance with this Act, and recommendations made during an inspection or at an inspection's closing meeting;

(ii) limit work to that for which competence and capacity are available;

(iii) treat information received, records, reports, and recommendations as confidential commercial or financial information or trade secret information, except such information may be made available to the Secretary;

(iv) promptly respond and attempt to resolve complaints regarding its activities for which it is accredited; and

(v) protect against the use, in carrying out paragraph (1), of any officer or employee of the accredited person who has a financial conflict of interest regarding any product regulated under this Act, and annually make available to

the public disclosures of the extent to which the accredited person, and the officers and employees of the person, have maintained compliance with requirements under this clause relating to financial conflicts of interest.

(F) Such person shall notify the Secretary of any withdrawal, suspension, restriction, or expiration of certificate of conformance with the quality systems standard referred to in paragraph (7) for any device establishment that such person inspects under this subsection not later than 30 days after such withdrawal, suspension, restriction, or expiration.

(G) Such person may conduct audits to establish conformance with the quality systems standard referred to in paragraph (7).

(4) The Secretary shall publish on the Internet site of the Food and Drug Administration a list of persons who are accredited under paragraph (2). Such list shall be updated to ensure that the identity of each accredited person, and the particular activities for which the person is accredited, is known to the public. The updating of such list shall be no later than one month after the accreditation of a person under this subsection or the suspension or withdrawal of accreditation, or the modification of the particular activities for which the person is accredited.

(5)(A) To ensure that persons accredited under this subsection continue to meet the standards of accreditation, the Secretary shall (i) audit the performance of such persons on a periodic basis through the review of inspection reports and inspections by persons designated by the Secretary to evaluate the compliance status of a device establishment and the performance of accredited persons, and (ii) take such additional measures as the Secretary determines to be appropriate.

(B) The Secretary may withdraw accreditation of any person accredited under paragraph (2), after providing notice and an opportunity for an informal hearing, when such person is substantially not in compliance with the standards of accreditation, poses a threat to public health, fails to act in a manner that is consistent with the purposes of this subsection, or where the Secretary determines that there is a financial conflict of interest in the relationship between the accredited person and the owner or operator of a device establishment that the accredited person has inspected under this subsection. The Secretary may suspend the accreditation of such person during the pendency of the process under the preceding sentence.

(6)(A) Subject to subparagraphs (B) and (C), a device establishment is eligible for inspection by persons accredited under paragraph (2) if the following conditions are met:

(i) The Secretary classified the results of the most recent inspection of the establishment as “no action indicated” or “voluntary action indicated”.

(ii) With respect to inspections of the establishment to be conducted by an accredited person, the owner or operator of the establishment submits to the Secretary a notice that—

(I) provides the date of the last inspection of the establishment by the Secretary and the classification of that inspection;

- (II) states the intention of the owner or operator to use an accredited person to conduct inspections of the establishment;
- (III) identifies the particular accredited person the owner or operator intends to select to conduct such inspections; and
- (IV) includes a certification that, with respect to the devices that are manufactured, prepared, propagated, compounded, or processed in the establishment—
- (aa) at least 1 of such devices is marketed in the United States; and
 - (bb) at least 1 of such devices is marketed, or is intended to be marketed, in 1 or more foreign countries, 1 of which countries certifies, accredits, or otherwise recognizes the person accredited under paragraph (2) and identified under subclause (III) as a person authorized to conduct inspections of device establishments.
- (B)(i) Except with respect to the requirement of subparagraph (A)(i), a device establishment is deemed to have clearance to participate in the program and to use the accredited person identified in the notice under subparagraph (A)(ii) for inspections of the establishment unless the Secretary, not later than 30 days after receiving such notice, issues a response that—
- (I) denies clearance to participate as provided under subparagraph (C); or
 - (II) makes a request under clause (ii).
- (ii) The Secretary may request from the owner or operator of a device establishment in response to the notice under subparagraph (A)(ii) with respect to the establishment, or from the particular accredited person identified in such notice—
- (I) compliance data for the establishment in accordance with clause (iii)(I); or
 - (II) information concerning the relationship between the owner or operator of the establishment and the accredited person identified in such notice in accordance with clause (iii)(II).
- The owner or operator of the establishment, or such accredited person, as the case may be, shall respond to such a request not later than 60 days after receiving such request.
- (iii)(I) The compliance data to be submitted by the owner or operator of a device establishment in response to a request under clause (ii)(I) are data describing whether the quality controls of the establishment have been sufficient for ensuring consistent compliance with current good manufacturing practice within the meaning of section 501(h) and with other applicable provisions of this Act. Such data shall include complete reports of inspectional findings regarding good manufacturing practice or other quality control audits that, during the preceding 2-year period, were conducted at the establishment by persons other than the owner or operator of the establishment, together with all other compliance data the Secretary deems necessary. Data under the preceding sentence shall demonstrate to the Secretary whether the establishment has facilitated consistent compliance by promptly correcting any compliance problems identified in such inspections.

(II) A request to an accredited person under clause (ii)(II) may not seek any information that is not required to be maintained by such person in records under subsection (f)(1).

(iv) A device establishment is deemed to have clearance to participate in the program and to use the accredited person identified in the notice under subparagraph (A)(ii) for inspections of the establishment unless the Secretary, not later than 60 days after receiving the information requested under clause (ii), issues a response that denies clearance to participate as provided under subparagraph (C).

(C)(i) The Secretary may deny clearance to a device establishment if the Secretary has evidence that the certification under subparagraph (A)(ii)(IV) is untrue and the Secretary provides to the owner or operator of the establishment a statement summarizing such evidence.

(ii) The Secretary may deny clearance to a device establishment if the Secretary determines that the establishment has failed to demonstrate consistent compliance for purposes of subparagraph (B)(iii)(I) and the Secretary provides to the owner or operator of the establishment a statement of the reasons for such determination.

(iii)(I) The Secretary may reject the selection of the accredited person identified in the notice under subparagraph (A)(ii) if the Secretary provides to the owner or operator of the establishment a statement of the reasons for such rejection. Reasons for the rejection may include that the establishment or the accredited person, as the case may be, has failed to fully respond to the request, or that the Secretary has concerns regarding the relationship between the establishment and such accredited person.

(II) If the Secretary rejects the selection of an accredited person by the owner or operator of a device establishment, the owner or operator may make an additional selection of an accredited person by submitting to the Secretary a notice that identifies the additional selection. Clauses (i) and (ii) of subparagraph (B), and subclause (I) of this clause, apply to the selection of an accredited person through a notice under the preceding sentence in the same manner and to the same extent as such provisions apply to a selection of an accredited person through a notice under subparagraph (A)(ii).

(iv) In the case of a device establishment that is denied clearance under clause (i) or (ii) or with respect to which the selection of the accredited person is rejected under clause (iii), the Secretary shall designate a person to review the statement of reasons, or statement summarizing such evidence, as the case may be, of the Secretary under such clause if, during the 30-day period beginning on the date on which the owner or operator of the establishment receives such statement, the owner or operator requests the review. The review shall commence not later than 30 days after the owner or operator requests the review, unless the Secretary and the owner or operator otherwise agree.

(7)(A) Persons accredited under paragraph (2) to conduct inspections shall record in writing their inspection observations and shall present the observations to the device establishment's designated representative and describe each observation. Additionally, such accredited person shall prepare an inspection report in a form and manner designated by the Secretary to conduct inspections, taking

into consideration the goals of international harmonization of quality systems standards. Any official classification of the inspection shall be determined by the Secretary.

(B) At a minimum, an inspection report under subparagraph (A) shall identify the persons responsible for good manufacturing practice compliance at the inspected device establishment, the dates of the inspection, the scope of the inspection, and shall describe in detail each observation identified by the accredited person, identify other matters that relate to or may influence compliance with this Act, and describe any recommendations during the inspection or at the inspection's closing meeting.

(C) An inspection report under subparagraph (A) shall be sent to the Secretary and to the designated representative of the inspected device establishment at the same time, but under no circumstances later than three weeks after the last day of the inspection. The report to the Secretary shall be accompanied by all written inspection observations previously provided to the designated representative of the establishment.

(D) Any statement or representation made by an employee or agent of a device establishment to a person accredited under paragraph (2) to conduct inspections shall be subject to section 1001 of title 18, United States Code.

(E) If at any time during an inspection by an accredited person the accredited person discovers a condition that could cause or contribute to an unreasonable risk to the public health, the accredited person shall immediately notify the Secretary of the identification of the device establishment subject to inspection and such condition.

(F) For the purpose of setting risk-based inspectional priorities, the Secretary shall accept voluntary submissions of reports of audits assessing conformance with appropriate quality systems standards set by the International Organization for Standardization (ISO) and identified by the Secretary in public notice. If the owner or operator of an establishment elects to submit audit reports under this subparagraph, the owner or operator shall submit all such audit reports with respect to the establishment during the preceding 2-year periods.

(8) Compensation for an accredited person shall be determined by agreement between the accredited person and the person who engages the services of the accredited person, and shall be paid by the person who engages such services.

(9) Nothing in this subsection affects the authority of the Secretary to inspect any device establishment pursuant to this Act.

(10)(A) For fiscal year 2005 and each subsequent fiscal year, no device establishment may be inspected during the fiscal year involved by a person accredited under paragraph (2) if—

(i) of the amounts appropriated for salaries and expenses of the Food and Drug Administration for the preceding fiscal year (referred to in this subparagraph as the "first prior fiscal year"), the amount obligated by the Secretary for inspections of device establishments by the Secretary was less than the adjusted base amount applicable to such first prior fiscal year; and

(ii) of the amounts appropriated for salaries and expenses of the Food and Drug Administration for the fiscal year preceding

the first prior fiscal year (referred to in this subparagraph as the “second prior fiscal year”), the amount obligated by the Secretary for inspections of device establishments by the Secretary was less than the adjusted base amount applicable to such second prior fiscal year.

(B)(i) Subject to clause (ii), the Comptroller General of the United States shall determine the amount that was obligated by the Secretary for fiscal year 2002 for compliance activities of the Food and Drug Administration with respect to devices (referred to in this subparagraph as the “compliance budget”), and of such amount, the amount that was obligated for inspections by the Secretary of device establishments (referred to in this subparagraph as the “inspection budget”).

(ii) For purposes of determinations under clause (i), the Comptroller General shall not include in the compliance budget or the inspection budget any amounts obligated for inspections of device establishments conducted as part of the process of reviewing applications under section 515.

(iii) Not later than March 31, 2003, the Comptroller General shall complete the determinations required in this subparagraph and submit to the Secretary and the Congress a report describing the findings made through such determinations.

(C) For purposes of this paragraph:

(i) The term “base amount” means the inspection budget determined under subparagraph (B) for fiscal year 2002.

(ii) The term “adjusted base amount”, in the case of applicability to fiscal year 2003, means an amount equal to the base amount increased by 5 percent.

(iii) The term “adjusted base amount”, with respect to applicability to fiscal year 2004 or any subsequent fiscal year, means the adjusted base amount applicable to the preceding year increased by 5 percent.

(11) The authority provided by this subsection terminates on **[October 1, 2017]** *October 1, 2022*.

(12) No later than four years after the enactment of this subsection the Comptroller General shall report to the Committee on Energy and Commerce of the House of Representatives and the Committee on Health, Education, Labor and Pensions of the Senate—

(A) the number of inspections conducted by accredited persons pursuant to this subsection and the number of inspections conducted by Federal employees pursuant to section 510(h) and of device establishments required to register under section 510(i);

(B) the number of persons who sought accreditation under this subsection, as well as the number of persons who were accredited under this subsection;

(C) the reasons why persons who sought accreditation, but were denied accreditation, were denied;

(D) the number of audits conducted by the Secretary of accredited persons, the quality of inspections conducted by accredited persons, whether accredited persons are meeting their obligations under this Act, and whether the number of audits conducted is sufficient to permit these assessments;

(E) whether this subsection is achieving the goal of ensuring more information about device establishment compliance is being presented to the Secretary, and whether that information is of a quality consistent with information obtained by the Secretary pursuant to inspections conducted by Federal employees;

(F) whether this subsection is advancing efforts to allow device establishments to rely upon third-party inspections for purposes of compliance with the laws of foreign governments; and

(G) whether the Congress should continue, modify, or terminate the program under this subsection.

(13) The Secretary shall include in the annual report required under section 1003(g) the names of all accredited persons and the particular activities under this subsection for which each such person is accredited and the name of each accredited person whose accreditation has been withdrawn during the year.

(14) Notwithstanding any provision of this subsection, this subsection does not have any legal effect on any agreement described in section 803(b) between the Secretary and a foreign country.

(15) Notwithstanding any other provision of this subsection, for purposes of conducting inspections of establishments that manufacture, prepare, propagate, compound, or process devices except types of devices licensed under section 351 of the Public Health Service Act, which inspections are required under section 510(h) or are inspections of such establishments required to register pursuant to section 510(i), the Secretary may recognize auditing organizations that are recognized by organizations established by governments to facilitate international harmonization. Nothing in this paragraph affects the authority of the Secretary to inspect any device establishment pursuant to this Act. Nothing in this paragraph affects the authority of the Secretary to determine the official classification of an inspection.

(h)(1) In the case of inspections other than for-cause inspections, the Secretary shall review processes and standards applicable to inspections of domestic and foreign device establishments in effect as of the date of the enactment of this subsection, and update such processes and standards through the adoption of uniform processes and standards applicable to such inspections. Such processes and standards shall provide for—

(A) exceptions to such processes and standards, as appropriate;

(B) announcing the inspection of the establishment within a reasonable time before such inspection occurs, including by providing to the owner, operator, or agent in charge of the establishment a notification regarding the type and nature of the inspection;

(C) a reasonable estimate of the timeframe for the inspection, an opportunity for advance communications between the officers or employees carrying out the inspection under subsection (a)(1) and the owner, operator, or agent in charge of the establishment concerning appropriate working hours during the inspection, and, to the extent feasible, advance notice of some records that will be requested in order to expedite the inspection; and

(D) regular communications during the inspection with the owner, operator, or agent in charge of the establishment regarding inspection status, which may be recorded by either party with advance notice and mutual consent.

(2)(A) The Secretary shall, with respect to a request described in subparagraph (B), provide nonbinding feedback with respect to such request not later than 45 days after the Secretary receives such request.

(B) A request described in this subparagraph is a request for feedback—

(i) that is made by the owner, operator, or agent in charge of such establishment in a timely manner; and

(ii) with respect to actions proposed to be taken by a device establishment in a response to a report received by such establishment pursuant to subsection (b) that involve a public health priority, that implicate systemic or major actions, or relate to emerging safety issues (as determined by the Secretary).

(3) Nothing in this subsection limits the authority of the Secretary to conduct inspections otherwise permitted under this Act in order to ensure compliance with this Act.

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SUBCHAPTER C—FEES

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PART 2—FEES RELATING TO DRUGS

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SEC. 736. AUTHORITY TO ASSESS AND USE DRUG FEES.

(a) TYPES OF FEES.—Beginning in [fiscal year 2013] *fiscal year 2018*, the Secretary shall assess and collect fees in accordance with this section as follows:

(1) HUMAN DRUG APPLICATION [AND SUPPLEMENT] FEE.—

(A) IN GENERAL.—Each person that submits, on or after September 1, 1992, a human drug application [or a supplement] shall be subject to a fee as follows:

(i) A fee established under subsection [(c)(4)] (c)(5) for a human drug application for which clinical data (other than bioavailability or bioequivalence studies) with respect to safety or effectiveness are required for approval.

(ii) [A fee established under subsection (c)(4) for a human drug application for which clinical data with respect to safety or effectiveness are not required or a supplement for which clinical data (other than bioavailability or bioequivalence studies) with respect to safety or effectiveness are required.] *A fee established under subsection (c)(5) for a human drug application for which clinical data (other than bioavailability or bioequivalence studies) with respect to safety or effectiveness are not required for approval. Such fee shall be half of the amount of the fee established under clause (i).*

(B) PAYMENT.—The fee required by subparagraph (A) shall be due upon submission of the application [or supplement].

(C) EXCEPTION FOR PREVIOUSLY FILED APPLICATION [OR SUPPLEMENT].—If a human drug application [or supplement] was submitted by a person that paid the fee for such application [or supplement], was accepted for filing, and was not approved or was withdrawn (without a waiver), the submission of a human drug application [or a supplement] for the same product by the same person (or the person's licensee, assignee, or successor) shall not be subject to a fee under subparagraph (A).

(D) REFUND OF FEE IF APPLICATION REFUSED FOR FILING OR WITHDRAWN BEFORE FILING.—The Secretary shall refund 75 percent of the fee paid under subparagraph (B) for any application [or supplement] which is refused for filing or withdrawn without a waiver before filing.

(E) FEES FOR APPLICATIONS PREVIOUSLY REFUSED FOR FILING OR WITHDRAWN BEFORE FILING.—A human drug application [or supplement] that was submitted but was refused for filing, or was withdrawn before being accepted or refused for filing, shall be subject to the full fee under subparagraph (A) upon being resubmitted or filed over protest, unless the fee is waived or reduced under subsection (d).

(F) EXCEPTION FOR DESIGNATED ORPHAN DRUG [OR INDICATION].—A human drug application for a prescription drug product that has been designated as a drug for a rare disease or condition pursuant to section 526 shall not be subject to a fee under subparagraph (A), unless the human drug application includes an indication for other than a rare disease or condition. [A supplement proposing to include a new indication for a rare disease or condition in a human drug application shall not be subject to a fee under subparagraph (A), if the drug has been designated pursuant to section 526 as a drug for a rare disease or condition with regard to the indication proposed in such supplement.]

(G) REFUND OF FEE IF APPLICATION WITHDRAWN.—If an application [or supplement] is withdrawn after the application [or supplement] was filed, the Secretary may refund the fee or a portion of the fee if no substantial work was performed on the application [or supplement] after the application [or supplement] was filed. The Secretary shall have the sole discretion to refund a fee or a portion of the fee under this subparagraph. A determination by the Secretary concerning a refund under this paragraph shall not be reviewable.

[(2) PRESCRIPTION DRUG ESTABLISHMENT FEE.—

[(A) IN GENERAL.—Except as provided in subparagraphs (B) and (C), each person that—

[(i) is named as the applicant in a human drug application; and

[(i) after September 1, 1992, had pending before the Secretary a human drug application or supplement, shall be assessed an annual fee established under subsection (c)(4) for each prescription drug establishment listed in its approved human drug application as an establishment that manufactures the prescription drug product named in the application. The annual establishment fee shall be assessed in each fiscal year in which the prescription drug product named in the application is assessed a fee under paragraph (3) unless the prescription drug establishment listed in the application does not engage in the manufacture of the prescription drug product during the fiscal year. The establishment fee shall be due on the later of the first business day on or after October 1 of each fiscal year or the first business day after the enactment of an appropriations Act providing for the collection and obligation of fees for such fiscal year under this section. Each such establishment shall be assessed only one fee per establishment, notwithstanding the number of prescription drug products manufactured at the establishment. In the event an establishment is listed in a human drug application by more than one applicant, the establishment fee for the fiscal year shall be divided equally and assessed among the applicants whose prescription drug products are manufactured by the establishment during the fiscal year and assessed product fees under paragraph (3).

[(B) EXCEPTION.—If, during the fiscal year, an applicant initiates or causes to be initiated the manufacture of a prescription drug product at an establishment listed in its human drug application—

[(i) that did not manufacture the product in the previous fiscal year; and

[(ii) for which the full establishment fee has been assessed in the fiscal year at a time before manufacture of the prescription drug product was begun;

the applicant will not be assessed a share of the establishment fee for the fiscal year in which the manufacture of the product began.

[(C) SPECIAL RULES FOR POSITRON EMISSION TOMOGRAPHY DRUGS.—

[(i) IN GENERAL.—Except as provided in clause (ii), each person who is named as the applicant in an approved human drug application for a positron emission tomography drug shall be subject under subparagraph (A) to one-sixth of an annual establishment fee with respect to each such establishment identified in the application as producing positron emission tomography drugs under the approved application.

[(ii) EXCEPTION FROM ANNUAL ESTABLISHMENT FEE.—Each person who is named as the applicant in an application described in clause (i) shall not be assessed an annual establishment fee for a fiscal year if the person certifies to the Secretary, at a time speci-

fied by the Secretary and using procedures specified by the Secretary, that—

[(I) the person is a not-for-profit medical center that has only 1 establishment for the production of positron emission tomography drugs; and

[(II) at least 95 percent of the total number of doses of each positron emission tomography drug produced by such establishment during such fiscal year will be used within the medical center.

[(iii) DEFINITION.—For purposes of this subparagraph, the term “positron emission tomography drug” has the meaning given to the term “compounded positron emission tomography drug” in section 201(ii), except that paragraph (1)(B) of such section shall not apply.

[(3)] (2) PRESCRIPTION DRUG [PRODUCT FEE] PROGRAM FEE.—

(A) IN GENERAL.—[Except as provided in subparagraph (B), each person who is named as the applicant in a human drug application, and who, after September 1, 1992, had pending before the Secretary a human drug application or supplement, shall pay for each such prescription drug product the annual fee established under subsection (c)(4).] *Except as provided in subparagraphs (B) and (C), each person who is named as the applicant in a human drug application, and who, after September 1, 1992, had pending before the Secretary a human drug application or supplement, shall pay the annual prescription drug program fee established for a fiscal year under subsection (c)(5) for each prescription drug product that is identified in such a human drug application approved as of October 1 of such fiscal year. Such fee shall be due on the later of the first business day on or after October 1 of each fiscal year or the first business day after the enactment of an appropriations Act providing for the collection and obligation of fees for such fiscal year under this section. Such fee shall be paid only once for each product for a fiscal year in which the fee is payable.*

(B) EXCEPTION FOR CERTAIN PRESCRIPTION DRUG PRODUCTS.—[A prescription drug product shall not be assessed a fee] *A prescription drug program fee shall not be assessed for a prescription drug product under subparagraph (A) if such product is—*

(i) identified on the list compiled under section 505(j)(7) with a potency described in terms of per 100 mL;

(ii) the same product as another product that—

(I) was approved under an application filed under section 505(b) or 505(j); and

(II) is not in the list of discontinued products compiled under section 505(j)(7);

(iii) the same product as another product that was approved under an abbreviated application filed under section 507 (as in effect on the day before the date of

enactment of the Food and Drug Administration Modernization Act of 1997); or

(iv) the same product as another product that was approved under an abbreviated new drug application pursuant to regulations in effect prior to the implementation of the Drug Price Competition and Patent Term Restoration Act of 1984.

(C) LIMITATION.—A person who is named as the applicant in an approved human drug application shall not be assessed more than 5 prescription drug program fees for a fiscal year for prescription drug products identified in such approved human drug application.

[(b) FEE REVENUE AMOUNTS.—

[(1) IN GENERAL.—For each of the fiscal years 2013 through 2017, fees under subsection (a) shall, except as provided in subsections (c), (d), (f), and (g), be established to generate a total revenue amount under such subsection that is equal to the sum of—

[(A) \$693,099,000;

[(B) the dollar amount equal to the inflation adjustment for fiscal year 2013 (as determined under paragraph (3)(A)); and

[(C) the dollar amount equal to the workload adjustment for fiscal year 2013 (as determined under paragraph (3)(B)).

[(2) TYPES OF FEES.—Of the total revenue amount determined for a fiscal year under paragraph (1)—

[(A) one-third shall be derived from fees under subsection (a)(1) (relating to human drug applications and supplements);

[(B) one-third shall be derived from fees under subsection (a)(2) (relating to prescription drug establishments); and

[(C) one-third shall be derived from fees under subsection (a)(3) (relating to prescription drug products).

[(3) FISCAL YEAR 2013 INFLATION AND WORKLOAD ADJUSTMENTS.—For purposes of paragraph (1), the dollar amount of the inflation and workload adjustments for fiscal year 2013 shall be determined as follows:

[(A) INFLATION ADJUSTMENT.—The inflation adjustment for fiscal year 2013 shall be the sum of—

[(i) \$652,709,000 multiplied by the result of an inflation adjustment calculation determined using the methodology described in subsection (c)(1)(B); and

[(ii) \$652,709,000 multiplied by the result of an inflation adjustment calculation determined using the methodology described in subsection (c)(1)(C).

[(B) WORKLOAD ADJUSTMENT.—Subject to subparagraph (C), the workload adjustment for fiscal 2013 shall be—

[(i) \$652,709,000 plus the amount of the inflation adjustment calculated under subparagraph (A); multiplied by

[(ii) the amount (if any) by which a percentage workload adjustment for fiscal year 2013, as determined using the methodology described in subsection

(c)(2)(A), would exceed the percentage workload adjustment (as so determined) for fiscal year 2012, if both such adjustment percentages were calculated using the 5-year base period consisting of fiscal years 2003 through 2007.

[(C) LIMITATION.—Under no circumstances shall the adjustment under subparagraph (B) result in fee revenues for fiscal year 2013 that are less than the sum of the amount under paragraph (1)(A) and the amount under paragraph (1)(B).

[(c) ADJUSTMENTS.—

[(1) INFLATION ADJUSTMENT.—For fiscal year 2014 and subsequent fiscal years, the revenues established in subsection (b) shall be adjusted by the Secretary by notice, published in the Federal Register, for a fiscal year by the amount equal to the sum of—

[(A) one;

[(B) the average annual percent change in the cost, per full-time equivalent position of the Food and Drug Administration, of all personnel compensation and benefits paid with respect to such positions for the first 3 years of the preceding 4 fiscal years, multiplied by the proportion of personnel compensation and benefits costs to total costs of the process for the review of human drug applications (as defined in section 735(6)) for the first 3 years of the preceding 4 fiscal years, and

[(C) the average annual percent change that occurred in the Consumer Price Index for urban consumers (Washington-Baltimore, DC-MD-VA-WV; Not Seasonally Adjusted; All items; Annual Index) for the first 3 years of the preceding 4 years of available data multiplied by the proportion of all costs other than personnel compensation and benefits costs to total costs of the process for the review of human drug applications (as defined in section 735(6)) for the first 3 years of the preceding 4 fiscal years.

The adjustment made each fiscal year under this paragraph shall be added on a compounded basis to the sum of all adjustments made each fiscal year after fiscal year 2013 under this paragraph.

[(2) WORKLOAD ADJUSTMENT.—For fiscal year 2014 and subsequent fiscal years, after the fee revenues established in subsection (b) are adjusted for a fiscal year for inflation in accordance with paragraph (1), the fee revenues shall be adjusted further for such fiscal year to reflect changes in the workload of the Secretary for the process for the review of human drug applications. With respect to such adjustment:

[(A) The adjustment shall be determined by the Secretary based on a weighted average of the change in the total number of human drug applications (adjusted for changes in review activities, as described in the notice that the Secretary is required to publish in the Federal Register under this subparagraph), efficacy supplements, and manufacturing supplements submitted to the Secretary, and the change in the total number of active commercial investigational new drug applications (adjusted for

changes in review activities, as so described) during the most recent 12-month period for which data on such submissions is available. The Secretary shall publish in the Federal Register the fee revenues and fees resulting from the adjustment and the supporting methodologies.

[(B) Under no circumstances shall the adjustment result in fee revenues for a fiscal year that are less than the sum of the amount under subsection (b)(1)(A) and the amount under subsection (b)(1)(B), as adjusted for inflation under paragraph (1).

[(C) The Secretary shall contract with an independent accounting or consulting firm to periodically review the adequacy of the adjustment and publish the results of those reviews. The first review shall be conducted and published by the end of fiscal year 2013 (to examine the performance of the adjustment since fiscal year 2009), and the second review shall be conducted and published by the end of fiscal year 2015 (to examine the continued performance of the adjustment). The reports shall evaluate whether the adjustment reasonably represents actual changes in workload volume and complexity and present options to discontinue, retain, or modify any elements of the adjustment. The reports shall be published for public comment. After review of the reports and receipt of public comments, the Secretary shall, if warranted, adopt appropriate changes to the methodology. If the Secretary adopts changes to the methodology based on the first report, the changes shall be effective for the first fiscal year for which fees are set after the Secretary adopts such changes and each subsequent fiscal year.

[(3) FINAL YEAR ADJUSTMENT.—For fiscal year 2017, the Secretary may, in addition to adjustments under this paragraph and paragraphs (1) and (2), further increase the fee revenues and fees established in subsection (b) if such an adjustment is necessary to provide for not more than 3 months of operating reserves of carryover user fees for the process for the review of human drug applications for the first 3 months of fiscal year 2018. If such an adjustment is necessary, the rationale for the amount of the increase shall be contained in the annual notice establishing fee revenues and fees for fiscal year 2017. If the Secretary has carryover balances for such process in excess of 3 months of such operating reserves, the adjustment under this paragraph shall not be made.

[(4) ANNUAL FEE SETTING.—The Secretary shall, not later than 60 days before the start of each fiscal year that begins after September 30, 2012, establish, for the next fiscal year, application, product, and establishment fees under subsection (a), based on the revenue amounts established under subsection (b) and the adjustments provided under this subsection.

[(5) LIMIT.—The total amount of fees charged, as adjusted under this subsection, for a fiscal year may not exceed the total costs for such fiscal year for the resources allocated for the process for the review of human drug applications.]

(b) *FEE REVENUE AMOUNTS.*—

(1) *IN GENERAL.*—For each of the fiscal years 2018 through 2022, fees under subsection (a) shall, except as provided in subsections (c), (d), (f), and (g), be established to generate a total revenue amount under such subsection that is equal to the sum of—

(A) the annual base revenue for the fiscal year (as determined under paragraph (3));

(B) the dollar amount equal to the inflation adjustment for the fiscal year (as determined under subsection (c)(1));

(C) the dollar amount equal to the capacity planning adjustment for the fiscal year (as determined under subsection (c)(2));

(D) the dollar amount equal to the operating reserve adjustment for the fiscal year, if applicable (as determined under subsection (c)(3));

(E) the dollar amount equal to the additional direct cost adjustment for the fiscal year (as determined under subsection (c)(4)); and

(F) additional dollar amounts for each fiscal year as follows:

(i) \$20,077,793 for fiscal year 2018.

(ii) \$21,317,472 for fiscal year 2019.

(iii) \$16,953,329 for fiscal year 2020.

(iv) \$5,426,896 for fiscal year 2021.

(v) \$2,769,609 for fiscal year 2022.

(2) *TYPES OF FEES.*—Of the total revenue amount determined for a fiscal year under paragraph (1)—

(A) 20 percent shall be derived from human drug application fees under subsection (a)(1); and

(B) 80 percent shall be derived from prescription drug program fees under subsection (a)(2).

(3) *ANNUAL BASE REVENUE.*—For purposes of paragraph (1), the dollar amount of the annual base revenue for a fiscal year shall be—

(A) for fiscal year 2018, \$878,590,000; and

(B) for fiscal years 2019 through 2022, the dollar amount of the total revenue amount established under paragraph (1) for the previous fiscal year, not including any adjustments made under subsection (c)(3) or (c)(4).

(c) *ADJUSTMENTS; ANNUAL FEE SETTING.*—

(1) *INFLATION ADJUSTMENT.*—

(A) *IN GENERAL.*—For purposes of subsection (b)(1)(B), the dollar amount of the inflation adjustment to the annual base revenue for each fiscal year shall be equal to the product of—

(i) such annual base revenue for the fiscal year under subsection (b)(1)(A); and

(ii) the inflation adjustment percentage under subparagraph (B).

(B) *INFLATION ADJUSTMENT PERCENTAGE.*—The inflation adjustment percentage under this subparagraph for a fiscal year is equal to the sum of—

(i) the average annual percent change in the cost, per full-time equivalent position of the Food and Drug Administration, of all personnel compensation and bene-

fits paid with respect to such positions for the first 3 years of the preceding 4 fiscal years, multiplied by the proportion of personnel compensation and benefits costs to total costs of the process for the review of human drug applications (as defined in section 735(6)) for the first 3 years of the preceding 4 fiscal years; and

(ii) the average annual percent change that occurred in the Consumer Price Index for urban consumers (Washington-Baltimore, DC-MD-VA-WV; Not Seasonally Adjusted; All items; Annual Index) for the first 3 years of the preceding 4 years of available data multiplied by the proportion of all costs other than personnel compensation and benefits costs to total costs of the process for the review of human drug applications (as defined in section 735(6)) for the first 3 years of the preceding 4 fiscal years.

(2) **CAPACITY PLANNING ADJUSTMENT.**—

(A) **IN GENERAL.**—*For each fiscal year, after the annual base revenue established in subsection (b)(1)(A) is adjusted for inflation in accordance with paragraph (1), such revenue shall be adjusted further for such fiscal year, in accordance with this paragraph, to reflect changes in the resource capacity needs of the Secretary for the process for the review of human drug applications.*

(B) **INTERIM METHODOLOGY.**—

(i) **IN GENERAL.**—*Until the capacity planning methodology described in subparagraph (C) is effective, the adjustment under this paragraph for a fiscal year shall be based on the product of—*

(I) the annual base revenue for such year, as adjusted for inflation under paragraph (1); and

(II) the adjustment percentage under clause (ii).

(ii) **ADJUSTMENT PERCENTAGE.**—*The adjustment percentage under this clause for a fiscal year is the weighted change in the 3-year average ending in the most recent year for which data are available, over the 3-year average ending in the previous year, for—*

(I) the total number of human drug applications, efficacy supplements, and manufacturing supplements submitted to the Secretary;

(II) the total number of active commercial investigational new drug applications; and

(III) the total number of formal meetings scheduled by the Secretary, and written responses issued by the Secretary in lieu of such formal meetings, as identified in section I.H of the letters described in section 101(b) of the Prescription Drug User Fee Amendments of 2017.

(C) **CAPACITY PLANNING METHODOLOGY.**—

(i) **DEVELOPMENT; EVALUATION AND REPORT.**—*The Secretary shall obtain, through a contract with an independent accounting or consulting firm, a report evaluating options and recommendations for a new methodology to accurately assess changes in the resource and capacity needs of the process for the review*

of human drug applications. The capacity planning methodological options and recommendations presented in such report shall utilize and be informed by personnel time reporting data as an input. The report shall be published for public comment no later than the end of fiscal year 2020.

(ii) *ESTABLISHMENT AND IMPLEMENTATION.*—After review of the report described in clause (i) and any public comments thereon, the Secretary shall establish a capacity planning methodology for purposes of this paragraph, which shall—

(I) replace the interim methodology under subparagraph (B);

(II) incorporate such approaches and attributes as the Secretary determines appropriate; and

(III) be effective beginning with the first fiscal year for which fees are set after such capacity planning methodology is established.

(D) *LIMITATION.*—Under no circumstances shall an adjustment under this paragraph result in fee revenue for a fiscal year that is less than the sum of the amounts under subsections (b)(1)(A) (the annual base revenue for the fiscal year) and (b)(1)(B) (the dollar amount of the inflation adjustment for the fiscal year).

(E) *PUBLICATION IN FEDERAL REGISTER.*—The Secretary shall publish in the Federal Register notice under paragraph (5) the fee revenue and fees resulting from the adjustment and the methodologies under this paragraph.

(3) *OPERATING RESERVE ADJUSTMENT.*—

(A) *INCREASE.*—For fiscal year 2018 and subsequent fiscal years, the Secretary may, in addition to adjustments under paragraphs (1) and (2), further increase the fee revenue and fees if such an adjustment is necessary to provide for not more than 14 weeks of operating reserves of carryover user fees for the process for the review of human drug applications.

(B) *DECREASE.*—If the Secretary has carryover balances for such process in excess of 14 weeks of such operating reserves, the Secretary shall decrease such fee revenue and fees to provide for not more than 14 weeks of such operating reserves.

(C) *NOTICE OF RATIONALE.*—If an adjustment under subparagraph (A) or (B) is made, the rationale for the amount of the increase or decrease (as applicable) in fee revenue and fees shall be contained in the annual Federal Register notice under paragraph (5) establishing fee revenue and fees for the fiscal year involved.

(4) *ADDITIONAL DIRECT COST ADJUSTMENT.*—

(A) *IN GENERAL.*—The Secretary shall, in addition to adjustments under paragraphs (1), (2), and (3), further increase the fee revenue and fees—

(i) for fiscal year 2018, by \$8,730,000; and

(ii) for fiscal year 2019 and subsequent fiscal years, by the amount determined under subparagraph (B).

(B) *AMOUNT.*—The amount determined under this subparagraph is—

- (i) \$8,730,000, multiplied by
- (ii) the Consumer Price Index for urban consumers (Washington-Baltimore, DC-MD-VA-WV; Not Seasonally Adjusted; All Items; Annual Index) for the most recent year of available data, divided by such Index for 2016.

(5) *ANNUAL FEE SETTING.*—The Secretary shall, not later than 60 days before the start of each fiscal year that begins after September 30, 2017—

(A) establish, for the next fiscal year, human drug application fees and prescription drug program fees under subsection (a), based on the revenue amounts established under subsection (b) and the adjustments provided under this subsection; and

(B) publish such fee revenue and fees in the Federal Register.

(6) *LIMIT.*—The total amount of fees charged, as adjusted under this subsection, for a fiscal year may not exceed the total costs for such fiscal year for the resources allocated for the process for the review of human drug applications.

(d) *FEE WAIVER OR REDUCTION.*—

(1) *IN GENERAL.*—The Secretary shall grant to a person who is named as the applicant in a human drug application a waiver from or a reduction of one or more fees assessed to that person under subsection (a) where the Secretary finds that—

(A) such waiver or reduction is necessary to protect the public health,

(B) the assessment of the fee would present a significant barrier to innovation because of limited resources available to such person or other circumstances, or

[(C) the fees to be paid by such person will exceed the anticipated present and future costs incurred by the Secretary in conducting the process for the review of human drug applications for such person, or]

[(D)] (C) the applicant involved is a small business submitting its first human drug application to the Secretary for review.

(2) *CONSIDERATIONS.*—In determining whether to grant a waiver or reduction of a fee under paragraph (1), the Secretary shall consider only the circumstances and assets of the applicant involved and any affiliate of the applicant.

[(3) *USE OF STANDARD COSTS.*—In making the finding in paragraph (1)(C), the Secretary may use standard costs.]

[(4)] (3) *RULES RELATING TO SMALL BUSINESSES.*—

(A) *DEFINITION.*—In [paragraph (1)(D)] paragraph (1)(C), the term “small business” means an entity that has fewer than 500 employees, including employees of affiliates, and that does not have a drug product that has been approved under a human drug application and introduced or delivered for introduction into interstate commerce.

(B) *WAIVER OF APPLICATION FEE.*—The Secretary shall waive under [paragraph (1)(D)] paragraph (1)(C) the application fee for the first human drug application that a

small business or its affiliate submits to the Secretary for review. After a small business or its affiliate is granted such a waiver, the small business or its affiliate ~~shall pay—~~

~~[(i)] [application fees] shall pay application fees for all subsequent human drug applications submitted to the Secretary for review in the same manner as an entity that does not qualify as a small business[; and].~~

~~[(ii)] all supplement fees for all supplements to human drug applications submitted to the Secretary for review in the same manner as an entity that does not qualify as a small business.]~~

(e) EFFECT OF FAILURE TO PAY FEES.—A human drug application or supplement submitted by a person subject to fees under subsection (a) shall be considered incomplete and shall not be accepted for filing by the Secretary until ~~[all fees]~~ *all such fees* owed by such person have been paid.

(f) LIMITATIONS.—

(1) IN GENERAL.—Fees under subsection (a) shall be refunded for a fiscal year beginning after fiscal year 1997 unless appropriations for salaries and expenses of the Food and Drug Administration for such fiscal year (excluding the amount of fees appropriated for such fiscal year) are equal to or greater than the amount of appropriations for the salaries and expenses of the Food and Drug Administration for the fiscal year 1997 (excluding the amount of fees appropriated for such fiscal year) multiplied by the adjustment factor applicable to the fiscal year involved.

(2) AUTHORITY.—If the Secretary does not assess fees under subsection (a) during any portion of a fiscal year because of paragraph (1) and if at a later date in such fiscal year the Secretary may assess such fees, the Secretary may assess and collect such fees, without any modification in the rate, for human drug applications and ~~[supplements, prescription drug establishments, and prescription drug products]~~ *prescription drug program fees* at any time in such fiscal year notwithstanding the provisions of subsection (a) relating to the date fees are to be paid.

(g) CREDITING AND AVAILABILITY OF FEES.—

(1) IN GENERAL.—Subject to paragraph (2)(C), fees authorized under subsection (a) shall be collected and available for obligation only to the extent and in the amount provided in advance in appropriations Acts. Such fees are authorized to remain available until expended. Such sums as may be necessary may be transferred from the Food and Drug Administration salaries and expenses appropriation account without fiscal year limitation to such appropriation account for salaries and expenses with such fiscal year limitation. The sums transferred shall be available solely for the process for the review of human drug applications.

(2) COLLECTIONS AND APPROPRIATION ACTS.—

(A) IN GENERAL.—The fees authorized by this section—

(i) subject to subparagraph (C), shall be collected and available in each fiscal year in an amount not to exceed the amount specified in appropriation Acts, or

otherwise made available for obligation, for such fiscal year, and

(ii) shall be available to defray increases in the costs of the resources allocated for the process for the review of human drug applications (including increases in such costs for an additional number of full-time equivalent positions in the Department of Health and Human Services to be engaged in such process) over such costs, excluding costs paid from fees collected under this section, for fiscal year 1997 multiplied by the adjustment factor.

(B) COMPLIANCE.—The Secretary shall be considered to have met the requirements of subparagraph (A)(ii) in any fiscal year if the costs funded by appropriations and allocated for the process for the review of human drug applications—

(i) are not more than 3 percent below the level specified in subparagraph (A)(ii); or

(ii)(I) are more than 3 percent below the level specified in subparagraph (A)(ii), and fees assessed for the fiscal year following the subsequent fiscal year are decreased by the amount in excess of 3 percent by which such costs fell below the level specified in such subparagraph; and

(II) such costs are not more than 5 percent below the level specified in such subparagraph.

(C) PROVISION FOR EARLY PAYMENTS.—Payment of fees authorized under this section for a fiscal year, prior to the due date for such fees, may be accepted by the Secretary in accordance with authority provided in advance in a prior year appropriations Act.

(3) AUTHORIZATION OF APPROPRIATIONS.—For each of the fiscal years **2013 through 2017** *2018 through 2022*, there is authorized to be appropriated for fees under this section an amount equal to the total revenue amount determined under subsection (b) for the fiscal year, as adjusted or otherwise affected under subsection (c) **and paragraph (4) of this subsection**.

[(4) OFFSET.—If the sum of the cumulative amount of fees collected under this section for the fiscal years 2013 through 2015 and the amount of fees estimated to be collected under this section for fiscal year 2016 exceeds the cumulative amount appropriated under paragraph (3) for the fiscal years 2013 through 2016, the excess shall be credited to the appropriation account of the Food and Drug Administration as provided in paragraph (1), and shall be subtracted from the amount of fees that would otherwise be authorized to be collected under this section pursuant to appropriation Acts for fiscal year 2017.]

(h) COLLECTION OF UNPAID FEES.—In any case where the Secretary does not receive payment of a fee assessed under subsection (a) within 30 days after it is due, such fee shall be treated as a claim of the United States Government subject to subchapter II of chapter 37 of title 31, United States Code.

(i) WRITTEN REQUESTS FOR WAIVERS, REDUCTIONS, AND REFUNDS.—To qualify for consideration for a waiver or reduction

under subsection (d), or for a refund of any fee collected in accordance with subsection (a), a person shall submit to the Secretary a written request for such waiver, reduction, or refund not later than 180 days after such fee is due.

(j) CONSTRUCTION.—This section may not be construed to require that the number of full-time equivalent positions in the Department of Health and Human Services, for officers, employers, and advisory committees not engaged in the process of the review of human drug applications, be reduced to offset the number of officers, employees, and advisory committees so engaged.

(k) ORPHAN DRUGS.—

(1) EXEMPTION.—A drug designated under section 526 for a rare disease or condition and approved under section 505 or under section 351 of the Public Health Service Act shall be exempt from [product and establishment fees] *prescription drug program fees* under this section, if the drug meets all of the following conditions:

(A) The drug meets the public health requirements contained in this Act as such requirements are applied to requests for waivers for [product and establishment fees] *prescription drug program fees*.

(B) The drug is owned or licensed and is marketed by a company that had less than \$50,000,000 in gross worldwide revenue during the previous year.

(2) EVIDENCE OF QUALIFICATION.—An exemption under paragraph (1) applies with respect to a drug only if the applicant involved submits a certification that its gross annual revenues did not exceed \$50,000,000 for the preceding 12 months before the exemption was requested.

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SEC. 736B. REAUTHORIZATION; REPORTING REQUIREMENTS.

(a) PERFORMANCE REPORT.—

(1) IN GENERAL.—Beginning with fiscal year [2013] 2018, not later than 120 days after the end of each fiscal year for which fees are collected under this part, the Secretary shall prepare and submit to the Committee on Energy and Commerce of the House of Representatives and the Committee on Health, Education, Labor, and Pensions of the Senate a report concerning—

(A) the progress of the Food and Drug Administration in achieving the goals identified in the letters described in section 101(b) of the [Prescription Drug User Fee Amendments of 2012] *Prescription Drug User Fee Amendments of 2017* during such fiscal year and the future plans of the Food and Drug Administration for meeting the goals, including the status of the independent assessment described in such letters; and

(B) the progress of the Center for Drug Evaluation and Research and the Center for Biologics Evaluation and Research in achieving the goals, and future plans for meeting the goals, including, for each review division—

(i) the number of original standard new drug applications and biologics license applications filed per fiscal year for each review division;

(ii) the number of original priority new drug applications and biologics license applications filed per fiscal year for each review division;

(iii) the number of standard efficacy supplements filed per fiscal year for each review division;

(iv) the number of priority efficacy supplements filed per fiscal year for each review division;

(v) the number of applications filed for review under accelerated approval per fiscal year for each review division;

(vi) the number of applications filed for review as fast track products per fiscal year for each review division;

(vii) the number of applications filed for orphan-designated products per fiscal year for each review division; and

(viii) the number of breakthrough designations for a fiscal year for each review division.

(2) INCLUSION.—The report under this subsection for a fiscal year shall include information on all previous cohorts for which the Secretary has not given a complete response on all human drug applications and supplements in the cohort.

(b) FISCAL REPORT.—Beginning with fiscal year **[2013]** 2018, not later than 120 days after the end of each fiscal year for which fees are collected under this part, the Secretary shall prepare and submit to the Committee on Energy and Commerce of the House of Representatives and the Committee on Health, Education, Labor, and Pensions of the Senate a report on the implementation of the authority for such fees during such fiscal year and the use, by the Food and Drug Administration, of the fees collected for such fiscal year.

(c) PUBLIC AVAILABILITY.—The Secretary shall make the reports required under subsections (a) and (b) available to the public on the Internet Web site of the Food and Drug Administration.

(d) REAUTHORIZATION.—

(1) CONSULTATION.—In developing recommendations to present to the Congress with respect to the goals, and plans for meeting the goals, for the process for the review of human drug applications for the first 5 fiscal years after fiscal year **[2017]** 2022, and for the reauthorization of this part for such fiscal years, the Secretary shall consult with—

(A) the Committee on Energy and Commerce of the House of Representatives;

(B) the Committee on Health, Education, Labor, and Pensions of the Senate;

(C) scientific and academic experts;

(D) health care professionals;

(E) representatives of patient and consumer advocacy groups; and

(F) the regulated industry.

(2) PRIOR PUBLIC INPUT.—Prior to beginning negotiations with the regulated industry on the reauthorization of this part, the Secretary shall—

(A) publish a notice in the Federal Register requesting public input on the reauthorization;

- (B) hold a public meeting at which the public may present its views on the reauthorization, including specific suggestions for changes to the goals referred to in subsection (a);
- (C) provide a period of 30 days after the public meeting to obtain written comments from the public suggesting changes to this part; and
- (D) publish the comments on the Food and Drug Administration's Internet Web site.
- (3) PERIODIC CONSULTATION.—Not less frequently than once every month during negotiations with the regulated industry, the Secretary shall hold discussions with representatives of patient and consumer advocacy groups to continue discussions of their views on the reauthorization and their suggestions for changes to this part as expressed under paragraph (2).
- (4) PUBLIC REVIEW OF RECOMMENDATIONS.—After negotiations with the regulated industry, the Secretary shall—
- (A) present the recommendations developed under paragraph (1) to the Congressional committees specified in such paragraph;
- (B) publish such recommendations in the Federal Register;
- (C) provide for a period of 30 days for the public to provide written comments on such recommendations;
- (D) hold a meeting at which the public may present its views on such recommendations; and
- (E) after consideration of such public views and comments, revise such recommendations as necessary.
- (5) TRANSMITTAL OF RECOMMENDATIONS.—Not later than January 15, [2017] 2022, the Secretary shall transmit to the Congress the revised recommendations under paragraph (4), a summary of the views and comments received under such paragraph, and any changes made to the recommendations in response to such views and comments.
- (6) MINUTES OF NEGOTIATION MEETINGS.—
- (A) PUBLIC AVAILABILITY.—Before presenting the recommendations developed under paragraphs (1) through (5) to the Congress, the Secretary shall make publicly available, on the public Web site of the Food and Drug Administration, minutes of all negotiation meetings conducted under this subsection between the Food and Drug Administration and the regulated industry.
- (B) CONTENT.—The minutes described under subparagraph (A) shall summarize any substantive proposal made by any party to the negotiations as well as significant controversies or differences of opinion during the negotiations and their resolution.

PART 3—FEES RELATING TO DEVICES

SEC. 737. DEFINITIONS.

For purposes of this part:

- (1) The term “premarket application” means—

(A) an application for approval of a device submitted under section 515(c) or section 351 of the Public Health Service Act; or

(B) a product development protocol described in section 515(f).

Such term does not include a supplement, a premarket report, or a premarket notification submission.

(2) The term “premarket report” means a report submitted under section 515(c)(2).

(3) The term “premarket notification submission” means a report submitted under section 510(k).

(4)(A) The term “supplement”, with respect to a panel-track supplement, a 180-day supplement, a real-time supplement, or an efficacy supplement, means a request to the Secretary to approve a change in a device for which—

(i) an application or report has been approved under section 515(d), or an application has been approved under section 351 of the Public Health Service Act; or

(ii) a notice of completion has become effective under section 515(f).

(B) The term “panel-track supplement” means a supplement to an approved premarket application or premarket report under section 515 that requests a significant change in design or performance of the device, or a new indication for use of the device, and for which substantial clinical data are necessary to provide a reasonable assurance of safety and effectiveness.

(C) The term “180-day supplement” means a supplement to an approved premarket application or premarket report under section 515 that is not a panel-track supplement and requests a significant change in components, materials, design, specification, software, color additives, or labeling.

(D) The term “real-time supplement” means a supplement to an approved premarket application or premarket report under section 515 that requests a minor change to the device, such as a minor change to the design of the device, software, sterilization, or labeling, and for which the applicant has requested and the agency has granted a meeting or similar forum to jointly review and determine the status of the supplement.

(E) The term “efficacy supplement” means a supplement to an approved premarket application under section 351 of the Public Health Service Act that requires substantive clinical data.

(5) The term “30-day notice” means a notice under section 515(d)(5) that is limited to a request to make modifications to manufacturing procedures or methods of manufacture affecting the safety and effectiveness of the device.

(6) The term “request for classification information” means a request made under section 513(g) for information respecting the class in which a device has been classified or the requirements applicable to a device.

(7) The term “annual fee”, for periodic reporting concerning a class III device, means the annual fee associated with periodic reports required by a premarket application approval order.

(8) *The term “de novo classification request” means a request made under section 513(f)(2)(A) with respect to the classification of a device.*

[(8)] (9) The term “process for the review of device applications” means the following activities of the Secretary with respect to the review of premarket applications, premarket reports, supplements, and premarket notification submissions:

(A) The activities necessary for the review of premarket applications, premarket reports, supplements, and premarket notification submissions.

(B) The issuance of action letters that allow the marketing of devices or which set forth in detail the specific deficiencies in such applications, reports, supplements, or submissions and, where appropriate, the actions necessary to place them in condition for approval.

(C) The inspection of manufacturing establishments and other facilities undertaken as part of the Secretary’s review of pending premarket applications, premarket reports, and supplements.

(D) Monitoring of research conducted in connection with the review of such applications, reports, supplements, and submissions.

(E) Review of device applications subject to section 351 of the Public Health Service Act for an investigational new drug application under section 505(i) or for an investigational device exemption under section 520(g) and activities conducted in anticipation of the submission of such applications under section 505(i) or 520(g).

(F) The development of guidance, policy documents, or regulations to improve the process for the review of premarket applications, premarket reports, supplements, and premarket notification submissions.

(G) The development of voluntary test methods, consensus standards, or mandatory performance standards under section 514 in connection with the review of such applications, reports, supplements, or submissions and related activities.

(H) The provision of technical assistance to device manufacturers in connection with the submission of such applications, reports, supplements, or submissions.

(I) Any activity undertaken under section 513 or 515(i) in connection with the initial classification or reclassification of a device or under section 515(b) in connection with any requirement for approval of a device.

(J) Evaluation of postmarket studies required as a condition of an approval of a premarket application or premarket report under section 515 or a premarket application under section 351 of the Public Health Service Act.

(K) Compiling, developing, and reviewing information on relevant devices to identify safety and effectiveness issues for devices subject to premarket applications, premarket reports, supplements, or premarket notification submissions.

[(9)] (10) The term “costs of resources allocated for the process for the review of device applications” means the expenses

in connection with the process for the review of device applications for—

(A) officers and employees of the Food and Drug Administration, contractors of the Food and Drug Administration, advisory committees, and costs related to such officers, employees, and committees and to contracts with such contractors;

(B) management of information, and the acquisition, maintenance, and repair of computer resources;

(C) leasing, maintenance, renovation, and repair of facilities and acquisition, maintenance, and repair of fixtures, furniture, scientific equipment, and other necessary materials and supplies; and

(D) collecting fees and accounting for resources allocated for the review of premarket applications, premarket reports, supplements, [and submissions] *submissions*, and *de novo classification requests*.

[(10)] (11) The term “adjustment factor” applicable to a fiscal year is the Consumer Price Index for all urban consumers (all items; United States city average) for October of the preceding fiscal year divided by such Index for October [2011] 2016.

[(11)] (12) The term “person” includes an affiliate thereof.

[(12)] (13) The term “affiliate” means a business entity that has a relationship with a second business entity (whether domestic or international) if, directly or indirectly—

(A) one business entity controls, or has the power to control, the other business entity; or

(B) a third party controls, or has power to control, both of the business entities.

[(13)] (14) The term “establishment subject to a registration fee” means an establishment that is registered (or is required to register) with the Secretary under section 510 because such establishment is engaged in the manufacture, preparation, propagation, compounding, or processing of a device.

SEC. 738. AUTHORITY TO ASSESS AND USE DEVICE FEES.

(a) TYPES OF FEES.—

(1) IN GENERAL.—Beginning in [fiscal year 2013] *fiscal year 2018*, the Secretary shall assess and collect fees in accordance with this section.

(2) PREMARKET APPLICATION, PREMARKET REPORT, SUPPLEMENT, AND SUBMISSION FEE, AND ANNUAL FEE FOR PERIODIC REPORTING CONCERNING A CLASS III DEVICE.—

(A) IN GENERAL.—Except as provided in subparagraph (B) and subsections [(d), (e), and (f)] *(d) and (e)* each person who submits any of the following, on or after [October 1, 2012] *October 1, 2017*, shall be subject to a fee established under subsection (c) for the fiscal year involved in accordance with the following:

(i) A premarket application.

(ii) For a premarket report, a fee equal to the fee that applies under clause (i).

(iii) For a panel track supplement, a fee equal to 75 percent of the fee that applies under clause (i).

(iv) For a 180-day supplement, a fee equal to 15 percent of the fee that applies under clause (i).

(v) For a real-time supplement, a fee equal to 7 percent of the fee that applies under clause (i).

(vi) For a 30-day notice, a fee equal to 1.6 percent of the fee that applies under clause (i).

(vii) For an efficacy supplement, a fee equal to the fee that applies under clause (i).

(viii) For a premarket notification submission, a fee equal to **[2]** 3.4 percent of the fee that applies under clause (i).

(ix) For a request for classification information, a fee equal to 1.35 percent of the fee that applies under clause (i).

(x) For periodic reporting concerning a class III device, an annual fee equal to 3.5 percent of the fee that applies under clause (i).

(xi) *For a de novo classification request, a fee equal to 30 percent of the fee that applies under clause (i).*

(B) EXCEPTIONS.—

(i) **HUMANITARIAN DEVICE EXEMPTION.**—An application under section 520(m) is not subject to any fee under subparagraph (A).

(ii) **FURTHER MANUFACTURING USE.**—No fee shall be required under subparagraph (A) for the submission of a premarket application under section 351 of the Public Health Service Act for a product licensed for further manufacturing use only.

(iii) **STATE OR FEDERAL GOVERNMENT SPONSORS.**—No fee shall be required under subparagraph (A) for a premarket application, premarket report, supplement, or premarket notification submission submitted by a State or Federal Government entity unless the device involved is to be distributed commercially.

(iv) **PREMARKET NOTIFICATIONS BY THIRD PARTIES.**—No fee shall be required under subparagraph (A) for a premarket notification submission reviewed by an accredited person pursuant to section 523.

(v) PEDIATRIC CONDITIONS OF USE.—

(I) IN GENERAL.—No fee shall be required under subparagraph (A) for a premarket application, premarket report, **[or premarket notification submission]** *premarket notification submission, or de novo classification request* if the proposed conditions of use for the device involved are solely for a pediatric population. No fee shall be required under such subparagraph for a supplement if the sole purpose of the supplement is to propose conditions of use for a pediatric population.

(II) SUBSEQUENT PROPOSAL OF ADULT CONDITIONS OF USE.—In the case of a person who submits a premarket application or premarket report for which, under subclause (I), a fee under subparagraph (A) is not required, any supplement to such application that proposes conditions of use

for any adult population is subject to the fee that applies under such subparagraph for a premarket application.

(C) PAYMENT.—The fee required by subparagraph (A) shall be due upon submission of the premarket application, premarket report, supplement, premarket notification submission, 30-day notice, request for classification information, or periodic reporting concerning a class III device. Applicants submitting portions of applications pursuant to section 515(c)(4) shall pay such fees upon submission of the first portion of such applications.

(D) REFUNDS.—

(i) APPLICATION REFUSED FOR FILING.—The Secretary shall refund 75 percent of the fee paid under subparagraph (A) for any application, report, or supplement that is refused for filing.

(ii) APPLICATION WITHDRAWN BEFORE FILING.—The Secretary shall refund 75 percent of the fee paid under subparagraph (A) for any application, report, or supplement that is withdrawn prior to the filing decision of the Secretary.

(iii) APPLICATION WITHDRAWN BEFORE FIRST ACTION.—After receipt of a request for a refund of the fee paid under subparagraph (A) for a premarket application, premarket report, or supplement that is withdrawn after filing but before a first action, the Secretary may return some or all of the fee. The amount of refund, if any, shall be based on the level of effort already expended on the review of such application, report, or supplement.

(iv) MODULAR APPLICATIONS WITHDRAWN BEFORE FIRST ACTION.—The Secretary shall refund 75 percent of the application fee paid for an application submitted under section 515(c)(4) that is withdrawn before a second portion is submitted and before a first action on the first portion.

(v) LATER WITHDRAWN MODULAR APPLICATIONS.—If an application submitted under section 515(c)(4) is withdrawn after a second or subsequent portion is submitted but before any first action, the Secretary may return a portion of the fee. The amount of refund, if any, shall be based on the level of effort already expended on the review of the portions submitted.

(vi) SOLE DISCRETION TO REFUND.—The Secretary shall have sole discretion to refund a fee or portion of the fee under clause (iii) or (v). A determination by the Secretary concerning a refund under clause (iii) or (v) shall not be reviewable.

(3) ANNUAL ESTABLISHMENT REGISTRATION FEE.—

(A) IN GENERAL.—Except as provided in subparagraph (B) [and subsection (f)], each establishment subject to a registration fee shall be subject to a fee for each initial or annual registration under section 510 beginning with its registration for fiscal year 2008.

(B) EXCEPTION.—No fee shall be required under subparagraph (A) for an establishment operated by a State or Federal governmental entity or an Indian tribe (as defined in the Indian Self Determination and Educational Assistance Act), unless a device manufactured by the establishment is to be distributed commercially.

(C) PAYMENT.—The fee required under subparagraph (A) shall be due once each fiscal year, upon the later of—

- (i) the initial or annual registration (as applicable) of the establishment under section 510; or
- (ii) the first business day after the date of enactment of an appropriations Act providing for the collection and obligation of fees for such year under this section.

[(b) FEE AMOUNTS.—

[(1) IN GENERAL.—Subject to subsections (c), (d), (e), (f), and (i), for each of fiscal years 2013 through 2017, fees under subsection (a) shall be derived from the base fee amounts specified in paragraph (2), to generate the total revenue amounts specified in paragraph (3).

[(2) BASE FEE AMOUNTS SPECIFIED.—For purposes of paragraph (1), the base fee amounts specified in this paragraph are as follows:

Fee Type	Fiscal Year 2013	Fiscal Year 2014	Fiscal Year 2015	Fiscal Year 2016	Fiscal Year 2017
Premarket Application ..	\$248,000	\$252,960	\$258,019	\$263,180	\$268,443
Establishment Registration	\$2,575	\$3,200	\$3,750	\$3,872	\$3,872

[(3) TOTAL REVENUE AMOUNTS SPECIFIED.—For purposes of paragraph (1), the total revenue amounts specified in this paragraph are as follows:

- [(A) \$97,722,301 for fiscal year 2013.**
- [(B) \$112,580,497 for fiscal year 2014.**
- [(C) \$125,767,107 for fiscal year 2015.**
- [(D) \$129,339,949 for fiscal year 2016.**
- [(E) \$130,184,348 for fiscal year 2017.]**

(b) FEE AMOUNTS.—

(1) IN GENERAL.—Subject to subsections (c), (d), (e), and (h), for each of fiscal years 2018 through 2022, fees under subsection (a) shall be derived from the base fee amounts specified in paragraph (2), to generate the total revenue amounts specified in paragraph (3).

(2) BASE FEE AMOUNTS SPECIFIED.—For purposes of paragraph (1), the base fee amounts specified in this paragraph are as follows:

Fee Type	Fiscal Year 2018	Fiscal Year 2019	Fiscal Year 2020	Fiscal Year 2021	Fiscal Year 2022
Premarket Application	\$294,000	\$300,000	\$310,000	\$328,000	\$329,000

<i>Fee Type</i>	<i>Fiscal Year 2018</i>	<i>Fiscal Year 2019</i>	<i>Fiscal Year 2020</i>	<i>Fiscal Year 2021</i>	<i>Fiscal Year 2022</i>
<i>Establishment Registra- tion</i>	\$4,375	\$4,548	\$4,760	\$4,975	\$4,978

(3) *TOTAL REVENUE AMOUNTS SPECIFIED.*—For purposes of paragraph (1), the total revenue amounts specified in this paragraph are as follows:

- (A) \$183,280,756 for fiscal year 2018.
- (B) \$190,654,875 for fiscal year 2019.
- (C) \$200,132,014 for fiscal year 2020.
- (D) \$211,748,789 for fiscal year 2021.
- (E) \$213,687,660 for fiscal year 2022.

(c) ANNUAL FEE SETTING; ADJUSTMENTS.—

(1) IN GENERAL.—The Secretary shall, 60 days before the start of each fiscal year after September 30, [2012] 2017, establish fees under subsection (a), based on amounts specified under subsection (b) and the adjustments provided under this subsection, and publish such fees, and the rationale for any adjustments to such fees, in the Federal Register.

(2) INFLATION ADJUSTMENTS.—

(A) ADJUSTMENT TO TOTAL REVENUE AMOUNTS.—For fiscal year [2014] 2018 and each subsequent fiscal year, the Secretary shall adjust the total revenue amount specified in subsection (b)(3) for such fiscal year by multiplying such amount by the applicable inflation adjustment under subparagraph (B) for such year.

[(B) APPLICABLE INFLATION ADJUSTMENT TO TOTAL REVENUE AMOUNTS.—The applicable inflation adjustment for a fiscal year is—

[(i) for fiscal year 2014, the base inflation adjustment under subparagraph (C) for such fiscal year; and

[(ii) for fiscal year 2015 and each subsequent fiscal year, the product of—

[(I) the base inflation adjustment under subparagraph (C) for such fiscal year; and

[(II) the product of the base inflation adjustment under subparagraph (C) for each of the fiscal years preceding such fiscal year, beginning with fiscal year 2014.]

(B) APPLICABLE INFLATION ADJUSTMENT.—The applicable inflation adjustment for fiscal year 2018 and each subsequent fiscal year is the product of—

(i) the base inflation adjustment under subparagraph (C) for such fiscal year; and

(ii) the product of the base inflation adjustment under subparagraph (C) for each of the fiscal years preceding such fiscal year, beginning with fiscal year 2016.

(C) BASE INFLATION ADJUSTMENT [TO TOTAL REVENUE AMOUNTS].—

(i) IN GENERAL.—Subject to further adjustment under clause (ii), the base inflation adjustment for a fiscal year is the sum of one plus—

(I) the average annual percent change in the cost, per full-time equivalent position of the Food and Drug Administration, of all personnel compensation and benefits paid with respect to such positions for the first 3 years of the preceding 4 fiscal years, multiplied by 0.60; and

(II) the average annual percent change that occurred in the Consumer Price Index for urban consumers (Washington-Baltimore, DC-MD-VA-WV; Not Seasonally Adjusted; All items; Annual Index) for the first 3 years of the preceding 4 years of available data multiplied by 0.40.

(ii) LIMITATIONS.—For purposes of subparagraph (B), if the base inflation adjustment for a fiscal year under clause (i)—

(I) is less than 1, such adjustment shall be considered to be equal to 1; or

(II) is greater than 1.04, such adjustment shall be considered to be equal to 1.04.

[(D) ADJUSTMENT TO BASE FEE AMOUNTS.—For each of fiscal years 2014 through 2017, the base fee amounts specified in subsection (b)(2) shall be adjusted as needed, on a uniform proportionate basis, to generate the total revenue amounts under subsection (b)(3), as adjusted for inflation under subparagraph (A).]

(D) ADJUSTMENT TO BASE FEE AMOUNTS.—For each of fiscal years 2018 through 2022, the Secretary shall—

(i) adjust the base fee amounts specified in subsection (b)(2) for such fiscal year by multiplying such amounts by the applicable inflation adjustment under subparagraph (B) for such year; and

(ii) if the Secretary determines necessary, increase (in addition to the adjustment under clause (i)) such base fee amounts, on a uniform proportionate basis, to generate the total revenue amounts under subsection (b)(3), as adjusted for inflation under subparagraph (A).

(3) VOLUME-BASED ADJUSTMENTS TO ESTABLISHMENT REGISTRATION BASE FEES.—For each of fiscal years [2014 through 2017] *2018 through 2022*, after the base fee amounts specified in subsection (b)(2) are adjusted under paragraph (2)(D), the base establishment registration fee amounts specified in such subsection shall be [further adjusted] *increased*, as the Secretary estimates is necessary in order for total fee collections for such fiscal year to generate the total revenue amounts, as adjusted under paragraph (2).

(4) LIMIT.—The total amount of fees charged, as adjusted under this subsection, for a fiscal year may not exceed the total costs for such fiscal year for the resources allocated for the process for the review of device applications.

(5) SUPPLEMENT.—

(A) IN GENERAL.—The Secretary may use unobligated carryover balances from fees collected in previous fiscal years to ensure that sufficient fee revenues are available in that fiscal year, so long as the Secretary maintains unobligated carryover balances of not less than 1 month of

operating reserves for the first month of the next fiscal year.

(B) NOTICE TO CONGRESS.—Not later than 14 days before the Secretary anticipates the use of funds described in subparagraph (A), the Secretary shall provide notice to the Committee on Health, Education, Labor, and Pensions and the Committee on Appropriations of the Senate and the Committee on Energy and Commerce and the Committee on Appropriations of the House of Representatives.

(d) SMALL BUSINESSES; FEE WAIVER AND FEE REDUCTION REGARDING PREMARKET APPROVAL FEES.—

(1) IN GENERAL.—The Secretary shall grant a waiver of the fee required under subsection (a) for one premarket application, or one premarket report, where the Secretary finds that the applicant involved is a small business submitting its first premarket application to the Secretary, or its first premarket report, respectively, for review. For the purposes of this paragraph, the term “small business” means an entity that reported \$30,000,000 or less of gross receipts or sales in its most recent Federal income tax return for a taxable year, including such returns of all of its affiliates. In addition, for subsequent premarket applications, premarket reports, and supplements where the Secretary finds that the applicant involved is a small business, the fees [specified in clauses (i) through (v) and clauses (vii), (ix), and (x)] *specified in clauses (i) through (vii) and clauses (ix), (x), and (xi)* of subsection (a)(2)(A) may be paid at a reduced rate in accordance with paragraph (2)(C).

(2) RULES RELATING TO PREMARKET APPROVAL FEES.—

(A) DEFINITION.—For purposes of this paragraph, the term “small business” means an entity that reported \$100,000,000 or less of gross receipts or sales in its most recent Federal income tax return for a taxable year, including such returns of all of its affiliates.

(B) EVIDENCE OF QUALIFICATION.—

(i) IN GENERAL.—An applicant shall pay the higher fees established by the Secretary each year unless the applicant submits evidence that it qualifies for a waiver of the fee or the lower fee rate.

(ii) FIRMS SUBMITTING TAX RETURNS TO THE UNITED STATES INTERNAL REVENUE SERVICE.—The applicant shall support its claim that it meets the definition under subparagraph (A) by submission of a copy of its most recent Federal income tax return for a taxable year, and a copy of such returns of its affiliates, which show an amount of gross sales or receipts that is less than the maximum established in subparagraph (A). The applicant, and each of such affiliates, shall certify that the information provided is a true and accurate copy of the actual tax forms they submitted to the Internal Revenue Service. If no tax forms are submitted for any affiliate, the applicant shall certify that the applicant has no affiliates.

(iii) FIRMS NOT SUBMITTING TAX RETURNS TO THE UNITED STATES INTERNAL REVENUE SERVICE.—In the case of an applicant that has not previously submitted

a Federal income tax return, the applicant and each of its affiliates shall demonstrate that it meets the definition under subparagraph (A) by submission of a signed certification, in such form as the Secretary may direct through a notice published in the Federal Register, that the applicant or affiliate meets the criteria for a small business and a certification, in English, from the national taxing authority of the country in which the applicant or, if applicable, affiliate is headquartered. The certification from such taxing authority shall bear the official seal of such taxing authority and shall provide the applicant's or affiliate's gross receipts or sales for the most recent year in both the local currency of such country and in United States dollars, the exchange rate used in converting such local currency to dollars, and the dates during which these receipts or sales were collected. The applicant shall also submit a statement signed by the head of the applicant's firm or by its chief financial officer that the applicant has submitted certifications for all of its affiliates, or that the applicant has no affiliates.

(C) REDUCED FEES.—Where the Secretary finds that the applicant involved meets the definition under subparagraph (A), the fees established under subsection (c)(1) may be paid at a reduced rate of—

(i) 25 percent of the fee established under such subsection for a premarket application, a premarket report, a [supplement, or] *supplement*, periodic reporting concerning a class III device, or a *de novo classification request*; and

(ii) 50 percent of the fee established under such subsection for a 30-day notice or a request for classification information.

(D) REQUEST FOR FEE WAIVER OR REDUCTION.—An applicant seeking a fee waiver or reduction under this subsection shall submit supporting information to the Secretary at least 60 days before the fee is required pursuant to subsection (a). The decision of the Secretary regarding whether an entity qualifies for such a waiver or reduction is not reviewable.

(e) SMALL BUSINESSES; FEE REDUCTION REGARDING PREMARKET NOTIFICATION SUBMISSIONS.—

(1) IN GENERAL.—For fiscal year 2008 and each subsequent fiscal year, where the Secretary finds that the applicant involved is a small business, the fee specified in subsection (a)(2)(A)(viii) may be paid at a reduced rate in accordance with paragraph (2)(C).

(2) RULES RELATING TO PREMARKET NOTIFICATION SUBMISSIONS.—

(A) DEFINITION.—For purposes of this subsection, the term “small business” means an entity that reported \$100,000,000 or less of gross receipts or sales in its most recent Federal income tax return for a taxable year, including such returns of all of its affiliates.

(B) EVIDENCE OF QUALIFICATION.—

(i) IN GENERAL.—An applicant shall pay the higher fees established by the Secretary each year unless the applicant submits evidence that it qualifies for the lower fee rate.

(ii) FIRMS SUBMITTING TAX RETURNS TO THE UNITED STATES INTERNAL REVENUE SERVICE.—The applicant shall support its claim that it meets the definition under subparagraph (A) by submission of a copy of its most recent Federal income tax return for a taxable year, and a copy of such returns of its affiliates, which show an amount of gross sales or receipts that is less than the maximum established in subparagraph (A). The applicant, and each of such affiliates, shall certify that the information provided is a true and accurate copy of the actual tax forms they submitted to the Internal Revenue Service. If no tax forms are submitted for any affiliate, the applicant shall certify that the applicant has no affiliates.

(iii) FIRMS NOT SUBMITTING TAX RETURNS TO THE UNITED STATES INTERNAL REVENUE SERVICE.—In the case of an applicant that has not previously submitted a Federal income tax return, the applicant and each of its affiliates shall demonstrate that it meets the definition under subparagraph (A) by submission of a signed certification, in such form as the Secretary may direct through a notice published in the Federal Register, that the applicant or affiliate meets the criteria for a small business and a certification, in English, from the national taxing authority of the country in which the applicant or, if applicable, affiliate is headquartered. The certification from such taxing authority shall bear the official seal of such taxing authority and shall provide the applicant's or affiliate's gross receipts or sales for the most recent year in both the local currency of such country and in United States dollars, the exchange rate used in converting such local currency to dollars, and the dates during which these receipts or sales were collected. The applicant shall also submit a statement signed by the head of the applicant's firm or by its chief financial officer that the applicant has submitted certifications for all of its affiliates, or that the applicant has no affiliates.

(C) REDUCED FEES.—For fiscal year 2008 and each subsequent fiscal year, where the Secretary finds that the applicant involved meets the definition under subparagraph (A), the fee for a premarket notification submission may be paid at [50] 25 percent of the fee that applies under subsection (a)(2)(A)(viii), and as established under subsection (c)(1).

(D) REQUEST FOR REDUCTION.—An applicant seeking a fee reduction under this subsection shall submit supporting information to the Secretary at least 60 days before the fee is required pursuant to subsection (a). The decision of the Secretary regarding whether an entity qualifies for such a reduction is not reviewable.

[(f) FEE WAIVER OR REDUCTION.—

[(1) IN GENERAL.—The Secretary may, at the Secretary's sole discretion, grant a waiver or reduction of fees under subsection (a)(2) or (a)(3) if the Secretary finds that such waiver or reduction is in the interest of public health.

[(2) LIMITATION.—The sum of all fee waivers or reductions granted by the Secretary in any fiscal year under paragraph (1) shall not exceed 2 percent of the total fee revenue amounts established for such year under subsection (c).

[(3) DURATION.—The authority provided by this subsection terminates October 1, 2017.]

[(g) (f) EFFECT OF FAILURE TO PAY FEES.—

(1) NO ACCEPTANCE OF SUBMISSIONS.—A premarket application, premarket report, supplement, premarket notification submission, 30-day notice, request for classification information, [or periodic reporting concerning a class III device] *periodic reporting concerning a class III device, or de novo classification request* submitted by a person subject to fees under subsections (a)(2) and (a)(3) shall be considered incomplete and shall not be accepted by the Secretary until [all fees] *all such fees* owed by such person have been paid.

(2) NO REGISTRATION.—Registration information submitted under section 510 by an establishment subject to a registration fee shall be considered incomplete and shall not be accepted by the Secretary until the registration fee under subsection (a)(3) owed for the establishment has been paid. Until the fee is paid and the registration is complete, the establishment is deemed to have failed to register in accordance with section 510.

[(h) (g) CONDITIONS.—

(1) PERFORMANCE GOALS; TERMINATION OF PROGRAM.—With respect to the amount that, under the salaries and expenses account of the Food and Drug Administration, is appropriated for a fiscal year for devices and radiological products, fees may not be assessed under subsection (a) for the fiscal year, and the Secretary is not expected to meet any performance goals identified for the fiscal year, if—

(A) the amount so appropriated for the fiscal year, excluding the amount of fees appropriated for the fiscal year, is more than 1 percent less than **[\$280,587,000]** *\$320,825,000* multiplied by the adjustment factor applicable to such fiscal year; or

(B) fees were not assessed under subsection (a) for the previous fiscal year.

(2) AUTHORITY.—If the Secretary does not assess fees under subsection (a) during any portion of a fiscal year because of paragraph (1) and if at a later date in such fiscal year the Secretary may assess such fees, the Secretary may assess and collect such fees, without any modification in the rate for premarket applications, supplements, premarket reports, premarket notification submissions, 30-day notices, requests for classification information, periodic reporting concerning a class III device, and establishment registrations at any time in such fiscal year, notwithstanding the provisions of subsection (a) relating to the date fees are to be paid.

[(i) (h) CREDITING AND AVAILABILITY OF FEES.—

(1) IN GENERAL.—Subject to paragraph (2)(C), fees authorized under subsection (a) shall be collected and available for obligation only to the extent and in the amount provided in advance in appropriation Acts. Such fees are authorized to be appropriated to remain available until expended. Such sums as may be necessary may be transferred from the Food and Drug Administration salaries and expenses appropriation account without fiscal year limitation to such appropriation account for salaries and expenses with such fiscal year limitation. The sums transferred shall be available solely for the process for the review of device applications.

(2) COLLECTIONS AND APPROPRIATION ACTS.—

(A) IN GENERAL.—The fees authorized by this section—

(i) subject to subparagraph (C), shall be collected and available in each fiscal year in an amount not to exceed the amount specified in appropriation Acts, or otherwise made available for obligation, for such fiscal year, and

(ii) shall be available to defray increases in the costs of the resources allocated for the process for the review of device applications (including increases in such costs for an additional number of full-time equivalent positions in the Department of Health and Human Services to be engaged in such process) over such costs, excluding costs paid from fees collected under this section, for fiscal year 2009 multiplied by the adjustment factor.

(B) COMPLIANCE.—

(i) IN GENERAL.—The Secretary shall be considered to have met the requirements of subparagraph (A)(ii) in any fiscal year if the costs funded by appropriations and allocated for the process for the review of device applications—

(I) are not more than 3 percent below the level specified in subparagraph (A)(ii); or

(II)(aa) are more than 3 percent below the level specified in subparagraph (A)(ii), and fees assessed for a subsequent fiscal year are decreased by the amount in excess of 3 percent by which such costs fell below the level specified in such subparagraph; and

(bb) such costs are not more than 5 percent below the level specified in such subparagraph.

(ii) MORE THAN 5 PERCENT.—To the extent such costs are more than 5 percent below the specified level in subparagraph (A)(ii), fees may not be collected under this section for that fiscal year.

(C) PROVISION FOR EARLY PAYMENTS.—Payment of fees authorized under this section for a fiscal year, prior to the due date for such fees, may be accepted by the Secretary in accordance with authority provided in advance in a prior year appropriations Act.

(3) AUTHORIZATIONS OF APPROPRIATIONS.—For each of the fiscal years **[2013 through 2017]** *2018 through 2022*, there is authorized to be appropriated for fees under this section an amount equal to the total revenue amount specified under sub-

section (b)(3) for the fiscal year, as adjusted under [subsection (c) and, for fiscal year 2017 only, as further adjusted under paragraph (4).] *subsection (c)*.

[(4) OFFSET.—If the cumulative amount of fees collected during fiscal years 2013, 2014, and 2015, added to the amount estimated to be collected for fiscal year 2016, which estimate shall be based upon the amount of fees received by the Secretary through June 30, 2016, exceeds the cumulative amount appropriated pursuant to paragraph (3) for these four fiscal years, the excess shall be credited to the appropriation account of the Food and Drug Administration as provided in paragraph (1), and shall be subtracted from the amount of fees that would otherwise be authorized to be collected under this section pursuant to appropriation Acts for fiscal year 2017.]

[(j)] *(i)* COLLECTION OF UNPAID FEES.—In any case where the Secretary does not receive payment of a fee assessed under subsection (a) within 30 days after it is due, such fee shall be treated as a claim of the United States Government subject to subchapter II of chapter 37 of title 31, United States Code.

[(k)] *(j)* WRITTEN REQUESTS FOR REFUNDS.—To qualify for consideration for a refund under subsection (a)(2)(D), a person shall submit to the Secretary a written request for such refund not later than 180 days after such fee is due.

[(l)] *(k)* CONSTRUCTION.—This section may not be construed to require that the number of full-time equivalent positions in the Department of Health and Human Services, for officers, employees, and advisory committees not engaged in the process of the review of device applications, be reduced to offset the number of officers, employees, and advisory committees so engaged.

SEC. 738A. REAUTHORIZATION; REPORTING REQUIREMENTS.

(a) REPORTS.—

(1) PERFORMANCE REPORT.—

(A) IN GENERAL.—Beginning with fiscal year [2013] 2018, for each fiscal year for which fees are collected under this part, the Secretary shall prepare and submit to the Committee on Health, Education, Labor, and Pensions of the Senate and the Committee on Energy and Commerce of the House of Representatives annual reports concerning the progress of the Food and Drug Administration in achieving the goals identified in the letters described in section 201(b) of [the Medical Device User Fee Amendments of 2012] *the Medical Device User Fee Amendments of 2017* during such fiscal year and the future plans of the Food and Drug Administration for meeting the goals.

(B) PUBLICATION.—With regard to information to be reported by the Food and Drug Administration to industry on a quarterly and annual basis pursuant to the letters described in section 201(b) of [the Medical Device User Fee Amendments Act of 2012] *the Medical Device User Fee Amendments of 2017*, the Secretary shall make such information publicly available on the Internet Web site of the Food and Drug Administration not later than 60 days after the end of each quarter or 120 days after the end of each fiscal year, respectively, to which such information applies. This information shall include the status of the inde-

pendent assessment identified in the letters described in such section 201(b).

(C) UPDATES.—The Secretary shall include in each report under subparagraph (A) information on all previous cohorts for which the Secretary has not given a complete response on all device premarket applications and reports, supplements, and premarket notifications in the cohort.

(2) FISCAL REPORT.—For fiscal years **[2013 through 2017]** *2018 through 2022*, not later than 120 days after the end of each fiscal year during which fees are collected under this part, the Secretary shall prepare and submit to the Committee on Health, Education, Labor, and Pensions of the Senate and the Committee on Energy and Commerce of the House of Representatives, a report on the implementation of the authority for such fees during such fiscal year and the use, by the Food and Drug Administration, of the fees collected during such fiscal year for which the report is made.

(3) PUBLIC AVAILABILITY.—The Secretary shall make the reports required under paragraphs (1) and (2) available to the public on the Internet Web site of the Food and Drug Administration.

(b) REAUTHORIZATION.—

(1) CONSULTATION.—In developing recommendations to present to Congress with respect to the goals, and plans for meeting the goals, for the process for the review of device applications for the first 5 fiscal years after fiscal year **[2017]** *2022*, and for the reauthorization of this part for such fiscal years, the Secretary shall consult with—

(A) the Committee on Energy and Commerce of the House of Representatives;

(B) the Committee on Health, Education, Labor, and Pensions of the Senate;

(C) scientific and academic experts;

(D) health care professionals;

(E) representatives of patient and consumer advocacy groups; and

(F) the regulated industry.

(2) PRIOR PUBLIC INPUT.—Prior to beginning negotiations with the regulated industry on the reauthorization of this part, the Secretary shall—

(A) publish a notice in the Federal Register requesting public input on the reauthorization;

(B) hold a public meeting at which the public may present its views on the reauthorization, including specific suggestions for changes to the goals referred to in subsection (a)(1);

(C) provide a period of 30 days after the public meeting to obtain written comments from the public suggesting changes to this part; and

(D) publish the comments on the Food and Drug Administration's Internet Web site.

(3) PERIODIC CONSULTATION.—Not less frequently than once every month during negotiations with the regulated industry, the Secretary shall hold discussions with representatives of patient and consumer advocacy groups to continue discussions of

their views on the reauthorization and their suggestions for changes to this part as expressed under paragraph (2).

(4) PUBLIC REVIEW OF RECOMMENDATIONS.—After negotiations with the regulated industry, the Secretary shall—

(A) present the recommendations developed under paragraph (1) to the Congressional committees specified in such paragraph;

(B) publish such recommendations in the Federal Register;

(C) provide for a period of 30 days for the public to provide written comments on such recommendations;

(D) hold a meeting at which the public may present its views on such recommendations; and

(E) after consideration of such public views and comments, revise such recommendations as necessary.

(5) TRANSMITTAL OF RECOMMENDATIONS.—Not later than January 15, ~~2017~~ 2022, the Secretary shall transmit to Congress the revised recommendations under paragraph (4), a summary of the views and comments received under such paragraph, and any changes made to the recommendations in response to such views and comments.

(6) MINUTES OF NEGOTIATION MEETINGS.—

(A) PUBLIC AVAILABILITY.—Before presenting the recommendations developed under paragraphs (1) through (5) to the Congress, the Secretary shall make publicly available, on the public Web site of the Food and Drug Administration, minutes of all negotiation meetings conducted under this subsection between the Food and Drug Administration and the regulated industry.

(B) CONTENT.—The minutes described under subparagraph (A) shall summarize any substantive proposal made by any party to the negotiations as well as significant controversies or differences of opinion during the negotiations and their resolution.

PART 4—FEES RELATING TO ANIMAL DRUGS

* * * * *

SEC. 740. AUTHORITY TO ASSESS AND USE ANIMAL DRUG FEES.

(a) TYPES OF FEES.—Beginning in fiscal year 2004, the Secretary shall assess and collect fees in accordance with this section as follows:

(1) ANIMAL DRUG APPLICATION AND SUPPLEMENT FEE.—

(A) IN GENERAL.—Each person that submits, on or after September 1, 2003, an animal drug application or a supplemental animal drug application shall be subject to a fee as follows:

(i) A fee established in subsection (c) for an animal drug application, except an animal drug application subject to the criteria set forth in section 512(d)(4).

(ii) A fee established in subsection (c), in an amount that is equal to 50 percent of the amount of the fee under clause (i), for—

(I) a supplemental animal drug application for which safety or effectiveness data are required; and

(II) an animal drug application subject to the criteria set forth in section 512(d)(4).

(B) PAYMENT.—The fee required by subparagraph (A) shall be due upon submission of the animal drug application or supplemental animal drug application.

(C) EXCEPTION FOR PREVIOUSLY FILED APPLICATION OR SUPPLEMENT.—If an animal drug application or a supplemental animal drug application was submitted by a person that paid the fee for such application or supplement, was accepted for filing, and was not approved or was withdrawn (without a waiver or refund), the submission of an animal drug application or a supplemental animal drug application for the same product by the same person (or the person's licensee, assignee, or successor) shall not be subject to a fee under subparagraph (A).

(D) REFUND OF FEE IF APPLICATION REFUSED FOR FILING.—The Secretary shall refund 75 percent of the fee paid under subparagraph (B) for any animal drug application or supplemental animal drug application which is refused for filing.

(E) REFUND OF FEE IF APPLICATION WITHDRAWN.—If an animal drug application or a supplemental animal drug application is withdrawn after the application or supplement was filed, the Secretary may refund the fee or portion of the fee paid under subparagraph (B) if no substantial work was performed on the application or supplement after the application or supplement was filed. The Secretary shall have the sole discretion to refund the fee under this paragraph. A determination by the Secretary concerning a refund under this paragraph shall not be reviewable.

(2) ANIMAL DRUG PRODUCT FEE.—

(A) IN GENERAL.—Each person—

(i) who is named as the applicant in an animal drug application or supplemental animal drug application for an animal drug product which has been submitted for listing under section 510; and

(ii) who, after September 1, 2003, had pending before the Secretary an animal drug application or supplemental animal drug application,

shall pay for each such animal drug product the annual fee established in subsection (c).

(B) PAYMENT; FEE DUE DATE.—Such fee shall be payable for the fiscal year in which the animal drug product is first submitted for listing under section 510, or is submitted for relisting under section 510 if the animal drug product has been withdrawn from listing and relisted. After such fee is paid for that fiscal year, such fee shall be due each subsequent fiscal year that the product remains listed, upon the later of—

(i) the first business day after the date of enactment of an appropriations Act providing for the collection

and obligation of fees for such fiscal year under this section; or

(ii) January 31 of each year.

(C) LIMITATION.—Such fee shall be paid only once for each animal drug product for a fiscal year in which the fee is payable.

(3) ANIMAL DRUG ESTABLISHMENT FEE.—

(A) IN GENERAL.—Each person—

(i) who owns or operates, directly or through an affiliate, an animal drug establishment;

(ii) who is named as the applicant in an animal drug application or supplemental animal drug application for an animal drug product which has been submitted for listing under section 510; and

(iii) who, after September 1, 2003, had pending before the Secretary an animal drug application or supplemental animal drug application,

shall be assessed an annual establishment fee as established in subsection (c) for each animal drug establishment listed in its approved animal drug application as an establishment that manufactures the animal drug product named in the application.

(B) PAYMENT; FEE DUE DATE.—The annual establishment fee shall be assessed in each fiscal year in which the animal drug product named in the application is assessed a fee under paragraph (2) unless the animal drug establishment listed in the application does not engage in the manufacture of the animal drug product during the fiscal year. The fee under this paragraph for a fiscal year shall be due upon the later of—

(i) the first business day after the date of enactment of an appropriations Act providing for the collection and obligation of fees for such fiscal year under this section; or

(ii) January 31 of each year.

[(C) LIMITATION.—

[(i) IN GENERAL.—An establishment shall be assessed only one fee per fiscal year under this section, subject to clause (ii).

[(ii) CERTAIN MANUFACTURERS.—If a single establishment manufactures both animal drug products and prescription drug products, as defined in section 735(3), such establishment shall be assessed both the animal drug establishment fee and the prescription drug establishment fee, as set forth in section 736(a)(2), within a single fiscal year.]

(C) LIMITATION.—*An establishment shall be assessed only one fee per fiscal year under this section.*

(4) ANIMAL DRUG SPONSOR FEE.—

(A) IN GENERAL.—Each person—

(i) who meets the definition of an animal drug sponsor within a fiscal year; and

(ii) who, after September 1, 2003, had pending before the Secretary an animal drug application, a sup-

plemental animal drug application, or an investigational animal drug submission, shall be assessed an annual sponsor fee as established under subsection (c).

(B) PAYMENT; FEE DUE DATE.—The fee under this paragraph for a fiscal year shall be due upon the later of—

(i) the first business day after the date of enactment of an appropriations Act providing for the collection and obligation of fees for such fiscal year under this section; or

(ii) January 31 of each year.

(C) LIMITATION.—Each animal drug sponsor shall pay only one such fee each fiscal year.

(b) FEE REVENUE AMOUNTS.—

(1) IN GENERAL.—Subject to subsections (c), (d), (f), and (g)—

(A) for fiscal year 2014, the fees required under subsection (a) shall be established to generate a total revenue amount of \$23,600,000; and

(B) for each of fiscal years 2015 through 2018, the fees required under subsection (a) shall be established to generate a total revenue amount of \$21,600,000.

(2) TYPES OF FEES.—Of the total revenue amount determined for a fiscal year under paragraph (1)—

(A) 20 percent shall be derived from fees under subsection (a)(1) (relating to animal drug applications and supplements);

(B) 27 percent shall be derived from fees under subsection (a)(2) (relating to animal drug products);

(C) 26 percent shall be derived from fees under subsection (a)(3) (relating to animal drug establishments); and

(D) 27 percent shall be derived from fees under subsection (a)(4) (relating to animal drug sponsors).

(c) ANNUAL FEE SETTING; ADJUSTMENTS.—

(1) ANNUAL FEE SETTING.—The Secretary shall establish, 60 days before the start of each fiscal year beginning after September 30, 2003, for that fiscal year, animal drug application fees, supplemental animal drug application fees, animal drug sponsor fees, animal drug establishment fees, and animal drug product fees based on the revenue amounts established under subsection (b) and the adjustments provided under this subsection.

(2) INFLATION ADJUSTMENT.—For fiscal year 2015 and subsequent fiscal years, the revenue amounts established in subsection (b) shall be adjusted by the Secretary by notice, published in the Federal Register, for a fiscal year, by an amount equal to the sum of—

(A) one;

(B) the average annual percent change in the cost, per full-time equivalent position of the Food and Drug Administration, of all personnel compensation and benefits paid with respect to such positions for the first 3 of the preceding 4 fiscal years for which data are available, multiplied by the average proportion of personnel compensation and benefits costs to total Food and Drug Administration

costs for the first 3 years of the preceding 4 fiscal years for which data are available; and

(C) the average annual percent change that occurred in the Consumer Price Index for urban consumers (Washington-Baltimore, DC-MD-VA-WV; not seasonally adjusted; all items less food and energy; annual index) for the first 3 years of the preceding 4 years for which data are available multiplied by the average proportion of all costs other than personnel compensation and benefits costs to total Food and Drug Administration costs for the first 3 years of the preceding 4 fiscal years for which data are available.

The adjustment made each fiscal year under this paragraph shall be added on a compounded basis to the sum of all adjustments made each fiscal year after fiscal year 2014 under this paragraph.

(3) **WORKLOAD ADJUSTMENT.**—For fiscal year 2015 and subsequent fiscal years, after the revenue amounts established in subsection (b) are adjusted for inflation in accordance with paragraph (2), the revenue amounts shall be further adjusted for such fiscal year to reflect changes in the workload of the Secretary for the process for the review of animal drug applications. With respect to such adjustment—

(A) such adjustment shall be determined by the Secretary based on a weighted average of the change in the total number of animal drug applications, supplemental animal drug applications for which data with respect to safety or effectiveness are required, manufacturing supplemental animal drug applications, investigational animal drug study submissions, and investigational animal drug protocol submissions submitted to the Secretary;

(B) the Secretary shall publish in the Federal Register the fees resulting from such adjustment and the supporting methodologies; and

(C) under no circumstances shall such adjustment result in fee revenues for a fiscal year that are less than the fee revenues for that fiscal year established in subsection (b), as adjusted for inflation under paragraph (2).

(4) **FINAL YEAR ADJUSTMENT.**—For fiscal year 2018, the Secretary may, in addition to other adjustments under this subsection, further increase the fees under this section, if such an adjustment is necessary, to provide for up to 3 months of operating reserves of carryover user fees for the process for the review of animal drug applications for the first 3 months of fiscal year 2019. If the Food and Drug Administration has carryover balances for the process for the review of animal drug applications in excess of 3 months of such operating reserves, then this adjustment will not be made. If this adjustment is necessary, then the rationale for the amount of the increase shall be contained in the annual notice setting fees for fiscal year 2018.

(5) **LIMIT.**—The total amount of fees charged, as adjusted under this subsection, for a fiscal year may not exceed the total costs for such fiscal year for the resources allocated for the process for the review of animal drug applications.

(d) FEE WAIVER OR REDUCTION.—

(1) IN GENERAL.—The Secretary shall grant a waiver from or a reduction of one or more fees assessed under subsection (a) where the Secretary finds that—

(A) the assessment of the fee would present a significant barrier to innovation because of limited resources available to such person or other circumstances;

(B) the fees to be paid by such person will exceed the anticipated present and future costs incurred by the Secretary in conducting the process for the review of animal drug applications for such person;

(C) the animal drug application or supplemental animal drug application is intended solely to provide for use of the animal drug in—

(i) a Type B medicated feed (as defined in section 558.3(b)(3) of title 21, Code of Federal Regulations (or any successor regulation)) intended for use in the manufacture of Type C free-choice medicated feeds; or

(ii) a Type C free-choice medicated feed (as defined in section 558.3(b)(4) of title 21, Code of Federal Regulations (or any successor regulation));

(D) the animal drug application or supplemental animal drug application is intended solely to provide for a minor use or minor species indication; or

(E) the sponsor involved is a small business submitting its first animal drug application to the Secretary for review.

(2) USE OF STANDARD COSTS.—In making the finding in paragraph (1)(B), the Secretary may use standard costs.

(3) RULES FOR SMALL BUSINESSES.—

(A) DEFINITION.—In paragraph (1)(E), the term “small business” means an entity that has fewer than 500 employees, including employees of affiliates.

(B) WAIVER OF APPLICATION FEE.—The Secretary shall waive under paragraph (1)(E) the application fee for the first animal drug application that a small business or its affiliate submits to the Secretary for review. After a small business or its affiliate is granted such a waiver, the small business or its affiliate shall pay application fees for all subsequent animal drug applications and supplemental animal drug applications for which safety or effectiveness data are required in the same manner as an entity that does not qualify as a small business.

(C) CERTIFICATION.—The Secretary shall require any person who applies for a waiver under paragraph (1)(E) to certify their qualification for the waiver. The Secretary shall periodically publish in the Federal Register a list of persons making such certifications.

(e) EFFECT OF FAILURE TO PAY FEES.—An animal drug application or supplemental animal drug application submitted by a person subject to fees under subsection (a) shall be considered incomplete and shall not be accepted for filing by the Secretary until all fees owed by such person have been paid. An investigational animal drug submission under section 739(5)(B) that is submitted by a person subject to fees under subsection (a) shall be considered in-

complete and shall not be accepted for review by the Secretary until all fees owed by such person have been paid. The Secretary may discontinue review of any animal drug application, supplemental animal drug application or investigational animal drug submission from a person if such person has not submitted for payment all fees owed under this section by 30 days after the date upon which they are due.

(f) ASSESSMENT OF FEES.—

(1) LIMITATION.—Fees may not be assessed under subsection (a) for a fiscal year beginning after fiscal year 2003 unless appropriations for salaries and expenses of the Food and Drug Administration for such fiscal year (excluding the amount of fees appropriated for such fiscal year) are equal to or greater than the amount of appropriations for the salaries and expenses of the Food and Drug Administration for the fiscal year 2003 (excluding the amount of fees appropriated for such fiscal year) multiplied by the adjustment factor applicable to the fiscal year involved.

(2) AUTHORITY.—If the Secretary does not assess fees under subsection (a) during any portion of a fiscal year because of paragraph (1) and if at a later date in such fiscal year the Secretary may assess such fees, the Secretary may assess and collect such fees, without any modification in the rate, for animal drug applications, supplemental animal drug applications, investigational animal drug submissions, animal drug sponsors, animal drug establishments and animal drug products at any time in such fiscal year notwithstanding the provisions of subsection (a) relating to the date fees are to be paid.

(g) CREDITING AND AVAILABILITY OF FEES.—

(1) IN GENERAL.—Subject to paragraph (2)(C), fees authorized under subsection (a) shall be collected and available for obligation only to the extent and in the amount provided in advance in appropriations Acts. Such fees are authorized to be appropriated to remain available until expended. Such sums as may be necessary may be transferred from the Food and Drug Administration salaries and expenses appropriation account without fiscal year limitation to such appropriation account for salary and expenses with such fiscal year limitation. The sums transferred shall be available solely for the process for the review of animal drug applications.

(2) COLLECTIONS AND APPROPRIATION ACTS.—

(A) IN GENERAL.—The fees authorized by this section—

(i) subject to subparagraph (C), shall be collected and available in each fiscal year in an amount not to exceed the amount specified in appropriation Acts, or otherwise made available for obligation for such fiscal year, and

(ii) shall be available to defray increases in the costs of the resources allocated for the process for the review of animal drug applications (including increases in such costs for an additional number of full-time equivalent positions in the Department of Health and Human Services to be engaged in such process) over such costs, excluding costs paid from fees collected

under this section, for fiscal year 2003 multiplied by the adjustment factor.

(B) COMPLIANCE.—The Secretary shall be considered to have met the requirements of subparagraph (A)(ii) in any fiscal year if the costs funded by appropriations and allocated for the process for the review of animal drug applications—

(i) are not more than 3 percent below the level specified in subparagraph (A)(ii); or

(ii)(I) are more than 3 percent below the level specified in subparagraph (A)(ii), and fees assessed for the fiscal year following the subsequent fiscal year are decreased by the amount in excess of 3 percent by which such costs fell below the level specified in subparagraph (A)(ii); and

(II) such costs are not more than 5 percent below the level specified in subparagraph (A)(ii).

(C) PROVISION FOR EARLY PAYMENTS.—Payment of fees authorized under this section for a fiscal year, prior to the due date for such fees, may be accepted by the Secretary in accordance with authority provided in advance in a prior year appropriations Act.

(3) AUTHORIZATION OF APPROPRIATIONS.—For each of the fiscal years 2014 through 2018, there is authorized to be appropriated for fees under this section an amount equal to the total revenue amount determined under subsection (b) for the fiscal year, as adjusted or otherwise affected under subsection (c) and paragraph (4).

(4) OFFSET OF OVERCOLLECTIONS; RECOVERY OF COLLECTION SHORTFALLS.—

(A) OFFSET OF OVERCOLLECTIONS.—If the sum of the cumulative amount of fees collected under this section for fiscal years 2014 through 2016 and the amount of fees estimated to be collected under this section for fiscal year 2017 (including any increased fee collections attributable to subparagraph (B)), exceeds the cumulative amount appropriated pursuant to paragraph (3) for the fiscal years 2014 through 2017, the excess amount shall be credited to the appropriation account of the Food and Drug Administration as provided in paragraph (1), and shall be subtracted from the amount of fees that would otherwise be authorized to be collected under this section pursuant to appropriation Acts for fiscal year 2018.

(B) RECOVERY OF COLLECTION SHORTFALLS.—

(i) FISCAL YEAR 2016.—For fiscal year 2016, the amount of fees otherwise authorized to be collected under this section shall be increased by the amount, if any, by which the amount collected under this section and appropriated for fiscal year 2014 falls below the amount of fees authorized for fiscal year 2014 under paragraph (3).

(ii) FISCAL YEAR 2017.—For fiscal year 2017, the amount of fees otherwise authorized to be collected under this section shall be increased by the amount, if any, by which the amount collected under this sec-

tion and appropriated for fiscal year 2015 falls below the amount of fees authorized for fiscal year 2015 under paragraph (3).

(iii) FISCAL YEAR 2018.—For fiscal year 2018, the amount of fees otherwise authorized to be collected under this section (including any reduction in the authorized amount under subparagraph (A)), shall be increased by the cumulative amount, if any, by which the amount collected under this section and appropriated for fiscal years 2016 and 2017 (including estimated collections for fiscal year 2017) falls below the cumulative amount of fees authorized under paragraph (3) for fiscal years 2016 and 2017.

(h) COLLECTION OF UNPAID FEES.—In any case where the Secretary does not receive payment of a fee assessed under subsection (a) within 30 days after it is due, such fee shall be treated as a claim of the United States Government subject to subchapter II of chapter 37 of title 31, United States Code.

(i) WRITTEN REQUESTS FOR WAIVERS, REDUCTIONS, AND REFUNDS.—To qualify for consideration for a waiver or reduction under subsection (d), or for a refund of any fee collected in accordance with subsection (a), a person shall submit to the Secretary a written request for such waiver, reduction, or refund not later than 180 days after such fee is due.

(j) CONSTRUCTION.—This section may not be construed to require that the number of full-time equivalent positions in the Department of Health and Human Services, for officers, employees, and advisory committees not engaged in the process of the review of animal drug applications, be reduced to offset the number of officers, employees, and advisory committees so engaged.

(k) ABBREVIATED NEW ANIMAL DRUG APPLICATIONS.—The Secretary shall—

(1) to the extent practicable, segregate the review of abbreviated new animal drug applications from the process for the review of animal drug applications; and

(2) adopt other administrative procedures to ensure that review times of abbreviated new animal drug applications do not increase from their current level due to activities under the user fee program.

* * * * *

PART 7—FEES RELATING TO GENERIC DRUGS

SEC. 744A. DEFINITIONS.

For purposes of this part:

(1) The term “abbreviated new drug application”—

(A) means an application submitted under section 505(j), an abbreviated application submitted under section 507 (as in effect on the day before the date of enactment of the Food and Drug Administration Modernization Act of 1997), or an abbreviated new drug application submitted pursuant to regulations in effect prior to the implementation of the Drug Price Competition and Patent Term Restoration Act of 1984; and

- (B) does not include an **application for a positron emission tomography drug.** *application—*
- (i) *for a positron emission tomography drug; or*
 - (ii) *submitted by a State or Federal governmental entity for a drug that is not distributed commercially.*
- (2) The term “active pharmaceutical ingredient” means—
- (A) a substance, or a mixture when the substance is unstable or cannot be transported on its own, intended—
 - (i) to be used as a component of a drug; and
 - (ii) to furnish pharmacological activity or other direct effect in the diagnosis, cure, mitigation, treatment, or prevention of disease, or to affect the structure or any function of the human body; or
 - (B) a substance intended for final crystallization, purification, or salt formation, or any combination of those activities, to become a substance or mixture described in subparagraph (A).
- (3) The term “adjustment factor” means a factor applicable to a fiscal year that is the Consumer Price Index for all urban consumers (all items; United States city average) for October of the preceding fiscal year divided by such Index for October 2011.
- (4) The term “affiliate” means a business entity that has a relationship with a second business entity if, directly or indirectly—
- (A) one business entity controls, or has the power to control, the other business entity; or
 - (B) a third party controls, or has power to control, both of the business entities.
- (5) *The term “contract manufacturing organization facility” means a manufacturing facility of a finished dosage form of a drug approved pursuant to an abbreviated new drug application, where such manufacturing facility is not identified in an approved abbreviated new drug application held by the owner of such facility or an affiliate of such owner or facility.*
- [(5)] (6)(A)** The term “facility”—
- (i) means a business or other entity—
 - (I) under one management, either direct or indirect; and
 - (II) at one geographic location or address engaged in manufacturing or processing an active pharmaceutical ingredient or a finished dosage form; and
 - (ii) does not include a business or other entity whose only manufacturing or processing activities are one or more of the following: repackaging, relabeling, or testing.
- (B) For purposes of subparagraph (A), separate buildings within close proximity are considered to be at one geographic location or address if the activities in them are—
- (i) closely related to the same business enterprise;
 - (ii) under the supervision of the same local management; and
 - (iii) capable of being inspected by the Food and Drug Administration during a single inspection.
- (C) If a business or other entity would meet the definition of a facility under this paragraph but for being under multiple

management, the business or other entity is deemed to constitute multiple facilities, one per management entity, for purposes of this paragraph.

[(6)] (7) The term “finished dosage form” means—

(A) a drug product in the form in which it will be administered to a patient, such as a tablet, capsule, solution, or topical application;

(B) a drug product in a form in which reconstitution is necessary prior to administration to a patient, such as oral suspensions or lyophilized powders; or

(C) any combination of an active pharmaceutical ingredient with another component of a drug product for purposes of production of a drug product described in subparagraph (A) or (B).

[(7)] (8) The term “generic drug submission” means an abbreviated new drug application, an amendment to an abbreviated new drug application, or a prior approval supplement to an abbreviated new drug application.

[(8)] (9) The term “human generic drug activities” means the following activities of the Secretary associated with generic drugs and inspection of facilities associated with generic drugs:

(A) The activities necessary for the review of generic drug submissions, including review of drug master files referenced in such submissions.

(B) The issuance of—

(i) approval letters which approve abbreviated new drug applications or supplements to such applications; or

(ii) complete response letters which set forth in detail the specific deficiencies in such applications and, where appropriate, the actions necessary to place such applications in condition for approval.

(C) The issuance of letters related to Type II active pharmaceutical drug master files which—

(i) set forth in detail the specific deficiencies in such submissions, and where appropriate, the actions necessary to resolve those deficiencies; or

(ii) document that no deficiencies need to be addressed.

(D) Inspections related to generic drugs.

(E) Monitoring of research conducted in connection with the review of generic drug submissions and drug master files.

(F) Postmarket safety activities with respect to drugs approved under abbreviated new drug applications or supplements, including the following activities:

(i) Collecting, developing, and reviewing safety information on approved drugs, including adverse event reports.

(ii) Developing and using improved adverse-event data-collection systems, including information technology systems.

(iii) Developing and using improved analytical tools to assess potential safety problems, including access to external data bases.

(iv) Implementing and enforcing section 505(o) (relating to postapproval studies and clinical trials and labeling changes) and section 505(p) (relating to risk evaluation and mitigation strategies) insofar as those activities relate to abbreviated new drug applications.

(v) Carrying out section 505(k)(5) (relating to adverse-event reports and postmarket safety activities).

(G) Regulatory science activities related to generic drugs.

[(9)] (10) The term “positron emission tomography drug” has the meaning given to the term “compounded positron emission tomography drug” in section 201(ii), except that paragraph (1)(B) of such section shall not apply.

[(10)] (11) The term “prior approval supplement” means a request to the Secretary to approve a change in the drug substance, drug product, production process, quality controls, equipment, or facilities covered by an approved abbreviated new drug application when that change has a substantial potential to have an adverse effect on the identity, strength, quality, purity, or potency of the drug product as these factors may relate to the safety or effectiveness of the drug product.

[(11)] (12) The term “resources allocated for human generic drug activities” means the expenses for—

(A) officers and employees of the Food and Drug Administration, contractors of the Food and Drug Administration, advisory committees, and costs related to such officers and employees and to contracts with such contractors;

(B) management of information, and the acquisition, maintenance, and repair of computer resources;

(C) leasing, maintenance, renovation, and repair of facilities and acquisition, maintenance, and repair of fixtures, furniture, scientific equipment, and other necessary materials and supplies; and

(D) collecting fees under subsection (a) and accounting for resources allocated for the review of abbreviated new drug applications and supplements and inspection related to generic drugs.

[(12)] (13) The term “Type II active pharmaceutical ingredient drug master file” means a submission of information to the Secretary by a person that intends to authorize the Food and Drug Administration to reference the information to support approval of a generic drug submission without the submitter having to disclose the information to the generic drug submission applicant.

SEC. 744B. AUTHORITY TO ASSESS AND USE HUMAN GENERIC DRUG FEES.

(a) TYPES OF FEES.—Beginning in [(fiscal year 2013)] *fiscal year 2018*, the Secretary shall assess and collect fees in accordance with this section as follows:

(1) ONE-TIME BACKLOG FEE FOR ABBREVIATED NEW DRUG APPLICATIONS PENDING ON OCTOBER 1, 2012.—

(A) IN GENERAL.—Each person that owns an abbreviated new drug application that is pending on October 1, 2012, and that has not received a tentative approval prior to that date, shall be subject to a fee for each such application, as calculated under subparagraph (B).

(B) METHOD OF FEE AMOUNT CALCULATION.—The amount of each one-time backlog fee shall be calculated by dividing \$50,000,000 by the total number of abbreviated new drug applications pending on October 1, 2012, that have not received a tentative approval as of that date.

(C) NOTICE.—Not later than October 31, 2012, the Secretary shall publish in the Federal Register a notice announcing the amount of the fee required by subparagraph (A).

(D) FEE DUE DATE.—The fee required by subparagraph (A) shall be due no later than 30 calendar days after the date of the publication of the notice specified in subparagraph (C).

(E) SUNSET.—*This paragraph shall cease to be effective October 1, 2022.*

(2) DRUG MASTER FILE FEE.—

(A) IN GENERAL.—Each person that owns a Type II active pharmaceutical ingredient drug master file that is referenced on or after October 1, 2012, in a generic drug submission by any initial letter of authorization shall be subject to a drug master file fee.

(B) ONE-TIME PAYMENT.—If a person has paid a drug master file fee for a Type II active pharmaceutical ingredient drug master file, the person shall not be required to pay a subsequent drug master file fee when that Type II active pharmaceutical ingredient drug master file is subsequently referenced in generic drug submissions.

[(C) NOTICE.—

[(i) FISCAL YEAR 2013.—Not later than October 31, 2012, the Secretary shall publish in the Federal Register a notice announcing the amount of the drug master file fee for fiscal year 2013.

[(ii) FISCAL YEAR 2014 THROUGH 2017.—Not later than 60 days before the start of each of fiscal years 2014 through 2017, the Secretary shall publish in the Federal Register the amount of the drug master file fee established by this paragraph for such fiscal year.]

(C) NOTICE.—*Not later than 60 days before the start of each of fiscal years 2018 through 2022, the Secretary shall publish in the Federal Register the amount of the drug master file fee established by this paragraph for such fiscal year.*

(D) AVAILABILITY FOR REFERENCE.—

(i) IN GENERAL.—Subject to subsection (g)(2)(C), for a generic drug submission to reference a Type II active pharmaceutical ingredient drug master file, the drug master file must be deemed available for reference by the Secretary.

(ii) CONDITIONS.—A drug master file shall be deemed available for reference by the Secretary if—

(I) the person that owns a Type II active pharmaceutical ingredient drug master file has paid the fee required under subparagraph (A) within 20 calendar days after the applicable due date under subparagraph (E); and

(II) the drug master file has not failed an initial completeness assessment by the Secretary, in accordance with criteria to be published by the Secretary.

(iii) LIST.—The Secretary shall make publicly available on the Internet Web site of the Food and Drug Administration a list of the drug master file numbers that correspond to drug master files that have successfully undergone an initial completeness assessment, in accordance with criteria to be published by the Secretary, and are available for reference.

(E) FEE DUE DATE.—

(i) IN GENERAL.—Subject to clause (ii), a drug master file fee shall be due **[no later than the date]** *on the earlier of—*

(I) *the date on which the first generic drug submission is submitted that references the associated Type II active pharmaceutical ingredient drug master file***[.];** or

(II) *the date on which the drug master file holder requests the initial completeness assessment.*

(ii) LIMITATION.—No fee shall be due under subparagraph (A) for a fiscal year until the later of—

(I) 30 calendar days after publication of the **[notice provided for in clause (i) or (ii) of subparagraph (C), as applicable]** *notice provided for in subparagraph (C);* or

(II) 30 calendar days after the date of enactment of an appropriations Act providing for the collection and obligation of fees for such year under this section.

(3) ABBREVIATED NEW DRUG APPLICATION **[AND PRIOR APPROVAL SUPPLEMENT]** FILING FEE.—

(A) IN GENERAL.—Each applicant that submits, on or after October 1, 2012, an abbreviated new drug application **[or a prior approval supplement to an abbreviated new drug application]** shall be subject to a fee for each such submission in the amount established under subsection (d).

[(B) NOTICE.—

[(i) FISCAL YEAR 2013.—Not later than October 31, 2012, the Secretary shall publish in the Federal Register a notice announcing the amount of the fees under subparagraph (A) for fiscal year 2013.

[(ii) FISCAL YEARS 2014 THROUGH 2017.—Not later than 60 days before the start of each of fiscal years 2014 through 2017, the Secretary shall publish in the Federal Register the amount of the fees under subparagraph (A) for such fiscal year.

[(C) FEE DUE DATE.—

[(i) IN GENERAL.—Except as provided in clause (ii), the fees required by subparagraphs (A) and (F) shall be due no later than the date of submission of the abbreviated new drug application or prior approval supplement for which such fee applies.

[(ii) SPECIAL RULE FOR 2013.—For fiscal year 2013, such fees shall be due on the later of—

[(I) the date on which the fee is due under clause (i);

[(II) 30 calendar days after publication of the notice referred to in subparagraph (B)(i); or

[(III) if an appropriations Act is not enacted providing for the collection and obligation of fees for such year under this section by the date of submission of the application or prior approval supplement for which the fees under subparagraphs (A) and (F) apply, 30 calendar days after the date that such an appropriations Act is enacted.]

(B) NOTICE.—*Not later than 60 days before the start of each of fiscal years 2018 through 2022, the Secretary shall publish in the Federal Register the amount of the fees under subparagraph (A) for such fiscal year.*

(C) FEE DUE DATE.—*The fees required by subparagraphs (A) and (F) shall be due no later than the date of submission of the abbreviated new drug application or prior approval supplement for which such fee applies.*

(D) REFUND OF FEE IF ABBREVIATED NEW DRUG APPLICATION IS NOT CONSIDERED TO HAVE BEEN RECEIVED, IS WITHDRAWN PRIOR TO BEING RECEIVED, OR IS NO LONGER RECEIVED.—[The Secretary shall refund 75 percent of the fee paid under subparagraph (A) for any abbreviated new drug application or prior approval supplement to an abbreviated new drug application that the Secretary considers not to have been received within the meaning of section 505(j)(5)(A) for a cause other than failure to pay fees.]

(i) APPLICATIONS NOT CONSIDERED TO HAVE BEEN RECEIVED AND APPLICATIONS WITHDRAWN PRIOR TO BEING RECEIVED.—*The Secretary shall refund 75 percent of the fee paid under subparagraph (A) for any abbreviated new drug application that the Secretary considers not to have been received within the meaning of section 505(j)(5)(A) for a cause other than failure to pay fees, or that has been withdrawn prior to being received within the meaning of section 505(j)(5)(A).*

(ii) APPLICATIONS NO LONGER RECEIVED.—*The Secretary shall refund 100 percent of the fee paid under subparagraph (A) for any abbreviated new drug application if the Secretary initially receives the application under section 505(j)(5)(A) and subsequently determines that an exclusivity period for a listed drug should have prevented the Secretary from receiving such application, such that the abbreviated new drug application is no longer received within the meaning of section 505(j)(5)(A).*

(E) FEE FOR AN APPLICATION THE SECRETARY CONSIDERS NOT TO HAVE BEEN RECEIVED, OR THAT HAS BEEN WITHDRAWN.—An abbreviated new drug application [or prior approval supplement] that was submitted on or after October 1, 2012, and that the Secretary considers not to have

been received, or that has been withdrawn, shall, upon re-submission of the application or a subsequent new submission following the applicant's withdrawal of the application, be subject to a full fee under subparagraph (A).

(F) ADDITIONAL FEE FOR ACTIVE PHARMACEUTICAL INGREDIENT INFORMATION NOT INCLUDED BY REFERENCE TO TYPE II ACTIVE PHARMACEUTICAL INGREDIENT DRUG MASTER FILE.—An applicant that submits a generic drug submission on or after October 1, ~~2012~~ 2017, shall pay a fee, in the amount determined under ~~subsection (d)(3)~~ *subsection (d)(2)*, in addition to the fee required under subparagraph (A), if—

(i) such submission contains information concerning the manufacture of an active pharmaceutical ingredient at a facility by means other than reference by a letter of authorization to a Type II active pharmaceutical drug master file; and

(ii) a fee in the amount equal to the drug master file fee established in paragraph (2) has not been previously paid with respect to such information.

(4) GENERIC DRUG FACILITY FEE AND ACTIVE PHARMACEUTICAL INGREDIENT FACILITY FEE.—

(A) IN GENERAL.—Facilities identified ~~], or intended to be identified, in at least one generic drug submission that is pending or]~~ *in at least one generic drug submission that is approved to produce a finished dosage form of a human generic drug or an active pharmaceutical ingredient contained in a human generic drug shall be subject to fees as follows:*

(i) GENERIC DRUG FACILITY.—Each person that owns a facility which is identified ~~], or intended to be identified in at least one generic drug submission that is pending or]~~ *in at least one generic drug submission that is approved to produce one or more finished dosage forms of a human generic drug shall be assessed an annual fee for each such facility.*

(ii) ACTIVE PHARMACEUTICAL INGREDIENT FACILITY.—Each person that owns a facility which ~~], produces, or which is pending review to produce, one or more active pharmaceutical ingredients identified, or intended to be identified, in at least one generic drug submission that is pending or approved or in a Type II active pharmaceutical ingredient drug master file referenced in such a]~~ *is identified in at least one generic drug submission in which the facility is approved to produce one or more active pharmaceutical ingredients or in a Type II active pharmaceutical ingredient drug master file referenced in at least one such generic drug submission, shall be assessed an annual fee for each such facility.*

(iii) FACILITIES PRODUCING BOTH ACTIVE PHARMACEUTICAL INGREDIENTS AND FINISHED DOSAGE FORMS.—Each person that owns a facility identified ~~], or intended to be identified, in at least one generic drug submission that is pending or]~~ *in at least one ge-*

neric drug submission that is approved to produce both one or more finished dosage forms subject to clause (i) and one or more active pharmaceutical ingredients subject to clause (ii) shall be subject [to fees under both such clauses] only to the fee attributable to the manufacture of the finished dosage forms for that facility.

(B) AMOUNT.—The amount of fees established under subparagraph (A) shall be established under subsection (d).

[(C) NOTICE.—

[(i) FISCAL YEAR 2013.—For fiscal year 2013, the Secretary shall publish in the Federal Register a notice announcing the amount of the fees provided for in subparagraph (A) within the timeframe specified in subsection (d)(1)(B).

[(ii) FISCAL YEARS 2014 THROUGH 2017.—Within the timeframe specified in subsection (d)(2), the Secretary shall publish in the Federal Register the amount of the fees under subparagraph (A) for such fiscal year.

[(D) FEE DUE DATE.—

[(i) FISCAL YEAR 2013.—For fiscal year 2013, the fees under subparagraph (A) shall be due on the later of—

[(I) not later than 45 days after the publication of the notice under subparagraph (B); or

[(II) if an appropriations Act is not enacted providing for the collection and obligation of fees for such year under this section by the date of the publication of such notice, 30 days after the date that such an appropriations Act is enacted.

[(ii) FISCAL YEARS 2014 THROUGH 2017.—For each of fiscal years 2014 through 2017, the fees under subparagraph (A) for such fiscal year shall be due on the later of—

[(I) the first business day on or after October 1 of each such year; or

[(II) the first business day after the enactment of an appropriations Act providing for the collection and obligation of fees for such year under this section for such year.]

(C) NOTICE.—*Within the timeframe specified in subsection (d)(1), the Secretary shall publish in the Federal Register the amount of the fees under subparagraph (A) for such fiscal year.*

(D) FEE DUE DATE.—*For each of fiscal years 2018 through 2022, the fees under subparagraph (A) for such fiscal year shall be due on the later of—*

(i) the first business day on or after October 1 of each such year; or

(ii) the first business day after the enactment of an appropriations Act providing for the collection and obligation of fees for such year under this section for such year.

(5) GENERIC DRUG APPLICANT PROGRAM FEE.—

(A) *IN GENERAL.*—A generic drug applicant program fee shall be assessed annually as described in subsection (b)(2)(E).

(B) *AMOUNT.*—The amount of fees established under subparagraph (A) shall be established under subsection (d).

(C) *NOTICE.*—Within the timeframe specified in subsection (d)(1), the Secretary shall publish in the Federal Register the amount of the fees under subparagraph (A) for such fiscal year.

(D) *FEE DUE DATE.*—For each of fiscal years 2018 through 2022, the fees under subparagraph (A) for such fiscal year shall be due on the later of—

(i) the first business day on or after October 1 of each such fiscal year; or

(ii) the first business day after the date of enactment of an appropriations Act providing for the collection and obligation of fees for such fiscal year under this section for such fiscal year.

[(5)] (6) *DATE OF SUBMISSION.*—For purposes of this Act, a generic drug submission or Type II pharmaceutical master file is deemed to be “submitted” to the Food and Drug Administration—

(A) if it is submitted via a Food and Drug Administration electronic gateway, on the day when transmission to that electronic gateway is completed, except that a submission or master file that arrives on a weekend, Federal holiday, or day when the Food and Drug Administration office that will review that submission is not otherwise open for business shall be deemed to be submitted on the next day when that office is open for business; or

(B) if it is submitted in physical media form, on the day it arrives at the appropriate designated document room of the Food and Drug Administration.

(b) *FEE REVENUE AMOUNTS.*—

(1) *IN GENERAL.*—

(A) *FISCAL YEAR [2013] 2018.*—For fiscal year [2013] 2018, fees under subsection (a) shall be established to generate a total estimated revenue amount under such subsection of [\$299,000,000] \$493,600,000. [Of that amount—]

[(i)] \$50,000,000 shall be generated by the one-time backlog fee for generic drug applications pending on October 1, 2012, established in subsection (a)(1); and

[(ii)] \$249,000,000 shall be generated by the fees under paragraphs (2) through (4) of subsection (a).]

(B) *FISCAL YEARS [2014 THROUGH 2017] 2019 THROUGH 2022.*—For each of the fiscal years [2014 through 2017] 2019 through 2022, fees under [paragraphs (2) through (4)] paragraphs (2) through (5) of subsection (a) shall be established to generate a total estimated revenue amount under such subsection that is equal to [\$299,000,000] \$493,600,000, as adjusted pursuant to subsection (c).

(2) *TYPES OF FEES.*—In establishing fees under paragraph (1) to generate the revenue amounts specified in [paragraph (1)(A)(ii) for fiscal year 2013 and paragraph (1)(B) for each of

fiscal years 2014 through 2017] *such paragraph for a fiscal year*, such fees shall be derived from the fees under paragraphs (2) [through (4)] *through (5)* of subsection (a) as follows:

(A) [Six percent] *Five percent* shall be derived from fees under subsection (a)(2) (relating to drug master files).

[(B) Twenty-four percent shall be derived from fees under subsection (a)(3) (relating to abbreviated new drug applications and supplements). The amount of a fee for a prior approval supplement shall be half the amount of the fee for an abbreviated new drug application.

[(C) Fifty-six percent shall be derived from fees under subsection (a)(4)(A)(i) (relating to generic drug facilities). The amount of the fee for a facility located outside the United States and its territories and possessions shall be not less than \$15,000 and not more than \$30,000 higher than the amount of the fee for a facility located in the United States and its territories and possessions, as determined by the Secretary on the basis of data concerning the difference in cost between inspections of facilities located in the United States, including its territories and possessions, and those located outside of the United States and its territories and possessions.]

(B) Thirty-three percent shall be derived from fees under subsection (a)(3) (relating to abbreviated new drug applications).

(C) Twenty percent shall be derived from fees under subsection (a)(4)(A)(i) (relating to generic drug facilities). The amount of the fee for a contract manufacturing organization facility shall be equal to one-third the amount of the fee for a facility that is not a contract manufacturing organization facility. The amount of the fee for a facility located outside the United States and its territories and possessions shall be \$15,000 higher than the amount of the fee for a facility located in the United States and its territories and possessions.

(D) [Fourteen percent] *Seven percent* shall be derived from fees under subsection (a)(4)(A)(ii) (relating to active pharmaceutical ingredient facilities). The amount of the fee for a facility located outside the United States and its territories and possessions shall be [not less than \$15,000 and not more than \$30,000] *\$15,000* higher than the amount of the fee for a facility located in the United States, including its territories and possessions[, as determined by the Secretary on the basis of data concerning the difference in cost between inspections of facilities located in the United States and its territories and possessions and those located outside of the United States and its territories and possessions.].

(E)(i) Thirty-five percent shall be derived from fees under subsection (a)(5) (relating to generic drug applicant program fees). For purposes of this subparagraph, if a person has affiliates, a single program fee shall be assessed with respect to that person, including its affiliates, and may be paid by that person or any one of its affiliates. The Secretary shall determine the fees as follows:

(I) If a person (including its affiliates) owns at least one but not more than 5 approved abbreviated new drug applications on the due date for the fee under this subsection, the person (including its affiliates) shall be assessed a small business generic drug applicant program fee equal to one-tenth of the large size operation generic drug applicant program fee.

(II) If a person (including its affiliates) owns at least 6 but not more than 19 approved abbreviated new drug applications on the due date for the fee under this subsection, the person (including its affiliates) shall be assessed a medium size operation generic drug applicant program fee equal to two-fifths of the large size operation generic drug applicant program fee.

(III) If a person (including its affiliates) owns 20 or more approved abbreviated new drug applications on the due date for the fee under this subsection, the person (including its affiliates) shall be assessed a large size operation generic drug applicant program fee.

(ii) For purposes of this subparagraph, an abbreviated new drug application shall be deemed not to be approved if the applicant has submitted a written request for withdrawal of approval of such abbreviated new drug application by April 1 of the previous fiscal year.

(c) ADJUSTMENTS.—

(1) INFLATION ADJUSTMENT.—For fiscal year **[2014]** 2019 and subsequent fiscal years, the revenues established in subsection (b) shall be adjusted by the Secretary by notice, published in the Federal Register, for a fiscal year, to equal the product of the total revenues established in such notice for the prior fiscal year multiplied by an amount equal to the sum of—

(A) one;

(B) the average annual percent change in the cost, per full-time equivalent position of the Food and Drug Administration, of all personnel compensation and benefits paid with respect to such positions for the first 3 years of the preceding 4 fiscal years multiplied by the proportion of personnel compensation and benefits costs to total costs of human generic drug activities for the first 3 years of the preceding 4 fiscal years; and

(C) the average annual percent change that occurred in the Consumer Price Index for urban consumers (Washington-Baltimore, DC-MD-VA-WV; Not Seasonally Adjusted; All items; Annual Index) for the first 3 years of the preceding 4 years of available data multiplied by the proportion of all costs other than personnel compensation and benefits costs to total costs of human generic drug activities for the first 3 years of the preceding 4 fiscal years.

[The adjustment made each fiscal year under this subsection shall be added on a compounded basis to the sum of all adjustments made each fiscal year after fiscal year 2013 under this subsection.]

(2) FINAL YEAR ADJUSTMENT.—For fiscal year **[2017]** 2022, the Secretary may, in addition to adjustments under paragraph (1), further increase the fee revenues and fees estab-

lished in subsection (b) if such an adjustment is necessary to provide for not more than 3 months of operating reserves of carryover user fees for human generic drug activities for **the first 3 months of fiscal year 2018** *the first 3 months of fiscal year 2023*. **Such fees may only be used in fiscal year 2018.** If such an adjustment is necessary, the rationale for the amount of the increase shall be contained in the annual notice establishing fee revenues and fees for fiscal year **2017** *2022*. If the Secretary has carryover balances for such activities in excess of 3 months of such operating reserves, the adjustment under this subparagraph shall not be made.

(d) ANNUAL FEE SETTING.—

[(1) FISCAL YEAR 2013.—For fiscal year 2013—

[(A) the Secretary shall establish, by October 31, 2012, the one-time generic drug backlog fee for generic drug applications pending on October 1, 2012, the drug master file fee, the abbreviated new drug application fee, and the prior approval supplement fee under subsection (a), based on the revenue amounts established under subsection (b); and

[(B) the Secretary shall establish, not later than 45 days after the date to comply with the requirement for identification of facilities in subsection (f)(2), the generic drug facility fee and active pharmaceutical ingredient facility fee under subsection (a) based on the revenue amounts established under subsection (b).

[(2) FISCAL YEARS 2014 THROUGH 2017.—Not more than 60 days before the first day of each of fiscal years 2014 through 2017, the Secretary shall establish the drug master file fee, the abbreviated new drug application fee, the prior approval supplement fee, the generic drug facility fee, and the active pharmaceutical ingredient facility fee under subsection (a) for such fiscal year, based on the revenue amounts established under subsection (b) and the adjustments provided under subsection (c).]

(1) FISCAL YEARS 2018 THROUGH 2022.—Not more than 60 days before the first day of each of fiscal years 2018 through 2022, the Secretary shall establish the fees described in paragraphs (2) through (5) of subsection (a), based on the revenue amounts established under subsection (b) and the adjustments provided under subsection (c).

[(3)] (2) FEE FOR ACTIVE PHARMACEUTICAL INGREDIENT INFORMATION NOT INCLUDED BY REFERENCE TO TYPE II ACTIVE PHARMACEUTICAL INGREDIENT DRUG MASTER FILE.—In establishing the **fees under paragraphs (1) and (2) *fee under paragraph (1)*, the amount of the fee under subsection (a)(3)(F) shall be determined by multiplying—**

(A) the sum of—

(i) the total number of such active pharmaceutical ingredients in such submission; and

(ii) for each such ingredient that is manufactured at more than one such facility, the total number of such additional facilities; and

(B) the amount equal to the drug master file fee established in subsection (a)(2) for such submission.

(e) LIMIT.—The total amount of fees charged, as adjusted under subsection (c), for a fiscal year may not exceed the total costs for such fiscal year for the resources allocated for human generic drug activities.

(f) IDENTIFICATION OF FACILITIES.—

[(1) PUBLICATION OF NOTICE; DEADLINE FOR COMPLIANCE.—

Not later than October 1, 2012, the Secretary shall publish in the Federal Register a notice requiring each person that owns a facility described in subsection (a)(4)(A), or a site or organization required to be identified by paragraph (4), to submit to the Secretary information on the identity of each such facility, site, or organization. The notice required by this paragraph shall specify the type of information to be submitted and the means and format for submission of such information.]

[(2)] (1) REQUIRED SUBMISSION OF FACILITY IDENTIFICATION.—Each person that owns a facility described in subsection (a)(4)(A) or a site or organization required to be identified by [paragraph (4)] *paragraph (3)* shall submit to the Secretary the information required under this subsection each year. [Such information shall—

[(A) for fiscal year 2013, be submitted not later than 60 days after the publication of the notice under paragraph (1); and

[(B) for each subsequent fiscal year, be submitted, updated, or reconfirmed on or before June 1 of the previous year.] *Such information shall, for each fiscal year, be submitted, updated, or reconfirmed on or before June 1 of the previous fiscal year.*

[(3) CONTENTS OF NOTICE.—] (2) INFORMATION REQUIRED TO BE SUBMITTED.—At a minimum, the submission required by [paragraph (2)] *paragraph (1)* shall include for each such facility—

(A) identification of a facility identified [or intended to be identified] in an approved or pending generic drug submission;

(B) whether the facility manufactures active pharmaceutical ingredients or finished dosage forms, or both;

(C) whether or not the facility is located within the United States and its territories and possessions;

(D) whether the facility manufactures positron emission tomography drugs solely, or in addition to other drugs; [and]

(E) whether the facility manufactures drugs that are not generic drugs[.]; and

(F) *whether the facility is a contract manufacturing organization facility.*

[(4)] (3) CERTAIN SITES AND ORGANIZATIONS.—

(A) IN GENERAL.—Any person that owns or operates a site or organization described in subparagraph (B) shall submit to the Secretary information concerning the ownership, name, and address of the site or organization.

(B) SITES AND ORGANIZATIONS.—A site or organization is described in this subparagraph if it is identified in a generic drug submission and is—

(i) a site in which a bioanalytical study is conducted;

- (ii) a clinical research organization;
- (iii) a contract analytical testing site; or
- (iv) a contract repackager site.

(C) NOTICE.—The Secretary may, by notice published in the Federal Register, specify the means and format for submission of the information under subparagraph (A) and may specify, as necessary for purposes of this section, any additional information to be submitted.

(D) INSPECTION AUTHORITY.—The Secretary's inspection authority under section 704(a)(1) shall extend to all such sites and organizations.

(g) EFFECT OF FAILURE TO PAY FEES.—

(1) GENERIC DRUG BACKLOG FEE.—Failure to pay the fee under subsection (a)(1) shall result in the Secretary placing the person that owns the abbreviated new drug application subject to that fee on a publicly available arrears list, such that no new abbreviated new drug applications or supplement submitted on or after October 1, 2012, from that person, or any affiliate of that person, will be received within the meaning of section 505(j)(5)(A) until such outstanding fee is paid. *This paragraph shall cease to be effective on October 1, 2022.*

(2) DRUG MASTER FILE FEE.—

(A) Failure to pay the fee under subsection (a)(2) within 20 calendar days after the applicable due date under subparagraph (E) of such subsection (as described in subsection (a)(2)(D)(ii)(I)) shall result in the Type II active pharmaceutical ingredient drug master file not being deemed available for reference.

(B)(i) Any generic drug submission submitted on or after October 1, 2012, that references, by a letter of authorization, a Type II active pharmaceutical ingredient drug master file that has not been deemed available for reference shall not be received within the meaning of section 505(j)(5)(A) unless the condition specified in clause (ii) is met.

(ii) The condition specified in this clause is that the fee established under subsection (a)(2) has been paid within 20 calendar days of the Secretary providing the notification to the sponsor of the abbreviated new drug application or supplement of the failure of the owner of the Type II active pharmaceutical ingredient drug master file to pay the drug master file fee as specified in subparagraph (C).

(C)(i) If an abbreviated new drug application or supplement to an abbreviated new drug application references a Type II active pharmaceutical ingredient drug master file for which a fee under subsection (a)(2)(A) has not been paid by the applicable date under subsection (a)(2)(E), the Secretary shall notify the sponsor of the abbreviated new drug application or supplement of the failure of the owner of the Type II active pharmaceutical ingredient drug master file to pay the applicable fee.

(ii) If such fee is not paid within 20 calendar days of the Secretary providing the notification, the abbreviated new drug application or supplement to an abbreviated new

drug application shall not be received within the meaning [of 505(j)(5)(A)] of section 505(j)(5)(A).

(3) ABBREVIATED NEW DRUG APPLICATION FEE AND PRIOR APPROVAL SUPPLEMENT FEE.—Failure to pay a fee under subparagraph (A) or (F) of subsection (a)(3) within 20 calendar days of the applicable due date under subparagraph (C) of such subsection shall result in the abbreviated new drug application or the prior approval supplement to an abbreviated new drug application not being received within the meaning of section 505(j)(5)(A) until such outstanding fee is paid.

(4) GENERIC DRUG FACILITY FEE AND ACTIVE PHARMACEUTICAL INGREDIENT FACILITY FEE.—

(A) IN GENERAL.—Failure to pay the fee under subsection (a)(4) within 20 calendar days of the due date as specified in subparagraph (D) of such subsection shall result in the following:

(i) The Secretary shall place the facility on a publicly available arrears list, such that no new abbreviated new drug application or supplement submitted on or after October 1, 2012, from the person that is responsible for paying such fee, or any affiliate of that person, will be received within the meaning of section 505(j)(5)(A).

(ii) Any new generic drug submission submitted on or after October 1, 2012, that references such a facility shall not be received, within the meaning of section 505(j)(5)(A) if the outstanding facility fee is not paid within 20 calendar days of the Secretary providing the notification to the sponsor of the failure of the owner of the facility to pay the facility fee under subsection (a)(4)(C).

(iii) All drugs or active pharmaceutical ingredients manufactured in such a facility or containing an ingredient manufactured in such a facility shall be deemed misbranded under section 502(aa).

(B) APPLICATION OF PENALTIES.—The penalties under this paragraph shall apply until the fee established by subsection (a)(4) is paid or the facility is removed from all generic drug submissions that refer to the facility.

(C) NONRECEIVAL FOR NONPAYMENT.—

(i) NOTICE.—If an abbreviated new drug application or supplement to an abbreviated new drug application submitted on or after October 1, 2012, references a facility for which a facility fee has not been paid by the applicable date under subsection (a)(4)(C), the Secretary shall notify the sponsor of the generic drug submission of the failure of the owner of the facility to pay the facility fee.

(ii) NONRECEIVAL.—If the facility fee is not paid within 20 calendar days of the Secretary providing the notification under clause (i), the abbreviated new drug application or supplement to an abbreviated new drug application shall not be received within the meaning of section 505(j)(5)(A).

(5) GENERIC DRUG APPLICANT PROGRAM FEE.—

(A) *IN GENERAL.*—A person who fails to pay a fee as required under subsection (a)(5) by the date that is 20 calendar days after the due date, as specified in subparagraph (D) of such subsection, shall be subject to the following:

(i) *The Secretary shall place the person on a publicly available arrears list.*

(ii) *Any abbreviated new drug application submitted by the generic drug applicant or an affiliate of such applicant shall not be received, within the meaning of section 505(j)(5)(A).*

(iii) *All drugs marketed pursuant to any abbreviated new drug application held by such applicant or an affiliate of such applicant shall be deemed misbranded under section 502(aa).*

(B) *APPLICATION OF PENALTIES.*—The penalties under subparagraph (A) shall apply until the fee required under subsection (a)(5) is paid.

(h) *LIMITATIONS.*—

(1) *IN GENERAL.*—Fees under subsection (a) shall be refunded for a fiscal year beginning after fiscal year 2012, unless appropriations for salaries and expenses of the Food and Drug Administration for such fiscal year (excluding the amount of fees appropriated for such fiscal year) are equal to or greater than the amount of appropriations for the salaries and expenses of the Food and Drug Administration for fiscal year 2009 (excluding the amount of fees appropriated for such fiscal year) multiplied by the adjustment factor (as defined in section 744A) applicable to the fiscal year involved.

(2) *AUTHORITY.*—If the Secretary does not assess fees under subsection (a) during any portion of a fiscal year and if at a later date in such fiscal year the Secretary may assess such fees, the Secretary may assess and collect such fees, without any modification in the rate, [for Type II active pharmaceutical ingredient drug master files, abbreviated new drug applications and prior approval supplements, and generic drug facilities and active pharmaceutical ingredient facilities] at any time in such fiscal year notwithstanding the provisions of subsection (a) relating to the date fees are to be paid.

(i) *CREDITING AND AVAILABILITY OF FEES.*—

(1) *IN GENERAL.*—Fees authorized under subsection (a) shall be collected and available for obligation only to the extent and in the amount provided in advance in appropriations Acts, subject to paragraph (2). Such fees are authorized to remain available until expended. Such sums as may be necessary may be transferred from the Food and Drug Administration salaries and expenses appropriation account without fiscal year limitation to such appropriation account for salaries and expenses with such fiscal year limitation. The sums transferred shall be available solely for human generic drug activities.

(2) *COLLECTIONS AND APPROPRIATION ACTS.*—

(A) *IN GENERAL.*—The fees authorized by this section—

(i) subject to subparagraphs (C) and (D), shall be collected and available in each fiscal year in an amount not to exceed the amount specified in appropriation

Acts, or otherwise made available for obligation for such fiscal year; and

(ii) shall be available for a fiscal year beginning after fiscal year 2012 to defray the costs of human generic drug activities (including such costs for an additional number of full-time equivalent positions in the Department of Health and Human Services to be engaged in such activities), only if the Secretary allocates for such purpose an amount for such fiscal year (excluding amounts from fees collected under this section) no less than \$97,000,000 multiplied by the adjustment factor defined in section 744A(3) applicable to the fiscal year involved.

(B) COMPLIANCE.—The Secretary shall be considered to have met the requirements of subparagraph (A)(ii) in any fiscal year if the costs funded by appropriations and allocated for human generic activities are not more than 10 percent below the level specified in such subparagraph.

[(C) FEE COLLECTION DURING FIRST PROGRAM YEAR.—Until the date of enactment of an Act making appropriations through September 30, 2013, for the salaries and expenses account of the Food and Drug Administration, fees authorized by this section for fiscal year 2013 may be collected and shall be credited to such account and remain available until expended.

[(D) (C) PROVISION FOR EARLY PAYMENTS [IN SUBSEQUENT YEARS].—Payment of fees authorized under this section for a fiscal year [(after fiscal year 2013)], prior to the due date for such fees, may be accepted by the Secretary in accordance with authority provided in advance in a prior year appropriations Act.

(3) AUTHORIZATION OF APPROPRIATIONS.—For each of the [fiscal years 2013 through 2017] *fiscal years 2018 through 2022*, there is authorized to be appropriated for fees under this section an amount equivalent to the total revenue amount determined under subsection (b) for the fiscal year, as adjusted under subsection (c), if applicable, or as otherwise affected under paragraph (2) of this subsection.

(j) COLLECTION OF UNPAID FEES.—In any case where the Secretary does not receive payment of a fee assessed under subsection (a) within 30 calendar days after it is due, such fee shall be treated as a claim of the United States Government subject to subchapter II of chapter 37 of title 31, United States Code.

(k) CONSTRUCTION.—This section may not be construed to require that the number of full-time equivalent positions in the Department of Health and Human Services, for officers, employees, and advisory committees not engaged in human generic drug activities, be reduced to offset the number of officers, employees, and advisory committees so engaged.

(l) POSITRON EMISSION TOMOGRAPHY DRUGS.—

(1) EXEMPTION FROM FEES.—Submission of an application for a positron emission tomography drug or active pharmaceutical ingredient for a positron emission tomography drug shall not require the payment of any fee under this section. Facilities that solely produce positron emission tomography drugs shall

not be required to pay a facility fee as established in subsection (a)(4).

(2) IDENTIFICATION REQUIREMENT.—Facilities that produce positron emission tomography drugs or active pharmaceutical ingredients of such drugs are required to be identified pursuant to subsection (f).

(m) DISPUTES CONCERNING FEES.—To qualify for the return of a fee claimed to have been paid in error under this section, a person shall submit to the Secretary a written request justifying such return within 180 calendar days after such fee was paid.

(n) SUBSTANTIALLY COMPLETE APPLICATIONS.—An abbreviated new drug application that is not considered to be received within the meaning of section 505(j)(5)(A) because of failure to pay an applicable fee under this provision within the time period specified in subsection (g) shall be deemed not to have been “substantially complete” on the date of its submission within the meaning of section 505(j)(5)(B)(iv)(II)(cc). An abbreviated new drug application that is not substantially complete on the date of its submission solely because of failure to pay an applicable fee under the preceding sentence shall be deemed substantially complete and received within the meaning of section 505(j)(5)(A) as of the date such applicable fee is received.

(o) INFORMATION ON ABBREVIATED NEW DRUG APPLICATIONS OWNED BY APPLICANTS AND THEIR AFFILIATES.—

(1) IN GENERAL.—By April 1 of each year, each person that owns an abbreviated new drug application, or any affiliate of such person, shall submit, on behalf of the person and its affiliates, to the Secretary a list of—

(A) all approved abbreviated new drug applications owned by such person; and

(B) if any affiliate of such person also owns an abbreviated new drug application, all affiliates that own any such abbreviated new drug applications and all approved abbreviated new drug applications owned by any such affiliate.

(2) FORMAT AND METHOD.—The Secretary shall specify in guidance the format and method for submission of lists under this subsection.

SEC. 744C. REAUTHORIZATION; REPORTING REQUIREMENTS.

(a) PERFORMANCE REPORT.—Beginning with fiscal year **[2013] 2018**, not later than 120 days after the end of each fiscal year for which fees are collected under this part, the Secretary shall prepare and submit to the Committee on Energy and Commerce of the House of Representatives and the Committee on Health, Education, Labor, and Pensions of the Senate a report concerning the progress of the Food and Drug Administration in achieving the goals identified in the letters described in section 301(b) of the **[Generic Drug User Fee Amendments of 2012] Generic Drug User Fee Amendments of 2017** during such fiscal year and the future plans of the Food and Drug Administration for meeting the goals.

(b) FISCAL REPORT.—Beginning with fiscal year **[2013] 2018**, not later than 120 days after the end of each fiscal year for which fees are collected under this part, the Secretary shall prepare and submit to the Committee on Energy and Commerce of the House of Representatives and the Committee on Health, Education, Labor,

and Pensions of the Senate a report on the implementation of the authority for such fees during such fiscal year and the use, by the Food and Drug Administration, of the fees collected for such fiscal year.

(c) PUBLIC AVAILABILITY.—The Secretary shall make the reports required under subsections (a) and (b) available to the public on the Internet Web site of the Food and Drug Administration.

(d) REAUTHORIZATION.—

(1) CONSULTATION.—In developing recommendations to present to the Congress with respect to the goals, and plans for meeting the goals, for human generic drug activities for the first 5 fiscal years after fiscal year ~~2017~~ 2022, and for the reauthorization of this part for such fiscal years, the Secretary shall consult with—

(A) the Committee on Energy and Commerce of the House of Representatives;

(B) the Committee on Health, Education, Labor, and Pensions of the Senate;

(C) scientific and academic experts;

(D) health care professionals;

(E) representatives of patient and consumer advocacy groups; and

(F) the generic drug industry.

(2) PRIOR PUBLIC INPUT.—Prior to beginning negotiations with the generic drug industry on the reauthorization of this part, the Secretary shall—

(A) publish a notice in the Federal Register requesting public input on the reauthorization;

(B) hold a public meeting at which the public may present its views on the reauthorization, including specific suggestions for changes to the goals referred to in subsection (a);

(C) provide a period of 30 days after the public meeting to obtain written comments from the public suggesting changes to this part; and

(D) publish the comments on the Food and Drug Administration's Internet Web site.

(3) PERIODIC CONSULTATION.—Not less frequently than once every month during negotiations with the generic drug industry, the Secretary shall hold discussions with representatives of patient and consumer advocacy groups to continue discussions of their views on the reauthorization and their suggestions for changes to this part as expressed under paragraph (2).

(4) PUBLIC REVIEW OF RECOMMENDATIONS.—After negotiations with the generic drug industry, the Secretary shall—

(A) present the recommendations developed under paragraph (1) to the congressional committees specified in such paragraph;

(B) publish such recommendations in the Federal Register;

(C) provide for a period of 30 days for the public to provide written comments on such recommendations;

(D) hold a meeting at which the public may present its views on such recommendations; and

(E) after consideration of such public views and comments, revise such recommendations as necessary.

(5) TRANSMITTAL OF RECOMMENDATIONS.—Not later than January 15, ~~2017~~ 2022, the Secretary shall transmit to the Congress the revised recommendations under paragraph (4), a summary of the views and comments received under such paragraph, and any changes made to the recommendations in response to such views and comments.

(6) MINUTES OF NEGOTIATION MEETINGS.—

(A) PUBLIC AVAILABILITY.—Before presenting the recommendations developed under paragraphs (1) through (5) to the Congress, the Secretary shall make publicly available, on the Internet Web site of the Food and Drug Administration, minutes of all negotiation meetings conducted under this subsection between the Food and Drug Administration and the generic drug industry.

(B) CONTENT.—The minutes described under subparagraph (A) shall summarize any substantive proposal made by any party to the negotiations as well as significant controversies or differences of opinion during the negotiations and their resolution.

PART 8—FEES RELATING TO BIOSIMILAR BIOLOGICAL PRODUCTS

SEC. 744G. DEFINITIONS.

For purposes of this part:

[(1) The term “adjustment factor” applicable to a fiscal year that is the Consumer Price Index for all urban consumers (Washington-Baltimore, DC-MD-VA-WV; Not Seasonally Adjusted; All items) of the preceding fiscal year divided by such Index for September 2011.]

(1) The term “adjustment factor” applicable to a fiscal year is the Consumer Price Index for urban consumers (Washington-Baltimore, DC-MD-VA-WV; Not Seasonally Adjusted; All items; Annual Index) for October of the preceding fiscal year divided by such Index for October 2011.

(2) The term “affiliate” means a business entity that has a relationship with a second business entity if, directly or indirectly—

(A) one business entity controls, or has the power to control, the other business entity; or

(B) a third party controls, or has power to control, both of the business entities.

(3) The term “biosimilar biological product” [means a product] *means a specific strength of a biological product in final dosage form for which a biosimilar biological product application has been approved.*

(4)(A) Subject to subparagraph (B), the term “biosimilar biological product application” means an application for licensure of a biological product under section 351(k) of the Public Health Service Act.

(B) Such term does not include—

(i) a supplement to such an application;

- (ii) an application filed under section 351(k) of the Public Health Service Act that cites as the reference product a bovine blood product for topical application licensed before September 1, 1992, or a large volume parenteral drug product approved before such date;
 - (iii) an application filed under section 351(k) of the Public Health Service Act with respect to—
 - (I) whole blood or a blood component for transfusion;
 - (II) an allergenic extract product;
 - (III) an in vitro diagnostic biological product; or
 - (IV) a biological product for further manufacturing use only; or
 - (iv) an application for licensure under section 351(k) of the Public Health Service Act that is submitted by a State or Federal Government entity for a product that is not distributed commercially.
- (5) The term “biosimilar biological product development meeting” means any meeting, other than a biosimilar initial advisory meeting, regarding the content of a development program, including a proposed design for, or data from, a study intended to support a biosimilar biological product application.
- (6) The term “biosimilar biological product development program” means the program under this part for expediting the process for the review of submissions in connection with biosimilar biological product development.
- (7)(A) The term “biosimilar biological product establishment” means a foreign or domestic place of business—
- (i) that is at one general physical location consisting of one or more buildings, all of which are within 5 miles of each other; and
 - (ii) at which one or more biosimilar biological products are manufactured in final dosage form.
- (B) For purposes of subparagraph (A)(ii), the term “manufactured” does not include packaging.
- (8) The term “biosimilar initial advisory meeting”—
- (A) means a meeting, if requested, that is limited to—
 - (i) a general discussion regarding whether licensure under section 351(k) of the Public Health Service Act may be feasible for a particular product; and
 - (ii) if so, general advice on the expected content of the development program; and
 - (B) does not include any meeting that involves substantive review of summary data or full study reports.
- (9) The term “costs of resources allocated for the process for the review of biosimilar biological product applications” means the expenses in connection with the process for the review of biosimilar biological product applications for—
- (A) officers and employees of the Food and Drug Administration, contractors of the Food and Drug Administration, advisory committees, and costs related to such officers employees and committees and to contracts with such contractors;
 - (B) management of information, and the acquisition, maintenance, and repair of computer resources;

(C) leasing, maintenance, renovation, and repair of facilities and acquisition, maintenance, and repair of fixtures, furniture, scientific equipment, and other necessary materials and supplies; and

(D) collecting fees under section 744H and accounting for resources allocated for the review of submissions in connection with biosimilar biological product development, biosimilar biological product applications, and supplements.

(10) The term “final dosage form” means, with respect to a biosimilar biological product, a finished dosage form which is approved for administration to a patient without substantial further manufacturing (such as lyophilized products before reconstitution).

(11) The term “financial hold”—

(A) means an order issued by the Secretary to prohibit the sponsor of a clinical investigation from continuing the investigation if the Secretary determines that the investigation is intended to support a biosimilar biological product application and the sponsor has failed to pay any fee for the product required under subparagraph (A), (B), or (D) of section 744H(a)(1); and

(B) does not mean that any of the bases for a “clinical hold” under section 505(i)(3) have been determined by the Secretary to exist concerning the investigation.

(12) The term “person” includes an affiliate of such person.

(13) The term “process for the review of biosimilar biological product applications” means the following activities of the Secretary with respect to the review of submissions in connection with biosimilar biological product development, biosimilar biological product applications, and supplements:

(A) The activities necessary for the review of submissions in connection with biosimilar biological product development, biosimilar biological product applications, and supplements.

(B) Actions related to submissions in connection with biosimilar biological product development, the issuance of action letters which approve biosimilar biological product applications or which set forth in detail the specific deficiencies in such applications, and where appropriate, the actions necessary to place such applications in condition for approval.

(C) The inspection of biosimilar biological product establishments and other facilities undertaken as part of the Secretary’s review of pending biosimilar biological product applications and supplements.

(D) Activities necessary for the release of lots of biosimilar biological products under section 351(k) of the Public Health Service Act.

(E) Monitoring of research conducted in connection with the review of biosimilar biological product applications.

(F) Postmarket safety activities with respect to biologics approved under biosimilar biological product applications or supplements, including the following activities:

(i) Collecting, developing, and reviewing safety information on biosimilar biological products, including adverse-event reports.

(ii) Developing and using improved adverse-event data-collection systems, including information technology systems.

(iii) Developing and using improved analytical tools to assess potential safety problems, including access to external data bases.

(iv) Implementing and enforcing section 505(o) (relating to postapproval studies and clinical trials and labeling changes) and section 505(p) (relating to risk evaluation and mitigation strategies).

(v) Carrying out section 505(k)(5) (relating to adverse-event reports and postmarket safety activities).

(14) The term “supplement” means a request to the Secretary to approve a change in a biosimilar biological product application which has been approved, including a supplement requesting that the Secretary determine that the biosimilar biological product meets the standards for interchangeability described in section 351(k)(4) of the Public Health Service Act.

SEC. 744H. AUTHORITY TO ASSESS AND USE BIOSIMILAR BIOLOGICAL PRODUCT FEES.

(a) TYPES OF FEES.—Beginning in [fiscal year 2013] *fiscal year 2018*, the Secretary shall assess and collect fees in accordance with this section as follows:

(1) [BIOSIMILAR] *BIOSIMILAR BIOLOGICAL PRODUCT DEVELOPMENT PROGRAM FEES.*—

(A) INITIAL BIOSIMILAR BIOLOGICAL PRODUCT DEVELOPMENT FEE.—

(i) IN GENERAL.—Each person that submits to the Secretary a meeting request described under clause (ii) or a clinical protocol for an investigational new drug protocol described under clause (iii) shall pay for the product named in the meeting request or the investigational new drug application the initial biosimilar biological product development fee established under subsection [(b)(1)(A)] (c)(5).

(ii) MEETING REQUEST.—The meeting request described in this clause is a request for a biosimilar biological product development meeting for a product.

(iii) CLINICAL PROTOCOL FOR IND.—A clinical protocol for an investigational new drug protocol described in this clause is a clinical protocol consistent with the provisions of section 505(i), including any regulations promulgated under section 505(i), (referred to in this section as “investigational new drug application”) describing an investigation that the Secretary determines is intended to support a biosimilar biological product application for a product.

(iv) DUE DATE.—The initial biosimilar biological product development fee shall be due by the earlier of the following:

(I) Not later than 5 days after the Secretary grants a request for a biosimilar biological product development meeting.

(II) The date of submission of an investigational new drug application describing an investigation that the Secretary determines is intended to support a biosimilar biological product application.

(v) TRANSITION RULE.—Each person that has submitted an investigational new drug application prior to the date of enactment of the Biosimilar User Fee Act of 2012 shall pay the initial biosimilar biological product development fee by the earlier of the following:

(I) Not later than 60 days after the date of the enactment of the Biosimilar User Fee Act of 2012, if the Secretary determines that the investigational new drug application describes an investigation that is intended to support a biosimilar biological product application.

(II) Not later than 5 days after the Secretary grants a request for a biosimilar biological product development meeting.

(B) ANNUAL BIOSIMILAR BIOLOGICAL PRODUCT DEVELOPMENT FEE.—

(i) IN GENERAL.—A person that pays an initial biosimilar biological product development fee for a product shall pay for such product, beginning in the fiscal year following the fiscal year in which the initial biosimilar biological product development fee was paid, an annual fee established under subsection [(b)(1)(B) for biosimilar biological product development] (c)(5) for the biosimilar biological product development program (referred to in this section as “annual biosimilar biological product development fee”).

(ii) DUE DATE.—The [annual biosimilar biological product development program fee] *annual biosimilar biological product development fee* for each fiscal year will be due on the later of—

(I) the first business day on or after October 1 of each such year; or

(II) the first business day after the enactment of an appropriations Act providing for the collection and obligation of fees for such year under this section.

(iii) EXCEPTION.—The [annual biosimilar development program fee] *annual biosimilar biological product development fee* for each fiscal year will be due on the date specified in clause (ii), unless the person has—

(I) submitted a marketing application for the biological product that was accepted for filing; or

(II) discontinued participation in the biosimilar biological product development program for the product under subparagraph (C).

(iv) *REFUND.*—If a person submits a marketing application for a biosimilar biological product before October 1 of a fiscal year and such application is accepted for filing on or after October 1 of such fiscal year, the person may request a refund equal to the annual biosimilar development fee paid by the person for the product for such fiscal year. To qualify for consideration for a refund under this clause, a person shall submit to the Secretary a written request for such refund not later than 180 days after the marketing application is accepted for filing.

(C) *DISCONTINUATION OF FEE OBLIGATION.*—A person may discontinue participation in the biosimilar biological product development program [for a product effective October 1 of a fiscal year by,] for a product, effective October 1 of a fiscal year, by, not later than August 1 of the preceding fiscal year—

(i) if no investigational new drug application concerning the product has been submitted, submitting to the Secretary a written declaration that the person has no present intention of further developing the product as a biosimilar biological product; or

(ii) if an investigational new drug application concerning the product has been submitted, withdrawing the investigational new drug application in accordance with part 312 of title 21, Code of Federal Regulations (or any successor regulations).

(D) *REACTIVATION FEE.*—

(i) *IN GENERAL.*—A person that has discontinued participation in the biosimilar biological product development program for a product under subparagraph (C) shall, if the person seeks to resume participation in such program, pay a fee (referred to in this section as “reactivation fee”) by the earlier of the following:

(I) Not later than 5 days after the Secretary grants a request by such person for a biosimilar biological product development meeting for the product (after the date on which such participation was discontinued).

(II) Upon the date of submission (after the date on which such participation was discontinued) by such person of an investigational new drug application describing an investigation that the Secretary determines is intended to support a biosimilar biological product application for that product.

(ii) *APPLICATION OF ANNUAL FEE.*—A person that pays a reactivation fee for a product shall pay for such product, beginning in the next fiscal year, the annual biosimilar biological product development fee under subparagraph (B).

(E) *EFFECT OF FAILURE TO PAY [BIOSIMILAR DEVELOPMENT PROGRAM] FEES.*—

(i) *NO BIOSIMILAR BIOLOGICAL PRODUCT DEVELOPMENT MEETINGS.*—If a person has failed to pay an ini-

tial or annual biosimilar biological product development fee as required under subparagraph (A) or (B), or a reactivation fee as required under subparagraph (D), the Secretary shall not provide a biosimilar biological product development meeting relating to the product for which fees are owed.

(ii) **NO RECEIPT OF INVESTIGATIONAL NEW DRUG APPLICATIONS.**—Except in extraordinary circumstances, the Secretary shall not consider an investigational new drug application to have been received under section 505(i)(2) if—

(I) the Secretary determines that the investigation is intended to support a biosimilar biological product application; and

(II) the sponsor has failed to pay an initial or annual biosimilar biological product development fee for the product as required under subparagraph (A) or (B), or a reactivation fee as required under subparagraph (D).

(iii) **FINANCIAL HOLD.**—Notwithstanding section 505(i)(2), except in extraordinary circumstances, the Secretary shall prohibit the sponsor of a clinical investigation from continuing the investigation if—

(I) the Secretary determines that the investigation is intended to support a biosimilar biological product application; and

(II) the sponsor has failed to pay an initial or annual biosimilar biological product development fee for the product as required under subparagraph (A) or (B), or a reactivation fee for the product as required under subparagraph (D).

(iv) **NO ACCEPTANCE OF BIOSIMILAR BIOLOGICAL PRODUCT APPLICATIONS OR SUPPLEMENTS.**—If a person has failed to pay an initial or annual biosimilar biological product development fee as required under subparagraph (A) or (B), or a reactivation fee as required under subparagraph (D), any biosimilar biological product application or supplement submitted by that person shall be considered incomplete and shall not be accepted for filing by the Secretary until all such fees owed by such person have been paid.

(F) **LIMITS REGARDING [BIOSIMILAR DEVELOPMENT PROGRAM] FEES.**—

[(i) **NO REFUNDS.**—The Secretary shall not refund any initial or annual biosimilar biological product development fee paid under subparagraph (A) or (B), or any reactivation fee paid under subparagraph (D).]

(i) **REFUNDS.**—*Except as provided in subparagraph (B)(iv), the Secretary shall not refund any initial or annual biosimilar biological product development fee paid under subparagraph (A) or (B), or any reactivation fee paid under subparagraph (D).*

(ii) **NO WAIVERS, EXEMPTIONS, OR REDUCTIONS.**—The Secretary shall not grant a waiver, exemption, or reduction of any initial or annual biosimilar biological

product development fee due or payable under subparagraph (A) or (B), or any reactivation fee due or payable under subparagraph (D).

(2) BIOSIMILAR BIOLOGICAL PRODUCT APPLICATION **[AND SUPPLEMENT] FEE.**—

[(A) IN GENERAL.—Each person that submits, on or after October 1, 2012, a biosimilar biological product application or a supplement shall be subject to the following fees:

[(i) A fee for a biosimilar biological product application that is equal to—

[(I) the amount of the fee established under subsection (b)(1)(D) for a biosimilar biological product application for which clinical data (other than comparative bioavailability studies) with respect to safety or effectiveness are required for approval; minus

[(II) the cumulative amount of fees paid, if any, under subparagraphs (A), (B), and (D) of paragraph (1) for the product that is the subject of the application.

[(ii) A fee for a biosimilar biological product application for which clinical data (other than comparative bioavailability studies) with respect to safety or effectiveness are not required, that is equal to—

[(I) half of the amount of the fee established under subsection (b)(1)(D) for a biosimilar biological product application; minus

[(II) the cumulative amount of fees paid, if any, under subparagraphs (A), (B), and (D) of paragraph (1) for that product.

[(iii) A fee for a supplement for which clinical data (other than comparative bioavailability studies) with respect to safety or effectiveness are required, that is equal to half of the amount of the fee established under subsection (b)(1)(D) for a biosimilar biological product application.

[(B) REDUCTION IN FEES.—Notwithstanding section 404 of the Biosimilar User Fee Act of 2012, any person who pays a fee under subparagraph (A), (B), or (D) of paragraph (1) for a product before October 1, 2017, but submits a biosimilar biological product application for that product after such date, shall be entitled to the reduction of any biosimilar biological product application fees that may be assessed at the time when such biosimilar biological product application is submitted, by the cumulative amount of fees paid under subparagraphs (A), (B), and (D) of paragraph (1) for that product.]

(A) IN GENERAL.—*Each person that submits, on or after October 1, 2017, a biosimilar biological product application shall be subject to the following fees:*

(i) A fee established under subsection (c)(5) for a biosimilar biological product application for which clinical data (other than comparative bioavailability studies) with respect to safety or effectiveness are required for approval.

(ii) A fee established under subsection (c)(5) for a biosimilar biological product application for which clinical data (other than comparative bioavailability studies) with respect to safety or effectiveness are not required for approval. Such fee shall be equal to half of the amount of the fee described in clause (i).

(B) **RULE OF APPLICABILITY; TREATMENT OF CERTAIN PREVIOUSLY PAID FEES.**—Any person who pays a fee under subparagraph (A), (B), or (D) of paragraph (1) for a product before October 1, 2017, but submits a biosimilar biological product application for that product after such date, shall—

(i) be subject to any biosimilar biological product application fees that may be assessed at the time when such biosimilar biological product application is submitted; and

(ii) be entitled to no reduction of such application fees based on the amount of fees paid for that product before October 1, 2017, under such subparagraphs (A), (B), or (D).

(C) **PAYMENT DUE DATE.**—Any fee required by subparagraph (A) shall be due upon submission of the application [or supplement] for which such fee applies.

(D) **EXCEPTION FOR PREVIOUSLY FILED APPLICATION [OR SUPPLEMENT].**—If a biosimilar biological product application [or supplement] was submitted by a person that paid the fee for such application [or supplement], was accepted for filing, and was not approved or was withdrawn (without a waiver), the submission of a biosimilar biological product application [or a supplement] for the same product by the same person (or the person's licensee, assignee, or successor) shall not be subject to a fee under subparagraph (A).

(E) **REFUND OF APPLICATION FEE IF APPLICATION REFUSED FOR FILING OR WITHDRAWN BEFORE FILING.**—The Secretary shall refund 75 percent of the fee paid under this paragraph for any application [or supplement] which is refused for filing or withdrawn without a waiver before filing.

(F) **FEES FOR APPLICATIONS PREVIOUSLY REFUSED FOR FILING OR WITHDRAWN BEFORE FILING.**—A biosimilar biological product application [or supplement] that was submitted but was refused for filing, or was withdrawn before being accepted or refused for filing, shall be subject to the full fee under subparagraph (A) upon being resubmitted or filed over protest, unless the fee is waived under [subsection (c)] subsection (d).

(3) **BIOSIMILAR BIOLOGICAL PRODUCT ESTABLISHMENT FEE.**—

[(A) **IN GENERAL.**—Except as provided in subparagraph (E), each person that is named as the applicant in a biosimilar biological product application shall be assessed an annual fee established under subsection (b)(1)(E) for each biosimilar biological product establishment that is listed in the approved biosimilar biological product application as

an establishment that manufactures the biosimilar biological product named in such application.

[(B) ASSESSMENT IN FISCAL YEARS.—The establishment fee shall be assessed in each fiscal year for which the biosimilar biological product named in the application is assessed a fee under paragraph (4) unless the biosimilar biological product establishment listed in the application does not engage in the manufacture of the biosimilar biological product during such fiscal year.

[(C) DUE DATE.—The establishment fee for a fiscal year shall be due on the later of—

[(i) the first business day on or after October 1 of such fiscal year; or

[(ii) the first business day after the enactment of an appropriations Act providing for the collection and obligation of fees for such fiscal year under this section.

[(D) APPLICATION TO ESTABLISHMENT.—

[(i) Each biosimilar biological product establishment shall be assessed only one fee per biosimilar biological product establishment, notwithstanding the number of biosimilar biological products manufactured at the establishment, subject to clause (ii).

[(ii) In the event an establishment is listed in a biosimilar biological product application by more than one applicant, the establishment fee for the fiscal year shall be divided equally and assessed among the applicants whose biosimilar biological products are manufactured by the establishment during the fiscal year and assessed biosimilar biological product fees under paragraph (4).

[(E) EXCEPTION FOR NEW PRODUCTS.—If, during the fiscal year, an applicant initiates or causes to be initiated the manufacture of a biosimilar biological product at an establishment listed in its biosimilar biological product application—

[(i) that did not manufacture the biosimilar biological product in the previous fiscal year; and

[(ii) for which the full biosimilar biological product establishment fee has been assessed in the fiscal year at a time before manufacture of the biosimilar biological product was begun,

the applicant shall not be assessed a share of the biosimilar biological product establishment fee for the fiscal year in which the manufacture of the product began.]

(3) *BIOSIMILAR BIOLOGICAL PRODUCT PROGRAM FEE.*—

(A) *IN GENERAL.*—*Each person who is named as the applicant in a biosimilar biological product application shall pay the annual biosimilar biological product program fee established for a fiscal year under subsection (c)(5) for each biosimilar biological product that—*

(i) is identified in such a biosimilar biological product application approved as of October 1 of such fiscal year; and

(ii) as of October 1 of such fiscal year, does not appear on a list, developed and maintained by the Secretary, of discontinued biosimilar biological products.

(B) DUE DATE.—The biosimilar biological product program fee for a fiscal year shall be due on the later of—

(i) the first business day on or after October 1 of each such year; or

(ii) the first business day after the enactment of an appropriations Act providing for the collection and obligation of fees for such year under this section.

(C) ONE FEE PER PRODUCT PER YEAR.—The biosimilar biological product program fee shall be paid only once for each product for each fiscal year.

(D) LIMITATION.—A person who is named as the applicant in a biosimilar biological product application shall not be assessed more than 5 biosimilar biological product program fees for a fiscal year for biosimilar biological products identified in such biosimilar biological product application.

(4) BIOSIMILAR BIOLOGICAL PRODUCT FEE.—

(A) IN GENERAL.—Each person who is named as the applicant in a biosimilar biological product application shall pay for each such biosimilar biological product the annual fee established under **subsection (b)(1)(F)** subsection (c)(5).

(B) DUE DATE.—The biosimilar biological product fee for a fiscal year shall be due on the later of—

(i) the first business day on or after October 1 of each such year; or

(ii) the first business day after the enactment of an appropriations Act providing for the collection and obligation of fees for such year under this section.

(C) ONE FEE PER PRODUCT PER YEAR.—The biosimilar biological product fee shall be paid only once for each product for each fiscal year.

(b) FEE SETTING AND AMOUNTS.—

(1) IN GENERAL.—Subject to paragraph (2), the Secretary shall, 60 days before the start of each fiscal year that begins after September 30, 2012, establish, for the next fiscal year, the fees under subsection (a). Except as provided in subsection (c), such fees shall be in the following amounts:

(A) INITIAL BIOSIMILAR BIOLOGICAL PRODUCT DEVELOPMENT FEE.—The initial biosimilar biological product development fee under subsection (a)(1)(A) for a fiscal year shall be equal to 10 percent of the amount established under section 736(c)(4) for a human drug application described in section 736(a)(1)(A)(i) for that fiscal year.

(B) ANNUAL BIOSIMILAR BIOLOGICAL PRODUCT DEVELOPMENT FEE.—The annual biosimilar biological product development fee under subsection (a)(1)(B) for a fiscal year shall be equal to 10 percent of the amount established under section 736(c)(4) for a human drug application described in section 736(a)(1)(A)(i) for that fiscal year.

(C) REACTIVATION FEE.—The reactivation fee under subsection (a)(1)(D) for a fiscal year shall be equal to 20

percent of the amount of the fee established under section 736(c)(4) for a human drug application described in section 736(a)(1)(A)(i) for that fiscal year.

[(D) BIOSIMILAR BIOLOGICAL PRODUCT APPLICATION FEE.—The biosimilar biological product application fee under subsection (a)(2) for a fiscal year shall be equal to the amount established under section 736(c)(4) for a human drug application described in section 736(a)(1)(A)(i) for that fiscal year.

[(E) BIOSIMILAR BIOLOGICAL PRODUCT ESTABLISHMENT FEE.—The biosimilar biological product establishment fee under subsection (a)(3) for a fiscal year shall be equal to the amount established under section 736(c)(4) for a prescription drug establishment for that fiscal year.

[(F) BIOSIMILAR BIOLOGICAL PRODUCT FEE.—The biosimilar biological product fee under subsection (a)(4) for a fiscal year shall be equal to the amount established under section 736(c)(4) for a prescription drug product for that fiscal year.

[(2) LIMIT.—The total amount of fees charged for a fiscal year under this section may not exceed the total amount for such fiscal year of the costs of resources allocated for the process for the review of biosimilar biological product applications.]

(b) FEE REVENUE AMOUNTS.—

(1) FISCAL YEAR 2018.—*For fiscal year 2018, fees under subsection (a) shall be established to generate a total revenue amount equal to the sum of—*

(A) \$45,000,000; and

(B) the dollar amount equal to the fiscal year 2018 adjustment (as determined under subsection (c)(4)).

(2) SUBSEQUENT FISCAL YEARS.—*For each of the fiscal years 2019 through 2022, fees under subsection (a) shall, except as provided in subsection (c), be established to generate a total revenue amount equal to the sum of—*

(A) the annual base revenue for the fiscal year (as determined under paragraph (4));

(B) the dollar amount equal to the inflation adjustment for the fiscal year (as determined under subsection (c)(1));

(C) the dollar amount equal to the capacity planning adjustment for the fiscal year (as determined under subsection (c)(2)); and

(D) the dollar amount equal to the operating reserve adjustment for the fiscal year, if applicable (as determined under subsection (c)(3)).

(3) ALLOCATION OF REVENUE AMOUNT AMONG FEES; LIMITATIONS ON FEE AMOUNTS.—

(A) ALLOCATION.—*The Secretary shall determine the percentage of the total revenue amount for a fiscal year to be derived from, respectively—*

(i) initial and annual biosimilar development fees and reactivation fees under subsection (a)(1);

(ii) biosimilar biological product application fees under subsection (a)(2); and

(iii) biosimilar biological product program fees under subsection (a)(3).

(B) *LIMITATIONS ON FEE AMOUNTS.*—Until the first fiscal year for which the capacity planning adjustment under subsection (c)(2) is effective, the amount of any fee under subsection (a) for a fiscal year after fiscal year 2018 shall not exceed 125 percent of the amount of such fee for fiscal year 2018.

(C) *BIOSIMILAR BIOLOGICAL PRODUCT DEVELOPMENT FEES.*—The initial biosimilar biological product development fee under subsection (a)(1)(A) for a fiscal year shall be equal to the annual biosimilar biological product development fee under subsection (a)(1)(B) for that fiscal year.

(D) *REACTIVATION FEE.*—The reactivation fee under subsection (a)(1)(D) for a fiscal year shall be equal to twice the amount of the annual biosimilar biological product development fee under subsection (a)(1)(B) for that fiscal year.

(4) *ANNUAL BASE REVENUE.*—For purposes of paragraph (2), the dollar amount of the annual base revenue for a fiscal year shall be the dollar amount of the total revenue amount for the previous fiscal year, excluding any adjustments to such revenue amount under subsection (c)(3).

(c) *ADJUSTMENTS; ANNUAL FEE SETTING.*—

(1) *INFLATION ADJUSTMENT.*—

(A) *IN GENERAL.*—For purposes of subsection (b)(2)(B), the dollar amount of the inflation adjustment to the annual base revenue for each fiscal year shall be equal to the product of—

(i) such annual base revenue for the fiscal year under subsection (b); and

(ii) the inflation adjustment percentage under subparagraph (B).

(B) *INFLATION ADJUSTMENT PERCENTAGE.*—The inflation adjustment percentage under this subparagraph for a fiscal year is equal to the sum of—

(i) the average annual percent change in the cost, per full-time equivalent position of the Food and Drug Administration, of all personnel compensation and benefits paid with respect to such positions for the first 3 years of the preceding 4 fiscal years, multiplied by the proportion of personnel compensation and benefits costs to total costs of the process for the review of biosimilar biological product applications (as defined in section 744G(13)) for the first 3 years of the preceding 4 fiscal years; and

(ii) the average annual percent change that occurred in the Consumer Price Index for urban consumers (Washington-Baltimore, DC-MD-VA-WV; Not Seasonally Adjusted; All items; Annual Index) for the first 3 years of the preceding 4 years of available data multiplied by the proportion of all costs other than personnel compensation and benefits costs to total costs of the process for the review of biosimilar biological product applications (as defined in section 744G(13)) for the first 3 years of the preceding 4 fiscal years.

(2) *CAPACITY PLANNING ADJUSTMENT.*—

(A) *IN GENERAL.*—Beginning with the fiscal year described in subparagraph (B)(ii)(II), the Secretary shall, in addition to the adjustment under paragraph (1), further increase the fee revenue and fees under this section for a fiscal year to reflect changes in the resource capacity needs of the Secretary for the process for the review of biosimilar biological product applications.

(B) *CAPACITY PLANNING METHODOLOGY.*—

(i) *DEVELOPMENT; EVALUATION AND REPORT.*—The Secretary shall obtain, through a contract with an independent accounting or consulting firm, a report evaluating options and recommendations for a new methodology to accurately assess changes in the resource and capacity needs of the process for the review of biosimilar biological product applications. The capacity planning methodological options and recommendations presented in such report shall utilize and be informed by personnel time reporting data as an input. The report shall be published for public comment not later than September 30, 2020.

(ii) *ESTABLISHMENT AND IMPLEMENTATION.*—After review of the report described in clause (i) and receipt and review of public comments thereon, the Secretary shall establish a capacity planning methodology for purposes of this paragraph, which shall—

(I) incorporate such approaches and attributes as the Secretary determines appropriate; and

(II) be effective beginning with the first fiscal year for which fees are set after such capacity planning methodology is established.

(C) *LIMITATION.*—Under no circumstances shall an adjustment under this paragraph result in fee revenue for a fiscal year that is less than the sum of the amounts under subsections (b)(2)(A) (the annual base revenue for the fiscal year) and (b)(2)(B) (the dollar amount of the inflation adjustment for the fiscal year).

(D) *PUBLICATION IN FEDERAL REGISTER.*—The Secretary shall publish in the Federal Register notice under paragraph (5) the fee revenue and fees resulting from the adjustment and the methodologies under this paragraph.

(3) *OPERATING RESERVE ADJUSTMENT.*—

(A) *INTERIM APPLICATION; FEE REDUCTION.*—Until the first fiscal year for which the capacity planning adjustment under paragraph (2) is effective, the Secretary may, in addition to the adjustment under paragraph (1), reduce the fee revenue and fees under this section for a fiscal year as the Secretary determines appropriate for long-term financial planning purposes.

(B) *GENERAL APPLICATION AND METHODOLOGY.*—Beginning with the first fiscal year for which the capacity planning adjustment under paragraph (2) is effective, the Secretary may, in addition to the adjustments under paragraphs (1) and (2)—

(i) reduce the fee revenue and fees under this section as the Secretary determines appropriate for long-term financial planning purposes; or

(ii) increase the fee revenue and fees under this section if such an adjustment is necessary to provide for not more than 21 weeks of operating reserves of carry-over user fees for the process for the review of biosimilar biological product applications.

(C) **FEDERAL REGISTER NOTICE.**—If an adjustment under subparagraph (A) or (B) is made, the rationale for the amount of the increase or decrease (as applicable) in fee revenue and fees shall be contained in the annual Federal Register notice under paragraph (5) establishing fee revenue and fees for the fiscal year involved.

(4) **FISCAL YEAR 2018 ADJUSTMENT.**—

(A) **IN GENERAL.**—For fiscal year 2018, the Secretary shall adjust the fee revenue and fees under this section in such amount (if any) as needed to reflect an updated assessment of the workload for the process for the review of biosimilar biological product applications.

(B) **METHODOLOGY.**—The Secretary shall publish under paragraph (5) a description of the methodology used to calculate the fiscal year 2018 adjustment under this paragraph in the Federal Register notice establishing fee revenue and fees for fiscal year 2018.

(C) **LIMITATION.**—No adjustment under this paragraph shall result in an increase in fee revenue and fees under this section in excess of \$9,000,000.

(5) **ANNUAL FEE SETTING.**—For fiscal year 2018 and each subsequent fiscal year, the Secretary shall, not later than 60 days before the start of each such fiscal year—

(A) establish, for the fiscal year, initial and annual biosimilar biological product development fees and reactivation fees under subsection (a)(1), biosimilar biological product application fees under subsection (a)(2), and biosimilar biological product program fees under subsection (a)(3), based on the revenue amounts established under subsection (b) and the adjustments provided under this subsection; and

(B) publish such fee revenue and fees in the Federal Register.

(6) **LIMIT.**—The total amount of fees assessed for a fiscal year under this section may not exceed the total costs for such fiscal year for the resources allocated for the process for the review of biosimilar biological product applications.

[(c)] (d) **APPLICATION FEE WAIVER FOR SMALL BUSINESS.**—

(1) **WAIVER OF APPLICATION FEE.**—The Secretary shall grant to a person who is named in a biosimilar biological product application a waiver from the application fee assessed to that person under subsection (a)(2)(A) for the first biosimilar biological product application that a small business or its affiliate submits to the Secretary for review. After a small business or its affiliate is granted such a waiver, the small business or its affiliate [shall pay—]

[(A)] [application fees] *shall pay application fees* for all subsequent biosimilar biological product applications submitted to the Secretary for review in the same manner as an entity that is not a small business[; and].

[(B)] all supplement fees for all supplements to biosimilar biological product applications submitted to the Secretary for review in the same manner as an entity that is not a small business.]

(2) CONSIDERATIONS.—In determining whether to grant a waiver of a fee under paragraph (1), the Secretary shall consider only the circumstances and assets of the applicant involved and any affiliate of the applicant.

(3) SMALL BUSINESS DEFINED.—In this subsection, the term “small business” means an entity that has fewer than 500 employees, including employees of affiliates, and does not have a drug product that has been approved under a human drug application (as defined in section 735) or a biosimilar biological product application (as defined in section 744G(4)) and introduced or delivered for introduction into interstate commerce.

[(d)] (e) EFFECT OF FAILURE TO PAY FEES.—A biosimilar biological product application or supplement submitted by a person subject to fees under subsection (a) shall be considered incomplete and shall not be accepted for filing by the Secretary until [all fees] *all such fees* owed by such person have been paid.

[(e)] (f) CREDITING AND AVAILABILITY OF FEES.—

(1) IN GENERAL.—Subject to paragraph (2), fees authorized under subsection (a) shall be collected and available for obligation only to the extent and in the amount provided in advance in appropriations Acts. Such fees are authorized to remain available until expended. Such sums as may be necessary may be transferred from the Food and Drug Administration salaries and expenses appropriation account without fiscal year limitation to such appropriation account for salaries and expenses with such fiscal year limitation. The sums transferred shall be available solely for the process for the review of biosimilar biological product applications.

(2) COLLECTIONS AND APPROPRIATION ACTS.—

(A) IN GENERAL.—Subject to subparagraphs (C) and (D), the fees authorized by this section shall be collected and available in each fiscal year in an amount not to exceed the amount specified in appropriation Acts, or otherwise made available for obligation for such fiscal year.

(B) USE OF FEES AND LIMITATION.—The fees authorized by this section shall be available for a fiscal year beginning after fiscal year 2012 to defray the costs of the process for the review of biosimilar biological product applications (including such costs for an additional number of full-time equivalent positions in the Department of Health and Human Services to be engaged in such process), only if the Secretary allocates for such purpose an amount for such fiscal year (excluding amounts from fees collected under this section) no less than \$20,000,000, multiplied by the adjustment factor applicable to the fiscal year involved.

[(C)] FEE COLLECTION DURING FIRST PROGRAM YEAR.—Until the date of enactment of an Act making appropria-

tions through September 30, 2013, for the salaries and expenses account of the Food and Drug Administration, fees authorized by this section for fiscal year 2013 may be collected and shall be credited to such account and remain available until expended.】

(C) *COMPLIANCE.*—*The Secretary shall be considered to have met the requirements of subparagraph (B) in any fiscal year if the costs described in such subparagraph are not more than 15 percent below the level specified in such subparagraph.*

(D) *PROVISION FOR EARLY PAYMENTS [IN SUBSEQUENT YEARS].*—Payment of fees authorized under this section for a fiscal year [(after fiscal year 2013)], prior to the due date for such fees, may be accepted by the Secretary in accordance with authority provided in advance in a prior year appropriations Act.

(3) *AUTHORIZATION OF APPROPRIATIONS.*—For each of fiscal years [2013 through 2017] *2018 through 2022*, there is authorized to be appropriated for fees under this section an amount equivalent to the total amount of fees assessed for such fiscal year under this section.

[(f)] (g) *COLLECTION OF UNPAID FEES.*—In any case where the Secretary does not receive payment of a fee assessed under subsection (a) within 30 days after it is due, such fee shall be treated as a claim of the United States Government subject to subchapter II of chapter 37 of title 31, United States Code.

[(g)] (h) *WRITTEN REQUESTS FOR WAIVERS AND REFUNDS.*—To qualify for consideration for a waiver under [subsection (c)] *subsection (d)*, or for a refund of any fee collected in accordance with subsection (a)(2)(A), a person shall submit to the Secretary a written request for such waiver or refund not later than 180 days after such fee is due.

[(h)] (i) *CONSTRUCTION.*—This section may not be construed to require that the number of full-time equivalent positions in the Department of Health and Human Services, for officers, employers, and advisory committees not engaged in the process of the review of biosimilar biological product applications, be reduced to offset the number of officers, employees, and advisory committees so engaged.

SEC. 744I. REAUTHORIZATION; REPORTING REQUIREMENTS.

(a) *PERFORMANCE REPORT.*—Beginning with fiscal year [2013] *2018*, not later than 120 days after the end of each fiscal year for which fees are collected under this part, the Secretary shall prepare and submit to the Committee on Energy and Commerce of the House of Representatives and the Committee on Health, Education, Labor, and Pensions of the Senate a report concerning the progress of the Food and Drug Administration in achieving the goals identified in the letters described in section 401(b) of the [Biosimilar User Fee Act of 2012] *Biosimilar User Fee Amendments of 2017* during such fiscal year and the future plans of the Food and Drug Administration for meeting such goals. The report for a fiscal year shall include information on all previous cohorts for which the Secretary has not given a complete response on all biosimilar biological product applications and supplements in the cohort.

(b) **FISCAL REPORT.**—Not later than 120 days after the end of fiscal year **[2013] 2018** and each subsequent fiscal year for which fees are collected under this part, the Secretary shall prepare and submit to the Committee on Energy and Commerce of the House of Representatives and the Committee on Health, Education, Labor, and Pensions of the Senate a report on the implementation of the authority for such fees during such fiscal year and the use, by the Food and Drug Administration, of the fees collected for such fiscal year.

(c) **PUBLIC AVAILABILITY.**—The Secretary shall make the reports required under subsections (a) and (b) available to the public on the Internet Web site of the Food and Drug Administration.

[(d) STUDY.—

[(1) IN GENERAL.—The Secretary shall contract with an independent accounting or consulting firm to study the workload volume and full costs associated with the process for the review of biosimilar biological product applications.

[(2) INTERIM RESULTS.—Not later than June 1, 2015, the Secretary shall publish, for public comment, interim results of the study described under paragraph (1).

[(3) FINAL RESULTS.—Not later than September 30, 2016, the Secretary shall publish, for public comment, the final results of the study described under paragraph (1).]

[(e) (d) REAUTHORIZATION.—

(1) CONSULTATION.—In developing recommendations to present to the Congress with respect to the goals described in subsection (a), and plans for meeting the goals, for the process for the review of biosimilar biological product applications for the first 5 fiscal years after fiscal year **[2017] 2022**, and for the reauthorization of this part for such fiscal years, the Secretary shall consult with—

- (A) the Committee on Energy and Commerce of the House of Representatives;
- (B) the Committee on Health, Education, Labor, and Pensions of the Senate;
- (C) scientific and academic experts;
- (D) health care professionals;
- (E) representatives of patient and consumer advocacy groups; and
- (F) the regulated industry.

(2) PUBLIC REVIEW OF RECOMMENDATIONS.—After negotiations with the regulated industry, the Secretary shall—

- (A) present the recommendations developed under paragraph (1) to the congressional committees specified in such paragraph;
- (B) publish such recommendations in the Federal Register;
- (C) provide for a period of 30 days for the public to provide written comments on such recommendations;
- (D) hold a meeting at which the public may present its views on such recommendations; and
- (E) after consideration of such public views and comments, revise such recommendations as necessary.

(3) TRANSMITTAL OF RECOMMENDATIONS.—Not later than January 15, **[2017] 2022**, the Secretary shall transmit to the

Congress the revised recommendations under paragraph (2), a summary of the views and comments received under such paragraph, and any changes made to the recommendations in response to such views and comments.

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SUBCHAPTER D—INFORMATION AND EDUCATION

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SEC. 745A. ELECTRONIC FORMAT FOR SUBMISSIONS.

(a) DRUGS AND BIOLOGICS.—

(1) IN GENERAL.—Beginning no earlier than 24 months after the issuance of a final guidance issued after public notice and opportunity for comment, submissions under subsection (b), (i), or (j) of section 505 of this Act or subsection (a) or (k) of section 351 of the Public Health Service Act shall be submitted in such electronic format as specified by the Secretary in such guidance.

(2) GUIDANCE CONTENTS.—In the guidance under paragraph (1), the Secretary may—

(A) provide a timetable for establishment by the Secretary of further standards for electronic submission as required by such paragraph; and

(B) set forth criteria for waivers of and exemptions from the requirements of this subsection.

(3) EXCEPTION.—This subsection shall not apply to submissions described in section 561.

(b) DEVICES.—

(1) IN GENERAL.—Beginning after the issuance of final guidance implementing this paragraph, presubmissions and submissions for devices under section 510(k), 513(f)(2)(A), 515(c), 515(d), 515(f), 520(g), 520(m), or 564 of this Act or section 351 of the Public Health Service Act, and any supplements to such presubmissions or submissions, shall include an electronic copy of such presubmissions or submissions.

(2) GUIDANCE CONTENTS.—In the guidance under paragraph (1), the Secretary may—

(A) provide standards for the electronic copy required under such paragraph; and

(B) set forth criteria for waivers of and exemptions from the requirements of this subsection.

(3) *PRESUBMISSIONS AND SUBMISSIONS SOLELY IN ELECTRONIC FORMAT.*—

(A) *IN GENERAL.*—*Beginning on such date as the Secretary specifies in final guidance issued under subparagraph (C), presubmissions and submissions for devices described in paragraph (1) (and any appeals of action taken by the Secretary with respect to such presubmissions or submissions) shall be submitted solely in such electronic format as specified by the Secretary in such guidance.*

(B) *DRAFT GUIDANCE.*—*The Secretary shall, not later than October 1, 2019, issue draft guidance providing for—*

(i) any further standards for the submission by electronic format required under subparagraph (A);

(ii) a timetable for the establishment by the Secretary of such further standards; and

(iii) criteria for waivers of and exemptions from the requirements of this subsection.

(C) FINAL GUIDANCE.—The Secretary shall, not later than 12 months after the close of the public comment period on the draft guidance issued under subparagraph (B), issue final guidance described in clauses (i) through (iii) of such subparagraph.

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CHAPTER VIII—IMPORTS AND EXPORTS

IMPORTS AND EXPORTS

SEC. 801. (a) The Secretary of the Treasury shall deliver to the Secretary of Health and Human Services, upon his request, samples of food, drugs, devices, tobacco products, and cosmetics which are being imported or offered for import into the United States, giving notice thereof to the owner or consignee, who may appear before the Secretary of Health and Human Services and have the right to introduce testimony. The Secretary of Health and Human Services shall furnish to the Secretary of the Treasury a list of establishments registered pursuant to subsection (i) of section 510 or section 905(h) and shall request that if any drugs, devices, or tobacco products manufactured, prepared, propagated, compounded, or processed in an establishment not so registered are imported or offered for import into the United States, samples of such drugs, devices, or tobacco products be delivered to the Secretary of Health and Human Services, with notice of such delivery to the owner or consignee, who may appear before the Secretary of Health and Human Services and have the right to introduce testimony. If it appears from the examination of such samples or otherwise that (1) such article has been manufactured, processed, or packed under insanitary conditions or, in the case of a device, the methods used in, or the facilities or controls used for, the manufacture, packing, storage, or installation of the device do not conform to the requirements of section 520(f), or (2) such article is forbidden or restricted in sale in the country in which it was produced or from which it was exported, or (3) such article is adulterated, misbranded, or in violation of section 505 or the importer (as defined in section 805) is in violation of such section 805, or prohibited from introduction or delivery for introduction into interstate commerce under section 301(l), or (4) the recordkeeping requirements under section 204 of the FDA Food Safety Modernization Act (other than the requirements under subsection (f) of such section) have not been complied with regarding such article, then such article shall be refused admission, except as provided in subsection (b) of this section. With respect to an article of food, if importation of such food is subject to, but not compliant with, the requirement under subsection (q) that such food be accompanied by a certification or other assurance that the food meets applicable requirements of this Act, then such article shall be refused admission. If such article is subject to a requirement under section 760 or 761 and if the Secretary has credible evidence or information indicating that the responsible person

(as defined in such section 760 or 761) has not complied with a requirement of such section 760 or 761 with respect to any such article, or has not allowed access to records described in such section 760 or 761, then such article shall be refused admission, except as provided in subsection (b) of this section. The Secretary of the Treasury shall cause the destruction of any such article refused admission unless such article is exported, under regulations prescribed by the Secretary of the Treasury, within ninety days of the date of notice of such refusal or within such additional time as may be permitted pursuant to such regulations, except that the Secretary of Health and Human Services may destroy, without the opportunity for export, any drug refused admission under this section, if such drug is valued at an amount that is \$2,500 or less (or such higher amount as the Secretary of the Treasury may set by regulation pursuant to section 498(a)(1) of the Tariff Act of 1930 (19 U.S.C. 1498(a)(1)) and was not brought into compliance as described under subsection (b).. The Secretary of Health and Human Services shall issue regulations providing for notice and an opportunity to appear before the Secretary of Health and Human Services and introduce testimony, as described in the first sentence of this subsection, on destruction of a drug under the sixth sentence of this subsection. The regulations shall provide that prior to destruction, appropriate due process is available to the owner or consignee seeking to challenge the decision to destroy the drug. Where the Secretary of Health and Human Services provides notice and an opportunity to appear and introduce testimony on the destruction of a drug, the Secretary of Health and Human Services shall store and, as applicable, dispose of the drug after the issuance of the notice, except that the owner and consignee shall remain liable for costs pursuant to subsection (c). Such process may be combined with the notice and opportunity to appear before the Secretary and introduce testimony, as described in the first sentence of this subsection, as long as appropriate notice is provided to the owner or consignee. Clause (2) of the third sentence of this paragraph shall not be construed to prohibit the admission of narcotic drugs the importation of which is permitted under the Controlled Substances Import and Export Act.

(b) Pending decision as to the admission of an article being imported or offered for import, the Secretary of the Treasury may authorize delivery of such article to the owner or consignee upon the execution by him of a good and sufficient bond providing for the payment of such liquidated damages in the event of default as may be required pursuant to regulations of the Secretary of the Treasury. If it appears to the Secretary of Health and Human Services that (1) an article included within the provisions of clause (3) of subsection (a) of this section can, by relabeling or other action, be brought into compliance with the Act or rendered other than a food, drug, device, or cosmetic, or (2) with respect to an article described in subsection (a) relating to the requirements of sections 760 or 761,, the responsible person (as defined in section 760 or 761) can take action that would assure that the responsible person is in compliance with section 760 or 761, as the case may be, final determination as to admission of such article may be deferred and, upon filing of timely written application by the owner or consignee and the execution by him of a bond as provided in the preceding

provisions of this subsection, the Secretary may, in accordance with regulations, authorize the applicant, or, with respect to clause (2), the responsible person, to perform such relabeling or other action specified in such authorization (including destruction or export of rejected articles or portions thereof, as may be specified in the Secretary's authorization). All such relabeling or other action pursuant to such authorization shall in accordance with regulations be under the supervision of an officer or employee of the Department of Health and Human Services designated by the Secretary, or an officer or employee of the Department of the Treasury designated by the Secretary of the Treasury.

(c) All expenses (including travel, per diem or subsistence, and salaries of officers or employees of the United States) in connection with the destruction provided for in subsection (a) of this section and the supervision of the relabeling or other action authorized under the provisions of subsection (b) of this section, the amount of such expenses to be determined in accordance with regulations, and all expenses in connection with the storage, cartage, or labor with respect to any article refused admission under subsection (a) of this section, shall be paid by the owner or consignee and, in default of such payment, shall constitute a lien against any future importations made by such owner or consignee.

(d) ~~[(1)]~~ **[Except as]** (1)(A) *Except as* provided in paragraph (2) and section 804, no drug subject to section 503(b) or composed wholly or partly of insulin which is manufactured in a State and exported may be imported into the United States unless the drug is imported by the manufacturer of the drug.

(B) *Except as authorized by the Secretary in the case of a drug that appears on the drug shortage list in effect under section 506E, no drug that would be subject to section 503(b), and which is manufactured outside the United States and intended by the manufacturer or labeled to be marketed outside the United States, may be imported into the United States for sale or commercial use.*

(2) The Secretary may authorize the importation of a drug the importation of which is prohibited by paragraph (1) if the drug is required for emergency medical care.

(3)(A) Subject to subparagraph (B), no component of a drug, no component part or accessory of a device, or other article of device requiring further processing, which is ready or suitable for use for health-related purposes, and no article of a food additive, color additive, or dietary supplement, including a product in bulk form, shall be excluded from importation into the United States under subsection (a) if each of the following conditions is met:

(i) The importer of such article of a drug or device or importer of such article of a food additive, color additive, or dietary supplement submits to the Secretary, at the time of initial importation, a statement in accordance with the following:

(I) Such statement provides that such article is intended to be further processed by the initial owner or consignee, or incorporated by the initial owner or consignee, into a drug, biological product, device, food, food additive, color additive, or dietary supplement that will be exported by the initial owner or consignee from the United States in accordance with subsection (e) or section 802, or with section 351(h) of the Public Health Service Act.

(II) The statement identifies the manufacturer of such article and each processor, packer, distributor, or other entity that had possession of the article in the chain of possession of the article from the manufacturer to such importer of the article.

(III) The statement is accompanied by such certificates of analysis as are necessary to identify such article, unless the article is a device or is an article described in paragraph (4).

(ii) At the time of initial importation and before the delivery of such article to the importer or the initial owner or consignee, such owner or consignee executes a good and sufficient bond providing for the payment of such liquidated damages in the event of default as may be required pursuant to regulations of the Secretary of the Treasury.

(iii) Such article is used and exported by the initial owner or consignee in accordance with the intent described under clause (i)(I), except for any portions of the article that are destroyed.

(iv) The initial owner or consignee maintains records on the use or destruction of such article or portions thereof, as the case may be, and submits to the Secretary any such records requested by the Secretary.

(v) Upon request of the Secretary, the initial owner or consignee submits a report that provides an accounting of the exportation or destruction of such article or portions thereof, and the manner in which such owner or consignee complied with the requirements of this subparagraph.

(B) Notwithstanding subparagraph (A), the Secretary may refuse admission to an article that otherwise would be imported into the United States under such subparagraph if the Secretary determines that there is credible evidence or information indicating that such article is not intended to be further processed by the initial owner or consignee, or incorporated by the initial owner or consignee, into a drug, biological product, device, food, food additive, color additive, or dietary supplement that will be exported by the initial owner or consignee from the United States in accordance with subsection (e) or section 802, or with section 351(h) of the Public Health Service Act.

(C) This section may not be construed as affecting the responsibility of the Secretary to ensure that articles imported into the United States under authority of subparagraph (A) meet each of the conditions established in such subparagraph for importation.

(4) The importation into the United States of blood, blood components, source plasma, or source leukocytes or of a component, accessory, or part thereof is not permitted pursuant to paragraph (3) unless the importation complies with section 351(a) of the Public Health Service Act or the Secretary permits the importation under appropriate circumstances and conditions, as determined by the Secretary. The importation of tissue or a component or part of tissue is not permitted pursuant to paragraph (3) unless the importation complies with section 361 of the Public Health Service Act.

(e)(1) A food, drug, device, tobacco product or cosmetic intended for export shall not be deemed to be adulterated or misbranded under this Act, and a tobacco product intended for export shall not

be deemed to be in violation of section 906(e), 907, 911, or 920(a), if it—

- (A) accords to the specifications of the foreign purchaser,
- (B) is not in conflict with the laws of the country to which it is intended for export,
- (C) is labeled on the outside of the shipping package that it is intended for export, and
- (D) is not sold or offered for sale in domestic commerce.

(2) Paragraph (1) does not apply to any device—

- (A) which does not comply with an applicable requirement of section 514 or 515,
- (B) which under section 520(g) is exempt from either such section, or
- (C) which is a banned device under section 516,

unless, in addition to the requirements of paragraph (1), either (i) the Secretary has determined that the exportation of the device is not contrary to public health and safety and has the approval of the country to which it is intended for export or (ii) the device is eligible for export under section 802.

(3) A new animal drug that requires approval under section 512 shall not be exported pursuant to paragraph (1) if such drug has been banned in the United States.

(4)(A) Any person who exports a food, drug, animal drug, or device may request that the Secretary—

- (i) certify in writing that the exported food, drug, animal drug, or device meets the requirements of paragraph (1) or section 802; or
- (ii) certify in writing that the food, drug, animal drug, or device being exported meets the applicable requirements of this Act upon a showing that the food, drug or device meets the applicable requirements of this Act.

The Secretary shall issue such a certification within 20 days of the receipt of a request for such certification.

(B) If the Secretary issues a written export certification within the 20 days prescribed by subparagraph (A), a fee for such certification may be charged but shall not exceed \$175 for each certification. Fees collected for a fiscal year pursuant to this subparagraph shall be credited to the appropriation account for salaries and expenses of the Food and Drug Administration and shall be available in accordance with appropriations Acts until expended without fiscal year limitation. Such fees shall be collected in each fiscal year in an amount equal to the amount specified in appropriations Acts for such fiscal year and shall only be collected and available for the costs of the Food and Drug Administration.

(C) For purposes of this paragraph, a certification by the Secretary shall be made on such basis, and in such form (including a publicly available listing) as the Secretary determines appropriate.

(D) With regard to fees pursuant to subparagraph (B) in connection with written export certifications for food:

- (i) Such fees shall be collected and available solely for the costs of the Food and Drug Administration associated with issuing such certifications.
- (ii) Such fees may not be retained in an amount that exceeds such costs for the respective fiscal year.

(E)(i) If the Secretary denies a request made under subparagraph (A)(ii) for certification with respect to a device, the Secretary shall provide, in writing, to the person seeking such certification the basis for such denial, and specifically identify the finding upon which such denial is based.

(ii) If the denial of a request as described in clause (i) is based on—

(I) grounds other than an injunction proceeding pursuant to section 302, seizure action pursuant to section 304, or a recall designated Class I or Class II pursuant to part 7, title 21, Code of Federal Regulations, and

(II) an establishment being considered out of compliance with part 820, title 21, Code of Federal Regulations, the Secretary shall provide a substantive summary of the specific grounds for noncompliance so identified, if such grounds have not been previously communicated to the manufacturer.

(iii) With respect to a device manufactured in an establishment that has received a report under section 704(b), the Secretary shall not deny a request for certification under subparagraph (A)(ii) based exclusively on the issuance of that report if the owner, operator, or agent in charge of such establishment has agreed to a plan of correction in response to such report.

(F)(i) The Secretary shall provide a process for a person who is denied a certification as described in subparagraph (E)(i) to request a review that conforms to the standards of section 517A(b).

(ii) Notwithstanding any previous review conducted pursuant to clause (i), a person who has been denied a certification for a device as described in subparagraph (E)(i) may, at any time, request a review of that denial in order to present new information relating to actions taken by such person to address the reasons identified by the Secretary for such denial, including evidence that corrective actions are being or have been implemented to address the grounds for noncompliance identified by the Secretary under subparagraph (E)(ii).

(G)(i) This paragraph applies to requests for certification on behalf of any device establishment registered under section 510, whether the establishment is located in the United States or another country.

(ii) The Secretary may charge a fee for the issuance of a certification described in clause (i), and such fee is subject to the same conditions and requirements as a fee charged under subparagraph (B) for a certification issued under such subparagraph.

(f)(1) If a drug (other than insulin, an antibiotic drug, an animal drug, or a drug exported under section 802) being exported in accordance with subsection (e) is being exported to a country that has different or additional labeling requirements or conditions for use and such country requires the drug to be labeled in accordance with those requirements or uses, such drug may be labeled in accordance with such requirements and conditions for use in the country to which such drug is being exported if it also is labeled in accordance with the requirements of this Act.

(2) If, pursuant to paragraph (1), the labeling of an exported drug includes conditions for use that have not been approved under this Act, the labeling must state that such conditions for use have not been approved under this Act. A drug exported under section 802 is exempt from this section.

(g)(1) With respect to a prescription drug being imported or offered for import into the United States, the Secretary, in the case of an individual who is not in the business of such importations, may not send a warning notice to the individual unless the following conditions are met:

(A) The notice specifies, as applicable to the importation of the drug, that the Secretary has made a determination that—

(i) importation is in violation of section 801(a) because the drug is or appears to be adulterated, misbranded, or in violation of section 505;

(ii) importation is in violation of section 801(a) because the drug is or appears to be forbidden or restricted in sale in the country in which it was produced or from which it was exported;

(iii) importation is or appears to be in violation of section 801(d)(1); or

(iv) importation otherwise is or appears to be in violation of Federal law.

(B) The notice does not specify any provision described in subparagraph (A) that is not applicable to the importation of the drug.

(C) The notice states the reasons underlying such determination by the Secretary, including a brief application to the principal facts involved of the provision of law described in subparagraph (A) that is the basis of the determination by the Secretary.

(2) For purposes of this section, the term “warning notice”, with respect to the importation of a drug, means a communication from the Secretary (written or otherwise) notifying a person, or clearly suggesting to the person, that importing the drug for personal use is, or appears to be, a violation of this Act.

(h)(1) The Secretary shall give high priority to increasing the number of inspections under this section for the purpose of enabling the Secretary to inspect food offered for import at ports of entry into the United States, with the greatest priority given to inspections to detect the intentional adulteration of food.

(2) The Secretary shall give high priority to making necessary improvements to the information management systems of the Food and Drug Administration that contain information related to foods imported or offered for import into the United States for purposes of improving the ability of the Secretary to allocate resources, detect the intentional adulteration of food, and facilitate the importation of food that is in compliance with this Act.

(3) The Secretary shall improve linkages with other regulatory agencies of the Federal Government that share responsibility for food safety, and shall with respect to such safety improve linkages with the States and Indian tribes (as defined in section 4(e) of the Indian Self-Determination and Education Assistance Act (25 U.S.C. 450b(e))).

(i)(1) For use in inspections of food under this section, the Secretary shall provide for research on the development of tests and sampling methodologies—

(A) whose purpose is to test food in order to rapidly detect the adulteration of the food, with the greatest priority given to detect the intentional adulteration of food; and

(B) whose results offer significant improvements over the available technology in terms of accuracy, timing, or costs.

(2) In providing for research under paragraph (1), the Secretary shall give priority to conducting research on the development of tests that are suitable for inspections of food at ports of entry into the United States.

(3) In providing for research under paragraph (1), the Secretary shall as appropriate coordinate with the Director of the Centers for Disease Control and Prevention, the Director of the National Institutes of Health, the Administrator of the Environmental Protection Agency, and the Secretary of Agriculture.

(4) The Secretary shall annually submit to the Committee on Energy and Commerce of the House of Representatives, and the Committee on Health, Education, Labor, and Pensions of the Senate, a report describing the progress made in research under paragraph (1), including progress regarding paragraph (2).

(j)(1) If an officer or qualified employee of the Food and Drug Administration has credible evidence or information indicating that an article of food presents a threat of serious adverse health consequences or death to humans or animals, and such officer or qualified employee is unable to inspect, examine, or investigate such article upon the article being offered for import at a port of entry into the United States, the officer or qualified employee shall request the Secretary of Treasury to hold the food at the port of entry for a reasonable period of time, not to exceed 24 hours, for the purpose of enabling the Secretary to inspect, examine, or investigate the article as appropriate.

(2) The Secretary shall request the Secretary of Treasury to remove an article held pursuant to paragraph (1) to a secure facility, as appropriate. During the period of time that such article is so held, the article shall not be transferred by any person from the port of entry into the United States for the article, or from the secure facility to which the article has been removed, as the case may be. Subsection (b) does not authorize the delivery of the article pursuant to the execution of a bond while the article is so held.

(3) An officer or qualified employee of the Food and Drug Administration may make a request under paragraph (1) only if the Secretary or an official designated by the Secretary approves the request. An official may not be so designated unless the official is the director of the district under this Act in which the article involved is located, or is an official senior to such director.

(4) With respect to an article of food for which a request under paragraph (1) is made, the Secretary, promptly after the request is made, shall notify the State in which the port of entry involved is located that the request has been made, and as applicable, that such article is being held under this subsection.

(k)(1) If an article of food is being imported or offered for import into the United States, and the importer, owner, or consignee of the article is a person who has been debarred under section 306(b)(3), such article shall be held at the port of entry for the article, and may not be delivered to such person. Subsection (b) does not authorize the delivery of the article pursuant to the execution of a bond while the article is so held. The article shall be removed to a secure facility, as appropriate. During the period of time that such article is so held, the article shall not be transferred by any

person from the port of entry into the United States for the article, or from the secure facility to which the article has been removed, as the case may be.

(2) An article of food held under paragraph (1) may be delivered to a person who is not a debarred person under section 306(b)(3) if such person affirmatively establishes, at the expense of the person, that the article complies with the requirements of this Act, as determined by the Secretary.

(1)(1) If an article of food is being imported or offered for import into the United States, and such article is from a foreign facility for which a registration has not been submitted to the Secretary under section 415 (or for which a registration has been suspended under such section), such article shall be held at the port of entry for the article, and may not be delivered to the importer, owner, or consignee of the article, until the foreign facility is so registered. Subsection (b) does not authorize the delivery of the article pursuant to the execution of a bond while the article is so held. The article shall be removed to a secure facility, as appropriate. During the period of time that such article is so held, the article shall not be transferred by any person from the port of entry into the United States for the article, or from the secure facility to which the article has been removed, as the case may be.

(m)(1) In the case of an article of food that is being imported or offered for import into the United States, the Secretary, after consultation with the Secretary of the Treasury, shall by regulation require, for the purpose of enabling such article to be inspected at ports of entry into the United States, the submission to the Secretary of a notice providing the identity of each of the following: The article; the manufacturer and shipper of the article; if known within the specified period of time that notice is required to be provided, the grower of the article; the country from which the article originates; the country from which the article is shipped; any country to which the article has been refused entry; and the anticipated port of entry for the article. An article of food imported or offered for import without submission of such notice in accordance with the requirements under this paragraph shall be refused admission into the United States. Nothing in this section may be construed as a limitation on the port of entry for an article of food.

(2)(A) Regulations under paragraph (1) shall require that a notice under such paragraph be provided by a specified period of time in advance of the time of the importation of the article of food involved or the offering of the food for import, which period shall be no less than the minimum amount of time necessary for the Secretary to receive, review, and appropriately respond to such notification, but may not exceed five days. In determining the specified period of time required under this subparagraph, the Secretary may consider, but is not limited to consideration of, the effect on commerce of such period of time, the locations of the various ports of entry into the United States, the various modes of transportation, the types of food imported into the United States, and any other such consideration. Nothing in the preceding sentence may be construed as a limitation on the obligation of the Secretary to receive, review, and appropriately respond to any notice under paragraph (1).

(B)(i) If an article of food is being imported or offered for import into the United States and a notice under paragraph (1) is not provided in advance in accordance with the requirements under paragraph (1), such article shall be held at the port of entry for the article, and may not be delivered to the importer, owner, or consignee of the article, until such notice is submitted to the Secretary, and the Secretary examines the notice and determines that the notice is in accordance with the requirements under paragraph (1). Subsection (b) does not authorize the delivery of the article pursuant to the execution of a bond while the article is so held. The article shall be removed to a secure facility, as appropriate. During the period of time that such article is so held, the article shall not be transferred by any person from the port of entry into the United States for the article, or from the secure facility to which the article has been removed, as the case may be.

(ii) In carrying out clause (i) with respect to an article of food, the Secretary shall determine whether there is in the possession of the Secretary any credible evidence or information indicating that such article presents a threat of serious adverse health consequences or death to humans or animals.

(3)(A) This subsection may not be construed as limiting the authority of the Secretary to obtain information under any other provision of this Act.

(B) This subsection may not be construed as authorizing the Secretary to impose any requirements with respect to a food to the extent that it is within the exclusive jurisdiction of the Secretary of Agriculture pursuant to the Federal Meat Inspection Act (21 U.S.C. 601 et seq.), the Poultry Products Inspection Act (21 U.S.C. 451 et seq.), or the Egg Products Inspection Act (21 U.S.C. 1031 et seq.).

(n)(1) If a food has been refused admission under subsection (a), other than such a food that is required to be destroyed, the Secretary may require the owner or consignee of the food to affix to the container of the food a label that clearly and conspicuously bears the statement: "UNITED STATES: REFUSED ENTRY".

(2) All expenses in connection with affixing a label under paragraph (1) shall be paid by the owner or consignee of the food involved, and in default of such payment, shall constitute a lien against future importations made by such owner or consignee.

(3) A requirement under paragraph (1) remains in effect until the Secretary determines that the food involved has been brought into compliance with this Act.

(o) If an article that is a device is being imported or offered for import into the United States, and the importer, owner, or consignee of such article does not, at the time of offering the article for import, submit to the Secretary a statement that identifies the registration under section 510(i) of each establishment that with respect to such article is required under such section to register with the Secretary, the article may be refused admission. If the article is refused admission for failure to submit such a statement, the article shall be held at the port of entry for the article, and may not be delivered to the importer, owner, or consignee of the article, until such a statement is submitted to the Secretary. Subsection (b) does not authorize the delivery of the article pursuant to the execution of a bond while the article is so held. The article shall be removed to a secure facility, as appropriate. During the period of

time that such article is so held, the article shall not be transferred by any person from the port of entry into the United States for the article, or from the secure facility to which the article has been removed, as the case may be.

(p)(1) Not later than 36 months after the date of enactment of the Family Smoking Prevention and Tobacco Control Act, and annually thereafter, the Secretary shall submit to the Committee on Health, Education, Labor, and Pensions of the Senate and the Committee on Energy and Commerce of the House of Representatives, a report regarding—

(A) the nature, extent, and destination of United States tobacco product exports that do not conform to tobacco product standards established pursuant to this Act;

(B) the public health implications of such exports, including any evidence of a negative public health impact; and

(C) recommendations or assessments of policy alternatives available to Congress and the executive branch to reduce any negative public health impact caused by such exports.

(2) The Secretary is authorized to establish appropriate information disclosure requirements to carry out this subsection.

(q) CERTIFICATIONS CONCERNING IMPORTED FOODS.—

(1) IN GENERAL.—The Secretary may require, as a condition of granting admission to an article of food imported or offered for import into the United States, that an entity described in paragraph (3) provide a certification, or such other assurances as the Secretary determines appropriate, that the article of food complies with applicable requirements of this Act. Such certification or assurances may be provided in the form of shipment-specific certificates, a listing of certified facilities that manufacture, process, pack, or hold such food, or in such other form as the Secretary may specify.

(2) FACTORS TO BE CONSIDERED IN REQUIRING CERTIFICATION.—The Secretary shall base the determination that an article of food is required to have a certification described in paragraph (1) on the risk of the food, including—

(A) known safety risks associated with the food;

(B) known food safety risks associated with the country, territory, or region of origin of the food;

(C) a finding by the Secretary, supported by scientific, risk-based evidence, that—

(i) the food safety programs, systems, and standards in the country, territory, or region of origin of the food are inadequate to ensure that the article of food is as safe as a similar article of food that is manufactured, processed, packed, or held in the United States in accordance with the requirements of this Act; and

(ii) the certification would assist the Secretary in determining whether to refuse or admit the article of food under subsection (a); and

(D) information submitted to the Secretary in accordance with the process established in paragraph (7).

(3) CERTIFYING ENTITIES.—For purposes of paragraph (1), entities that shall provide the certification or assurances described in such paragraph are—

- (A) an agency or a representative of the government of the country from which the article of food at issue originated, as designated by the Secretary; or
- (B) such other persons or entities accredited pursuant to section 808 to provide such certification or assurance.
- (4) RENEWAL AND REFUSAL OF CERTIFICATIONS.—The Secretary may—
- (A) require that any certification or other assurance provided by an entity specified in paragraph (2) be renewed by such entity at such times as the Secretary determines appropriate; and
- (B) refuse to accept any certification or assurance if the Secretary determines that such certification or assurance is not valid or reliable.
- (5) ELECTRONIC SUBMISSION.—The Secretary shall provide for the electronic submission of certifications under this subsection.
- (6) FALSE STATEMENTS.—Any statement or representation made by an entity described in paragraph (2) to the Secretary shall be subject to section 1001 of title 18, United States Code.
- (7) ASSESSMENT OF FOOD SAFETY PROGRAMS, SYSTEMS, AND STANDARDS.—If the Secretary determines that the food safety programs, systems, and standards in a foreign region, country, or territory are inadequate to ensure that an article of food is as safe as a similar article of food that is manufactured, processed, packed, or held in the United States in accordance with the requirements of this Act, the Secretary shall, to the extent practicable, identify such inadequacies and establish a process by which the foreign region, country, or territory may inform the Secretary of improvements made to such food safety program, system, or standard and demonstrate that those controls are adequate to ensure that an article of food is as safe as a similar article of food that is manufactured, processed, packed, or held in the United States in accordance with the requirements of this Act.
- (r)(1) The Secretary may require, pursuant to the regulations promulgated under paragraph (4)(A), as a condition of granting admission to a drug imported or offered for import into the United States, that the importer electronically submit information demonstrating that the drug complies with applicable requirements of this Act.
- (2) The information described under paragraph (1) may include—
- (A) information demonstrating the regulatory status of the drug, such as the new drug application, abbreviated new drug application, or investigational new drug or drug master file number;
- (B) facility information, such as proof of registration and the unique facility identifier;
- (C) indication of compliance with current good manufacturing practice, testing results, certifications relating to satisfactory inspections, and compliance with the country of export regulations; and
- (D) any other information deemed necessary and appropriate by the Secretary to assess compliance of the article being offered for import.

(3) Information requirements referred to in paragraph (2)(C) may, at the discretion of the Secretary, be satisfied—

(A) through representation by a foreign government, if an inspection is conducted by a foreign government using standards and practices as determined appropriate by the Secretary;

(B) through representation by a foreign government or an agency of a foreign government recognized under section 809; or

(C) other appropriate documentation or evidence as described by the Secretary.

(4)(A) Not later than 18 months after the date of enactment of the Food and Drug Administration Safety and Innovation Act, the Secretary shall adopt final regulations implementing this subsection. Such requirements shall be appropriate for the type of import, such as whether the drug is for import into the United States for use in preclinical research or in a clinical investigation under an investigational new drug exemption under 505(i).

(B) In promulgating the regulations under subparagraph (A), the Secretary—

(i) may, as appropriate, take into account differences among importers and types of imports, and, based on the level of risk posed by the imported drug, provide for expedited clearance for those importers that volunteer to participate in partnership programs for highly compliant companies and pass a review of internal controls, including sourcing of foreign manufacturing inputs, and plant inspections; and

(ii) shall—

(I) issue a notice of proposed rulemaking that includes the proposed regulation;

(II) provide a period of not less than 60 days for comments on the proposed regulation; and

(III) publish the final regulation not less than 30 days before the effective date of the regulation.

(C) Notwithstanding any other provision of law, the Secretary shall promulgate regulations implementing this subsection only as described in subparagraph (B).

(s) REGISTRATION OF COMMERCIAL IMPORTERS.—

(1) REGISTRATION.—The Secretary shall require a commercial importer of drugs—

(A) to be registered with the Secretary in a form and manner specified by the Secretary; and

(B) subject to paragraph (4), to submit, at the time of registration, a unique identifier for the principal place of business for which the importer is required to register under this subsection.

(2) REGULATIONS.—

(A) IN GENERAL.—The Secretary, in consultation with the Secretary of Homeland Security acting through U.S. Customs and Border Protection, shall promulgate regulations to establish good importer practices that specify the measures an importer shall take to ensure imported drugs are in compliance with the requirements of this Act and the Public Health Service Act.

(B) PROCEDURE.—In promulgating a regulation under subparagraph (A), the Secretary shall—

- (i) issue a notice of proposed rulemaking that includes the proposed regulation;
- (ii) provide a period of not less than 60 days for comments on the proposed regulation; and
- (iii) publish the final regulation not less than 30 days before the regulation's effective date.

(C) RESTRICTIONS.—Notwithstanding any other provision of Federal law, in implementing this subsection, the Secretary shall only promulgate regulations as described in subparagraph (B).

(D) EFFECTIVE DATE.—In establishing the effective date of the regulations under subparagraph (A), the Secretary shall, in consultation with the Secretary of Homeland Security acting through U.S. Customs and Border Protection, as determined appropriate by the Secretary of Health and Human Services, provide a reasonable period of time for an importer of a drug to comply with good importer practices, taking into account differences among importers and types of imports, including based on the level of risk posed by the imported product.

(3) DISCONTINUANCE OF REGISTRATION.—The Secretary shall discontinue the registration of any commercial importer of drugs that fails to comply with the regulations promulgated under this subsection.

(4) UNIQUE FACILITY IDENTIFIER.—The Secretary shall specify the unique facility identifier system that shall be used by registrants under paragraph (1). The requirement to include a unique facility identifier in a registration under paragraph (1) shall not apply until the date that the identifier system is specified by the Secretary under the preceding sentence.

(5) EXEMPTIONS.—The Secretary, by notice in the Federal Register, may establish exemptions from the requirements of this subsection.

* * * * *

SEC. 809. RECOGNITION OF FOREIGN GOVERNMENT INSPECTIONS.

(a) INSPECTION.—The Secretary—

(1) may enter into arrangements and agreements with a foreign government or an agency of a foreign government to recognize the inspection of foreign establishments registered under section 510(i) in order to facilitate risk-based inspections in accordance with the schedule established in section 510(h)(3) or 510(h)(2) (as applicable);

(2) may enter into arrangements and agreements with a foreign government or an agency of a foreign government under this section only with a foreign government or an agency of a foreign government that the Secretary has determined as having the capability of conducting inspections that meet the applicable requirements of this Act; and

(3) shall perform such reviews and audits of drug safety programs, systems, and standards of a foreign government or agency for the foreign government as the Secretary deems necessary to determine that the foreign government or agency of the foreign government is capable of conducting inspections that meet the applicable requirements of this Act.

(b) RESULTS OF INSPECTION.—The results of inspections performed by a foreign government or an agency of a foreign government under this section may be used as—

- (1) evidence of compliance with section 501(a)(2)(B) or section 801(r); and
- (2) for any other purposes as determined appropriate by the Secretary.

* * * * *

FOOD AND DRUG ADMINISTRATION SAFETY AND INNOVATION ACT

* * * * *

SEC. 2. TABLE OF CONTENTS; REFERENCES IN ACT.

(a) TABLE OF CONTENTS.—The table of contents of this Act is as follows:

* * * * *

TITLE IV—FEES RELATING TO BIOSIMILAR BIOLOGICAL PRODUCTS

* * * * *

【Sec. 404. Sunset dates.】

* * * * *

TITLE I—FEES RELATING TO DRUGS

* * * * *

SEC. 105. SUNSET DATES.

【(a) AUTHORIZATION.—Sections 735 and 736 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 379g; 379h) shall cease to be effective October 1, 2017.

【(b) REPORTING REQUIREMENTS.—Section 736B of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 379h-2) shall cease to be effective January 31, 2018.】

(c) PREVIOUS SUNSET PROVISION.—

(1) IN GENERAL.—Section 106 of the Food and Drug Administration Amendments Act of 2007 (Public Law 110-85) is repealed.

(2) CONFORMING AMENDMENT.—The Food and Drug Administration Amendments Act of 2007 (Public Law 110-85) is amended in the table of contents in section 2, by striking the item relating to section 106.

(d) TECHNICAL CLARIFICATIONS.—

(1) Effective September 30, 2007—

(A) section 509 of the Prescription Drug User Fee Amendments Act of 2002 (Title V of Public Law 107-188) is repealed; and

(B) the Public Health Security and Bioterrorism Preparedness and Response Act of 2002 (Public Law 107-188) is amended in the table of contents in section 1(b), by striking the item relating to section 509.

(2) Effective September 30, 2002—

- (A) section 107 of the Food and Drug Administration Modernization Act of 1997 (Public Law 105-115) is repealed; and
- (B) the table of contents in section 1(c) of such Act is amended by striking the item related to section 107.
- (3) Effective September 30, 1997, section 105 of the Prescription Drug User Fee Act of 1992 (Public Law 102-571) is repealed.

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TITLE III—FEES RELATING TO GENERIC DRUGS

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SEC. 304. SUNSET DATES.

[(a) AUTHORIZATION.—Sections 744A and 744B of the Federal Food, Drug, and Cosmetic Act, as added by section 302 of this Act, shall cease to be effective October 1, 2017.

[(b) REPORTING REQUIREMENTS.—Section 744C of the Federal Food, Drug, and Cosmetic Act, as added by section 303 of this Act, shall cease to be effective January 31, 2018.]

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TITLE IV—FEES RELATING TO BIOSIMILAR BIOLOGICAL PRODUCTS

* * * * *

[SEC. 404. SUNSET DATES.

[(a) AUTHORIZATION.—Sections 744G and 744H of the Federal Food, Drug, and Cosmetic Act, as added by section 402 of this Act, shall cease to be effective October 1, 2017.

[(b) REPORTING REQUIREMENTS.—Section 744I of the Federal Food, Drug, and Cosmetic Act, as added by section 403 of this Act, shall cease to be effective January 31, 2018.]

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MEDICAL DEVICE USER FEE AMENDMENTS OF 2012

* * * * *

TITLE II—FEES RELATING TO DEVICES

* * * * *

SEC. 207. SUNSET CLAUSE.

[(a) IN GENERAL.—Sections 737 and 738 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 739i; 739j) shall cease to be effective October 1, 2017. Section 738A (21 U.S.C. 739j-1) of the Federal Food, Drug, and Cosmetic Act (regarding reauthorization and

reporting requirements) shall cease to be effective January 31, 2018.】

(b) PREVIOUS SUNSET PROVISION.—

(1) IN GENERAL.—Section 217 of the Food and Drug Administration Amendments Act of 2007 (Title II of Public Law 110-85) is repealed.

(2) CONFORMING AMENDMENT.—The Food and Drug Administration Amendments Act of 2007 (Public Law 110-85) is amended in the table of contents in section 2, by striking the item relating to section 217.

(c) TECHNICAL CLARIFICATION.—Effective September 30, 2007—

(1) section 107 of the Medical Device User Fee and Modernization Act of 2002 (Public Law 107-250) is repealed; and

(2) the table of contents in section 1(b) of such Act is amended by striking the item related to section 107.

* * * * *

ORPHAN DRUG ACT

GRANTS AND CONTRACTS FOR DEVELOPMENT OF DRUGS FOR RARE DISEASES AND CONDITIONS

SEC. 5. (a) The Secretary may make grants to and enter into contracts with public and private entities and individuals to assist in (1) defraying the costs of developing drugs for rare diseases or conditions, including qualified testing expenses, (2) defraying the costs of developing medical devices for rare diseases or conditions, and (3) defraying the costs of developing medical foods for rare diseases or conditions.

(b) For purposes of subsection (a):

(1) The term “qualified testing” means—

(A) human clinical testing—

(i) which is carried out under an exemption for a drug for a rare disease or condition under section 505(i) of the Federal Food, Drug, and Cosmetic Act (or regulations issued under such section); and

(ii) which occurs before the date on which an application with respect to such drug is submitted under section 505(b) of such Act or under section 351 of the Public Health Service Act;

(B) preclinical testing involving a drug for a rare disease or condition which occurs after the date such drug is designated under section 526 of such Act and before the date on which an application with respect to such drug is submitted under section 505(b) of such Act or under section 351 of the Public Health Service Act; and

(C) prospectively planned and designed observational studies and other analyses conducted to assist in the understanding of the natural history of a rare disease or condition and in the development of a therapy, including studies and analyses to—

(i) develop or validate a drug development tool related to a rare disease or condition; or

(ii) understand the full spectrum of the disease manifestations, including describing genotypic and phenotypic variability and identifying and defining distinct subpopulations affected by a rare disease or condition.

(2) The term “rare disease or condition” means (1) in the case of a drug, any disease or condition which (A) affects less than 200,000 persons in the United States, or (B) affects more than 200,000 in the United States and for which there is no reasonable expectation that the cost of developing and making available in the United States a drug for such disease or condition will be recovered from sales in the United States of such drugs, (2) in the case of a medical device, any disease or condition that occurs so infrequently in the United States that there is no reasonable expectation that a medical device for such disease or condition will be developed without assistance under subsection (a), and (3) in the case of a medical food, any disease or condition that occurs so infrequently in the United States that there is no reasonable expectation that a medical food for such disease or condition will be developed without assistance under subsection (a). Determinations under the preceding sentence with respect to any drug shall be made on the basis of the facts and circumstances as of the date the request for designation of the drug under section 526 of the Federal Food, Drug, and Cosmetic Act is made.

(3) The term “medical food” means a food which is formulated to be consumed or administered enterally under the supervision of a physician and which is intended for the specific dietary management of a disease or condition for which distinctive nutritional requirements, based on recognized scientific principles, are established by medical evaluation.

(c) AUTHORIZATION OF APPROPRIATIONS.—For grants and contracts under subsection (a), there is authorized to be appropriated \$30,000,000 for each of fiscal years [2013 through 2017] 2018 through 2022.

PUBLIC HEALTH SERVICE ACT

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TITLE IV—NATIONAL RESEARCH INSTITUTES

* * * * *

PART B—GENERAL PROVISIONS RESPECTING NATIONAL RESEARCH INSTITUTES

* * * * *

SEC. 409I. PROGRAM FOR PEDIATRIC STUDIES OF DRUGS.

(a) LIST OF PRIORITY ISSUES IN PEDIATRIC THERAPEUTICS.—

(1) IN GENERAL.—Not later than one year after the date of the enactment of the Best Pharmaceuticals for Children Act of 2007, the Secretary, acting through the Director of the National Institutes of Health and in consultation with the Commissioner of Food and Drugs and experts in pediatric research, shall develop and publish a priority list of needs in pediatric

therapeutics, including drugs, biological products, or indications that require study. The list shall be revised every three years.

(2) CONSIDERATION OF AVAILABLE INFORMATION.—In developing and prioritizing the list under paragraph (1), the Secretary—

(A) shall consider—

(i) therapeutic gaps in pediatrics that may include developmental pharmacology, pharmacogenetic determinants of drug response, metabolism of drugs and biologics in children, and pediatric clinical trials;

(ii) particular pediatric diseases, disorders or conditions where more complete knowledge and testing of therapeutics, including drugs and biologics, may be beneficial in pediatric populations; and

(iii) the adequacy of necessary infrastructure to conduct pediatric pharmacological research, including research networks and trained pediatric investigators; and

(B) may consider the availability of qualified countermeasures (as defined in section 319F-1), security countermeasures (as defined in section 319F-2), and qualified pandemic or epidemic products (as defined in section 319F-3) to address the needs of pediatric populations, in consultation with the Assistant Secretary for Preparedness and Response, consistent with the purposes of this section.

(b) PEDIATRIC STUDIES AND RESEARCH.—The Secretary, acting through the National Institutes of Health, shall award funds to entities that have the expertise to conduct pediatric clinical trials or other research (including qualified universities, hospitals, laboratories, contract research organizations, practice groups, federally funded programs such as pediatric pharmacology research units, other public or private institutions, or individuals) to enable the entities to conduct the drug studies or other research on the issues described in paragraphs (1) and (2)(A) of subsection (a). The Secretary may use contracts, grants, or other appropriate funding mechanisms to award funds under this subsection.

(c) PROCESS FOR PROPOSED PEDIATRIC STUDY REQUESTS AND LABELING CHANGES.—

(1) SUBMISSION OF PROPOSED PEDIATRIC STUDY REQUEST.—The Director of the National Institutes of Health shall, as appropriate, submit proposed pediatric study requests for consideration by the Commissioner of Food and Drugs for pediatric studies of a specific pediatric indication identified under subsection (a). Such a proposed pediatric study request shall be made in a manner equivalent to a written request made under subsection (b) or (c) of section 505A of the Federal Food, Drug, and Cosmetic Act, or section 351(m) of this Act, including with respect to the information provided on the pediatric studies to be conducted pursuant to the request. The Director of the National Institutes of Health may submit a proposed pediatric study request for a drug for which—

(A)(i) there is an approved application under section 505(j) of the Federal Food, Drug, and Cosmetic Act or section 351(k) of this Act; or

(ii) there is a submitted application that could be approved under the criteria of such section; and

(B) there remains no patent listed pursuant to section 505(b)(1) of the Federal Food, Drug, and Cosmetic Act, and every three-year and five-year period referred to in subsection (c)(3)(E)(ii), (c)(3)(E)(iii), (c)(3)(E)(iv), (j)(5)(F)(ii), (j)(5)(F)(iii), or (j)(5)(F)(iv) of section 505 of the Federal Food, Drug, and Cosmetic Act, or applicable twelve-year period referred to in section 351(k)(7) of this Act, and any seven-year period referred to in section 527 of the Federal Food, Drug, and Cosmetic Act has ended for at least one form of the drug; and

(C) additional studies are needed to assess the safety and effectiveness of the use of the drug in the pediatric population.

(2) WRITTEN REQUEST TO HOLDERS OF APPROVED APPLICATIONS.—The Commissioner of Food and Drugs, in consultation with the Director of the National Institutes of Health, may issue a written request based on the proposed pediatric study request for the indication or indications submitted pursuant to paragraph (1) (which shall include a timeframe for negotiations for an agreement) for pediatric studies concerning a drug identified under subsection (a) to all holders of an approved application for the drug. Such a written request shall be made in a manner equivalent to the manner in which a written request is made under subsection (b) or (c) of section 505A of the Federal Food, Drug, and Cosmetic Act or section 351(m) of this Act, including with respect to information provided on the pediatric studies to be conducted pursuant to the request and using appropriate formulations for each age group for which the study is requested.

(3) REQUESTS FOR PROPOSALS.—If the Commissioner of Food and Drugs does not receive a response to a written request issued under paragraph (2) not later than 30 days after the date on which a request was issued, the Secretary, acting through the Director of the National Institutes of Health and in consultation with the Commissioner of Food and Drugs, shall publish a request for proposals to conduct the pediatric studies described in the written request in accordance with subsection (b).

(4) DISQUALIFICATION.—A holder that receives a first right of refusal shall not be entitled to respond to a request for proposals under paragraph (3).

(5) CONTRACTS, GRANTS, OR OTHER FUNDING MECHANISMS.—A contract, grant, or other funding may be awarded under this section only if a proposal is submitted to the Secretary in such form and manner, and containing such agreements, assurances, and information as the Secretary determines to be necessary to carry out this section.

(6) REPORTING OF STUDIES.—

(A) IN GENERAL.—On completion of a pediatric study in accordance with an award under this section, a report concerning the study shall be submitted to the Director of the National Institutes of Health and the Commissioner of Food and Drugs. The report shall include all data gen-

erated in connection with the study, including a written request if issued.

(B) AVAILABILITY OF REPORTS.—Each report submitted under subparagraph (A) shall be considered to be in the public domain (subject to section 505A(d)(4) of the Federal Food, Drug, and Cosmetic Act) and shall be assigned a docket number by the Commissioner of Food and Drugs. An interested person may submit written comments concerning such pediatric studies to the Commissioner of Food and Drugs, and the written comments shall become part of the docket file with respect to each of the drugs.

(C) ACTION BY COMMISSIONER.—The Commissioner of Food and Drugs shall take appropriate action in response to the reports submitted under subparagraph (A) in accordance with paragraph (7).

(7) REQUESTS FOR LABELING CHANGE.—During the 180-day period after the date on which a report is submitted under paragraph (6)(A), the Commissioner of Food and Drugs shall—

(A) review the report and such other data as are available concerning the safe and effective use in the pediatric population of the drug studied;

(B) negotiate with the holders of approved applications for the drug studied for any labeling changes that the Commissioner of Food and Drugs determines to be appropriate and requests the holders to make; and

(C)(i) place in the public docket file a copy of the report and of any requested labeling changes; and

(ii) publish in the Federal Register and through a posting on the Web site of the Food and Drug Administration a summary of the report and a copy of any requested labeling changes.

(8) DISPUTE RESOLUTION.—

(A) REFERRAL TO PEDIATRIC ADVISORY COMMITTEE.—If, not later than the end of the 180-day period specified in paragraph (7), the holder of an approved application for the drug involved does not agree to any labeling change requested by the Commissioner of Food and Drugs under that paragraph, the Commissioner of Food and Drugs shall refer the request to the Pediatric Advisory Committee.

(B) ACTION BY THE PEDIATRIC ADVISORY COMMITTEE.—Not later than 90 days after receiving a referral under subparagraph (A), the Pediatric Advisory Committee shall—

(i) review the available information on the safe and effective use of the drug in the pediatric population, including study reports submitted under this section; and

(ii) make a recommendation to the Commissioner of Food and Drugs as to appropriate labeling changes, if any.

(9) FDA DETERMINATION.—Not later than 30 days after receiving a recommendation from the Pediatric Advisory Committee under paragraph (8)(B)(ii) with respect to a drug, the Commissioner of Food and Drugs shall consider the recommendation and, if appropriate, make a request to the hold-

ers of approved applications for the drug to make any labeling change that the Commissioner of Food and Drugs determines to be appropriate.

(10) FAILURE TO AGREE.—If a holder of an approved application for a drug, within 30 days after receiving a request to make a labeling change under paragraph (9), does not agree to make a requested labeling change, the Commissioner of Food and Drugs may deem the drug to be misbranded under the Federal Food, Drug, and Cosmetic Act.

(11) NO EFFECT ON AUTHORITY.—Nothing in this subsection limits the authority of the United States to bring an enforcement action under the Federal Food, Drug, and Cosmetic Act when a drug lacks appropriate pediatric labeling. Neither course of action (the Pediatric Advisory Committee process or an enforcement action referred to in the preceding sentence) shall preclude, delay, or serve as the basis to stay the other course of action.

(d) DISSEMINATION OF PEDIATRIC INFORMATION.—Not later than one year after the date of the enactment of the Best Pharmaceuticals for Children Act of 2007, the Secretary, acting through the Director of the National Institutes of Health, shall study the feasibility of establishing a compilation of information on pediatric drug use and report the findings to Congress.

(e) AUTHORIZATION OF APPROPRIATIONS.—

(1) IN GENERAL.—There are authorized to be appropriated to carry out this section, \$25,000,000 for each of fiscal years **[2013 through 2017]** *2018 through 2022*.

(2) AVAILABILITY.—Any amount appropriated under paragraph (1) shall remain available to carry out this section until expended.

* * * * *

SECTION 305 OF THE PEDIATRIC MEDICAL DEVICE SAFETY AND IMPROVEMENT ACT OF 2007

SEC. 305. DEMONSTRATION GRANTS FOR IMPROVING PEDIATRIC DEVICE AVAILABILITY.

(a) IN GENERAL.—

(1) REQUEST FOR PROPOSALS.—Not later than 90 days after the date of the enactment of this Act, the Secretary of Health and Human Services shall issue a request for proposals for 1 or more grants or contracts to nonprofit consortia for demonstration projects to promote pediatric device development.

(2) DETERMINATION ON GRANTS OR CONTRACTS.—Not later than 180 days after the date the Secretary of Health and Human Services issues a request for proposals under paragraph (1), the Secretary shall make a determination on the grants or contracts under this section.

(b) APPLICATION.—A nonprofit consortium that desires to receive a grant or contract under this section shall submit an application to the Secretary of Health and Human Services at such time, in such manner, and containing such information as the Secretary may require.

(c) USE OF FUNDS.—A nonprofit consortium that receives a grant or contract under this section shall facilitate the development, production, and distribution of pediatric medical devices by—

- (1) encouraging innovation and connecting qualified individuals with pediatric device ideas with potential manufacturers;
- (2) mentoring and managing pediatric device projects through the development process, including product identification, prototype design, device development, and marketing;
- (3) connecting innovators and physicians to existing Federal and non-Federal resources, including resources from the Food and Drug Administration, the National Institutes of Health, the Small Business Administration, the Department of Energy, the Department of Education, the National Science Foundation, the Department of Veterans Affairs, the Agency for Healthcare Research and Quality, and the National Institute of Standards and Technology;
- (4) assessing the scientific and medical merit of proposed pediatric device projects; and
- (5) providing assistance and advice as needed on business development, personnel training, prototype development, postmarket needs, and other activities consistent with the purposes of this section.

(d) COORDINATION.—

(1) NATIONAL INSTITUTES OF HEALTH.—Each consortium that receives a grant or contract under this section shall—

(A) coordinate with the National Institutes of Health’s pediatric device contact point or office, designated under section 402(b)(23) of the Public Health Service Act, as added by section 304(a) of this Act; and

(B) provide to the National Institutes of Health any identified pediatric device needs that the consortium lacks sufficient capacity to address or those needs in which the consortium has been unable to stimulate manufacturer interest.

(2) FOOD AND DRUG ADMINISTRATION.—Each consortium that receives a grant or contract under this section shall coordinate with the Commissioner of Food and Drugs and device companies to facilitate the application for approval or clearance of devices labeled for pediatric use.

(3) EFFECTIVENESS AND OUTCOMES.—Each consortium that receives a grant or contract under this section shall annually report to the Secretary of Health and Human Services on the status of pediatric device development, production, and distribution that has been facilitated by the consortium.

(e) AUTHORIZATION OF APPROPRIATIONS.—There are authorized to be appropriated to carry out this section \$5,250,000 for each of fiscal years [2013 through 2017] *2018 through 2022*.

21ST CENTURY CURES ACT

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TITLE III—DEVELOPMENT

* * * * *

Subtitle F—Medical Device Innovations

SEC. 3051. BREAKTHROUGH DEVICES.

(a) IN GENERAL.—Chapter V of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 351 et seq.) is amended [by inserting after section 515B] *by inserting after section 515A*, as added by section 3034(b), the following:

“SEC. 515C. BREAKTHROUGH DEVICES

“(a) PURPOSE.—The purpose of this section is to encourage the Secretary, and provide the Secretary with sufficient authority, to apply efficient and flexible approaches to expedite the development of, and prioritize the Food and Drug Administration’s review of, devices that represent breakthrough technologies.

“(b) ESTABLISHMENT OF PROGRAM.—The Secretary shall establish a program to expedite the development of, and provide for the priority review for, devices, as determined by the Secretary—

“(1) that provide for more effective treatment or diagnosis of life-threatening or irreversibly debilitating human disease or conditions; and

“(2)(A) that represent breakthrough technologies;

“(B) for which no approved or cleared alternatives exist;

“(C) that offer significant advantages over existing approved or cleared alternatives, including the potential, compared to existing approved alternatives, to reduce or eliminate the need for hospitalization, improve patient quality of life, facilitate patients’ ability to manage their own care (such as through self-directed personal assistance), or establish long-term clinical efficiencies; or

“(D) the availability of which is in the best interest of patients.

“(c) REQUEST FOR DESIGNATION.—A sponsor of a device may request that the Secretary designate such device for expedited development and priority review under this section. Any such request for designation may be made at any time prior to the submission of an application under section 515(c), a notification under section 510(k), or a petition for classification under section 513(f)(2).

“(d) DESIGNATION PROCESS.—

“(1) IN GENERAL.—Not later than 60 calendar days after the receipt of a request under subsection (c), the Secretary shall determine whether the device that is the subject of the request meets the criteria described in subsection (b). If the Secretary determines that the device meets the criteria, the Secretary shall designate the device for expedited development and priority review.

“(2) REVIEW.—Review of a request under subsection (c) shall be undertaken by a team that is composed of experienced staff and senior managers of the Food and Drug Administration.

“(3) WITHDRAWAL.—The Secretary may not withdraw a designation granted under this section on the basis of the criteria

under subsection (b) no longer applying because of the subsequent clearance or approval of another device that—

“(A) was designated under this section; or

“(B) was given priority review under section 515(d)(5), as in effect prior to the date of enactment of the 21st Century Cures Act.

“(e) EXPEDITED DEVELOPMENT AND PRIORITY REVIEW.—

“(1) ACTIONS.—For purposes of expediting the development and review of devices designated under subsection (d) the Secretary shall—

“(A) assign a team of staff, including a team leader with appropriate subject matter expertise and experience, for each device for which a request is submitted under subsection (c);

“(B) provide for oversight of the team by senior agency personnel to facilitate the efficient development of the device and the efficient review of any submission described in subsection (c) for the device;

“(C) adopt an efficient process for timely dispute resolution;

“(D) provide for interactive and timely communication with the sponsor of the device during the development program and review process;

“(E) expedite the Secretary’s review of manufacturing and quality systems compliance, as applicable;

“(F) disclose to the sponsor, not less than 5 business days in advance, the topics of any consultation the Secretary intends to undertake with external experts or an advisory committee concerning the sponsor’s device and provide the sponsor the opportunity to recommend such external experts;

“(G) provide for advisory committee input, as the Secretary determines appropriate (including in response to the request of the sponsor) for applications submitted under section 515(c); and

“(H) assign staff to be available within a reasonable time to address questions by institutional review committees concerning the conditions and clinical testing requirements applicable to the investigational use of the device pursuant to an exemption under section 520(g).

“(2) ADDITIONAL ACTIONS.—In addition to the actions described in paragraph (1), for purposes of expediting the development and review of devices designated under subsection (d), the Secretary, in collaboration with the device sponsor, may, as appropriate—

“(A) coordinate with the sponsor regarding early agreement on a data development plan;

“(B) take steps to ensure that the design of clinical trials is as efficient and flexible as practicable, when scientifically appropriate;

“(C) facilitate, when scientifically appropriate, expedited and efficient development and review of the device through utilization of timely postmarket data collection with regard to application for approval under section 515(c); and

“(D) agree in writing to clinical protocols that the Secretary will consider binding on the Secretary and the sponsor, subject to—

“(i) changes to such protocols agreed to in writing by the sponsor and the Secretary; or

“(ii) a decision, made by the director of the office responsible for reviewing the device submission, that a substantial scientific issue essential to determining the safety or effectiveness of such device exists, provided that such decision is in writing, and is made only after the Secretary provides to the device sponsor or applicant an opportunity for a meeting at which the director and the sponsor or applicant are present and at which the director documents the substantial scientific issue.

“(f) PRIORITY REVIEW GUIDANCE.—

“(1) CONTENT.—Not later than 1 year after the date of enactment of the 21st Century Cures Act, the Secretary shall issue guidance on the implementation of this section. Such guidance shall—

“(A) set forth the process by which a person may seek a designation under subsection (d);

“(B) provide a template for requests under subsection (c);

“(C) identify the criteria the Secretary will use in evaluating a request for designation under this section; and

“(D) identify the criteria and processes the Secretary will use to assign a team of staff, including team leaders, to review devices designated for expedited development and priority review, including any training required for such personnel to ensure effective and efficient review.

“(2) PROCESS.—Prior to finalizing the guidance under paragraph (1), the Secretary shall seek public comment on a proposed guidance.

“(g) RULE OF CONSTRUCTION.—Nothing in this section shall be construed to affect—

“(1) the criteria and standards for evaluating an application pursuant to section 515(c), a report and request for classification under section 513(f)(2), or a report under section 510(k), including the recognition of valid scientific evidence as described in section 513(a)(3)(B) and consideration and application of the least burdensome means of evaluating device effectiveness or demonstrating substantial equivalence between devices with differing technological characteristics, as applicable;

“(2) the authority of the Secretary with respect to clinical holds under section 520(g)(8)(A);

“(3) the authority of the Secretary to act on an application pursuant to section 515(d) before completion of an establishment inspection, as the Secretary determines appropriate; or

“(4) the authority of the Secretary with respect to postmarket surveillance under sections 519(h) and 522.”.

(b) DOCUMENTATION AND REVIEW OF SIGNIFICANT DECISIONS.—Section 517A(a)(1) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360g-1(a)(1)) is amended by inserting “a request for designation under section 515C,” after “application under section 515,”.

(c) TERMINATION OF PREVIOUS PROGRAM.—

(1) IN GENERAL.—Section 515(d) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360e(d)) is amended—

(A) by striking paragraph (5); and

(B) by redesignating paragraph (6) as paragraph (5).

(2) CONFORMING AMENDMENT.—Section 737(5) of the Federal Food, Drug, and Cosmetics Act (21 U.S.C. 379i(5)) is amended by striking “515(d)(6)” and inserting “515(d)(5)”.

(d) REPORT.—On January 1, 2019, the Secretary of Health and Human Services shall issue a report to the Committee on Health, Education, Labor, and Pensions of the Senate and the Committee on Energy and Commerce of the House of Representatives—

(1) on the program under section 515C of the Federal Food, Drug, and Cosmetic Act, as added by subsection (a), in bringing safe and effective devices included in such program to patients as soon as possible; and

(2) that includes recommendations, if any, to strengthen the program to better meet patient device needs in a manner as timely as possible.

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Subtitle G—Improving Scientific Expertise and Outreach at FDA

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SEC. 3075. DRUG SURVEILLANCE.

(a) NEW DRUGS.—Section 505(k)(5) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(k)(5)), [as amended by section 2074] as amended by section 3102, is further amended—

(1) in subparagraph (A), by striking “, bi-weekly screening” and inserting “screenings”;

(2) in subparagraph (B), as redesignated by [section 2074(1)(C)] section 3102(1)(C), by striking the period at the end and inserting “; and”; and

(3) by adding at the end the following:

“(C) make available on the Internet website of the Food and Drug Administration—

“(i) guidelines, developed with input from experts qualified by scientific training and experience to evaluate the safety and effectiveness of drugs, that detail best practices for drug safety surveillance using the Adverse Event Reporting System; and

“(ii) criteria for public posting of adverse event signals.”.

(b) FAERS REVISION.—Section 505(r)(2)(D) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(r)(2)(D)) is amended by striking “, by 18 months” and all that follows through the semicolon at the end of the subparagraph and inserting “and making publicly available on the Internet website established under paragraph (1) best practices for drug safety surveillance activities for drugs approved under this section or section 351 of the Public Health Service Act;”.

(c) RISK EVALUATION AND MITIGATION STRATEGIES.—Section 505-1(f)(5) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355-1(f)(5)) is amended—

- (1) in the matter preceding subparagraph (A), by inserting “or other advisory committee” after “(or successor committee)”; and
- (2) in subparagraph (B), by striking “at least annually,” and inserting “periodically”.

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