

115TH CONGRESS
1ST SESSION

H. R. 2430

AN ACT

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.

1 *Be it enacted by the Senate and House of Representa-*
2 *tives of the United States of America in Congress assembled,*

1 **SECTION 1. SHORT TITLE.**

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

4 **SEC. 2. TABLE OF CONTENTS.**

5 The table of contents for this Act is as follows:

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1 **TITLE I—FEES RELATING TO**
2 **DRUGS**

3 **SEC. 101. SHORT TITLE; FINDING.**

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

6 (b) **FINDING.**—The Congress finds that the fees au-
7 thorized by the amendments made in this title will be dedi-
8 cated toward expediting the drug development process and
9 the process for the review of human drug applications, in-
10 cluding postmarket drug safety activities, as set forth in
11 the goals identified for purposes of part 2 of subchapter
12 C of chapter VII of the Federal Food, Drug, and Cosmetic
13 Act, in the letters from the Secretary of Health and
14 Human Services to the Chairman of the Committee on
15 Health, Education, Labor, and Pensions of the Senate and
16 the Chairman of the Committee on Energy and Commerce
17 of the House of Representatives, as set forth in the Con-
18 gressional Record.

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

20 (a) **TYPES OF FEES.**—

21 (1) **IN GENERAL.**—Section 736(a) of the Fed-
22 eral Food, Drug, and Cosmetic Act (21 U.S.C.
23 379h(a)) is amended—

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

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

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

9 (D) in paragraph (1)(A)—

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

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

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

23 (F) in paragraph (1)(F)—

24 (i) in the heading, by striking “OR IN-
25 DICATION”; and

1 (ii) by striking the second sentence;

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

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

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

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

23 (K) in subparagraph (B) of such para-
24 graph (2)—

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

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

10 (L) by adding at the end of such para-
11 graph (2) the following:

12 “(C) LIMITATION.—A person who is
13 named as the applicant in an approved human
14 drug application shall not be assessed more
15 than 5 prescription drug program fees for a fis-
16 cal year for prescription drug products identi-
17 fied in such approved human drug applica-
18 tion.”.

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

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

1 (b) FEE REVENUE AMOUNTS.—Subsection (b) of sec-
2 tion 736 of the Federal Food, Drug, and Cosmetic Act
3 (21 U.S.C. 379h) is amended to read as follows:

4 “(b) FEE REVENUE AMOUNTS.—

5 “(1) IN GENERAL.—For each of the fiscal years
6 2018 through 2022, fees under subsection (a) shall,
7 except as provided in subsections (c), (d), (f), and
8 (g), be established to generate a total revenue
9 amount under such subsection that is equal to the
10 sum of—

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

13 “(B) the dollar amount equal to the infla-
14 tion adjustment for the fiscal year (as deter-
15 mined under subsection (c)(1));

16 “(C) the dollar amount equal to the capac-
17 ity planning adjustment for the fiscal year (as
18 determined under subsection (c)(2));

19 “(D) the dollar amount equal to the oper-
20 ating reserve adjustment for the fiscal year, if
21 applicable (as determined under subsection
22 (c)(3));

23 “(E) the dollar amount equal to the addi-
24 tional direct cost adjustment for the fiscal year
25 (as determined under subsection (c)(4)); and

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

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

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

5 “(iii) \$16,953,329 for fiscal year
6 2020.

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

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

9 “(2) TYPES OF FEES.—Of the total revenue
10 amount determined for a fiscal year under para-
11 graph (1)—

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

15 “(B) 80 percent shall be derived from pre-
16 scription drug program fees under subsection
17 (a)(2).

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

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

23 “(B) for fiscal years 2019 through 2022,
24 the dollar amount of the total revenue amount
25 established under paragraph (1) for the pre-

1 vious fiscal year, not including any adjustments
2 made under subsection (c)(3) or (c)(4).”.

3 (c) ADJUSTMENTS; ANNUAL FEE SETTING.—Sub-
4 section (c) of section 736 of the Federal Food, Drug, and
5 Cosmetic Act (21 U.S.C. 379h) is amended to read as fol-
6 lows:

7 “(c) ADJUSTMENTS; ANNUAL FEE SETTING.—

8 “(1) INFLATION ADJUSTMENT.—

9 “(A) IN GENERAL.—For purposes of sub-
10 section (b)(1)(B), the dollar amount of the in-
11 flation adjustment to the annual base revenue
12 for each fiscal year shall be equal to the prod-
13 uct of—

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

16 “(ii) the inflation adjustment percent-
17 age under subparagraph (B).

18 “(B) INFLATION ADJUSTMENT PERCENT-
19 AGE.—The inflation adjustment percentage
20 under this subparagraph for a fiscal year is
21 equal to the sum of—

22 “(i) the average annual percent
23 change in the cost, per full-time equivalent
24 position of the Food and Drug Administra-
25 tion, of all personnel compensation and

1 benefits paid with respect to such positions
2 for the first 3 years of the preceding 4 fis-
3 cal years, multiplied by the proportion of
4 personnel compensation and benefits costs
5 to total costs of the process for the review
6 of human drug applications (as defined in
7 section 735(6)) for the first 3 years of the
8 preceding 4 fiscal years; and

9 “(ii) the average annual percent
10 change that occurred in the Consumer
11 Price Index for urban consumers (Wash-
12 ington-Baltimore, DC–MD–VA–WV; Not
13 Seasonally Adjusted; All items; Annual
14 Index) for the first 3 years of the pre-
15 ceding 4 years of available data multiplied
16 by the proportion of all costs other than
17 personnel compensation and benefits costs
18 to total costs of the process for the review
19 of human drug applications (as defined in
20 section 735(6)) for the first 3 years of the
21 preceding 4 fiscal years.

22 “(2) CAPACITY PLANNING ADJUSTMENT.—

23 “(A) IN GENERAL.—For each fiscal year,
24 after the annual base revenue established in
25 subsection (b)(1)(A) is adjusted for inflation in

1 accordance with paragraph (1), such revenue
2 shall be adjusted further for such fiscal year, in
3 accordance with this paragraph, to reflect
4 changes in the resource capacity needs of the
5 Secretary for the process for the review of
6 human drug applications.

7 “(B) INTERIM METHODOLOGY.—

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

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

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

18 “(ii) ADJUSTMENT PERCENTAGE.—

19 The adjustment percentage under this
20 clause for a fiscal year is the weighted
21 change in the 3-year average ending in the
22 most recent year for which data are avail-
23 able, over the 3-year average ending in the
24 previous year, for—

1 “(I) the total number of human
2 drug applications, efficacy supple-
3 ments, and manufacturing supple-
4 ments submitted to the Secretary;

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

8 “(III) the total number of formal
9 meetings scheduled by the Secretary,
10 and written responses issued by the
11 Secretary in lieu of such formal meet-
12 ings, as identified in section I.H of
13 the letters described in section 101(b)
14 of the Prescription Drug User Fee
15 Amendments of 2017.

16 “(C) CAPACITY PLANNING METHODOLOGY.—
17

18 “(i) DEVELOPMENT; EVALUATION
19 AND REPORT.—The Secretary shall obtain,
20 through a contract with an independent ac-
21 counting or consulting firm, a report evalu-
22 ating options and recommendations for a
23 new methodology to accurately assess
24 changes in the resource and capacity needs
25 of the process for the review of human

1 drug applications. The capacity planning
2 methodological options and recommenda-
3 tions presented in such report shall utilize
4 and be informed by personnel time report-
5 ing data as an input. The report shall be
6 published for public comment no later than
7 the end of fiscal year 2020.

8 “(ii) ESTABLISHMENT AND IMPLE-
9 MENTATION.—After review of the report
10 described in clause (i) and any public com-
11 ments thereon, the Secretary shall estab-
12 lish a capacity planning methodology for
13 purposes of this paragraph, which shall—

14 “(I) replace the interim method-
15 ology under subparagraph (B);

16 “(II) incorporate such ap-
17 proaches and attributes as the Sec-
18 retary determines appropriate; and

19 “(III) be effective beginning with
20 the first fiscal year for which fees are
21 set after such capacity planning meth-
22 odology is established.

23 “(D) LIMITATION.—Under no cir-
24 cumstances shall an adjustment under this
25 paragraph result in fee revenue for a fiscal year

1 that is less than the sum of the amounts under
2 subsections (b)(1)(A) (the annual base revenue
3 for the fiscal year) and (b)(1)(B) (the dollar
4 amount of the inflation adjustment for the fis-
5 cal year).

6 “(E) PUBLICATION IN FEDERAL REG-
7 ISTER.—The Secretary shall publish in the Fed-
8 eral Register notice under paragraph (5) of the
9 fee revenue and fees resulting from the adjust-
10 ment and the methodologies under this para-
11 graph.

12 “(3) OPERATING RESERVE ADJUSTMENT.—

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

21 “(B) DECREASE.—If the Secretary has
22 carryover balances for such process in excess of
23 14 weeks of such operating reserves, the Sec-
24 retary shall decrease such fee revenue and fees

1 to provide for not more than 14 weeks of such
2 operating reserves.

3 “(C) NOTICE OF RATIONALE.—If an ad-
4 justment under subparagraph (A) or (B) is
5 made, the rationale for the amount of the in-
6 crease or decrease (as applicable) in fee revenue
7 and fees shall be contained in the annual Fed-
8 eral Register notice under paragraph (5) estab-
9 lishing fee revenue and fees for the fiscal year
10 involved.

11 “(4) ADDITIONAL DIRECT COST ADJUST-
12 MENT.—

13 “(A) IN GENERAL.—The Secretary shall,
14 in addition to adjustments under paragraphs
15 (1), (2), and (3), further increase the fee rev-
16 enue and fees—

17 “(i) for fiscal year 2018, by
18 \$8,730,000; and

19 “(ii) for fiscal year 2019 and subse-
20 quent fiscal years, by the amount deter-
21 mined under subparagraph (B).

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

24 “(i) \$8,730,000, multiplied by

1 “(ii) the Consumer Price Index for
2 urban consumers (Washington-Baltimore,
3 DC–MD–VA–WV; Not Seasonally Ad-
4 justed; All Items; Annual Index) for the
5 most recent year of available data, divided
6 by such Index for 2016.

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

10 “(A) establish, for each such fiscal year,
11 human drug application fees and prescription
12 drug program fees under subsection (a), based
13 on the revenue amounts established under sub-
14 section (b) and the adjustments provided under
15 this subsection; and

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

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

23 (d) FEE WAIVER OR REDUCTION.—Section 736(d) of
24 the Federal Food, Drug, and Cosmetic Act (21 U.S.C.
25 379h(d)) is amended—

1 (1) in paragraph (1)—

2 (A) by inserting “or” at the end of sub-
3 paragraph (B);

4 (B) by striking subparagraph (C); and

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

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

9 (3) by redesignating paragraph (4) as para-
10 graph (3); and

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

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

15 (B) in subparagraph (B)—

16 (i) by striking clause (ii);

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

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

22 (e) EFFECT OF FAILURE TO PAY FEES.—Section
23 736(e) of the Federal Food, Drug, and Cosmetic Act (21
24 U.S.C. 379h(e)) is amended by striking “all fees” and in-
25 serting “all such fees”.

1 (f) LIMITATIONS.—Section 736(f)(2) of the Federal
2 Food, Drug, and Cosmetic Act (21 U.S.C. 379h(f)(2)) is
3 amended by striking “supplements, prescription drug es-
4 tablishments, and prescription drug products” and insert-
5 ing “prescription drug program fees”.

6 (g) CREDITING AND AVAILABILITY OF FEES.—Sec-
7 tion 736(g) of the Federal Food, Drug, and Cosmetic Act
8 (21 U.S.C. 379h(g)) is amended—

9 (1) in paragraph (3)—

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

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

14 (2) by striking paragraph (4).

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

20 **SEC. 103. REAUTHORIZATION; REPORTING REQUIREMENTS.**

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

23 (1) in subsection (a)(1)—

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

1 (B) in subparagraph (A), by striking “Pre-
2 prescription Drug User Fee Amendments of 2012”
3 and inserting “Prescription Drug User Fee
4 Amendments of 2017”;

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

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

9 **SEC. 104. SUNSET DATES.**

10 (a) AUTHORIZATION.—Sections 735 and 736 of the
11 Federal Food, Drug, and Cosmetic Act (21 U.S.C. 379g;
12 379h) shall cease to be effective October 1, 2022.

13 (b) REPORTING REQUIREMENTS.—Section 736B of
14 the Federal Food, Drug, and Cosmetic Act (21 U.S.C.
15 379h–2) shall cease to be effective January 31, 2023.

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

20 **SEC. 105. EFFECTIVE DATE.**

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

1 applications received on or after October 1, 2017, regard-
2 less of the date of the enactment of this Act.

3 **SEC. 106. SAVINGS CLAUSE.**

4 Notwithstanding the amendments made by this title,
5 part 2 of subchapter C of chapter VII of the Federal Food,
6 Drug, and Cosmetic Act, as in effect on the day before
7 the date of the enactment of this title, shall continue to
8 be in effect with respect to human drug applications and
9 supplements (as defined in such part as of such day) that
10 on or after October 1, 2012, but before October 1, 2017,
11 were accepted by the Food and Drug Administration for
12 filing with respect to assessing and collecting any fee re-
13 quired by such part for a fiscal year prior to fiscal year
14 2018.

15 **TITLE II—FEES RELATING TO**
16 **DEVICES**

17 **SEC. 201. SHORT TITLE; FINDING.**

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

20 (b) **FINDING.**—The Congress finds that the fees au-
21 thorized under the amendments made by this title will be
22 dedicated toward expediting the process for the review of
23 device applications and for assuring the safety and effec-
24 tiveness of devices, as set forth in the goals identified for
25 purposes of part 3 of subchapter C of chapter VII of the

1 Federal Food, Drug, and Cosmetic Act in the letters from
2 the Secretary of Health and Human Services to the Chair-
3 man of the Committee on Health, Education, Labor, and
4 Pensions of the Senate and the Chairman of the Com-
5 mittee on Energy and Commerce of the House of Rep-
6 resentatives, as set forth in the Congressional Record.

7 **SEC. 202. DEFINITIONS.**

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

10 (1) by redesignating paragraphs (8) through
11 (13) as paragraphs (9) through (14), respectively;

12 (2) by inserting after paragraph (7) the fol-
13 lowing new paragraph:

14 “(8) The term ‘de novo classification request’
15 means a request made under section 513(f)(2)(A)
16 with respect to the classification of a device.”;

17 (3) in subparagraph (D) of paragraph (10) (as
18 redesignated by paragraph (1)), by striking “and
19 submissions” and inserting “submissions, and de
20 novo classification requests”; and

21 (4) in paragraph (11) (as redesignated by para-
22 graph (1)), by striking “2011” and inserting
23 “2016”.

24 (b) CONFORMING AMENDMENT.—Section 714(b)(1)
25 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C.

1 379d–3(b)(1)) is amended by striking “737(8)” and in-
2 serting “737(9)”.

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

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

7 (1) in paragraph (1), by striking “fiscal year
8 2013” and inserting “fiscal year 2018”; and

9 (2) in paragraph (2)—

10 (A) in subparagraph (A)—

11 (i) in the matter preceding clause (i),
12 by striking “October 1, 2012” and insert-
13 ing “October 1, 2017”;

14 (ii) in clause (viii), by striking “2”
15 and inserting “3.4”; and

16 (iii) by adding at the end the fol-
17 lowing new clause:

18 “(xi) For a de novo classification re-
19 quest, a fee equal to 30 percent of the fee
20 that applies under clause (i).”; and

21 (B) in subparagraph (B)(v)(I), by striking
22 “or premarket notification submission” and in-
23 serting “premarket notification submission, or
24 de novo classification request”.

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

4 “(b) FEE AMOUNTS.—

5 “(1) IN GENERAL.—Subject to subsections (c),
 6 (d), (e), and (h), for each of fiscal years 2018
 7 through 2022, fees under subsection (a) shall be de-
 8 rived from the base fee amounts specified in para-
 9 graph (2), to generate the total revenue amounts
 10 specified in paragraph (3).

11 “(2) BASE FEE AMOUNTS SPECIFIED.—For
 12 purposes of paragraph (1), the base fee amounts
 13 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

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

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

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

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

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

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

1 (c) ANNUAL FEE SETTING; ADJUSTMENTS.—Section
2 738(c) of the Federal Food, Drug, and Cosmetic Act (21
3 U.S.C. 379j(c)) is amended—

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

6 (2) in paragraph (2)—

7 (A) in subparagraph (A), by striking
8 “2014” and inserting “2018”;

9 (B) by striking subparagraph (B) and in-
10 sserting the following new subparagraph:

11 “(B) APPLICABLE INFLATION ADJUST-
12 MENT.—The applicable inflation adjustment for
13 fiscal year 2018 and each subsequent fiscal
14 year is the product of—

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

18 “(ii) the product of the base inflation
19 adjustment under subparagraph (C) for
20 each of the fiscal years preceding such fis-
21 cal year, beginning with fiscal year 2016.”;

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

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

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

6 “(i) adjust the base fee amounts spec-
7 ified in subsection (b)(2) for such fiscal
8 year by multiplying such amounts by the
9 applicable inflation adjustment under sub-
10 paragraph (B) for such year; and

11 “(ii) if the Secretary determines nec-
12 essary, increase (in addition to the adjust-
13 ment under clause (i)) such base fee
14 amounts, on a uniform proportionate basis,
15 to generate the total revenue amounts
16 under subsection (b)(3), as adjusted for in-
17 flation under subparagraph (A).”; and

18 (3) in paragraph (3)—

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

21 (B) by striking “further adjusted” and in-
22 serting “increased”.

23 (d) SMALL BUSINESSES; FEE WAIVER AND FEE RE-
24 DUCATION REGARDING PREMARKET APPROVAL FEES.—

1 Section 738(d) of the Federal Food, Drug, and Cosmetic
2 Act (21 U.S.C. 379j(d)) is amended—

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

7 (2) in paragraph (2)(C)—

8 (A) by striking “supplement, or” and in-
9 serting “supplement,”; and

10 (B) by inserting “, or a de novo classifica-
11 tion request” after “class III device”.

12 (e) SMALL BUSINESSES; FEE REDUCTION REGARD-
13 ING PREMARKET NOTIFICATION SUBMISSIONS.—Section
14 738(e)(2)(C) of the Federal Food, Drug, and Cosmetic
15 Act (21 U.S.C. 379j(e)(2)(C)) is amended by striking
16 “50” and inserting “25”.

17 (f) FEE WAIVER OR REDUCTION.—

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

21 (2) CONFORMING AMENDMENTS.—

22 (A) Section 515(c)(4)(A) of the Federal
23 Food, Drug, and Cosmetic Act (21 U.S.C.
24 360e(c)(4)(A)) is amended by striking “738(h)”
25 and inserting “738(g)”.

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

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

7 (ii) in subsection (a)(2)(A), by strik-
8 ing “(d), (e), and (f)” and inserting “(d)
9 and (e)”; and

10 (iii) in subsection (a)(3)(A), by strik-
11 ing “and subsection (f)”.

12 (g) EFFECT OF FAILURE TO PAY FEES.—Subsection
13 (f)(1), as so redesignated, of section 738 of the Federal
14 Food, Drug, and Cosmetic Act (21 U.S.C. 379j) is amend-
15 ed—

16 (1) by striking “or periodic reporting con-
17 cerning a class III device” and inserting “periodic
18 reporting concerning a class III device, or de novo
19 classification request”; and

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

22 (h) CONDITIONS.—Subsection (g)(1)(A), as so redesi-
23 gnated, of section 738 of the Federal Food, Drug, and
24 Cosmetic Act (21 U.S.C. 379j) is amended by striking
25 “\$280,587,000” and inserting “\$320,825,000”.

1 (i) CREDITING AND AVAILABILITY OF FEES.—Sub-
2 section (h), as so redesignated, of section 738 of the Fed-
3 eral Food, Drug, and Cosmetic Act (21 U.S.C. 379j) is
4 amended—

5 (1) in paragraph (3)—

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

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

11 (2) by striking paragraph (4).

12 **SEC. 204. REAUTHORIZATION; REPORTING REQUIREMENTS.**

13 (a) PERFORMANCE REPORTS.—Section 738A(a) of
14 the Federal Food, Drug, and Cosmetic Act (21 U.S.C.
15 379j–1(a)) is amended—

16 (1) in paragraph (1)—

17 (A) in subparagraph (A)—

18 (i) by striking “2013” and inserting
19 “2018”; and

20 (ii) by striking “the Medical Device
21 User Fee Amendments of 2012” and in-
22 sserting “the Medical Device User Fee
23 Amendments of 2017”; and

24 (B) in subparagraph (B), by striking “the
25 Medical Device User Fee Amendments Act of

1 2012” and inserting “the Medical Device User
2 Fee Amendments of 2017”; and

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

5 (b) REAUTHORIZATION.—Section 738A(b) of the
6 Federal Food, Drug, and Cosmetic Act (21 U.S.C. 379j–
7 1(b)) is amended—

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

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

12 **SEC. 205. CONFORMITY ASSESSMENT PILOT PROGRAM.**

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

16 “(d) PILOT ACCREDITATION SCHEME FOR CON-
17 FORMITY ASSESSMENT.—

18 “(1) IN GENERAL.—The Secretary shall estab-
19 lish a pilot program under which—

20 “(A) testing laboratories may be accred-
21 ited, by accreditation bodies meeting criteria
22 specified by the Secretary, to assess the con-
23 formance of a device with certain standards rec-
24 ognized under this section; and

1 “(B) subject to paragraph (2), determina-
2 tions by testing laboratories so accredited that
3 a device conforms with such standard or stand-
4 ards shall be accepted by the Secretary for pur-
5 poses of demonstrating such conformity under
6 this section unless the Secretary finds that a
7 particular such determination shall not be so
8 accepted.

9 “(2) SECRETARIAL REVIEW OF ACCREDITED
10 LABORATORY DETERMINATIONS.—The Secretary
11 may—

12 “(A) review determinations by testing lab-
13 oratories accredited pursuant to this subsection,
14 including by conducting periodic audits of such
15 determinations or processes of accredited bodies
16 or testing laboratories and, following such re-
17 view, taking additional measures under this
18 Act, such as suspension or withdrawal of ac-
19 creditation of such testing laboratory under
20 paragraph (1)(A) or requesting additional infor-
21 mation with respect to such device, as the Sec-
22 retary determines appropriate; and

23 “(B) if the Secretary becomes aware of in-
24 formation materially bearing on safety or effec-
25 tiveness of a device assessed for conformity by

1 a testing laboratory so accredited, take such ad-
2 ditional measures under this Act as the Sec-
3 retary determines appropriate, such as suspen-
4 sion or withdrawal of accreditation of such test-
5 ing laboratory under paragraph (1)(A), or re-
6 questing additional information with regard to
7 such device.

8 “(3) IMPLEMENTATION AND REPORTING.—

9 “(A) PUBLIC MEETING.—The Secretary
10 shall publish in the Federal Register a notice of
11 a public meeting to be held no later than Sep-
12 tember 30, 2018, to discuss and obtain input
13 and recommendations from stakeholders regard-
14 ing the goals and scope of, and a suitable
15 framework and procedures and requirements
16 for, the pilot program under this subsection.

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

19 “(i) not later than September 30,
20 2019, issue draft guidance regarding the
21 goals and implementation of the pilot pro-
22 gram under this subsection; and

23 “(ii) not later than September 30,
24 2021, issue final guidance with respect to
25 the implementation of such program.

1 “(C) PILOT PROGRAM INITIATION.—Not
2 later than September 30, 2020, the Secretary
3 shall initiate the pilot program under this sub-
4 section.

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

10 “(4) SUNSET.—As of October 1, 2022—

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

15 “(B) the Secretary—

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

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

21 “(C) except for purposes of accepting a de-
22 termination described in subparagraph (B)(ii),
23 the Secretary shall not continue to recognize
24 the accreditation of testing laboratories accred-
25 ited under paragraph (1)(A); and

1 “(D) the Secretary may take actions in ac-
2 cordance with paragraph (2) with respect to the
3 determinations made prior to such date and
4 recognition of the accreditation of testing lab-
5 oratories pursuant to determinations made
6 prior to such date.”.

7 **SEC. 206. REAUTHORIZATION OF REVIEW.**

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

10 (1) in subsection (a)(3)—

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

13 “(ii) a device classified under section
14 513(f)(2) or designated under section
15 515C(d);

16 “(iii) a device that is intended to be
17 permanently implantable, life sustaining,
18 or life supporting, unless otherwise deter-
19 mined by the Secretary in accordance with
20 subparagraph (B)(i)(II) and listed as eligi-
21 ble for review under subparagraph (B)(iii);
22 or

23 “(iv) a device that is of a type, or sub-
24 set of a type, listed as not eligible for re-
25 view under subparagraph (B)(iii).”;

1 (B) by striking subparagraph (B) and in-
2 serting the following:

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

5 “(i) issue draft guidance on the fac-
6 tors the Secretary will use in determining
7 whether a class I or class II device type, or
8 subset of such device types, is eligible for
9 review by an accredited person, includ-
10 ing—

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

13 “(II) whether the device type, or
14 subset of such device type, is perma-
15 nently implantable, life sustaining, or
16 life supporting, and whether there is a
17 detailed public health justification for
18 permitting the review by an accredited
19 person of such device type or subset;

20 “(ii) not later than 24 months after
21 the date on which the Secretary issues
22 such draft guidance, finalize such guid-
23 ance; and

24 “(iii) beginning on the date such guid-
25 ance is finalized, designate and post on the

1 internet website of the Food and Drug Ad-
2 ministration, an updated list of class I and
3 class II device types, or subsets of such de-
4 vice types, and the Secretary’s determina-
5 tion with respect to whether each such de-
6 vice type, or subset of a device type, is eli-
7 gible or not eligible for review by an ac-
8 credited person under this section based on
9 the factors described in clause (i).”; and

10 (C) by adding at the end the following:

11 “(C) INTERIM RULE.—Until the date on
12 which the updated list is designated and posted
13 in accordance with subparagraph (B)(iii), the
14 list in effect on the date of enactment the Med-
15 ical Device User Fee Amendments of 2017 shall
16 be in effect.”;

17 (2) in subsection (b)—

18 (A) in paragraph (2)—

19 (i) by striking subparagraph (D); and

20 (ii) by redesignating subparagraph

21 (E) as subparagraph (D); and

22 (B) in paragraph (3)—

23 (i) by redesignating subparagraph (E)

24 as subparagraph (F);

1 (ii) in subparagraph (F) (as so reded-
2 ignated), by striking “The operations of”
3 and all that follows through “it will—”
4 and inserting “Such person shall agree, at
5 a minimum, to include in its request for
6 accreditation a commitment to, at the time
7 of accreditation, and at any time it is per-
8 forming any review pursuant to this sec-
9 tion—”; and

10 (iii) by inserting after subparagraph
11 (D) the following new subparagraph:

12 “(E) The operations of such person shall
13 be in accordance with generally accepted profes-
14 sional and ethical business practices.”; and

15 (3) in subsection (c), by striking “2017” and
16 inserting “2022”.

17 **SEC. 207. ELECTRONIC FORMAT FOR SUBMISSIONS.**

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

21 “(3) PRESUBMISSIONS AND SUBMISSIONS SOLE-
22 LY IN ELECTRONIC FORMAT.—

23 “(A) IN GENERAL.—Beginning on such
24 date as the Secretary specifies in final guidance
25 issued under subparagraph (C), presubmissions

1 and submissions for devices described in para-
2 graph (1) (and any appeals of action taken by
3 the Secretary with respect to such
4 presubmissions or submissions) shall be sub-
5 mitted solely in such electronic format as speci-
6 fied by the Secretary in such guidance.

7 “(B) DRAFT GUIDANCE.—The Secretary
8 shall, not later than October 1, 2019, issue
9 draft guidance providing for—

10 “(i) any further standards for the
11 submission by electronic format required
12 under subparagraph (A);

13 “(ii) a timetable for the establishment
14 by the Secretary of such further standards;
15 and

16 “(iii) criteria for waivers of and ex-
17 emptions from the requirements of this
18 subsection.

19 “(C) FINAL GUIDANCE.—The Secretary
20 shall, not later than 1 year after the close of
21 the public comment period on the draft guid-
22 ance issued under subparagraph (B), issue final
23 guidance.”.

1 **SEC. 208. SAVINGS CLAUSE.**

2 Notwithstanding the amendments made by this title,
3 part 3 of subchapter C of chapter VII of the Federal Food,
4 Drug, and Cosmetic Act (21 U.S.C. 379i et seq.), as in
5 effect on the day before the date of the enactment of this
6 title, shall continue to be in effect with respect to the sub-
7 missions listed in section 738(a)(2)(A) of such Act (as de-
8 fined in such part as of such day) that on or after October
9 1, 2012, but before October 1, 2017, were accepted by
10 the Food and Drug Administration for filing with respect
11 to assessing and collecting any fee required by such part
12 for a fiscal year prior to fiscal year 2018.

13 **SEC. 209. EFFECTIVE DATE.**

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

22 **SEC. 210. SUNSET DATES.**

23 (a) AUTHORIZATION.—Sections 737 and 738 of the
24 Federal Food, Drug, and Cosmetic Act (21 U.S.C. 739i;
25 739j) shall cease to be effective October 1, 2022.

1 (b) REPORTING REQUIREMENTS.—Section 738A (21
2 U.S.C. 739j–1) of the Federal Food, Drug, and Cosmetic
3 Act (regarding reauthorization and reporting require-
4 ments) shall cease to be effective January 31, 2023.

5 (c) PREVIOUS SUNSET PROVISION.—Effective Octo-
6 ber 1, 2017, section 207(a) of the Food and Drug Admin-
7 istration Safety and Innovation Act (Public Law 112–144)
8 is repealed.

9 **TITLE III—FEES RELATING TO**
10 **GENERIC DRUGS**

11 **SEC. 301. SHORT TITLE; FINDING.**

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

14 (b) FINDING.—The Congress finds that the fees au-
15 thorized by the amendments made in this title will be dedi-
16 cated to human generic drug activities, as set forth in the
17 goals identified for purposes of part 7 of subchapter C
18 of chapter VII of the Federal Food, Drug, and Cosmetic
19 Act, in the letters from the Secretary of Health and
20 Human Services to the Chairman of the Committee on
21 Health, Education, Labor, and Pensions of the Senate and
22 the Chairman of the Committee on Energy and Commerce
23 of the House of Representatives, as set forth in the Con-
24 gressional Record.

1 **SEC. 302. DEFINITIONS.**

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

4 (1) in paragraph (1)(B), by striking “applica-
5 tion for a positron emission tomography drug.” and
6 inserting “application—

7 “(i) for a positron emission tomog-
8 raphy drug; or

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

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

15 (3) by inserting after paragraph (4) the fol-
16 lowing:

17 “(5) The term ‘contract manufacturing organi-
18 zation facility’ means a manufacturing facility of a
19 finished dosage form of a drug approved pursuant to
20 an abbreviated new drug application, where such
21 manufacturing facility is not identified in an ap-
22 proved abbreviated new drug application held by the
23 owner of such facility or an affiliate of such owner
24 or facility.”.

1 **SEC. 303. AUTHORITY TO ASSESS AND USE HUMAN GE-**
2 **NERIC DRUG FEES.**

3 (a) TYPES OF FEES.—Section 744B(a) of the Fed-
4 eral Food, Drug, and Cosmetic Act (21 U.S.C. 379j-
5 42(a)) is amended—

6 (1) in the matter preceding paragraph (1), by
7 striking “fiscal year 2013” and inserting “fiscal year
8 2018”;

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

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

13 (3) in paragraph (2)—

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

16 “(C) NOTICE.—Not later than 60 days be-
17 fore the start of each of fiscal years 2018
18 through 2022, the Secretary shall publish in the
19 Federal Register the amount of the drug mas-
20 ter file fee established by this paragraph for
21 such fiscal year.”; and

22 (B) in subparagraph (E)—

23 (i) in clause (i)—

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

1 “(I) the date”;

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

4 (III) by adding at the end the
5 following:

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

9 (ii) in clause (ii), by striking “notice
10 provided for in clause (i) or (ii) of subpara-
11 graph (C), as applicable” and inserting
12 “notice provided for in subparagraph (C)”;

13 (4) in paragraph (3)—

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

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

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

21 “(B) NOTICE.—Not later than 60 days be-
22 fore the start of each of fiscal years 2018
23 through 2022, the Secretary shall publish in the
24 Federal Register the amount of the fees under
25 subparagraph (A) for such fiscal year.

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

6 (D) in subparagraph (D)—

7 (i) in the heading, by inserting “, IS
8 WITHDRAWN PRIOR TO BEING RECEIVED,
9 OR IS NO LONGER RECEIVED” after “RE-
10 CEIVED”; and

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

14 “(i) APPLICATIONS NOT CONSIDERED
15 TO HAVE BEEN RECEIVED AND APPLICA-
16 TIONS WITHDRAWN PRIOR TO BEING RE-
17 CEIVED.—The Secretary shall refund 75
18 percent of the fee paid under subparagraph
19 (A) for any abbreviated new drug applica-
20 tion that the Secretary considers not to
21 have been received within the meaning of
22 section 505(j)(5)(A) for a cause other than
23 failure to pay fees, or that has been with-
24 drawn prior to being received within the
25 meaning of section 505(j)(5)(A).

1 “(ii) APPLICATIONS NO LONGER RE-
2 CEIVED.—The Secretary shall refund 100
3 percent of the fee paid under subparagraph
4 (A) for any abbreviated new drug applica-
5 tion if the Secretary initially receives the
6 application under section 505(j)(5)(A) and
7 subsequently determines that an exclusivity
8 period for a listed drug should have pre-
9 vented the Secretary from receiving such
10 application, such that the abbreviated new
11 drug application is no longer received with-
12 in the meaning of section 505(j)(5)(A).”;

13 (E) in subparagraph (E), by striking “or
14 prior approval supplement”; and

15 (F) in the matter preceding clause (i) of
16 subparagraph (F)—

17 (i) by striking “2012” and inserting
18 “2017”; and

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

21 (5) in paragraph (4)—

22 (A) in subparagraph (A)—

23 (i) in the matter preceding clause (i)
24 and in clause (iii), by striking “, or in-
25 tended to be identified, in at least one ge-

1 neric drug submission that is pending or”
2 and inserting “in at least one generic drug
3 submission that is”;

4 (ii) in clause (i), by striking “or in-
5 tended to be identified in at least one ge-
6 neric drug submission that is pending or”
7 and inserting “in at least one generic drug
8 submission that is”;

9 (iii) in clause (ii), by striking “pro-
10 duces,” and all that follows through “such
11 a” and inserting “is identified in at least
12 one generic drug submission in which the
13 facility is approved to produce one or more
14 active pharmaceutical ingredients or in a
15 Type II active pharmaceutical ingredient
16 drug master file referenced in at least one
17 such”; and

18 (iv) in clause (iii), by striking “to fees
19 under both such clauses” and inserting
20 “only to the fee attributable to the manu-
21 facture of the finished dosage forms”; and

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

24 “(C) NOTICE.—Within the timeframe spec-
25 ified in subsection (d)(1), the Secretary shall

1 publish in the Federal Register the amount of
2 the fees under subparagraph (A) for such fiscal
3 year.

4 “(D) FEE DUE DATE.—For each of fiscal
5 years 2018 through 2022, the fees under sub-
6 paragraph (A) for such fiscal year shall be due
7 on the later of—

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

10 “(ii) the first business day after the
11 enactment of an appropriations Act pro-
12 viding for the collection and obligation of
13 fees for such year under this section for
14 such year.”;

15 (6) by redesignating paragraph (5) as para-
16 graph (6); and

17 (7) by inserting after paragraph (4) the fol-
18 lowing:

19 “(5) GENERIC DRUG APPLICANT PROGRAM
20 FEE.—

21 “(A) IN GENERAL.—A generic drug appli-
22 cant program fee shall be assessed annually as
23 described in subsection (b)(2)(E).

1 “(B) AMOUNT.—The amount of fees estab-
2 lished under subparagraph (A) shall be estab-
3 lished under subsection (d).

4 “(C) NOTICE.—Within the timeframe spec-
5 ified in subsection (d)(1), the Secretary shall
6 publish in the Federal Register the amount of
7 the fees under subparagraph (A) for such fiscal
8 year.

9 “(D) FEE DUE DATE.—For each of fiscal
10 years 2018 through 2022, the fees under sub-
11 paragraph (A) for such fiscal year shall be due
12 on the later of—

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

15 “(ii) the first business day after the
16 date of enactment of an appropriations Act
17 providing for the collection and obligation
18 of fees for such fiscal year under this sec-
19 tion for such fiscal year.”.

20 (b) FEE REVENUE AMOUNTS.—Section 744B(b) of
21 the Federal Food, Drug, and Cosmetic Act (21 U.S.C.
22 379j–42(b)) is amended—

23 (1) in paragraph (1)—

24 (A) in subparagraph (A)—

1 (i) in the heading, by striking “2013”
2 and inserting “2018”;

3 (ii) by striking “2013” and inserting
4 “2018”;

5 (iii) by striking “\$299,000,000” and
6 inserting “\$493,600,000”; and

7 (iv) by striking “Of that amount” and
8 all that follows through the end of clause
9 (ii); and

10 (B) in subparagraph (B)—

11 (i) in the heading, by striking “2014
12 THROUGH 2017” and inserting “2019
13 THROUGH 2022”;

14 (ii) by striking “2014 through 2017”
15 and inserting “2019 through 2022”;

16 (iii) by striking “paragraphs (2)
17 through (4)” and inserting “paragraphs
18 (2) through (5)”;

19 (iv) by striking “\$299,000,000” and
20 inserting “\$493,600,000”; and

21 (2) in paragraph (2)—

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

24 (i) by striking “paragraph (1)(A)(ii)
25 for fiscal year 2013 and paragraph (1)(B)

1 for each of fiscal years 2014 through
2 2017” and inserting “such paragraph for a
3 fiscal year”; and

4 (ii) by striking “through (4)” and in-
5 serting “through (5)”;

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

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

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

13 “(C) Twenty percent shall be derived from
14 fees under subsection (a)(4)(A)(i) (relating to
15 generic drug facilities). The amount of the fee
16 for a contract manufacturing organization facil-
17 ity shall be equal to one-third the amount of the
18 fee for a facility that is not a contract manufac-
19 turing organization facility. The amount of the
20 fee for a facility located outside the United
21 States and its territories and possessions shall
22 be \$15,000 higher than the amount of the fee
23 for a facility located in the United States and
24 its territories and possessions.”;

25 (D) in subparagraph (D)—

1 (i) by striking “Fourteen percent”
2 and inserting “Seven percent”;

3 (ii) by striking “not less than \$15,000
4 and not more than \$30,000” and inserting
5 “\$15,000”; and

6 (iii) by striking “, as determined” and
7 all that follows through the period at the
8 end and inserting a period; and

9 (E) by adding at the end the following:

10 “(E)(i) Thirty-five percent shall be derived
11 from fees under subsection (a)(5) (relating to
12 generic drug applicant program fees). For pur-
13 poses of this subparagraph, if a person has af-
14 filiates, a single program fee shall be assessed
15 with respect to that person, including its affili-
16 ates, and may be paid by that person or any
17 one of its affiliates. The Secretary shall deter-
18 mine the fees as follows:

19 “(I) If a person (including its affili-
20 ates) owns at least one but not more than
21 5 approved abbreviated new drug applica-
22 tions on the due date for the fee under this
23 subsection, the person (including its affili-
24 ates) shall be assessed a small business ge-
25 neric drug applicant program fee equal to

1 one-tenth of the large size operation ge-
2 neric drug applicant program fee.

3 “(II) If a person (including its affili-
4 ates) owns at least 6 but not more than 19
5 approved abbreviated new drug applica-
6 tions on the due date for the fee under this
7 subsection, the person (including its affili-
8 ates) shall be assessed a medium size oper-
9 ation generic drug applicant program fee
10 equal to two-fifths of the large size oper-
11 ation generic drug applicant program fee.

12 “(III) If a person (including its affili-
13 ates) owns 20 or more approved abbrevi-
14 ated new drug applications on the due
15 date for the fee under this subsection, the
16 person (including its affiliates) shall be as-
17 sessed a large size operation generic drug
18 applicant program fee.

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

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

4 (1) in paragraph (1)—

5 (A) by striking “2014” and inserting
6 “2019”;

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

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

13 (2) in paragraph (2)—

14 (A) by striking “2017” each place it ap-
15 pears and inserting “2022”;

16 (B) by striking “the first 3 months of fis-
17 cal year 2018” and inserting “the first 3
18 months of fiscal year 2023”; and

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

21 (d) ANNUAL FEE SETTING.—Section 744B(d) of the
22 Federal Food, Drug, and Cosmetic Act (21 U.S.C. 379j–
23 42(d)) is amended—

24 (1) by striking paragraphs (1) and (2) and in-
25 serting the following:

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

8 (2) by redesignating paragraph (3) as para-
9 graph (2); and

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

14 (e) IDENTIFICATION OF FACILITIES.—Section
15 744B(f) of the Federal Food, Drug, and Cosmetic Act (21
16 U.S.C. 379j–42(f)) is amended—

17 (1) by striking paragraph (1);

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

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

21 (A) by striking “paragraph (4)” and in-
22 serting “paragraph (3)”; and

23 (B) by striking “Such information shall”
24 and all that follows through the end of subpara-
25 graph (B) and inserting “Such information

1 shall, for each fiscal year, be submitted, up-
2 dated, or reconfirmed on or before June 1 of
3 the previous fiscal year.”; and

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

5 (A) in the heading, by striking “CONTENTS
6 OF NOTICE” and inserting “INFORMATION RE-
7 QUIRED TO BE SUBMITTED”;

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

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

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

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

17 (F) by adding at the end the following:

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

20 (f) EFFECT OF FAILURE TO PAY FEES.—Section
21 744B(g) of the Federal Food, Drug, and Cosmetic Act
22 (21 U.S.C. 379j–42(g)) is amended—

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

1 (2) in paragraph (2)(C)(ii), by striking “of
2 505(j)(5)(A)” and inserting “of section
3 505(j)(5)(A)”; and

4 (3) by adding at the end the following:

5 “(5) GENERIC DRUG APPLICANT PROGRAM
6 FEE.—

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

12 “(i) The Secretary shall place the per-
13 son on a publicly available arrears list.

14 “(ii) Any abbreviated new drug appli-
15 cation submitted by the generic drug appli-
16 cant or an affiliate of such applicant shall
17 not be received, within the meaning of sec-
18 tion 505(j)(5)(A).

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

24 “(B) APPLICATION OF PENALTIES.—The
25 penalties under subparagraph (A) shall apply

1 until the fee required under subsection (a)(5) is
2 paid.”.

3 (g) LIMITATIONS.—Section 744B(h)(2) of the Fed-
4 eral Food, Drug, and Cosmetic Act (21 U.S.C. 379j-
5 42(h)(2)) is amended by striking “for Type II active phar-
6 maceutical ingredient drug master files, abbreviated new
7 drug applications and prior approval supplements, and ge-
8 neric drug facilities and active pharmaceutical ingredient
9 facilities”.

10 (h) CREDITING AND AVAILABILITY OF FEES.—Sec-
11 tion 744B(i) of the Federal Food, Drug, and Cosmetic Act
12 (21 U.S.C. 379j-42(i)) is amended—

13 (1) in paragraph (2)—

14 (A) in subparagraph (A), by striking “sub-
15 paragraphs (C) and (D)” and inserting “sub-
16 paragraph (C)”;

17 (B) by striking subparagraph (C) (relating
18 to fee collection during first program year);

19 (C) in subparagraph (D)—

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

22 (ii) by striking “(after fiscal year
23 2013)”; and

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

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

4 (i) INFORMATION ON ABBREVIATED NEW DRUG AP-
5 PLICATIONS OWNED BY APPLICANTS AND THEIR AFFILI-
6 ATES.—Section 744B of the Federal Food, Drug, and
7 Cosmetic Act (21 U.S.C. 379j–42) is amended by adding
8 at the end the following:

9 “(o) INFORMATION ON ABBREVIATED NEW DRUG
10 APPLICATIONS OWNED BY APPLICANTS AND THEIR AF-
11 FILIATES.—

12 “(1) IN GENERAL.—By April 1 of each year,
13 each person that owns an abbreviated new drug ap-
14 plication, or a designated affiliate of such person,
15 shall submit, on behalf of the person and the affili-
16 ates of such person, to the Secretary a list of—

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

19 “(B) if any affiliate of such person also
20 owns an abbreviated new drug application, all
21 affiliates that own any such abbreviated new
22 drug application and all approved abbreviated
23 new drug applications owned by any such affil-
24 iate.

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

4 **SEC. 304. REAUTHORIZATION; REPORTING REQUIREMENTS.**

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

7 (1) in subsection (a)—

8 (A) by striking “2013” and inserting
9 “2018”; and

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

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

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

17 **SEC. 305. SUNSET DATES.**

18 (a) **AUTHORIZATION.**—Sections 744A and 744B of
19 the Federal Food, Drug, and Cosmetic Act (21 U.S.C.
20 379j–41; 379j–42) shall cease to be effective October 1,
21 2022.

22 (b) **REPORTING REQUIREMENTS.**—Section 744C of
23 the Federal Food, Drug, and Cosmetic Act (21 U.S.C.
24 379j–43) shall cease to be effective January 31, 2023.

25 (c) **PREVIOUS SUNSET PROVISION.**—

1 (1) IN GENERAL.—Effective October 1, 2017,
2 section 304 of the Food and Drug Administration
3 Safety and Innovation Act (Public Law 112–144) is
4 repealed.

5 (2) CONFORMING AMENDMENT.—The Food and
6 Drug Administration Safety and Innovation Act
7 (Public Law 112–144) is amended in the table of
8 contents in section 2 by striking the item relating to
9 section 304.

10 **SEC. 306. EFFECTIVE DATE.**

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

18 **SEC. 307. SAVINGS CLAUSE.**

19 Notwithstanding the amendments made by this title,
20 part 7 of subchapter C of chapter VII of the Federal Food,
21 Drug, and Cosmetic Act, as in effect on the day before
22 the date of the enactment of this title, shall continue to
23 be in effect with respect to abbreviated new drug applica-
24 tions (as defined in such part as of such day) that were
25 received by the Food and Drug Administration within the

1 meaning of section 505(j)(5)(A) of such Act (21 U.S.C.
2 355(j)(5)(A)), prior approval supplements that were sub-
3 mitted, and drug master files for Type II active pharma-
4 ceutical ingredients that were first referenced on or after
5 October 1, 2012, but before October 1, 2017, with respect
6 to assessing and collecting any fee required by such part
7 for a fiscal year prior to fiscal year 2018.

8 **TITLE IV—FEES RELATING TO**
9 **BIOSIMILAR BIOLOGICAL**
10 **PRODUCTS**

11 **SEC. 401. SHORT TITLE; FINDING.**

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

14 (b) **FINDING.**—The Congress finds that the fees au-
15 thorized by the amendments made in this title will be dedi-
16 cated to expediting the process for the review of biosimilar
17 biological product applications, including postmarket safe-
18 ty activities, as set forth in the goals identified for pur-
19 poses of part 8 of subchapter C of chapter VII of the Fed-
20 eral Food, Drug, and Cosmetic Act, in the letters from
21 the Secretary of Health and Human Services to the Chair-
22 man of the Committee on Health, Education, Labor, and
23 Pensions of the Senate and the Chairman of the Com-
24 mittee on Energy and Commerce of the House of Rep-
25 resentatives, as set forth in the Congressional Record.

1 **SEC. 402. DEFINITIONS.**

2 (a) ADJUSTMENT FACTOR.—Section 744G(1) of the
3 Federal Food, Drug, and Cosmetic Act (21 U.S.C. 379j–
4 51(1)) is amended to read as follows:

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

11 (b) BIOSIMILAR BIOLOGICAL PRODUCT.—Section
12 744G(3) of the Federal Food, Drug, and Cosmetic Act
13 (21 U.S.C. 379j–51(3)) is amended by striking “means
14 a product” and inserting “means a specific strength of
15 a biological product in final dosage form”.

16 **SEC. 403. AUTHORITY TO ASSESS AND USE BIOSIMILAR**
17 **FEEES.**

18 (a) TYPES OF FEEES.—Section 744H(a) of the Fed-
19 eral Food, Drug, and Cosmetic Act (21 U.S.C. 379j–
20 52(a)) is amended—

21 (1) in the matter preceding paragraph (1), by
22 striking “fiscal year 2013” and inserting “fiscal year
23 2018”;

24 (2) in the heading of paragraph (1), by striking
25 “BIOSIMILAR” and inserting “BIOSIMILAR BIOLOGI-
26 CAL PRODUCT”;

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

3 (4) in paragraph (1)(B)(i), by striking
4 “(b)(1)(B) for biosimilar biological product develop-
5 ment” and inserting “(c)(5) for the biosimilar bio-
6 logical product development program”;

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

11 (6) in paragraph (1)(B)(iii), by striking “an-
12 nual biosimilar development program fee” and in-
13 serting “annual biosimilar biological product devel-
14 opment fee”;

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

17 “(iv) REFUND.—If a person submits a
18 marketing application for a biosimilar bio-
19 logical product before October 1 of a fiscal
20 year and such application is accepted for
21 filing on or after October 1 of such fiscal
22 year, the person may request a refund
23 equal to the annual biosimilar biological
24 product development fee paid by the per-
25 son for the product for such fiscal year. To

1 qualify for consideration for a refund
2 under this clause, a person shall submit to
3 the Secretary a written request for such
4 refund not later than 180 days after the
5 marketing application is accepted for fil-
6 ing.”;

7 (8) in paragraph (1)(C), by striking “for a
8 product effective October 1 of a fiscal year by,” and
9 inserting “for a product, effective October 1 of a fis-
10 cal year, by,”;

11 (9) in paragraph (1)(D)—

12 (A) in clause (i) in the matter preceding
13 subclause (I), by inserting “, if the person seeks
14 to resume participation in such program,” be-
15 fore “pay a fee”;

16 (B) in clause (i)(I), by inserting after
17 “grants a request” the following: “by such per-
18 son”; and

19 (C) in clause (i)(II), by inserting after
20 “discontinued)” the following: “by such per-
21 son”;

22 (10) in the heading of paragraph (1)(E), by
23 striking “BIOSIMILAR DEVELOPMENT PROGRAM”;

24 (11) in paragraph (1)(F)—

1 (A) in the subparagraph heading, by strik-
2 ing “BIOSIMILAR DEVELOPMENT PROGRAM”;
3 and

4 (B) by amending clause (i) to read as fol-
5 lows:

6 “(i) REFUNDS.—Except as provided
7 in subparagraph (B)(iv), the Secretary
8 shall not refund any initial or annual bio-
9 similar biological product development fee
10 paid under subparagraph (A) or (B), or
11 any reactivation fee paid under subpara-
12 graph (D).”;

13 (12) in paragraph (2)—

14 (A) in the paragraph heading, by striking
15 “AND SUPPLEMENT”;

16 (B) by amending subparagraphs (A) and
17 (B) to read as follows:

18 “(A) IN GENERAL.—Each person that sub-
19 mits, on or after October 1, 2017, a biosimilar
20 biological product application shall be subject to
21 the following fees:

22 “(i) A fee established under sub-
23 section (c)(5) for a biosimilar biological
24 product application for which clinical data
25 (other than comparative bioavailability

1 studies) with respect to safety or effective-
2 ness are required for approval.

3 “(ii) A fee established under sub-
4 section (c)(5) for a biosimilar biological
5 product application for which clinical data
6 (other than comparative bioavailability
7 studies) with respect to safety or effective-
8 ness are not required for approval. Such
9 fee shall be equal to half of the amount of
10 the fee described in clause (i).

11 “(B) RULE OF APPLICABILITY; TREAT-
12 MENT OF CERTAIN PREVIOUSLY PAID FEES.—
13 Any person who pays a fee under subparagraph
14 (A), (B), or (D) of paragraph (1) for a product
15 before October 1, 2017, but submits a bio-
16 similar biological product application for that
17 product after such date, shall—

18 “(i) be subject to any biosimilar bio-
19 logical product application fees that may
20 be assessed at the time when such bio-
21 similar biological product application is
22 submitted; and

23 “(ii) be entitled to no reduction of
24 such application fees based on the amount
25 of fees paid for that product before Octo-

1 ber 1, 2017, under such subparagraph (A),
2 (B), or (D).”;

3 (C) in the heading of subparagraph (D),
4 by striking “OR SUPPLEMENT”;

5 (D) in subparagraphs (C) through (F), by
6 striking “or supplement” each place it appears;

7 and

8 (E) in subparagraph (D), by striking “or
9 a supplement”;

10 (13) by amending paragraph (3) to read as fol-
11 lows:

12 “(3) BIOSIMILAR BIOLOGICAL PRODUCT PRO-
13 GRAM FEE.—

14 “(A) IN GENERAL.—Each person who is
15 named as the applicant in a biosimilar biologi-
16 cal product application shall pay the annual bio-
17 similar biological product program fee estab-
18 lished for a fiscal year under subsection (c)(5)
19 for each biosimilar biological product that—

20 “(i) is identified in such a biosimilar
21 biological product application approved as
22 of October 1 of such fiscal year; and

23 “(ii) as of October 1 of such fiscal
24 year, does not appear on a list, developed

1 and maintained by the Secretary, of dis-
2 continued biosimilar biological products.

3 “(B) DUE DATE.—The biosimilar biologi-
4 cal product program fee for a fiscal year shall
5 be due on the later of—

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

8 “(ii) the first business day after the
9 enactment of an appropriations Act pro-
10 viding for the collection and obligation of
11 fees for such year under this section.

12 “(C) ONE FEE PER PRODUCT PER YEAR.—
13 The biosimilar biological product program fee
14 shall be paid only once for each product for
15 each fiscal year.

16 “(D) LIMITATION.—A person who is
17 named as the applicant in a biosimilar biologi-
18 cal product application shall not be assessed
19 more than 5 biosimilar biological product pro-
20 gram fees for a fiscal year for biosimilar bio-
21 logical products identified in such biosimilar bi-
22 ological product application.”.

23 (b) FEE REVENUE AMOUNTS.—Subsection (b) of sec-
24 tion 744H of the Federal Food, Drug, and Cosmetic Act
25 (21 U.S.C. 379j–52) is amended to read as follows:

1 “(b) FEE REVENUE AMOUNTS.—

2 “(1) FISCAL YEAR 2018.—For fiscal year 2018,
3 fees under subsection (a) shall be established to gen-
4 erate a total revenue amount equal to the sum of—

5 “(A) \$45,000,000; and

6 “(B) the dollar amount equal to the fiscal
7 year 2018 adjustment (as determined under
8 subsection (c)(4)).

9 “(2) SUBSEQUENT FISCAL YEARS.—For each of
10 the fiscal years 2019 through 2022, fees under sub-
11 section (a) shall, except as provided in subsection
12 (c), be established to generate a total revenue
13 amount equal to the sum of—

14 “(A) the annual base revenue for the fiscal
15 year (as determined under paragraph (4));

16 “(B) the dollar amount equal to the infla-
17 tion adjustment for the fiscal year (as deter-
18 mined under subsection (c)(1));

19 “(C) the dollar amount equal to the capac-
20 ity planning adjustment for the fiscal year (as
21 determined under subsection (c)(2)); and

22 “(D) the dollar amount equal to the oper-
23 ating reserve adjustment for the fiscal year, if
24 applicable (as determined under subsection
25 (c)(3)).

1 “(3) ALLOCATION OF REVENUE AMOUNT
2 AMONG FEES; LIMITATIONS ON FEE AMOUNTS.—

3 “(A) ALLOCATION.—The Secretary shall
4 determine the percentage of the total revenue
5 amount for a fiscal year to be derived from, re-
6 spectively—

7 “(i) initial and annual biosimilar bio-
8 logical product development fees and reac-
9 tivation fees under subsection (a)(1);

10 “(ii) biosimilar biological product ap-
11 plication fees under subsection (a)(2); and

12 “(iii) biosimilar biological product pro-
13 gram fees under subsection (a)(3).

14 “(B) LIMITATIONS ON FEE AMOUNTS.—
15 Until the first fiscal year for which the capacity
16 planning adjustment under subsection (c)(2) is
17 effective, the amount of any fee under sub-
18 section (a) for a fiscal year after fiscal year
19 2018 shall not exceed 125 percent of the
20 amount of such fee for fiscal year 2018.

21 “(C) BIOSIMILAR BIOLOGICAL PRODUCT
22 DEVELOPMENT FEES.—The initial biosimilar bi-
23 ological product development fee under sub-
24 section (a)(1)(A) for a fiscal year shall be equal
25 to the annual biosimilar biological product de-

1 development fee under subsection (a)(1)(B) for
2 that fiscal year.

3 “(D) REACTIVATION FEE.—The reactiva-
4 tion fee under subsection (a)(1)(D) for a fiscal
5 year shall be equal to twice the amount of the
6 annual biosimilar biological product develop-
7 ment fee under subsection (a)(1)(B) for that
8 fiscal year.

9 “(4) ANNUAL BASE REVENUE.—For purposes
10 of paragraph (2), the dollar amount of the annual
11 base revenue for a fiscal year shall be the dollar
12 amount of the total revenue amount for the previous
13 fiscal year, excluding any adjustments to such rev-
14 enue amount under subsection (c)(3).”.

15 (c) ADJUSTMENTS; ANNUAL FEE SETTING.—Section
16 744H of the Federal Food, Drug, and Cosmetic Act (21
17 U.S.C. 379j–52) is amended—

18 (1) by redesignating subsections (e) through (h)
19 as subsections (d) through (i), respectively;

20 (2) in subsections (a)(2)(F) and (h) (as redesign-
21 ated by paragraph (1)), by striking “subsection
22 (c)” and inserting “subsection (d)”;

23 (3) in subsection (a)(4)(A), by striking “sub-
24 section (b)(1)(F)” and inserting “subsection (c)(5)”;

25 and

1 (4) by inserting after subsection (b) the fol-
2 lowing:

3 “(c) ADJUSTMENTS; ANNUAL FEE SETTING.—

4 “(1) INFLATION ADJUSTMENT.—

5 “(A) IN GENERAL.—For purposes of sub-
6 section (b)(2)(B), the dollar amount of the in-
7 flation adjustment to the annual base revenue
8 for each fiscal year shall be equal to the prod-
9 uct of—

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

12 “(ii) the inflation adjustment percent-
13 age under subparagraph (B).

14 “(B) INFLATION ADJUSTMENT PERCENT-
15 AGE.—The inflation adjustment percentage
16 under this subparagraph for a fiscal year is
17 equal to the sum of—

18 “(i) the average annual percent
19 change in the cost, per full-time equivalent
20 position of the Food and Drug Administra-
21 tion, of all personnel compensation and
22 benefits paid with respect to such positions
23 for the first 3 years of the preceding 4 fis-
24 cal years, multiplied by the proportion of
25 personnel compensation and benefits costs

1 to total costs of the process for the review
2 of biosimilar biological product applications
3 (as defined in section 744G(13)) for the
4 first 3 years of the preceding 4 fiscal
5 years; and

6 “(ii) the average annual percent
7 change that occurred in the Consumer
8 Price Index for urban consumers (Wash-
9 ington-Baltimore, DC–MD–VA–WV; Not
10 Seasonally Adjusted; All items; Annual
11 Index) for the first 3 years of the pre-
12 ceding 4 years of available data multiplied
13 by the proportion of all costs other than
14 personnel compensation and benefits costs
15 to total costs of the process for the review
16 of biosimilar biological product applications
17 (as defined in section 744G(13)) for the
18 first 3 years of the preceding 4 fiscal
19 years.

20 “(2) CAPACITY PLANNING ADJUSTMENT.—

21 “(A) IN GENERAL.—Beginning with the
22 fiscal year described in subparagraph
23 (B)(ii)(II), the Secretary shall, in addition to
24 the adjustment under paragraph (1), further in-
25 crease the fee revenue and fees under this sec-

1 tion for a fiscal year to reflect changes in the
2 resource capacity needs of the Secretary for the
3 process for the review of biosimilar biological
4 product applications.

5 “(B) CAPACITY PLANNING METHOD-
6 OLOGY.—

7 “(i) DEVELOPMENT; EVALUATION
8 AND REPORT.—The Secretary shall obtain,
9 through a contract with an independent ac-
10 counting or consulting firm, a report evalu-
11 ating options and recommendations for a
12 new methodology to accurately assess
13 changes in the resource and capacity needs
14 of the process for the review of biosimilar
15 biological product applications. The capac-
16 ity planning methodological options and
17 recommendations presented in such report
18 shall utilize and be informed by personnel
19 time reporting data as an input. The re-
20 port shall be published for public comment
21 not later than September 30, 2020.

22 “(ii) ESTABLISHMENT AND IMPLE-
23 MENTATION.—After review of the report
24 described in clause (i) and receipt and re-
25 view of public comments thereon, the Sec-

1 retary shall establish a capacity planning
2 methodology for purposes of this para-
3 graph, which shall—

4 “(I) incorporate such approaches
5 and attributes as the Secretary deter-
6 mines appropriate; and

7 “(II) be effective beginning with
8 the first fiscal year for which fees are
9 set after such capacity planning meth-
10 odology is established.

11 “(C) LIMITATION.—Under no cir-
12 cumstances shall an adjustment under this
13 paragraph result in fee revenue for a fiscal year
14 that is less than the sum of the amounts under
15 subsections (b)(2)(A) (the annual base revenue
16 for the fiscal year) and (b)(2)(B) (the dollar
17 amount of the inflation adjustment for the fis-
18 cal year).

19 “(D) PUBLICATION IN FEDERAL REG-
20 ISTER.—The Secretary shall publish in the Fed-
21 eral Register notice under paragraph (5) the fee
22 revenue and fees resulting from the adjustment
23 and the methodologies under this paragraph.

24 “(3) OPERATING RESERVE ADJUSTMENT.—

1 “(A) INTERIM APPLICATION; FEE REDUC-
2 TION.—Until the first fiscal year for which the
3 capacity planning adjustment under paragraph
4 (2) is effective, the Secretary may, in addition
5 to the adjustment under paragraph (1), reduce
6 the fee revenue and fees under this section for
7 a fiscal year as the Secretary determines appro-
8 priate for long-term financial planning pur-
9 poses.

10 “(B) GENERAL APPLICATION AND METH-
11 ODOLOGY.—Beginning with the first fiscal year
12 for which the capacity planning adjustment
13 under paragraph (2) is effective, the Secretary
14 may, in addition to the adjustments under
15 paragraphs (1) and (2)—

16 “(i) reduce the fee revenue and fees
17 under this section as the Secretary deter-
18 mines appropriate for long-term financial
19 planning purposes; or

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

1 “(C) FEDERAL REGISTER NOTICE.—If an
2 adjustment under subparagraph (A) or (B) is
3 made, the rationale for the amount of the in-
4 crease or decrease (as applicable) in fee revenue
5 and fees shall be contained in the annual Fed-
6 eral Register notice under paragraph (5)(B) es-
7 tablishing fee revenue and fees for the fiscal
8 year involved.

9 “(4) FISCAL YEAR 2018 ADJUSTMENT.—

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

16 “(B) METHODOLOGY.—The Secretary shall
17 publish under paragraph (5)(B) a description of
18 the methodology used to calculate the fiscal
19 year 2018 adjustment under this paragraph in
20 the Federal Register notice establishing fee rev-
21 enue and fees for fiscal year 2018.

22 “(C) LIMITATION.—No adjustment under
23 this paragraph shall result in an increase in fee
24 revenue and fees under this section in excess of
25 \$9,000,000.

1 “(5) ANNUAL FEE SETTING.—For fiscal year
2 2018 and each subsequent fiscal year, the Secretary
3 shall, not later than 60 days before the start of each
4 such fiscal year—

5 “(A) establish, for the fiscal year, initial
6 and annual biosimilar biological product devel-
7 opment fees and reactivation fees under sub-
8 section (a)(1), biosimilar biological product ap-
9 plication fees under subsection (a)(2), and bio-
10 similar biological product program fees under
11 subsection (a)(3), based on the revenue
12 amounts established under subsection (b) and
13 the adjustments provided under this subsection;
14 and

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

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

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

1 (1) by striking subparagraph (B);

2 (2) by striking “; and” at the end of subpara-
3 graph (A) and inserting a period; and

4 (3) by striking “shall pay—” and all that fol-
5 lows through “application fees” and inserting “shall
6 pay application fees”.

7 (e) EFFECT OF FAILURE TO PAY FEES.—Subsection
8 (e) of section 744H of the Federal Food, Drug, and Cos-
9 metic Act (21 U.S.C. 379j–52), as redesignated by sub-
10 section (c)(1), is amended by striking “all fees” and in-
11 serting “all such fees”.

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

16 (1) in paragraph (2)—

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

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

1 (B) in subparagraph (D)—

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

4 (ii) by striking “(after fiscal year
5 2013)”; and

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

8 **SEC. 404. REAUTHORIZATION; REPORTING REQUIREMENTS.**

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

11 (1) in subsection (a)—

12 (A) by striking “2013” and inserting
13 “2018”; and

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

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

19 (3) by striking subsection (d);

20 (4) by redesignating subsection (e) as sub-
21 section (d); and

22 (5) in subsection (d), as so redesignated, by
23 striking “2017” each place it appears and inserting
24 “2022”.

1 **SEC. 405. SUNSET DATES.**

2 (a) AUTHORIZATION.—Sections 744G and 744H of
3 the Federal Food, Drug, and Cosmetic Act shall cease to
4 be effective October 1, 2022.

5 (b) REPORTING REQUIREMENTS.—Section 744I of
6 the Federal Food, Drug, and Cosmetic Act shall cease to
7 be effective January 31, 2023.

8 (c) PREVIOUS SUNSET PROVISION.—

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

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

18 **SEC. 406. EFFECTIVE DATE.**

19 The amendments made by this title shall take effect
20 on October 1, 2017, or the date of the enactment of this
21 Act, whichever is later, except that fees under part 8 of
22 subchapter C of chapter VII of the Federal Food, Drug,
23 and Cosmetic Act shall be assessed for all biosimilar bio-
24 logical product applications received on or after October
25 1, 2017, regardless of the date of the enactment of this
26 Act.

1 **SEC. 407. SAVINGS CLAUSE.**

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

13 **TITLE V—PEDIATRIC DRUGS**
14 **AND DEVICES**

15 **SEC. 501. BEST PHARMACEUTICALS FOR CHILDREN.**

16 Section 409I of the Public Health Service Act (42
17 U.S.C. 284m) is amended—

18 (1) in subsection (a)(2)(A)(ii), by inserting
19 “and identification of biomarkers for such diseases,
20 disorders, or conditions,” after “biologics,”;

21 (2) in subsection (c)—

22 (A) in paragraph (6)—

23 (i) by amending subparagraph (B) to
24 read as follows:

25 “(B) AVAILABILITY OF REPORTS.—

1 “(i) IN GENERAL.—Each report sub-
2 mitted under subparagraph (A) shall be
3 considered to be in the public domain (sub-
4 ject to section 505A(d)(4) of the Federal
5 Food, Drug, and Cosmetic Act) and not
6 later than 90 days after submission of
7 such report, shall be—

8 “(I) posted on the internet
9 website of the National Institutes of
10 Health in a manner that is accessible
11 and consistent with all applicable Fed-
12 eral laws and regulations, including
13 such laws and regulations for the pro-
14 tection of—

15 “(aa) human research par-
16 ticipants, including with respect
17 to privacy, security, informed
18 consent, and protected health in-
19 formation; and

20 “(bb) proprietary interests,
21 confidential commercial informa-
22 tion, and intellectual property
23 rights; and

24 “(II) assigned a docket number
25 by the Commissioner of Food and

1 Drugs and made available for the sub-
2 mission of public comments.

3 “(ii) SUBMISSION OF COMMENTS.—An
4 interested person may submit written com-
5 ments concerning such pediatric studies to
6 the Commissioner of Food and Drugs, and
7 the submitted comments shall become part
8 of the docket file with respect to each of
9 the drugs.”; and

10 (ii) in subparagraph (C), by striking
11 “appropriate action” and all that follows
12 through the period and inserting “action in
13 a timely and appropriate manner in re-
14 sponse to the reports submitted under sub-
15 paragraph (A), and shall begin such action
16 upon receipt of the report under subpara-
17 graph (A), in accordance with paragraph
18 (7).”; and

19 (B) in paragraph (7)—

20 (i) in the matter preceding subpara-
21 graph (A), by striking “During” and in-
22 serting “Within”;

23 (ii) in subparagraph (C)(i), by strik-
24 ing “place” and all that follows through
25 “and of” and inserting “include in the

1 public docket file a reference to the loca-
2 tion of the report on the internet website
3 of the National Institutes of Health and a
4 copy of”; and

5 (iii) in clause (ii), by striking “in the
6 Federal Register and”;

7 (3) by striking subsection (d);

8 (4) by redesignating subsection (e) as sub-
9 section (d); and

10 (5) in paragraph (1) of subsection (d), as so re-
11 designated, by striking “2013 through 2017” and
12 inserting “2018 through 2022”.

13 **SEC. 502. PEDIATRIC DEVICES.**

14 (a) PEDIATRIC USE OF DEVICES.—Section
15 515A(a)(3) of the Federal Food, Drug, and Cosmetic Act
16 (21 U.S.C. 360e–1(a)(3)) is amended—

17 (1) by redesignating subparagraphs (B)
18 through (D) as subparagraphs (D) through (F), re-
19 spectively;

20 (2) by inserting after subparagraph (A) the fol-
21 lowing:

22 “(B) any information, based on a review of
23 data available to the Secretary, regarding de-
24 vices used in pediatric patients but not labeled
25 for such use for which the Secretary determines

1 that approved pediatric labeling could confer a
2 benefit to pediatric patients;

3 “(C) the number of pediatric devices that
4 receive a humanitarian use exemption under
5 section 520(m);”;

6 (3) in subparagraph (E), as so redesignated, by
7 striking “; and” and inserting “;”;

8 (4) in subparagraph (F) (as so redesignated),
9 by striking “(B), and (C).” and inserting “(C), (D),
10 and (E);”; and

11 (5) by adding at the end the following:

12 “(G) the number of devices for which the
13 Secretary relied on data with respect to adults
14 to support a determination of a reasonable as-
15 surance of safety and effectiveness in pediatric
16 patients; and

17 “(H) the number of devices for which the
18 Secretary relied on data from one pediatric sub-
19 population to support a determination of a rea-
20 sonable assurance of safety and effectiveness in
21 another pediatric subpopulation.

22 For the items described in this paragraph, such re-
23 port shall disaggregate the number of devices by pe-
24 diatric subpopulation.”.

1 (b) HUMANITARIAN DEVICE EXEMPTION.—Section
2 520(m) of the Federal Food, Drug, and Cosmetic Act (21
3 U.S.C. 360j(m)) is amended—

4 (1) in paragraph (4)—

5 (A) in subparagraph (B), by inserting “or
6 an appropriate local committee” after “review
7 committee” each place such term appears; and

8 (B) in the matter following subparagraph
9 (B), by inserting “or an appropriate local com-
10 mittee” after “review committee” each place
11 such term appears; and

12 (2) in paragraph (6)(A)(iv), by striking “2017”
13 and inserting “2022”.

14 (c) DEMONSTRATION GRANTS FOR IMPROVING PEDI-
15 ATRIC AVAILABILITY.—Section 305 of the Pediatric Med-
16 ical Device Safety and Improvement Act of 2007 (Public
17 Law 110–85; 42 U.S.C. 282 note)) is amended—

18 (1) in subsection (c)—

19 (A) in paragraph (4), by striking “and” at
20 the end;

21 (B) in paragraph (5), by striking the pe-
22 riod and inserting “; and”; and

23 (C) by adding at the end the following:

1 “(6) providing regulatory consultation to device
2 sponsors in support of the submission of an applica-
3 tion for a pediatric device, where appropriate.”; and

4 (2) in subsection (e), by striking “2013 through
5 2017” and inserting “2018 through 2022”.

6 (d) MEETING ON PEDIATRIC DEVICE DEVELOP-
7 MENT.—

8 (1) IN GENERAL.—Not later than 1 year after
9 the date of enactment of this Act, the Secretary of
10 Health and Human Services shall convene a public
11 meeting on the development, approval or clearance,
12 and labeling of pediatric medical devices. The Sec-
13 retary shall invite to such meeting representatives
14 from the medical device industry, academia, recipi-
15 ents of funding under section 305 of the Pediatric
16 Medical Device Safety and Improvement Act of 2007
17 (Public Law 110–85; 42 U.S.C. 282 note), medical
18 provider organizations, and organizations rep-
19 resenting patients and consumers.

20 (2) TOPICS.—The meeting described in para-
21 graph (1) shall include consideration of ways to—

22 (A) improve research infrastructure and
23 research networks to facilitate the conduct of
24 clinical studies of devices for pediatric popu-
25 lations that would result in the approval or

1 clearance, and labeling, of medical devices for
2 such populations;

3 (B) appropriately use extrapolation under
4 section 515A(b) of the Federal Food, Drug,
5 and Cosmetic Act (21 U.S.C. 360e–1(b));

6 (C) enhance the appropriate use of
7 postmarket registries and data to increase pedi-
8 atric medical device labeling;

9 (D) increase Food and Drug Administra-
10 tion assistance to medical device manufacturers
11 in developing devices for pediatric populations
12 that are approved or cleared, and labeled, for
13 their use; and

14 (E) identify current barriers to pediatric
15 device development and incentives to address
16 such barriers.

17 (3) REPORT.—The report submitted under sec-
18 tion 515A(a)(3) of the Federal Food, Drug, and
19 Cosmetic Act (21 U.S.C. 360e–1(a)(3)) with respect
20 to the calendar year in which the meeting described
21 in paragraph (1) is held shall include a summary of,
22 and responses to, recommendations raised in such
23 meeting.

1 **SEC. 503. EARLY MEETING ON PEDIATRIC STUDY PLAN.**

2 (a) IN GENERAL.—Clause (i) of section
3 505B(e)(2)(C) of the Federal Food, Drug, and Cosmetic
4 Act (21 U.S.C. 355c(e)(2)(C)) is amended to read as fol-
5 lows:

6 “(i) shall meet with the applicant—
7 “(I) if requested by the applicant
8 with respect to a drug or biological
9 product that is intended to treat a se-
10 rious or life-threatening disease or
11 condition, to discuss preparation of
12 the initial pediatric study plan, not
13 later than the end-of-Phase 1 meeting
14 (as such term is used in section
15 312.82(b) of title 21, Code of Federal
16 Regulations, or successor regulations)
17 or within 30 calendar days of receipt
18 of such request, whichever is later;

19 “(II) to discuss the initial pedi-
20 atric study plan as soon as prac-
21 ticable, but not later than 90 calendar
22 days after the receipt of such plan
23 under subparagraph (A); and

24 “(III) to discuss the bases for the
25 deferral under subsection (a)(4) or a

1 full or partial waiver under subsection
2 (a)(5);”.

3 (b) CONFORMING CHANGES.—Section 505B(e) of the
4 Federal Food, Drug, and Cosmetic Act (21 U.S.C.
5 355c(e)) is amended—

6 (1) in the heading of paragraph (2), by striking
7 “MEETING” and inserting “MEETINGS”;

8 (2) in the heading of paragraph (2)(C), by
9 striking “MEETING” and inserting “MEETINGS”;

10 (3) in clauses (ii) and (iii) of paragraph (2)(C),
11 by striking “no meeting” each place it appears and
12 inserting “no meeting under clause (i)(II)”;

13 (4) in paragraph (3) by striking “meeting
14 under paragraph (2)(C)(i)” and inserting “meeting
15 under paragraph (2)(C)(i)(II)”.

16 **SEC. 504. DEVELOPMENT OF DRUGS AND BIOLOGICAL**
17 **PRODUCTS FOR PEDIATRIC CANCERS.**

18 (a) MOLECULAR TARGETS REGARDING CANCER
19 DRUGS AND BIOLOGICAL PRODUCTS.—Section 505B of
20 the Federal Food, Drug, and Cosmetic Act (21 U.S.C.
21 355c) is amended—

22 (1) in subsection (a)—

23 (A) in paragraph (1)—

24 (i) by redesignating subparagraphs

25 (A) and (B) as clauses (i) and (ii), respec-

1 tively, and adjusting the margins accord-
2 ingly;

3 (ii) by striking “A person” and insert-
4 ing the following:

5 “(A) GENERAL REQUIREMENTS.—Except
6 with respect to an application for which sub-
7 paragraph (B) applies, a person”;

8 (iii) in clause (i), as so redesignated,
9 by striking “, or” at the end and inserting
10 “; or”; and

11 (iv) by adding after subparagraph
12 (A), as so designated by clause (ii), the fol-
13 lowing:

14 “(B) CERTAIN MOLECULARLY TARGETED
15 CANCER INDICATIONS.—A person that submits,
16 on or after the date that is 3 years after the
17 date of enactment of the FDA Reauthorization
18 Act of 2017, an original application for a new
19 active ingredient under section 505 of this Act
20 or section 351 of the Public Health Service Act,
21 shall submit with the application reports on the
22 investigation described in paragraph (3) if the
23 drug or biological product that is the subject of
24 the application is—

1 “(i) intended for the treatment of an
2 adult cancer; and

3 “(ii) directed at a molecular target
4 that the Secretary determines to be sub-
5 stantially relevant to the growth or pro-
6 gression of a pediatric cancer.”;

7 (B) in paragraph (2)(A), by striking
8 “paragraph (1)” and inserting “paragraph
9 (1)(A)”;

10 (C) by redesignating paragraphs (3) and
11 (4) as paragraphs (4) and (5), respectively;

12 (D) by inserting after paragraph (2) the
13 following:

14 “(3) MOLECULARLY TARGETED PEDIATRIC
15 CANCER INVESTIGATION.—

16 “(A) IN GENERAL.—With respect to a
17 drug or biological product described in para-
18 graph (1)(B), the investigation described in this
19 paragraph is a molecularly targeted pediatric
20 cancer investigation, which shall be designed to
21 yield clinically meaningful pediatric study data,
22 gathered using appropriate formulations for
23 each age group for which the study is required,
24 regarding dosing, safety, and preliminary effi-
25 cacy to inform potential pediatric labeling.

1 “(B) EXTRAPOLATION OF DATA.—Para-
2 graph (2)(B) shall apply to investigations de-
3 scribed in this paragraph to the same extent
4 and in the same manner as paragraph (2)(B)
5 applies with respect to the assessments required
6 under paragraph (1)(A).

7 “(C) DEFERRALS AND WAIVERS.—Defer-
8 rals and waivers under paragraphs (4) and (5)
9 shall apply to investigations described in this
10 paragraph to the same extent and in the same
11 manner as such deferrals and waivers apply
12 with respect to the assessments under para-
13 graph (2)(B).”;

14 (E) in paragraph (4), as so redesignated—

15 (i) by striking “assessments required
16 under paragraph (1)” each place it ap-
17 pears and inserting “assessments required
18 under paragraph (1)(A) or reports on the
19 investigation required under paragraph
20 (1)(B)”;

21 (ii) in subparagraph (A)(ii)(I), by in-
22 sserting “or reports on the investigation”
23 after “assessments”;

24 (iii) in subparagraph (B)(ii), by strik-
25 ing “assessment under paragraph (1)” and

1 inserting “assessment under paragraph
2 (1)(A) or reports on the investigation
3 under paragraph (1)(B)”;

4 (iv) in subparagraph (C)(ii)(II), by in-
5 serting “or investigation” after “assess-
6 ment”;

7 (F) in paragraph (5), as so redesignated,
8 by inserting “or reports on the investigation”
9 after “assessments” each place it appears;
10 (2) in subsection (d)—

11 (A) by striking “subsection (a)(3)” each
12 place it appears and inserting “subsection
13 (a)(4)”;

14 (B) by inserting “AND REPORTS ON THE
15 INVESTIGATION” after “SUBMISSION OF AS-
16 SESSMENTS” in the heading; and

17 (C) by inserting “or the investigation de-
18 scribed in subsection (a)(3)” after “assessment
19 described in subsection (a)(2)” each place it ap-
20 pears;

21 (3) in subsection (e)—

22 (A) in paragraph (1), by inserting “or the
23 investigation described in subsection (a)(3)”
24 after “under subsection (a)(2)”;

1 (B) in paragraph (2)(A)(i), by inserting
2 “or the investigation described in subsection
3 (a)(3)” after “under subsection (a)(2)”; and
4 (4) by adding at the end the following:

5 “(m) LIST OF PRIMARY MOLECULAR TARGETS.—

6 “(1) IN GENERAL.—Within one year of the date
7 of enactment of the FDA Reauthorization Act of
8 2017, the Secretary shall establish and update regu-
9 larly, and shall publish on the internet website of the
10 Food and Drug Administration—

11 “(A) a list of molecular targets considered,
12 on the basis of data the Secretary determines to
13 be adequate, to be substantially relevant to the
14 growth and progression of a pediatric cancer,
15 and that may trigger the requirements under
16 this section; and

17 “(B) a list of molecular targets of new
18 cancer drugs and biological products in develop-
19 ment for which pediatric cancer study require-
20 ments under this section will be automatically
21 waived.

22 “(2) CONSULTATION.—In establishing the lists
23 described in paragraph (1), the Secretary shall con-
24 sult the National Cancer Institute, members of the
25 internal committee under section 505C, and the Pe-

1 diatric Oncology Subcommittee of the Oncologic
2 Drugs Advisory Committee, and shall take into ac-
3 count comments from the meeting under subsection
4 (c).

5 “(3) RULE OF CONSTRUCTION.—Nothing in
6 paragraph (1) shall be construed—

7 “(A) to require the inclusion of a molec-
8 ular target on the list published under such
9 paragraph as a condition for triggering the re-
10 quirements under subsection (a)(1)(B) with re-
11 spect to a drug or biological product directed at
12 such molecular target; or

13 “(B) to authorize the disclosure of con-
14 fidential commercial information, as prohibited
15 under section 301(j) of this Act or section 1905
16 of title 18, United States Code.”.

17 (b) ORPHAN DRUGS.—Section 505B(k) of the Fed-
18 eral Food, Drug, and Cosmetic Act (21 U.S.C. 355c(k))
19 is amended to read as follows:

20 “(k) RELATION TO ORPHAN DRUGS.—

21 “(1) IN GENERAL; EXEMPTION FOR ORPHAN IN-
22 DICATIONS.—Unless the Secretary requires other-
23 wise by regulation and except as provided in para-
24 graph (2), this section does not apply to any drug
25 or biological product for an indication for which or-

1 phan designation has been granted under section
2 526.

3 “(2) APPLICABILITY DESPITE ORPHAN DES-
4 IGNATION OF CERTAIN INDICATIONS.—This section
5 shall apply with respect to a drug or biological prod-
6 uct for which an indication has been granted orphan
7 designation under 526 if the investigation described
8 in subsection (a)(3) applies to the drug or biological
9 product as described in subsection (a)(1)(B).”.

10 (c) MEETING, CONSULTATION, AND GUIDANCE.—

11 (1) MEETING.—The Secretary of Health and
12 Human Services (referred to in this subsection as
13 the “Secretary”), acting through the Commissioner
14 of Food and Drugs and in collaboration with the Di-
15 rector of the National Cancer Institute, shall con-
16 vene a public meeting not later than 1 year after the
17 date of enactment of this Act to solicit feedback
18 from physicians and researchers (including pediatric
19 oncologists and rare disease specialists), patients,
20 and other stakeholders to provide input on develop-
21 ment of the guidance under paragraph (2) and the
22 list under subsection (m) of section 505B of the
23 Federal Food, Drug, and Cosmetic Act (21 U.S.C.
24 355c), as added by subsection (a). The Secretary
25 shall seek input at such meeting on—

1 (A) the data necessary to determine that
2 there is scientific evidence that a drug or bio-
3 logical product is directed at a molecular target
4 that is considered to be substantially relevant to
5 the growth or progression of a pediatric cancer;

6 (B) the data necessary to determine that
7 there is scientific evidence that a molecular tar-
8 get is considered to be substantially relevant to
9 the growth or progression of a pediatric cancer;

10 (C) the data needed to meet the require-
11 ment of conducting an investigation described
12 in section 505B(a)(3) of the Federal Food,
13 Drug, and Cosmetic Act, as amended by sub-
14 section (a);

15 (D) considerations when developing the list
16 under section 505B(m) of the Federal Food,
17 Drug, and Cosmetic Act that contains molec-
18 ular targets shared between different tumor
19 types;

20 (E) the process the Secretary shall utilize
21 to update regularly a list of molecular targets
22 that may trigger a pediatric study under section
23 505B of the Federal Food, Drug, and Cosmetic
24 Act, as so amended, and how often such up-
25 dates shall occur;

1 (F) how to overcome the challenges related
2 to pediatric cancer drug and biological product
3 development, including issues related to the eth-
4 ical, practical, and other barriers to conducting
5 clinical trials in pediatric cancer with small pa-
6 tient populations;

7 (G) scientific or operational challenges as-
8 sociated with performing an investigation de-
9 scribed in section 505B(a)(1)(B) of the Federal
10 Food, Drug, and Cosmetic Act, including the
11 effect on pediatric studies currently underway
12 in a pediatric patient population, treatment of
13 a pediatric patient population, and the ability to
14 complete adult clinical trials;

15 (H) the advantages and disadvantages of
16 innovative clinical trial designs in addressing
17 the development of cancer drugs or biological
18 products directed at molecular targets in pedi-
19 atric cancer patients;

20 (I) the ways in which the Secretary can
21 improve the current process outlined under sec-
22 tions 505A and 505B of the Federal Food,
23 Drug, and Cosmetic Act (21 U.S.C. 355a,
24 355c) to encourage additional research and de-
25 velopment of pediatric cancer treatments;

1 (J) the ways in which the Secretary might
2 streamline and improve the written request
3 process, including when studies contained in a
4 request under such section 505A are not fea-
5 sible due to the ethical, practical, or other bar-
6 riers to conducting clinical trials in pediatric
7 cancer populations;

8 (K) how the Secretary will facilitate col-
9 laboration among pediatric networks, academic
10 centers and experts in pediatric cancer to con-
11 duct an investigation described in such section
12 505B(a)(3);

13 (L) how the Secretary may facilitate col-
14 laboration among sponsors of same-in-class
15 drugs and biological products that would be
16 subject to the requirements for an investigation
17 under such section 505B based on shared mo-
18 lecular targets; and

19 (M) the ways in which the Secretary will
20 help to mitigate the risks, if any, of discour-
21 aging the research and development of orphan
22 drugs when implementing such section 505B as
23 amended.

24 (2) GUIDANCE.—Not later than 2 years after
25 the date of enactment of this Act, the Secretary, act-

1 ing through the Commissioner of Food and Drugs,
2 shall issue final guidance on implementation of the
3 amendments to section 505B of the Federal Food,
4 Drug, and Cosmetic Act (21 U.S.C. 355c) regarding
5 molecularly targeted cancer drugs made by this sec-
6 tion, including—

7 (A) the scientific criteria, types of data,
8 and regulatory considerations for determining
9 whether a molecular target is substantially rel-
10 evant to the growth or progression of a pedi-
11 atric cancer and would trigger an investigation
12 under section 505B of the Federal Food, Drug,
13 and Cosmetic Act, as amended;

14 (B) the process by which the Secretary will
15 engage with sponsors to discuss determinations,
16 investigation requirements, deferrals, waivers,
17 and any other issues that need to be resolved
18 to ensure that any required investigation based
19 on a molecular target can be reasonably con-
20 ducted;

21 (C) the scientific or operational challenges
22 for which the Secretary may issue deferrals or
23 waivers for an investigation described in sub-
24 section (a)(3) of such section 505B, including
25 adverse impacts on current pediatric studies un-

1 derway in a pediatric patient population, stud-
2 ies involving drugs designated as orphan drugs,
3 treatment of a pediatric patient population, or
4 the ability to complete adult clinical trials;

5 (D) how the Secretary and sponsors will
6 facilitate collaboration among pediatric net-
7 works, academic centers, and experts in pedi-
8 atric cancer to conduct an investigation de-
9 scribed in subsection (a)(3) of such section
10 505B;

11 (E) scientific and regulatory considerations
12 for study designs, including the applicability of
13 innovative clinical trial designs for pediatric
14 cancer drug and biological product develop-
15 ments under sections 505A and 505B of the
16 Federal Food, Drug, and Cosmetic Act (21
17 U.S.C. 355a, 355c);

18 (F) approaches to streamline and improve
19 the amendment process, including when studies
20 contained in a request under such section 505A
21 are not feasible due to the ethical, practical, or
22 other barriers to conducting clinical trials in pe-
23 diatric cancer populations;

24 (G) the process for submission of an initial
25 pediatric study plan for the investigation de-

1 scribed in section 505B(a)(3) of the Federal
2 Food, Drug, and Cosmetic Act (21 U.S.C.
3 355c(a)(3)), including the process for a sponsor
4 to meet and reach agreement with the Secretary
5 on the initial pediatric study plan; and

6 (H) considerations for implementation of
7 such section 505B, as so amended, and waivers
8 of the requirements of such section 505B with
9 regard to molecular targets for which several
10 drugs or biological products may be under in-
11 vestigation.

12 (d) REPORT TO CONGRESS.—Section 508(b) of the
13 Food and Drug Administration Safety and Innovation Act
14 (21 U.S.C. 355c–1(b)) is amended—

15 (1) in paragraph (10), by striking “; and” and
16 inserting “;”; and

17 (2) by striking paragraph (11) and inserting
18 the following:

19 “(11) an assessment of the impact of the
20 amendments to such section 505B made by the
21 FDA Reauthorization Act of 2017 on pediatric re-
22 search and labeling of drugs and biological products
23 and pediatric labeling of molecularly targeted drugs
24 and biological products for the treatment of cancer;

1 “(12) an assessment of the efforts of the Sec-
2 retary to implement the plan developed under sec-
3 tion 505C–1 of the Federal Food, Drug, and Cos-
4 metic Act, regarding earlier submission of pediatric
5 studies under sections 505A and 505B of such Act
6 and section 351(m) of the Public Health Service
7 Act, including—

8 “(A) the average length of time after the
9 approval of an application under section
10 505(b)(1) of the Federal Food, Drug, and Cos-
11 metic Act (21 U.S.C. 355(b)(1)) or section
12 351(a) of the Public Health Service Act (42
13 U.S.C. 262(a)) before studies conducted pursu-
14 ant to such section 505A, 505B, or section
15 351(m) are completed, submitted, and incor-
16 porated into labeling;

17 “(B) the average length of time after the
18 receipt of a proposed pediatric study request be-
19 fore the Secretary responds to such request;

20 “(C) the average length of time after the
21 submission of a proposed pediatric study re-
22 quest before the Secretary issues a written re-
23 quest for such studies;

24 “(D) the number of written requests issued
25 for each investigational new drug or biological

1 product prior to the submission of an applica-
2 tion under section 505(b)(1) of the Federal
3 Food, Drug, and Cosmetic Act or section
4 351(a) of the Public Health Service Act; and

5 “(E) the average number, and range of
6 numbers, of amendments to written requests
7 issued, and the time the Secretary requires to
8 review and act on proposed amendments to
9 written requests;

10 “(13) a list of sponsors of applications or hold-
11 ers of approved applications who received exclusivity
12 under such section 505A or such section 351(m)
13 after receiving a letter issued under such section
14 505B(d)(1) for any drug or biological product before
15 the studies referred to in such letter were completed
16 and submitted;

17 “(14) a list of assessments and investigations
18 required under such section 505B;

19 “(15) how many requests under such section
20 505A for molecular targeted cancer drugs, as de-
21 fined by subsection (a)(1)(B) of such section 505B,
22 approved prior to 3 years after the date of enact-
23 ment of the FDA Reauthorization Act of 2017, have
24 been issued by the Food and Drug Administration,

1 and how many such requests have been completed;
2 and

3 “(16) the Secretary’s assessment of the overall
4 impact of the amendments made by section 504 of
5 the FDA Reauthorization Act of 2017 on the con-
6 duct and effectiveness of pediatric cancer research
7 and the orphan drug program, as well any subse-
8 quent recommendations.”.

9 (e) RULE OF CONSTRUCTION.—Nothing in this sec-
10 tion, including the amendments made by this section, shall
11 limit the authority of the Secretary of Health and Human
12 Services to issue written requests under section 505A of
13 the Federal Food, Drug, and Cosmetic Act (21 U.S.C.
14 355a) or section 351(m) of the Public Health Service Act
15 (42 U.S.C. 262(m)), or to negotiate or implement amend-
16 ments to such requests proposed by the an applicant.

17 (f) GAO REPORT.—

18 (1) IN GENERAL.—Beginning on the date that
19 is 5 years after the date of enactment of this Act,
20 the Comptroller General of the United States shall
21 conduct a study of the effectiveness of requiring as-
22 sessments and investigations described in section
23 505B of the Federal Food, Drug, and Cosmetic Act
24 (21 U.S.C. 355e), as amended by this section, in the
25 development of drugs and biological products for pe-

1 diatric cancer indications. The Comptroller General
2 shall examine—

3 (A) the indications and associated molec-
4 ular targets studied in assessments and inves-
5 tigations required for drugs or biological prod-
6 ucts intended for the treatment of an adult can-
7 cer;

8 (B) the indication for which the study was
9 requested as compared to the indication re-
10 quested under the new drug application filed by
11 the sponsor;

12 (C) the number of pediatric cancer indica-
13 tions for which assessments and investigations
14 have been required under such section 505B;

15 (D) the number of requests for deferral
16 and waiver of pediatric assessments and inves-
17 tigations required under such section and the
18 number of such deferral and waiver requests
19 granted and denied;

20 (E) the number of orphan-designated indi-
21 cations for drugs and biological products for
22 which assessments and investigations were re-
23 quired under such section;

24 (F) the number of drugs and biological
25 products approved for the treatment of cancer

1 in the pediatric population for which the sup-
2 portive studies were required to be conducted
3 under such section;

4 (G) the number of written requests made
5 under section 505A of the Federal Food, Drug,
6 and Cosmetic Act (21 U.S.C. 355a) relating to
7 investigations required under subsection
8 (a)(1)(B) of such section 505B; and

9 (H) any additional considerations by the
10 Secretary regarding the effectiveness of requir-
11 ing pediatric assessments described in such sec-
12 tion 505B in the development of drugs and bio-
13 logical products for pediatric cancer indications.

14 (2) REVIEW.—The study under paragraph (1)
15 shall include a review of the Food and Drug Admin-
16 istration’s use of the authority under section 505B
17 of the Federal Food, Drug, and Cosmetic Act (21
18 U.S.C. 355e), as amended by this section, including
19 the amendments to the deferral and waiver criteria
20 under such section and how such criteria have been
21 applied.

22 (3) CONSULTATION.—In conducting the study
23 under paragraph (1), the Comptroller General of the
24 United States shall consult with appropriate stake-
25 holders that may be required to conduct the trials

1 under section 505B of the Federal Food, Drug, and
2 Cosmetic Act, and the ability of such stakeholders to
3 adhere to the requests issued by the Food and Drug
4 Administration.

5 (4) REPORT.—Not later than the date that is
6 6 years after the date of enactment of this Act, the
7 Comptroller General of the United States shall sub-
8 mit a report containing the results of the study
9 under paragraph (1) to the Secretary of Health and
10 Human Services, the Committee on Health, Edu-
11 cation, Labor, and Pensions of the Senate, and the
12 Committee on Energy and Commerce of the House
13 of Representatives.

14 **SEC. 505. ADDITIONAL PROVISIONS ON DEVELOPMENT OF**
15 **DRUGS AND BIOLOGICAL PRODUCTS FOR PE-**
16 **DIATRIC USE.**

17 (a) INFORMING INTERNAL REVIEW COMMITTEE.—
18 Section 505A(f) of the Federal Food, Drug, and Cosmetic
19 Act (21 U.S.C. 355a(f)) is amended by adding at the end
20 the following:

21 “(7) INFORMING INTERNAL REVIEW COM-
22 MITTEE.—The Secretary shall provide to the com-
23 mittee referred to in paragraph (1) any response
24 issued to an applicant or holder with respect to a
25 proposed pediatric study request.”.

1 (b) ACTION ON SUBMISSIONS.—

2 (1) IN GENERAL.—Section 505A(d) of the Fed-
3 eral Food, Drug, and Cosmetic Act (21 U.S.C.
4 355a(d)) is amended—

5 (A) by redesignating paragraphs (3)
6 through (5) as paragraphs (4) through (6), re-
7 spectively; and

8 (B) by inserting after paragraph (2) the
9 following:

10 “(3) ACTION ON SUBMISSIONS.—The Secretary
11 shall review and act upon a submission by a sponsor
12 or holder of a proposed pediatric study request or a
13 proposed amendment to a written request for pedi-
14 atric studies within 120 calendar days of the sub-
15 mission.”.

16 (2) CONFORMING AMENDMENTS.—

17 (A) FEDERAL FOOD, DRUG, AND COSMETIC
18 ACT.—Section 505A of the Federal Food, Drug,
19 and Cosmetic Act (21 U.S.C. 355a), as amend-
20 ed by paragraph (1), is further amended by
21 striking subsection “(d)(3)” each place it ap-
22 pears and inserting “(d)(4)”.

23 (B) PUBLIC HEALTH SERVICE ACT.—Para-
24 graphs (2), (3), and (4) of section 351(m) of
25 the Public Health Service Act (42 U.S.C.

1 262(m)) are amended by striking “section
2 505A(d)(3)” each place it appears and inserting
3 “section 505A(d)(4)”.

4 (c) PLAN.—The Secretary of Health and Human
5 Services, acting through the internal review committee es-
6 tablished under section 505C of the Federal Food, Drug,
7 and Cosmetic Act (21 U.S.C. 355d) shall, not later than
8 one year after the date of enactment of this Act, develop
9 and implement a plan to achieve, when appropriate, earlier
10 submission of pediatric studies under section 505A of the
11 Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355a)
12 or section 351(m) of the Public Health Service Act (42
13 U.S.C. 262(m)). Such plan shall include recommendations
14 to achieve—

15 (1) earlier discussion of proposed pediatric
16 study requests and written requests with sponsors,
17 and if appropriate, discussion of such requests at the
18 meeting required under section 505B(e)(2)(C) of the
19 Federal Food, Drug, and Cosmetic Act (21 U.S.C.
20 355c(e)(2)(C)), as amended by section 503(a);

21 (2) earlier issuance of written requests for a pe-
22 diatric study under such section 505A, including for
23 investigational new drugs prior to the submission of
24 an application under section 505(b)(1) of such Act
25 (21 U.S.C. 355(b)(1)); and

1 (3) shorter timelines, when appropriate, for the
2 completion of studies pursuant to a written request
3 under such section 505A or such section 351(m).

4 (d) NEONATOLOGY EXPERTISE.—

5 (1) IN GENERAL.—Section 6(d) of the Best
6 Pharmaceuticals for Children Act (21 U.S.C.
7 393a(d)) is amended by striking “For the 5-year pe-
8 riod beginning on the date of enactment of this sub-
9 section, at” and inserting “At”.

10 (2) DRAFT GUIDANCE.—Not later than 2 years
11 after the date of enactment of this Act, the Sec-
12 retary shall issue draft guidance on clinical pharma-
13 cology considerations for neonatal studies for drugs
14 and biological products.

15 (e) SUBMISSION OF ASSESSMENTS.—Section
16 505B(d)(1) of the Federal Food, Drug, and Cosmetic Act
17 (21 U.S.C. 355c(d)(1)) is amended by adding at the end
18 the following: “The Secretary shall inform the Pediatric
19 Advisory Committee of letters issued under this paragraph
20 and responses to such letters.”.

21 (f) INTERNAL COMMITTEE.—Section 505C of the
22 Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355d)
23 is amended by inserting “or pediatric rare diseases” after
24 “psychiatry”.

25 (g) REPORT ON LABELING OF ORPHAN DRUGS.—

1 (1) IN GENERAL.—Not later than 2 years after
2 the date of the enactment of this Act, the Secretary
3 of Health and Human Services shall submit to the
4 Committee on Health, Education, Labor and Pen-
5 sions of the Senate and the Committee on Energy
6 and Commerce of the House of Representatives, and
7 make publicly available, including through posting
8 on the internet website of the Food and Drug Ad-
9 ministration, a report on the lack of information in
10 the labeling of drugs for indications that have re-
11 ceived an orphan designation under section 526 of
12 the Federal Food, Drug, and Cosmetic Act (21
13 U.S.C. 360bbb) with respect to the use of such
14 drugs pediatric populations.

15 (2) CONTENTS.—The report described in para-
16 graph (1) shall include—

17 (A) a list of drugs for which—

18 (i) an indication was granted an or-
19 phan designation under section 526 of the
20 Federal Food, Drug, and Cosmetic Act (21
21 U.S.C. 360bbb);

22 (ii) an application described under
23 section 505B(a)(1) of the Federal Food,
24 Drug, and Cosmetic Act (21 U.S.C.
25 355c(a)(1)) for such indication was sub-

1 mitted to the Secretary of Health and
2 Human Services on or after April 1, 1999;
3 and

4 (iii) the labeling for such indication
5 lacks important pediatric information, in-
6 cluding information related to safety, dos-
7 ing, and effectiveness;

8 (B) a description of the lack of information
9 referred to in subparagraph (A)(iii) for each
10 drug for an indication on such list; and

11 (C) Federal policy recommendations to im-
12 prove the labeling of drugs for indications that
13 have received an orphan designation under such
14 section 526 with respect to the use of such
15 drugs pediatric populations.”

16 **TITLE VI—REAUTHORIZATIONS**
17 **AND IMPROVEMENTS RE-**
18 **LATED TO DRUGS**

19 **SEC. 601. REAUTHORIZATION OF PROVISION RELATING TO**
20 **EXCLUSIVITY OF CERTAIN DRUGS CON-**
21 **TAINING SINGLE ENANTIOMERS.**

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

1 **SEC. 602. REAUTHORIZATION OF THE CRITICAL PATH PUB-**
2 **LIC-PRIVATE PARTNERSHIPS.**

3 Section 566(f) of the Federal Food, Drug, and Cos-
4 metic Act (21 U.S.C. 360bbb–5(f)) is amended by striking
5 “2013 through 2017” and inserting “2018 through
6 2022”.

7 **SEC. 603. REAUTHORIZATION OF ORPHAN GRANTS PRO-**
8 **GRAM.**

9 Section 5(c) of the Orphan Drug Act (21 U.S.C.
10 360ee(e)) is amended by striking “2013 through 2017”
11 and inserting “2018 through 2022”.

12 **SEC. 604. PROTECTING AND STRENGTHENING THE DRUG**
13 **SUPPLY CHAIN.**

14 (a) **DIVERTED DRUGS.**—Paragraph (1) of section
15 801(d) of the Federal Food, Drug, and Cosmetic Act (21
16 U.S.C. 381(d)) is amended—

17 (1) by striking “(d)(1) Except as” and insert-
18 ing “(d)(1)(A) Except as”; and

19 (2) by adding at the end the following:

20 “(B) Except as authorized by the Secretary in the
21 case of a drug that appears on the drug shortage list
22 under section 506E or in the case of importation pursuant
23 to section 804, no drug that is subject to section 503(b)(1)
24 may be imported into the United States for commercial
25 use if such drug is manufactured outside the United
26 States, unless the manufacturer has authorized the drug

1 to be marketed in the United States and has caused the
2 drug to be labeled to be marketed in the United States.”.

3 (b) COUNTERFEIT DRUGS.—Subsection (b) of section
4 303 of the Federal Food, Drug, and Cosmetic Act (21
5 U.S.C. 333) is amended by adding at the end the fol-
6 lowing:

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

13 **SEC. 605. PATIENT EXPERIENCE DATA.**

14 Section 569C(c)(2)(A) of the Federal Food, Drug,
15 and Cosmetic Act (21 U.S.C. 360bbb–8c(c)(2)(A)) is
16 amended by striking “impact of such disease or condition,
17 or a related therapy,” and inserting “impact (including
18 physical and psychosocial impacts) of such disease or con-
19 dition, or a related therapy or clinical investigation”.

20 **SEC. 606. COMMUNICATION PLANS.**

21 Section 505–1(e)(3) of the Federal Food, Drug, and
22 Cosmetic Act (21 U.S.C. 355–1(e)(3)) is amended—

23 (1) in subparagraph (B), by striking “; or”;

24 (2) in subparagraph (C), by striking the period

25 and inserting “; or”; and

1 (3) by adding at the end the following:

2 “(D) disseminating information to health
3 care providers about drug formulations or prop-
4 erties, including information about the limita-
5 tions or patient care implications of such for-
6 mulations or properties, and how such formula-
7 tions or properties may be related to serious ad-
8 verse drug events associated with use of the
9 drug.”.

10 **SEC. 607. ORPHAN DRUGS.**

11 (a) IN GENERAL.—Section 527 of the Federal Food,
12 Drug, and Cosmetic Act (21 U.S.C. 360cc) is amended—

13 (1) in subsection (a), in the matter following
14 paragraph (2), by striking “such drug for such dis-
15 ease or condition” and inserting “the same drug for
16 the same disease or condition”;

17 (2) in subsection (b)—

18 (A) in the matter preceding paragraph (1),
19 by striking “If an application” and all that fol-
20 lows through “such license if” and inserting
21 “During the 7-year period described in sub-
22 section (a) for an approved application under
23 section 505 or license under section 351 of the
24 Public Health Service Act, the Secretary may
25 approve an application or issue a license for a

1 drug that is otherwise the same, as determined
2 by the Secretary, as the already approved drug
3 for the same rare disease or condition if”;

4 (B) in paragraph (1), by striking “notice”
5 and all that follows through “assure” and in-
6 serting “of exclusive approval or licensure no-
7 tice and opportunity for the submission of
8 views, that during such period the holder of the
9 exclusive approval or licensure cannot ensure”;
10 and

11 (C) in paragraph (2), by striking “such
12 holder provides” and inserting “the holder pro-
13 vides”; and

14 (3) by adding at the end the following:

15 “(c) CONDITION OF CLINICAL SUPERIORITY.—

16 “(1) IN GENERAL.—If a sponsor of a drug that
17 is designated under section 526 and is otherwise the
18 same, as determined by the Secretary, as an already
19 approved or licensed drug is seeking exclusive ap-
20 proval or exclusive licensure described in subsection
21 (a) for the same rare disease or condition as the al-
22 ready approved drug, the Secretary shall require
23 such sponsor, as a condition of such exclusive ap-
24 proval or licensure, to demonstrate that such drug is

1 clinically superior to any already approved or li-
2 censed drug that is the same drug.

3 “(2) DEFINITION.—For purposes of paragraph
4 (1), the term ‘clinically superior’ with respect to a
5 drug means that the drug provides a significant
6 therapeutic advantage over and above an already ap-
7 proved or licensed drug in terms of greater efficacy,
8 greater safety, or by providing a major contribution
9 to patient care.

10 “(d) REGULATIONS.—The Secretary may promulgate
11 regulations for the implementation of subsection (c). Be-
12 ginning on the date of enactment of the FDA Reauthor-
13 ization Act of 2017, until such time as the Secretary pro-
14 mulgates regulations in accordance with this subsection,
15 the Secretary may apply any definitions set forth in regu-
16 lations that were promulgated prior to such date of enact-
17 ment, to the extent such definitions are not inconsistent
18 with the terms of this section, as amended by such Act.

19 “(e) DEMONSTRATION OF CLINICAL SUPERIORITY
20 STANDARD.—To assist sponsors in demonstrating clinical
21 superiority as described in subsection (c), the Secretary—

22 “(1) upon the designation of any drug under
23 section 526, shall notify the sponsor of such drug in
24 writing of the basis for the designation, including, as
25 applicable, any plausible hypothesis offered by the

1 sponsor and relied upon by the Secretary that the
2 drug is clinically superior to a previously approved
3 drug; and

4 “(2) upon granting exclusive approval or licen-
5 sure under subsection (a) on the basis of a dem-
6 onstration of clinical superiority as described in sub-
7 section (c), shall publish a summary of the clinical
8 superiority findings.”.

9 (b) **RULE OF CONSTRUCTION.**—Nothing in the
10 amendments made by subsection (a) shall affect any deter-
11 mination under sections 526 and 527 of the Federal Food,
12 Drug, and Cosmetic Act (21 U.S.C. 360bb, 360cc) made
13 prior to the date of enactment of the FDA Reauthoriza-
14 tion Act of 2017.

15 **SEC. 608. PEDIATRIC INFORMATION ADDED TO LABELING.**

16 Section 505A(o) of the Federal Food, Drug, and Cos-
17 metic Act (21 U.S.C. 355a(o)) is amended—

18 (1) in the subsection heading, by striking

19 “**UNDER SECTION 505(j)**”;

20 (2) in paragraph (1)—

21 (A) by striking “under section 505(j)” and
22 inserting “under subsection (b)(2) or (j) of sec-
23 tion 505”; and

24 (B) by striking “or by exclusivity under
25 clause (iii) or (iv) of section 505(j)(5)(F)” and

1 inserting “, or by exclusivity under clause (iii)
2 or (iv) of section 505(j)(5)(F), clause (iii) or
3 (iv) of section 505(c)(3)(E), or section 527(a),
4 or by an extension of such exclusivity under this
5 section or section 505E”;

6 (3) in paragraph (2), in the matter preceding
7 subparagraph (A)—

8 (A) by inserting “clauses (iii) and (iv) of
9 section 505(c)(3)(E), or section 527,” after
10 “section 505(j)(5)(F),”; and

11 (B) by striking “drug approved under sec-
12 tion 505(j)” and inserting “drug approved pur-
13 suant to an application submitted under sub-
14 section (b)(2) or (j) of section 505”; and

15 (4) by amending paragraph (3) to read as fol-
16 lows:

17 “(3) PRESERVATION OF PEDIATRIC EXCLU-
18 SIVITY AND EXTENSIONS.—This subsection does not
19 affect—

20 “(A) the availability or scope of exclusivity
21 under—

22 “(i) this section;

23 “(ii) section 505 for pediatric formu-
24 lations; or

25 “(iii) section 527;

1 “(B) the availability or scope of an exten-
2 sion to any such exclusivity, including an exten-
3 sion under this section or section 505E;

4 “(C) the question of the eligibility for ap-
5 proval under section 505 of any application de-
6 scribed in subsection (b)(2) or (j) of such sec-
7 tion that omits any other aspect of labeling pro-
8 tected by exclusivity under—

9 “(i) clause (iii) or (iv) of section
10 505(j)(5)(F);

11 “(ii) clause (iii) or (iv) of section
12 505(e)(3)(E); or

13 “(iii) section 527(a); or

14 “(D) except as expressly provided in para-
15 graphs (1) and (2), the operation of section 505
16 or section 527.”.

17 **SEC. 609. SENSE OF CONGRESS ON LOWERING THE COST**
18 **OF PRESCRIPTION DRUGS.**

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

1 (1) will lower the cost of prescription drugs for
2 consumers and reduce the burden of such cost on
3 taxpayers; and

4 (2) in lowering such cost, will—

5 (A) balance the need to encourage innova-
6 tion with the need to improve affordability; and

7 (B) strive to increase competition in the
8 pharmaceutical market, prevent anticompetitive
9 behavior, and promote the timely availability of
10 affordable, high-quality generic drugs and
11 biosimilars.

12 **SEC. 610. EXPANDED ACCESS.**

13 (a) PATIENT ACCESS TO INVESTIGATIONAL
14 DRUGS.—

15 (1) PUBLIC MEETING.—

16 (A) IN GENERAL.—The Secretary of
17 Health and Human Services (referred to in this
18 section as the “Secretary”), acting through the
19 Commissioner of Food and Drugs, in coordina-
20 tion with the Director of the National Institutes
21 of Health, and in consultation with patients,
22 health care providers, drug sponsors,
23 bioethicists, and other stakeholders, shall, not
24 later than 270 days after the date of enactment
25 of this Act, convene a public meeting to discuss

1 clinical trial inclusion and exclusion criteria to
2 inform the guidance under paragraph (3). The
3 Secretary shall inform the Comptroller General
4 of the United States of the date when the pub-
5 lic meeting will take place.

6 (B) TOPICS.—The Secretary shall make
7 available on the internet website of the Food
8 and Drug Administration a report on the topics
9 discussed at the meeting described in subpara-
10 graph (A) within 90 days of such meeting. Such
11 topics shall include discussion of—

12 (i) the rationale for, and potential
13 barriers for patients created by, research
14 clinical trial inclusion and exclusion cri-
15 teria;

16 (ii) how appropriate patient popu-
17 lations can benefit from the results of
18 trials that employ alternative designs;

19 (iii) barriers to participation in clin-
20 ical trials, including—

21 (I) information regarding any po-
22 tential risks and benefits of participa-
23 tion;

24 (II) regulatory, geographical, and
25 socioeconomic barriers; and

1 (III) the impact of exclusion cri-
2 teria on the enrollment in clinical
3 trials of particular populations, in-
4 cluding infants and children, pregnant
5 and lactating women, seniors, individ-
6 uals with advanced disease, and indi-
7 viduals with co-morbid conditions;

8 (iv) clinical trial designs and methods,
9 including expanded access trials, that in-
10 crease enrollment of more diverse patient
11 populations, when appropriate, while facili-
12 tating the collection of data to establish
13 safe use and support substantial evidence
14 of effectiveness, including data obtained
15 from expanded access trials; and

16 (v) how changes to clinical trial inclu-
17 sion and exclusion criteria may impact the
18 complexity and length of clinical trials, the
19 data necessary to demonstrate safety and
20 effectiveness, and potential approaches to
21 mitigating those impacts.

22 (2) REPORT.—Not later than 1 year after the
23 Secretary issues the report under paragraph (1)(B),
24 the Comptroller General of the United States shall
25 report to the Committee on Health, Education,

1 Labor, and Pensions of the Senate and the Com-
2 mittee on Energy and Commerce of the House of
3 Representatives on individual access to investiga-
4 tional drugs through the expanded access program
5 under section 561(b) of the Federal Food, Drug,
6 and Cosmetic Act (21 U.S.C. 360bbb(b)). The re-
7 port shall include—

8 (A) a description of actions taken by man-
9 ufacturers and distributors under section 561A
10 of the Federal Food, Drug, and Cosmetic Act
11 (21 U.S.C. 360bbb-0);

12 (B) consideration of whether Form FDA
13 3926 and the guidance documents titled “Ex-
14 panded Access to Investigational Drugs for
15 Treatment Use—Questions and Answers” and
16 “Individual Patient Expanded Access Applica-
17 tions: Form FDA 3926”, issued by the Food
18 and Drug Administration in June 2016, have
19 reduced application burden with respect to indi-
20 viduals and physicians seeking access to inves-
21 tigational new drugs pursuant to section 561(b)
22 of the Federal Food, Drug, and Cosmetic Act
23 (21 U.S.C. 360bbb) and improved clarity for
24 patients, physicians, and drug manufacturers
25 about such process;

1 (C) consideration of whether the guidance
2 or regulations issued to implement section 561
3 of the Federal Food, Drug, and Cosmetic Act
4 (21 U.S.C. 360bbb) have improved access for
5 individual patients to investigational drugs who
6 do not qualify for clinical trials of such inves-
7 tigational drugs, and what barriers to such ac-
8 cess remain;

9 (D) an assessment of methods patients and
10 health care providers use to engage with the
11 Food and Drug Administration or drug spon-
12 sors on expanded access; and

13 (E) an analysis of the Secretary's report
14 under paragraph (1)(B).

15 (3) GUIDANCE.—

16 (A) IN GENERAL.—Not later than 1 year
17 after the publication of the report under para-
18 graph (1)(B), the Secretary, acting through the
19 Commissioner of Food and Drugs, shall issue
20 one or more draft guidances regarding eligi-
21 bility criteria for clinical trials. Not later than
22 1 year after the public comment period on each
23 such draft guidance ends, the Secretary shall
24 issue a revised draft guidance or final guidance.

1 (B) CONTENTS.—The guidance documents
2 described in subparagraph (A) shall address
3 methodological approaches that a manufacturer
4 or sponsor of an investigation of a new drug
5 may take to—

6 (i) broaden eligibility criteria for clin-
7 ical trials and expanded access trials, espe-
8 cially with respect to drugs for the treat-
9 ment of serious and life-threatening condi-
10 tions or diseases for which there is an
11 unmet medical need;

12 (ii) develop eligibility criteria for, and
13 increase trial recruitment to, clinical trials
14 so that enrollment in such trials more ac-
15 curately reflects the patients most likely to
16 receive the drug, as applicable and as ap-
17 propriate, while establishing safe use and
18 supporting findings of substantial evidence
19 of effectiveness; and

20 (iii) use the criteria described in
21 clauses (i) and (ii) in a manner that is ap-
22 propriate for drugs intended for the treat-
23 ment of rare diseases or conditions.

24 (b) IMPROVING INSTITUTIONAL REVIEW BOARD RE-
25 VIEW OF SINGLE PATIENT EXPANDED ACCESS PRO-

1 TOCOL.—Not later than 1 year after the date of enactment
2 of this Act, the Secretary, acting through the Commis-
3 sioner of Food and Drugs, shall issue guidance or regula-
4 tions, or revise existing guidance or regulations, to stream-
5 line the institutional review board review of individual pa-
6 tient expanded access protocols submitted under 561(b)
7 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C.
8 360bbb(b)). To facilitate the use of expanded access proto-
9 cols, any guidance or regulations so issued or revised may
10 include a description of the process for any person acting
11 through a physician licensed in accordance with State law
12 to request that an institutional review board chair (or des-
13 ignated member of the institutional review board) review
14 a single patient expanded access protocol submitted under
15 such section 561(b) for a drug. The Secretary shall update
16 any relevant forms associated with individual patient ex-
17 panded access requests under such section 561(b) as nec-
18 essary.

19 (c) EXPANDED ACCESS POLICY TRANSPARENCY.—
20 Section 561A(f) of the Federal Food, Drug, and Cosmetic
21 Act (21 U.S.C. 360bbb–0(f)) is amended—

22 (1) in the matter preceding paragraph (1), by
23 striking “later” and inserting “earlier”;

24 (2) by striking paragraph (1);

1 (3) by redesignating paragraph (2) as para-
2 graph (1);

3 (4) in paragraph (1) as so redesignated, by
4 striking the period at the end and inserting “; or”;
5 and

6 (5) by adding at the end the following:

7 “(2) as applicable, 15 days after the drug re-
8 ceives a designation as a breakthrough therapy, fast
9 track product, or regenerative advanced therapy
10 under subsection (a), (b), or (g), respectively, of sec-
11 tion 506.”.

12 **SEC. 611. TROPICAL DISEASE PRODUCT APPLICATION.**

13 (a) IN GENERAL.—Subparagraph (A) of section
14 524(a)(4) of the Federal Food, Drug, and Cosmetic Act
15 (21 U.S.C. 360n(a)(4)) is amended—

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

18 (2) by adding at the end the following:

19 “(iii) that contains reports of one or
20 more new clinical investigations (other
21 than bioavailability studies) that are essen-
22 tial to the approval of the application and
23 conducted or sponsored by the sponsor of
24 such application; and

1 “(iv) that contains an attestation
2 from the sponsor of the application that
3 such reports were not submitted as part of
4 an application for marketing approval or li-
5 censure by a regulatory authority in India,
6 Brazil, Thailand, or any country that is a
7 member of the Pharmaceutical Inspection
8 Convention or the Pharmaceutical Inspec-
9 tion Cooperation Scheme prior to Sep-
10 tember 27, 2007.”.

11 (b) **EFFECTIVE DATE.**—The amendments made by
12 subsection (a) shall apply to human drug applications sub-
13 mitted after September 30, 2017.

14 **TITLE VII—DEVICE INSPECTION**
15 **AND REGULATORY IMPROVE-**
16 **MENTS**

17 **SEC. 701. RISK-BASED INSPECTIONS FOR DEVICES.**

18 (a) **IN GENERAL.**—Section 510(h) of the Federal
19 Food, Drug, and Cosmetic Act (21 U.S.C. 360(h)) is
20 amended—

21 (1) by striking paragraph (2) and inserting the
22 following:

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

24 “(A) **IN GENERAL.**—The Secretary, acting
25 through one or more officers or employees duly

1 designated by the Secretary, shall inspect estab-
2 lishments described in paragraph (1) that are
3 engaged in the manufacture, propagation,
4 compounding, or processing of a device or de-
5 vices (referred to in this subsection as ‘device
6 establishments’) in accordance with a risk-based
7 schedule established by the Secretary.

8 “(B) FACTORS AND CONSIDERATIONS.—In
9 establishing the risk-based schedule under sub-
10 paragraph (A), the Secretary shall—

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

14 “(ii) consider the participation of the
15 device establishment, as applicable, in
16 international device audit programs in
17 which the United States participates or the
18 United States recognizes for purposes of
19 inspecting device establishments.”; and

20 (2) in paragraph (4)—

21 (A) in the matter preceding subparagraph
22 (A), by striking “paragraph (3)” and inserting
23 “paragraph (2) or (3)”; and

24 (B) in subparagraph (C), by inserting “or
25 device” after “drug”.

1 (b) FOREIGN INSPECTIONS.—Section 809(a)(1) of
2 the Federal Food, Drug, and Cosmetic Act (21 U.S.C.
3 384e(a)(1)) is amended by striking “section 510(h)(3)”
4 and inserting “paragraph (2) or (3) of section 510(h)”.

5 **SEC. 702. IMPROVEMENTS TO INSPECTIONS PROCESS FOR**
6 **DEVICE ESTABLISHMENTS.**

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

10 “(h)(1) In the case of inspections other than for-
11 cause inspections, the Secretary shall review processes and
12 standards applicable to inspections of domestic and for-
13 eign device establishments in effect as of the date of the
14 enactment of this subsection, and update such processes
15 and standards through the adoption of uniform processes
16 and standards applicable to such inspections. Such uni-
17 form processes and standards shall provide for—

18 “(A) exceptions to such processes and stand-
19 ards, as appropriate;

20 “(B) announcing the inspection of the establish-
21 ment within a reasonable time before such inspection
22 occurs, including by providing to the owner, oper-
23 ator, or agent in charge of the establishment a noti-
24 fication regarding the type and nature of the inspec-
25 tion;

1 “(C) a reasonable estimate of the timeframe for
2 the inspection, an opportunity for advance commu-
3 nications between the officers or employees carrying
4 out the inspection under subsection (a)(1) and the
5 owner, operator, or agent in charge of the establish-
6 ment concerning appropriate working hours during
7 the inspection, and, to the extent feasible, advance
8 notice of some records that will be requested; and

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

14 “(2)(A) The Secretary shall, with respect to a request
15 described in subparagraph (B), provide nonbinding feed-
16 back with respect to such request not later than 45 days
17 after the Secretary receives such request.

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

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

23 “(ii) with respect to actions proposed to be
24 taken by a device establishment in a response to a
25 report received by such establishment pursuant to

1 subsection (b) that involve a public health priority,
2 that implicate systemic or major actions, or relate to
3 emerging safety issues (as determined by the Sec-
4 retary).

5 “(3) Nothing in this subsection affects the authority
6 of the Secretary to conduct inspections otherwise per-
7 mitted under this Act in order to ensure compliance with
8 this Act.”.

9 (b) GUIDANCE.—

10 (1) DRAFT GUIDANCE.—Not later than 18
11 months after the date of enactment of this Act, the
12 Secretary of Health and Human Services, acting
13 through the Commissioner of Food and Drugs, shall
14 issue draft guidance that—

15 (A) specifies how the Food and Drug Ad-
16 ministration will implement the processes and
17 standards described in paragraph (1) of sub-
18 section (h) of section 704 of the Federal Food,
19 Drug, and Cosmetic Act (21 U.S.C. 374), as
20 added by subsection (a), and the requirements
21 described in paragraph (2) of such subsection
22 (h);

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

1 (C) establishes, with respect to inspections
2 of both domestic and foreign device establish-
3 ments (as referred to in section 510(h)(2) of
4 the Federal Food, Drug, and Cosmetic Act, as
5 amended by subsection (a)), a standard time-
6 frame for such inspections—

7 (i) that occurs over consecutive days;

8 and

9 (ii) to which each investigator con-
10 ducting such an inspection shall adhere un-
11 less the investigator identifies to the estab-
12 lishment involved a reason that more time
13 is needed to conduct such investigation;

14 and

15 (D) identifies practices for investigators
16 and device establishments to facilitate the con-
17 tinuity of inspections of such establishments.

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

1 (c) ADULTERATED DEVICES.—Subsection (j) of sec-
2 tion 501 of the Federal Food, Drug, and Cosmetic Act
3 (21 U.S.C. 351) is amended by inserting “or device” after
4 “drug”.

5 **SEC. 703. REAUTHORIZATION OF INSPECTION PROGRAM.**

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

9 **SEC. 704. CERTIFICATES TO FOREIGN GOVERNMENTS FOR**
10 **DEVICES.**

11 Subsection (e)(4) of section 801 of the Federal Food,
12 Drug, and Cosmetic Act (21 U.S.C. 381(e)(4)) is amend-
13 ed—

14 (1) by adding at the end the following:

15 “(E)(i)(I) If the Secretary denies a request for certifi-
16 cation under subparagraph (A)(ii) with respect to a device
17 manufactured in an establishment (foreign or domestic)
18 registered under section 510, the Secretary shall provide
19 in writing to the person seeking such certification the
20 basis for such denial, and specifically identify the finding
21 upon which such denial is based.

22 “(II) If the denial of a request as described in sub-
23 clause (I) is based on grounds other than an injunction
24 proceeding pursuant to section 302, seizure action pursu-
25 ant to section 304, or a recall designated Class I or Class

1 II pursuant to part 7, title 21, Code of Federal Regula-
2 tions, and is based on the facility being out of compliance
3 with part 820 of title 21, Code of Federal Regulations,
4 the Secretary shall provide a substantive summary of the
5 specific grounds for noncompliance identified by the Sec-
6 retary.

7 “(III) With respect to a device manufactured in an
8 establishment that has received a report under section
9 704(b), the Secretary shall not deny a request for certifi-
10 cation as described in subclause (I) with respect to a de-
11 vice based solely on the issuance of that report if the
12 owner, operator, or agent in charge of such establishment
13 has agreed to a plan of correction in response to such re-
14 port.

15 “(ii)(I) The Secretary shall provide a process for a
16 person who is denied a certification as described in clause
17 (i)(I) to request a review that conforms to the standards
18 of section 517A(b).

19 “(II) Notwithstanding any previous review conducted
20 pursuant to subclause (I), a person who has been denied
21 a certification as described in clause (i)(I) may at any time
22 request a review in order to present new information relat-
23 ing to actions taken by such person to address the reasons
24 identified by the Secretary for the denial of certification,
25 including evidence that corrective actions are being or

1 have been implemented to address grounds for noncompli-
2 ance identified by the Secretary.

3 “(III) Not later than 1 year after the date of enact-
4 ment of the FDA Reauthorization Act of 2017, the Sec-
5 retary shall issue guidance providing for a process to carry
6 out this subparagraph. Not later than 1 year after the
7 close of the comment period for such guidance, the Sec-
8 retary shall issue final guidance.

9 “(iii)(I) Subject to subclause (II), this subparagraph
10 applies to requests for certification on behalf of any device
11 establishment registered under section 510, whether the
12 establishment is located inside or outside of the United
13 States, and regardless of whether such devices are to be
14 exported from the United States.

15 “(II) If an establishment described in subclause (I)
16 is not located within the United States and does not dem-
17 onstrate that the devices manufactured, prepared, propa-
18 gated, compounded, or processed at such establishment
19 are to be exported from the United States, this subpara-
20 graph shall apply only if—

21 “(aa) the establishment has been inspected by
22 the Secretary within 3 years of the date of the re-
23 quest; or

24 “(bb) the establishment participates in an audit
25 program in which the United States participates or

1 the United States recognizes, an audit under such
2 program has been conducted, and the findings of
3 such audit are provided to the Secretary within 3
4 years of the date of the request.”; and

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

7 **SEC. 705. FACILITATING INTERNATIONAL HARMONIZATION.**

8 Section 704(g) of the Federal Food, Drug and Cos-
9 metic Act (21 U.S.C. 374) is amended by adding at the
10 end the following:

11 “(15)(A) Notwithstanding any other provision of this
12 subsection, the Secretary may recognize auditing organi-
13 zations that are recognized by organizations established
14 by governments to facilitate international harmonization
15 for purposes of conducting inspections of—

16 “(i) establishments that manufacture, prepare,
17 propagate, compound, or process devices (other than
18 types of devices licensed under section 351 of the
19 Public Health Service Act), as required under sec-
20 tion 510(h); or

21 “(ii) establishments required to register pursu-
22 ant to section 510(i).

23 “(B) Nothing in this paragraph affects—

24 “(i) the authority of the Secretary to inspect
25 any device establishment pursuant to this Act; or

1 “(ii) the authority of the Secretary to determine
2 the official classification of an inspection.”.

3 **SEC. 706. FOSTERING INNOVATION IN MEDICAL IMAGING.**

4 (a) APPROVAL OF APPLICATIONS FOR CERTAIN DI-
5 AGNOSTIC MEDICAL IMAGING DEVICES.—Section 520 of
6 the Federal Food, Drug, and Cosmetic Act (42 U.S.C.
7 360j) is amended by adding at the end the following:

8 “(p) DIAGNOSTIC IMAGING DEVICES INTENDED FOR
9 USE WITH CONTRAST AGENTS.—

10 “(1) IN GENERAL.—The Secretary may, subject
11 to the succeeding provisions of this subsection, ap-
12 prove an application (or a supplement to such an ap-
13 plication) submitted under section 515 with respect
14 to an applicable medical imaging device, or, in the
15 case of an applicable medical imaging device for
16 which a notification is submitted under section
17 510(k), may make a substantial equivalence deter-
18 mination with respect to an applicable medical imag-
19 ing device, or may grant a request submitted under
20 section 513(f)(2) for an applicable medical imaging
21 device, if such application, notification, or request
22 involves the use of a contrast agent that is not—

23 “(A) in a concentration, rate of adminis-
24 tration, or route of administration that is dif-
25 ferent from those described in the approved la-

1 belong of the contrast agent, except that the
2 Secretary may approve such application, make
3 such substantial equivalence determination, or
4 grant such request if the Secretary determines
5 that such differences in concentration, rate of
6 administration, or route of administration exist
7 but do not adversely affect the safety and effec-
8 tiveness of the contrast agent when used with
9 the device;

10 “(B) in a region, organ, or system of the
11 body that is different from those described in
12 the approved labeling of the contrast agent, ex-
13 cept that the Secretary may approve such appli-
14 cation, make such substantial equivalence deter-
15 mination, or grant such request if the Secretary
16 determines that such differences in region,
17 organ, or system of the body exist but do not
18 adversely affect the safety and effectiveness of
19 the contrast agent when used with the device;

20 “(C) in a patient population that is dif-
21 ferent from those described in the approved la-
22 beling of the contrast agent, except that the
23 Secretary may approve such application, make
24 such substantial equivalence determination, or
25 grant such request if the Secretary determines

1 such differences in patient population exist but
2 do not adversely affect the safety and effective-
3 ness of the contrast agent when used with the
4 device; or

5 “(D) in an imaging modality that is dif-
6 ferent from those described in the approved la-
7 beling of the contrast agent.

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

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

17 “(B) review information and data provided
18 to the Secretary by the sponsor of a contrast
19 agent in an application submitted under section
20 505 of this Act or section 351 of the Public
21 Health Service Act, so long as the sponsor of
22 such contrast agent has provided to the sponsor
23 of the applicable medical imaging device that is
24 the subject of such review a right of reference

1 and the application is submitted in accordance
2 with this subsection.

3 “(3) APPLICABLE REQUIREMENTS.—An appli-
4 cation submitted under section 515, a notification
5 submitted under section 510(k), or a request sub-
6 mitted under section 513(f)(2), as described in para-
7 graph (1), with respect to an applicable medical im-
8 aging device shall be subject to the requirements of
9 such respective section. Such application, notifica-
10 tion, or request shall only be subject to the require-
11 ments of this Act applicable to devices.

12 “(4) DEFINITIONS.—For purposes of this sub-
13 section—

14 “(A) the term ‘applicable medical imaging
15 device’ means a device intended to be used in
16 conjunction with a contrast agent (or class of
17 contrast agents) for an imaging use that is not
18 described in the approved labeling of such con-
19 trast agent (or the approved labeling of any
20 contrast agent in the same class as such con-
21 trast agent); and

22 “(B) the term ‘contrast agent’ means a
23 drug that is approved under section 505 or li-
24 censed under section 351 of the Public Health
25 Service Act, is intended for use in conjunction

1 with an applicable medical imaging device,
2 and—

3 “(i) is a diagnostic radiopharma-
4 ceutical, as defined in section 315.2 and
5 601.31 of title 21, Code of Federal Regula-
6 tions (or any successor regulations); or

7 “(ii) is a diagnostic agent that im-
8 proves the visualization of structure or
9 function within the body by increasing the
10 relative difference in signal intensity within
11 the target tissue, structure, or fluid.”.

12 (b) APPLICATIONS FOR APPROVAL OF CONTRAST
13 AGENTS INTENDED FOR USE WITH CERTAIN DIAG-
14 NOSTIC MEDICAL IMAGING DEVICES.—Section 505 of the
15 Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355)
16 is amended by adding at the end the following:

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

19 “(1) IN GENERAL.—The sponsor of a contrast
20 agent for which an application has been approved
21 under this section may submit a supplement to the
22 application seeking approval for a new use following
23 the authorization of a premarket submission for an
24 applicable medical imaging device for that use with
25 the contrast agent pursuant to section 520(p)(1).

1 “(2) REVIEW OF SUPPLEMENT.—In reviewing a
2 supplement submitted under this subsection, the
3 agency center charged with the premarket review of
4 drugs may—

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

7 “(B) review information and data sub-
8 mitted to the Secretary by the sponsor of an
9 applicable medical imaging device pursuant to
10 section 515, 510(k), or 513(f)(2) so long as the
11 sponsor of such applicable medical imaging de-
12 vice has provided to the sponsor of the contrast
13 agent a right of reference.

14 “(3) DEFINITIONS.—For purposes of this sub-
15 section—

16 “(A) the term ‘new use’ means a use of a
17 contrast agent that is described in the approved
18 labeling of an applicable medical imaging device
19 described in section 520(p), but that is not de-
20 scribed in the approved labeling of the contrast
21 agent; and

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

1 **SEC. 707. RISK-BASED CLASSIFICATION OF ACCESSORIES.**

2 (a) IN GENERAL.—Subsection (f) of section 513 of
3 the Federal Food, Drug, and Cosmetic Act (21 U.S.C.
4 360c) is amended by adding at the end the following new
5 paragraph:

6 “(6)(A) Subject to the succeeding subparagraphs of
7 this paragraph, the Secretary shall, by written order, clas-
8 sify an accessory under this section based on the risks of
9 the accessory when used as intended and the level of regu-
10 latory controls necessary to provide a reasonable assur-
11 ance of safety and effectiveness of the accessory, notwith-
12 standing the classification of any other device with which
13 such accessory is intended to be used.

14 “(B) The classification of any accessory distinct from
15 another device by regulation or written order issued prior
16 to December 13, 2016, shall continue to apply unless and
17 until the accessory is reclassified by the Secretary, not-
18 withstanding the classification of any other device with
19 which such accessory is intended to be used. Nothing in
20 this paragraph shall preclude the Secretary’s authority to
21 initiate the classification of an accessory through regula-
22 tion or written order, as appropriate.

23 “(C)(i) In the case of a device intended to be used
24 with an accessory, where the accessory has been included
25 in an application for premarket approval of such device
26 under section 515 or a report under section 510(k) for

1 clearance of such device and the Secretary has not classi-
2 fied such accessory distinctly from another device in ac-
3 cordance with subparagraph (A), the person filing the ap-
4 plication or report (as applicable) at the time such applica-
5 tion or report is filed—

6 “(I) may include a written request for the prop-
7 er classification of the accessory pursuant to sub-
8 paragraph (A);

9 “(II) shall include in any such request such in-
10 formation as may be necessary for the Secretary to
11 evaluate, based on the least burdensome approach,
12 the appropriate class for the accessory under sub-
13 section (a); and

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

19 “(ii) The Secretary’s response under section 515(d)
20 or section 510(n) (as applicable) to an application or re-
21 port described in clause (i) shall also contain the Sec-
22 retary’s granting or denial of the request for classification
23 of the accessory involved.

24 “(iii) The Secretary’s evaluation of an accessory
25 under clause (i) shall constitute an order establishing a

1 new classification for such accessory for the specified in-
2 tended use or uses of such accessory and for any accessory
3 with the same intended use or uses as such accessory.

4 “(D) For accessories that have been granted mar-
5 keting authorization as part of a submission for another
6 device with which the accessory involved is intended to be
7 used, through an application for such other device under
8 section 515(c), a report under section 510(k), or a request
9 for classification under paragraph (2) of this subsection,
10 the following shall apply:

11 “(i) Not later than the date that is one year
12 after the date of enactment of the FDA Reauthor-
13 ization Act of 2017 and at least once every 5 years
14 thereafter, and as the Secretary otherwise deter-
15 mines appropriate, pursuant to this paragraph, the
16 Secretary shall publish in the Federal Register a no-
17 tice proposing a list of such accessories that the Sec-
18 retary determines may be suitable for a distinct clas-
19 sification in class I and the proposed regulations for
20 such classifications. In developing such list, the Sec-
21 retary shall consider recommendations from spon-
22 sors of device submissions and other stakeholders for
23 accessories to be included on such list. The notices
24 shall provide for a period of not less than 60 cal-
25 endar days for public comment. Within 180 days

1 after the end of the comment period, the Secretary
2 shall publish in the Federal Register a final action
3 classifying such suitable accessories into class I.

4 “(ii) A manufacturer or importer of an acces-
5 sory that has been granted such marketing author-
6 ization may submit to the Secretary a written re-
7 quest for the appropriate classification of the acces-
8 sory based on the risks and appropriate level of reg-
9 ulatory controls as described in subparagraph (A),
10 and shall, if the request is requesting classification
11 of the accessory in class II, include in the submis-
12 sion an initial draft proposal for special controls, if
13 special controls would be required pursuant to sub-
14 section (a)(1)(B). Such request shall include such
15 information as may be necessary for the Secretary to
16 evaluate, based on the least burdensome approach,
17 the appropriate class for the accessory under sub-
18 section (a). The Secretary shall provide an oppor-
19 tunity for a manufacturer or importer to meet with
20 appropriate personnel of the Food and Drug Admin-
21 istration to discuss the appropriate classification of
22 such accessory prior to submitting a written request
23 under this clause for classification of the accessory.

24 “(iii) The Secretary shall respond to a request
25 made under clause (ii) not later than 85 calendar

1 days after receiving such request by issuing a writ-
2 ten order classifying the accessory or denying the re-
3 quest. If the Secretary does not agree with the rec-
4 ommendation for classification submitted by the
5 manufacturer or importer, the response shall include
6 a detailed description and justification for such de-
7 termination. Within 30 calendar days after granting
8 such a request, the Secretary shall publish a notice
9 in the Federal Register announcing such response.

10 “(E) Nothing in this paragraph may be construed as
11 precluding a manufacturer of an accessory of a new type
12 from using the classification process described in sub-
13 section (f)(2) to obtain classification of such accessory in
14 accordance with the criteria and requirements set forth
15 in that subsection.”.

16 (b) CONFORMING CHANGE.—Section 513(b) of the
17 Federal Food, Drug, and Cosmetic Act (21 U.S.C.
18 360e(b)) is amended by striking paragraph (9) (relating
19 to classification of an accessory).

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

1 **SEC. 708. DEVICE PILOT PROJECTS.**

2 (a) POSTMARKET PILOT.—Section 519 of the Fed-
3 eral Food, Drug, and Cosmetic Act (21 U.S.C. 360i) is
4 amended by adding at the end the following:

5 “(i) POSTMARKET PILOT.—

6 “(1) IN GENERAL.—In order to provide timely
7 and reliable information on the safety and effective-
8 ness of devices approved under section 515, cleared
9 under section 510(k), or classified under section
10 513(f)(2), including responses to adverse events and
11 malfunctions, and to advance the objectives of part
12 803 of title 21, Code of Federal Regulations (or suc-
13 cessor regulations), and advance the objectives of,
14 and evaluate innovative new methods of compliance
15 with, this section and section 522, the Secretary
16 shall, within one year of the date of enactment of
17 the FDA Reauthorization Act of 2017, initiate one
18 or more pilot projects for voluntary participation by
19 a manufacturer or manufacturers of a device or de-
20 vice type, or continue existing projects, in accord-
21 ance with paragraph (3), that—

22 “(A) are designed to efficiently generate
23 reliable and timely safety and active surveil-
24 lance data for use by the Secretary or manufac-
25 turers of the devices that are involved in the
26 pilot project;

1 “(B) inform the development of methods,
2 systems, data criteria, and programs that could
3 be used to support safety and active surveil-
4 lance activities for devices included or not in-
5 cluded in such project;

6 “(C) may be designed and conducted in co-
7 ordination with a comprehensive system for
8 evaluating medical device technology that oper-
9 ates under a governing board with appropriate
10 representation of stakeholders, including patient
11 groups and device manufacturers;

12 “(D) use electronic health data including
13 claims data, patient survey data, or any other
14 data, as the Secretary determines appropriate;
15 and

16 “(E) prioritize devices and device types
17 that meet one or more of the following criteria:

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

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

1 “(iii) Devices and device types, the
2 failure of which has significant health con-
3 sequences.

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

6 “(I) has received public rec-
7 ommendations in accordance with
8 paragraph (2)(B); and

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

13 “(2) PARTICIPATION.—The Secretary shall es-
14 tablish the conditions and processes—

15 “(A) under which a manufacturer of a de-
16 vice may voluntarily participate in a pilot
17 project described in paragraph (1); and

18 “(B) for facilitating public recommenda-
19 tions for devices to be prioritized under such a
20 pilot project, including requirements for the
21 data necessary to support such a recommenda-
22 tion.

23 “(3) CONTINUATION OF ONGOING PROJECTS.—
24 The Secretary may continue or expand projects, with
25 respect to providing timely and reliable information

1 on the safety and effectiveness of devices approved
2 under section 515, cleared under section 510(k), or
3 classified under section 513(f)(2), that are being
4 carried out as of the date of the enactment of the
5 FDA Reauthorization Act of 2017. The Secretary
6 shall, beginning on such date of enactment, take
7 such steps as may be necessary—

8 “(A) to ensure such projects meet the re-
9 quirements of subparagraphs (A) through (E)
10 of paragraph (1); and

11 “(B) to increase the voluntary participa-
12 tion in such projects of manufacturers of de-
13 vices and facilitate public recommendations for
14 any devices prioritized under such a project.

15 “(4) IMPLEMENTATION.—

16 “(A) CONTRACTING AUTHORITY.—The
17 Secretary may carry out a pilot project meeting
18 the criteria specified in subparagraphs (A)
19 through (E) of paragraph (1) or a project con-
20 tinued or expanded under paragraph (3) by en-
21 tering into contracts, cooperative agreements,
22 grants, or other appropriate agreements with
23 public or private entities that have a significant
24 presence in the United States and meet the fol-
25 lowing conditions:

1 “(i) If such an entity is a component
2 of another organization, the entity and the
3 organization have established an agree-
4 ment under which appropriate security
5 measures are implemented to maintain the
6 confidentiality and privacy of the data de-
7 scribed in paragraph (1)(D) and such
8 agreement ensures that the entity will not
9 make an unauthorized disclosure of such
10 data to the other components of the orga-
11 nization in breach of requirements with re-
12 spect to confidentiality and privacy of such
13 data established under such security meas-
14 ures.

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

20 “(I) The entity or entities shall
21 continue to comply with the require-
22 ments with respect to confidentiality
23 and privacy referred to in clause (i)
24 with respect to all data disclosed to
25 the entity under such an agreement.

1 “(II) The entity or entities shall
2 return any data disclosed to such enti-
3 ty pursuant to this subsection and to
4 which it would not otherwise have ac-
5 cess or, if returning such data is not
6 practicable, destroy the data.

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

10 “(I) research, statistical, epi-
11 demiologic, or clinical capability and
12 expertise to conduct and complete the
13 activities under this subsection, in-
14 cluding the capability and expertise to
15 provide the Secretary access to de-
16 identified data consistent with the re-
17 quirements of this subsection;

18 “(II) an information technology
19 infrastructure to support electronic
20 data and operational standards to
21 provide security for such data, as ap-
22 propriate;

23 “(III) experience with, and exper-
24 tise on, the development of research
25 on, and surveillance of, device safety

1 and effectiveness using electronic
2 health data; or

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

6 “(B) REVIEW OF CONTRACT IN THE
7 EVENT OF A MERGER OR ACQUISITION.—The
8 Secretary shall review any contract, cooperative
9 agreement, grant, or other appropriate agree-
10 ment entered into under this paragraph with an
11 entity meeting the conditions specified in sub-
12 paragraph (A) in the event of a merger or ac-
13 quisition of the entity in order to ensure that
14 the requirements specified in this subsection
15 will continue to be met.

16 “(5) COMPLIANCE WITH REQUIREMENTS FOR
17 RECORDS OR REPORTS ON DEVICES.—The participa-
18 tion of a manufacturer in pilot projects under this
19 subsection or a project continued or expanded under
20 paragraph (3) shall not affect the eligibility of such
21 manufacturer to participate in any quarterly report-
22 ing program with respect to devices carried out
23 under this section 519 or section 522. The Secretary
24 may determine that, for a specified time period to be
25 determined by the Secretary, a manufacturer’s par-

1 participation in a pilot project under this subsection or
2 a project continued or expanded under paragraph
3 (3) may meet the applicable requirements of this
4 section or section 522, if—

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

8 “(B) the Secretary has established proce-
9 dures for making adverse event and safety in-
10 formation collected from such project public, to
11 the extent possible.

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

15 “(A) individually identifiable health infor-
16 mation so collected shall not be disclosed when
17 presenting any information from such project;
18 and

19 “(B) any such disclosure shall be made in
20 compliance with regulations issued pursuant to
21 section 264(c) of the Health Insurance Port-
22 ability and Accountability Act of 1996 (42
23 U.S.C. 1320d–2 note) and sections 552 and
24 552a of title 5, United States Code.

1 “(7) LIMITATIONS.—No pilot project under this
2 subsection, or in coordination with the comprehen-
3 sive system described in paragraph (1)(C), may
4 allow for an entity participating in such project,
5 other than the Secretary, to make determinations of
6 safety or effectiveness, or substantial equivalence,
7 for purposes of this Act.

8 “(8) OTHER PROJECTS REQUIRED TO COM-
9 PLY.—Paragraphs (1)(B), (4)(A)(i), (4)(A)(ii), (5),
10 (6), and (7) shall apply with respect to any pilot
11 project undertaken in coordination with the com-
12 prehensive system described in paragraph (1)(C)
13 that relates to the use of real world evidence for de-
14 vices in the same manner and to the same extent as
15 such paragraphs apply with respect to pilot projects
16 conducted under this subsection.

17 “(9) REPORT TO CONGRESS.—Not later than
18 18 months after the date of enactment of this Act,
19 and annually thereafter, the Secretary shall submit
20 to the Committee on Energy and Commerce of the
21 House of Representatives and the Committee on
22 Health, Education, Labor and Pensions of the Sen-
23 ate a report containing a description of the pilot
24 projects being conducted under this subsection and

1 projects continued or expanded pursuant to para-
2 graph (3), including for each such project—

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

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

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

12 “(D) the devices or device categories in-
13 volved in such project;

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

16 “(F) the findings of the project in relation
17 to device safety, including adverse events, mal-
18 functions, and other safety information.

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

22 (b) REPORT.—Not later than January 31, 2021, the
23 Secretary of Health and Human Services, acting through
24 the Commissioner of Food and Drugs, shall conduct a re-
25 view through an independent third party to evaluate the

1 strengths, limitations, and appropriate use of evidence col-
 2 lected pursuant to real world evidence pilot projects de-
 3 scribed in the letters described in section 201(b) of the
 4 Medical Device User Fee Amendments of 2017 and sub-
 5 section (i) of section 519 of the Federal Food, Drug, and
 6 Cosmetic Act (21 U.S.C. 360i), as amended by subsection
 7 (a), for informing premarket and postmarket decision-
 8 making for multiple device types, and to determine wheth-
 9 er the methods, systems, and programs in such pilot
 10 projects efficiently generate reliable and timely evidence
 11 about the effectiveness or safety surveillance of devices.

12 **SEC. 709. REGULATION OF OVER-THE-COUNTER HEARING**
 13 **AIDS.**

14 (a) IN GENERAL.—Section 520 of the Federal Food,
 15 Drug, and Cosmetic Act (21 U.S.C. 360j), as amended
 16 by section 708, is further amended by adding at the end
 17 the following:

18 “(q) REGULATION OF OVER-THE-COUNTER HEARING
 19 AIDS.—

20 “(1) DEFINITION.—

21 “(A) IN GENERAL.—In this subsection, the
 22 term ‘over-the-counter hearing aid’ means a de-
 23 vice that—

24 “(i) uses the same fundamental sci-
 25 entific technology as air conduction hear-

1 ing aids (as defined in section 874.3300 of
2 title 21, Code of Federal Regulations) (or
3 any successor regulation) or wireless air
4 conduction hearing aids (as defined in sec-
5 tion 874.3305 of title 21, Code of Federal
6 Regulations) (or any successor regulation);

7 “(ii) is intended to be used by adults
8 age 18 and older to compensate for per-
9 ceived mild to moderate hearing impair-
10 ment;

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

15 “(iv) may—

16 “(I) use wireless technology; or

17 “(II) include tests for self-assess-
18 ment of hearing loss; and

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

24 “(B) EXCEPTION.—Such term does not in-
25 clude a personal sound amplification product in-

1 tended to amplify sound for nonhearing im-
2 paired consumers in situations including hunt-
3 ing and bird-watching.

4 “(2) REGULATION.—An over-the-counter hear-
5 ing aid shall be subject to the regulations promul-
6 gated in accordance with section 709(b) of the FDA
7 Reauthorization Act of 2017 and shall be exempt
8 from sections 801.420 and 801.421 of title 21, Code
9 of Federal Regulations (or any successor regula-
10 tions).”.

11 (b) REGULATIONS TO ESTABLISH CATEGORY.—

12 (1) IN GENERAL.—The Secretary of Health and
13 Human Services (referred to in this section as the
14 “Secretary”), not later than 3 years after the date
15 of enactment of this Act, shall promulgate proposed
16 regulations to establish a category of over-the-
17 counter hearing aids, as defined in subsection (q) of
18 section 520 of the Federal Food, Drug, and Cos-
19 metic Act (21 U.S.C. 360j) as amended by sub-
20 section (a), and, not later than 180 days after the
21 date on which the public comment period on the pro-
22 posed regulations closes, shall issue such final regu-
23 lations.

24 (2) REQUIREMENTS.—In promulgating the reg-
25 ulations under paragraph (1), the Secretary shall—

1 (A) include requirements that provide rea-
2 sonable assurances of the safety and effective-
3 ness of over-the-counter hearing aids;

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

7 (C) include requirements for appropriate
8 labeling of over-the-counter hearing aids, in-
9 cluding requirements that such labeling include
10 a conspicuous statement that the device is only
11 intended for adults age 18 and older, informa-
12 tion on how consumers may report adverse
13 events, information on any contraindications,
14 conditions, or symptoms of medically treatable
15 causes of hearing loss, and advisements to con-
16 sult promptly with a licensed health care practi-
17 tioner; and

18 (D) describe the requirements under which
19 the sale of over-the-counter hearing aids is per-
20 mitted, without the supervision, prescription, or
21 other order, involvement, or intervention of a li-
22 censed person, to consumers through in-person
23 transactions, by mail, or online.

24 (3) PREMARKET NOTIFICATION.—The Sec-
25 retary shall make findings under section 510(m) of

1 the Federal Food, Drug, and Cosmetic Act (21
2 U.S.C. 360(m)) to determine whether over-the-
3 counter hearing aids (as defined in section 520(q) of
4 the Federal Food, Drug, and Cosmetic Act (21
5 U.S.C. 360j), as amended by subsection (a)) require
6 a report under section 510(k) to provide reasonable
7 assurance of safety and effectiveness.

8 (4) EFFECT ON STATE LAW.—No State or local
9 government shall establish or continue in effect any
10 law, regulation, order, or other requirement specifi-
11 cally related to hearing products that would restrict
12 or interfere with the servicing, marketing, sale, dis-
13 pensing, use, customer support, or distribution of
14 over-the-counter hearing aids (as defined in section
15 520(q) of the Federal Food, Drug, and Cosmetic Act
16 (21 U.S.C. 360j), as amended by subsection (a))
17 through in-person transactions, by mail, or online,
18 that is different from, in addition to, or otherwise
19 not identical to, the regulations promulgated under
20 this subsection, including any State or local require-
21 ment for the supervision, prescription, or other
22 order, involvement, or intervention of a licensed per-
23 son for consumers to access over-the-counter hearing
24 aids.

1 (5) NO EFFECT ON PRIVATE REMEDIES.—Noth-
2 ing in this section shall be construed to modify or
3 otherwise affect the ability of any person to exercise
4 a private right of action under any State or Federal
5 product liability, tort, warranty, contract, or con-
6 sumer protection law.

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

20 (d) REPORT.—Not later than 2 years after the date
21 on which the final regulations described in subsection
22 (b)(1) are issued, the Secretary of Health and Human
23 Services shall submit to Congress a report analyzing any
24 adverse events relating to over-the-counter hearing aids

1 (as defined in subsection (q)(1) of section 520 of the Fed-
2 eral Food, Drug, and Cosmetic Act (21 U.S.C. 360j)).

3 **SEC. 710. REPORT ON SERVICING OF DEVICES.**

4 (a) IN GENERAL.—Not later than 270 days after the
5 date of enactment of this Act, the Secretary of Health and
6 Human Services, acting through the Commissioner of
7 Food and Drugs, shall post on the internet website of the
8 Food and Drug Administration a report on the continued
9 quality, safety, and effectiveness of devices (as defined in
10 section 201(h) of the Federal Food, Drug, and Cosmetic
11 Act (21 U.S.C. 321(h))) with respect to servicing (as de-
12 fined in subsection (c)).

13 (b) CONTENTS.—The report submitted under sub-
14 section (a) shall contain—

15 (1) the status of, and findings to date, with re-
16 spect to, the proposed rule entitled “Refurbishing,
17 Reconditioning, Rebuilding, Remarketing, Remanu-
18 facturing, and Servicing of Medical Devices Per-
19 formed by Third-Party Entities and Original Equip-
20 ment Manufacturers; Request for Comments” pub-
21 lished in the Federal Register by the Food and Drug
22 Administration on March 4, 2016 (81 Fed. Reg.
23 11477);

24 (2) information presented during the October
25 2016 public workshop entitled “Refurbishing, Recon-

1 conditioning, Rebuilding, Remarketing, Remanufac-
2 turing, and Servicing of Medical Devices Performed
3 by Third-Party Entities and Original Equipment
4 Manufacturers”;

5 (3) a description of the statutory and regu-
6 latory authority of the Food and Drug Administra-
7 tion with respect to the servicing of devices con-
8 ducted by any entity, including original equipment
9 manufacturers and third party entities;

10 (4) details regarding how the Food and Drug
11 Administration currently regulates devices with re-
12 spect to servicing to ensure safety and effectiveness,
13 how the agency could improve such regulation using
14 the authority described in paragraph (3), and wheth-
15 er additional authority is recommended;

16 (5) information on actions the Food and Drug
17 Administration could take under the authority de-
18 scribed in paragraphs (3) and (4) to assess the serv-
19 icing of devices, including the size, scope, location,
20 and composition of third party entities;

21 (6) information on actions the Food and Drug
22 Administration could take to track adverse events
23 caused by servicing errors performed by any entity,
24 including original equipment manufacturers and
25 third party entities;

1 (7) information regarding the regulation by
2 States, the Joint Commission, or other regulatory
3 bodies of device servicing performed by any entity,
4 including original equipment manufacturers and
5 third party entities; and

6 (8) any additional information determined by
7 the Secretary (acting through the Commissioner) to
8 be relevant to ensuring the quality, safety, and effec-
9 tiveness of devices with respect to servicing.

10 (c) SERVICING DEFINED.—In this section, the term
11 “servicing” includes, with respect to a device, refurbishing,
12 reconditioning, rebuilding, remarketing, repairing, re-
13 manufacturing, or other servicing of the device.

14 **TITLE VIII—IMPROVING**
15 **GENERIC DRUG ACCESS**

16 **SEC. 801. PRIORITY REVIEW OF GENERIC DRUGS.**

17 Section 505(j) of the Federal Food, Drug, and Cos-
18 metic Act (21 U.S.C. 355(j)) is amended by adding at the
19 end the following:

20 “(11)(A) Subject to subparagraph (B), the Secretary
21 shall prioritize the review of, and act within 8 months of
22 the date of the submission of, an original abbreviated new
23 drug application submitted for review under this sub-
24 section that is for a drug—

1 “(i) for which there are not more than 3 ap-
2 proved drug products listed under paragraph (7) and
3 for which there are no blocking patents and
4 exclusivities; or

5 “(ii) that has been included on the list under
6 section 506E.

7 “(B) To qualify for priority review under this para-
8 graph, not later than 60 days prior to the submission of
9 an application described in subparagraph (A) or that the
10 Secretary may prioritize pursuant to subparagraph (D),
11 the applicant shall provide complete, accurate information
12 regarding facilities involved in manufacturing processes
13 and testing of the drug that is the subject of the applica-
14 tion, including facilities in corresponding Type II active
15 pharmaceutical ingredients drug master files referenced in
16 an application and sites or organizations involved in bio-
17 equivalence and clinical studies used to support the appli-
18 cation, to enable the Secretary to make a determination
19 regarding whether an inspection of a facility is necessary.
20 Such information shall include the relevant (as determined
21 by the Secretary) sections of such application, which shall
22 be unchanged relative to the date of the submission of
23 such application, except to the extent that a change is
24 made to such information to exclude a facility that was
25 not used to generate data to meet any application require-

1 ments for such submission and that is not the only facility
2 intended to conduct one or more unit operations in com-
3 mercial production. Information provided by an applicant
4 under this subparagraph shall not be considered the sub-
5 mission of an application under this subsection.

6 “(C) The Secretary may expedite an inspection or re-
7 inspection under section 704 of an establishment that pro-
8 poses to manufacture a drug described in subparagraph
9 (A).

10 “(D) Nothing in this paragraph shall prevent the Sec-
11 retary from prioritizing the review of other applications
12 as the Secretary determines appropriate.

13 “(12) The Secretary shall publish on the internet
14 website of the Food and Drug Administration, and update
15 at least once every 6 months, a list of all drugs approved
16 under subsection (c) for which all patents and periods of
17 exclusivity under this Act have expired and for which no
18 application has been approved under this subsection.”.

19 **SEC. 802. ENHANCING REGULATORY TRANSPARENCY TO**
20 **ENHANCE GENERIC COMPETITION.**

21 Section 505(j) of the Federal Food, Drug, and Cos-
22 metic Act (21 U.S.C. 355), as amended by section 801,
23 is further amended by adding at the end the following:

24 “(13) Upon the request of an applicant regarding one
25 or more specified pending applications under this sub-

1 section, the Secretary shall, as appropriate, provide review
2 status updates indicating the categorical status of the ap-
3 plications by each relevant review discipline.”.

4 **SEC. 803. COMPETITIVE GENERIC THERAPIES.**

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

8 **“SEC. 506H. COMPETITIVE GENERIC THERAPIES.**

9 “(a) IN GENERAL.—The Secretary may, at the re-
10 quest of an applicant of a drug that is designated as a
11 competitive generic therapy pursuant to subsection (b), ex-
12 pedite the development and review of an abbreviated new
13 drug application under section 505(j) for such drug.

14 “(b) DESIGNATION PROCESS.—

15 “(1) REQUEST.—The applicant may request the
16 Secretary to designate the drug as a competitive ge-
17 neric therapy.

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

22 “(3) CRITERIA.—A drug is eligible for designa-
23 tion as a competitive generic therapy under this sec-
24 tion if the Secretary determines that there is inad-
25 equate generic competition.

1 “(4) DESIGNATION.—Not later than 60 cal-
2 endar days after the receipt of a request under para-
3 graph (1), the Secretary may—

4 “(A) determine whether the drug that is
5 the subject of the request meets the criteria de-
6 scribed in paragraph (3); and

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

10 “(c) ACTIONS.—In expediting the development and
11 review of an application under subsection (a), the Sec-
12 retary may, as requested by the applicant, take actions
13 including the following:

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

18 “(2) Provide timely advice to, and interactive
19 communication with, the applicant regarding the de-
20 velopment of the drug to ensure that the develop-
21 ment program to gather the data necessary for ap-
22 proval is as efficient as practicable.

23 “(3) Involve senior managers and experienced
24 review staff, as appropriate, in a collaborative, co-
25 ordinated review of such application, including with

1 respect to drug-device combination products and
2 other complex products.

3 “(4) Assign a cross-disciplinary project lead—

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

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

9 “(d) REPORTING REQUIREMENT.—Not later than
10 one year after the date of the approval of an application
11 under section 505(j) with respect to a drug for which the
12 development and review is expedited under this section,
13 the sponsor of such drug shall report to the Secretary on
14 whether the drug has been marketed in interstate com-
15 merce since the date of such approval.

16 “(e) DEFINITIONS.—In this section:

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

19 “(2) The term ‘inadequate generic competition’
20 means, with respect to a drug, there is not more
21 than one approved drugs on the list of drugs de-
22 scribed in section 505(j)(7)(A) (not including drugs
23 on the discontinued section of such list) that is—

24 “(A) the reference listed drug; or

1 “(B) a generic drug with the same ref-
2 erence listed drug as the drug for which des-
3 ignation as a competitive generic therapy is
4 sought.

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

8 (b) GUIDANCE; AMENDED REGULATIONS.—

9 (1) IN GENERAL.—

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

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

17 (ii) not later than 1 year after the
18 close of the comment period for the draft
19 guidance, issue final guidance on such sec-
20 tion 506H.

21 (B) CONTENTS.—The guidance issued
22 under this paragraph shall—

23 (i) specify the process and criteria by
24 which the Secretary makes a designation
25 under section 506H of the Federal Food,

1 Drug, and Cosmetic Act, as added by sub-
2 section (a);

3 (ii) specify the actions the Secretary
4 may take to expedite the development and
5 review of a competitive generic therapy
6 pursuant to such a designation; and

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

9 (2) AMENDED REGULATIONS.—The Secretary
10 of Health and Human Services shall issue or revise
11 any regulations as may be necessary to carry out
12 this section not later than 2 years after the date of
13 enactment of this Act.

14 **SEC. 804. ACCURATE INFORMATION ABOUT DRUGS WITH**
15 **LIMITED COMPETITION.**

16 Chapter V of the Federal Food, Drug, and Cosmetic
17 Act (21 U.S.C. 351 et seq.) is amended by inserting after
18 section 506H, as added by section 803, the following:

19 **“SEC. 506I. PROMPT REPORTS OF MARKETING STATUS.**

20 “(a) NOTIFICATION OF WITHDRAWAL.—The holder
21 of an application approved under subsection (c) or (j) of
22 section 505 shall notify the Secretary in writing 180 days
23 prior to withdrawing the approved drug from sale, or if
24 180 days is not practicable as soon as practicable but not

1 later than the date of withdrawal. The holder shall include
2 with such notice the—

3 “(1) National Drug Code;

4 “(2) identity of the drug by established name
5 and by proprietary name, if any;

6 “(3) new drug application number or abbrevi-
7 viated application number;

8 “(4) strength of the drug;

9 “(5) date on which the drug is expected to no
10 longer be available for sale; and

11 “(6) reason for withdrawal of the drug.

12 “(b) NOTIFICATION OF DRUG NOT AVAILABLE FOR
13 SALE.—The holder of an application approved under sub-
14 section (c) or (j) shall notify the Secretary in writing with-
15 in 180 calendar days of the date of approval of the drug
16 if the drug will not be available for sale within 180 cal-
17 endar days of such date of approval. The holder shall in-
18 clude with such notice the—

19 “(1) identity of the drug by established name
20 and by proprietary name, if any;

21 “(2) new drug application number or abbrevi-
22 viated application number;

23 “(3) strength of the drug;

24 “(4) date on which the drug will be available
25 for sale, if known; and

1 “(5) reason for not marketing the drug after
2 approval.

3 “(c) ADDITIONAL ONE-TIME REPORT.—Within 180
4 days of the date of enactment of this section, all holders
5 of applications approved under subsection (c) or (j) of sec-
6 tion 505 shall review the information in the list published
7 under subsection 505(j)(7)(A) and shall notify the Sec-
8 retary in writing that—

9 “(1) all of the application holder’s drugs in the
10 active section of the list published under subsection
11 505(j)(7)(A) are available for sale; or

12 “(2) one or more of the application holder’s
13 drugs in the active section of the list published
14 under subsection 505(j)(7)(A) have been withdrawn
15 from sale or have never been available for sale, and
16 include with such notice the information required
17 pursuant to subsection (a) or (b), as applicable.

18 “(d) FAILURE TO MEET REQUIREMENTS.—If a hold-
19 er of an approved application fails to submit the informa-
20 tion required under subsection (a), (b), or (c), the Sec-
21 retary may move the application holder’s drugs from the
22 active section of the list published under subsection
23 505(j)(7)(A) to the discontinued section of the list, except
24 that the Secretary shall remove from the list in accordance
25 with subsection 505(j)(7)(C) drugs the Secretary deter-

1 mines have been withdrawn from sale for reasons of safety
2 of effectiveness.

3 “(e) UPDATES.—The Secretary shall update the list
4 published under subsection 505(j)(7)(A) based on the in-
5 formation provided under subsections (a), (b), and (c) by
6 moving drugs that are not available for sale from the ac-
7 tive section to the discontinued section of the list, except
8 that drugs the Secretary determines have been withdrawn
9 from sale for reasons of safety or effectiveness shall be
10 removed from the list in accordance with subsection
11 505(j)(7)(C). The Secretary shall make monthly updates
12 to the list based on the information provided pursuant to
13 subsections (a) and (b), and shall update the list based
14 on the information provided under subsection (c) as soon
15 as practicable.

16 “(f) LIMITATION ON USE OF NOTICES.—Any notice
17 submitted under this section shall not be made public by
18 the Secretary and shall be used solely for the purpose of
19 the updates described in subsection (e).”.

20 **SEC. 805. SUITABILITY PETITIONS.**

21 (a) IN GENERAL.—It is the sense of Congress that
22 the Food and Drug Administration shall meet the require-
23 ment under section 505(j)(2)(C) of the Federal Food,
24 Drug, and Cosmetic Act (21 U.S.C. 355(j)(2)(C)) and sec-
25 tion 314.93(e) of title 21, Code of Federal Regulations,

1 of responding to suitability petitions within 90 days of
2 submission.

3 (b) REPORT.—The Secretary of Health and Human
4 Services shall include in the annual reports under section
5 807—

6 (1) the number of pending petitions under sec-
7 tion 505(j)(2)(C) of the Federal Food, Drug, and
8 Cosmetic Act (21 U.S.C. 355(j)(2)(C)); and

9 (2) the number of such petitions pending a sub-
10 stantive response for more than 180 days from the
11 date of receipt.

12 **SEC. 806. INSPECTIONS.**

13 Within 6 months of the date of enactment of this Act,
14 the Secretary of Health and Human Services shall develop
15 and implement a protocol for expediting review of timely
16 responses to reports of observations from an inspection
17 under section 704 of the Federal Food, Drug, and Cos-
18 metic Act (21 U.S.C. 374). Such protocol shall—

19 (1) apply to responses to such reports per-
20 taining to applications submitted under section 505
21 of the Federal Food, Drug, and Cosmetic Act (21
22 U.S.C. 355)—

23 (A) for which the approval is dependent
24 upon remediation of conditions identified in the
25 report;

1 (B) for which concerns related to observa-
2 tions from an inspection under such section 704
3 are the only barrier to approval; and

4 (C) where the drug that is the subject of
5 the application is a drug—

6 (i) for which there are not more than
7 3 other approved applications under sec-
8 tion 505(j) of the Federal Food, Drug, and
9 Cosmetic Act (21 U.S.C. 355(j)) that ref-
10 erence the same listed drug and for which
11 there are less than 6 abbreviated new drug
12 applications tentatively approved; or

13 (ii) that is included on the list under
14 section 506E of such Act (21 U.S.C.
15 356e);

16 (2) address expedited re-inspection of facilities,
17 as appropriate; and

18 (3) establish a 6-month timeline for completion
19 of review of such responses to such reports.

20 **SEC. 807. REPORTING ON PENDING GENERIC DRUG APPLI-**
21 **CATIONS AND PRIORITY REVIEW APPLICA-**
22 **TIONS.**

23 Not later than 180 calendar days after the date of
24 enactment of this Act, and quarterly thereafter until Octo-
25 ber 1, 2022, the Secretary of Health and Human Services

1 shall post on the internet website of the Food and Drug
2 Administration a report that provides, with respect to the
3 months covered by the report—

4 (1) with respect to applications filed under sec-
5 tion 505(j) of the Federal Food, Drug, and Cosmetic
6 Act (21 U.S.C. 355(j)) that, during the most recent
7 calendar year, were subject to priority review under
8 paragraph (11) of such section 505(j) (as added by
9 section 801) or expedited development and review
10 under section 506H of the Federal Food, Drug, and
11 Cosmetic Act (as added by section 803), the num-
12 bers of such applications (with denotation of such
13 applications that were filed prior to October 1,
14 2014) that are—

15 (A) awaiting action by the applicant;
16 (B) awaiting action by the Secretary; and
17 (C) approved by the Secretary;

18 (2) the number of applications filed under sec-
19 tion 505(j) of the Federal Food, Drug, and Cosmetic
20 Act (21 U.S.C. 355(j)) and prior approval supple-
21 ments withdrawn in each month;

22 (3) the mean and median approval and ten-
23 tative approval times and the number of review cy-
24 cles for such applications;

1 (4) the number and type of meetings requested
2 and held under such section 506H (as added by sec-
3 tion 803); and

4 (5) the number of such applications on which
5 the Secretary has taken action pursuant to sub-
6 section (c) of such section 506H (as added by sec-
7 tion 803) and any effect such section 506H may
8 have on the length of time for approval of applica-
9 tions under such section 505(j) and the number of
10 review cycles for such approvals.

11 **SEC. 808. INCENTIVIZING COMPETITIVE GENERIC DRUG**
12 **DEVELOPMENT.**

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

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

17 “(v) 180-DAY EXCLUSIVITY PERIOD FOR COM-
18 PETITIVE GENERIC THERAPIES.—

19 “(I) EFFECTIVENESS OF APPLICATION.—

20 Subject to subparagraph (D)(iv), if the applica-
21 tion is for a drug that is the same as a competi-
22 tive generic therapy for which any first ap-
23 proved applicant has commenced commercial
24 marketing, the application shall be made effec-
25 tive on the date that is 180 days after the date

1 of the first commercial marketing of the com-
2 petitive generic therapy (including the commer-
3 cial marketing of the listed drug) by any first
4 approved applicant.

5 “(II) LIMITATION.—The exclusivity period
6 under subclause (I) shall not apply with respect
7 to a competitive generic therapy that has pre-
8 viously received an exclusivity period under sub-
9 clause (I).

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

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

14 “(AA) that is designated as a
15 competitive generic therapy under sec-
16 tion 506H; and

17 “(BB) for which there are no un-
18 expired patents or exclusivities on the
19 list of products described in section
20 505(j)(7)(A) at the time of submis-
21 sion.

22 “(bb) The term ‘first approved appli-
23 cant’ means any applicant that has sub-
24 mitted an application that—

1 “(AA) is for a competitive ge-
2 neric therapy that is approved on the
3 first day on which any application for
4 such competitive generic therapy is
5 approved;

6 “(BB) is not eligible for a 180-
7 day exclusivity period under clause
8 (iv) for the drug that is the subject of
9 the application for the competitive ge-
10 neric therapy; and

11 “(CC) is not for a drug for which
12 all drug versions have forfeited eligi-
13 bility for a 180-day exclusivity period
14 under clause (iv) pursuant to subpara-
15 graph (D).”; and

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

18 “(iv) SPECIAL FORFEITURE RULE FOR
19 COMPETITIVE GENERIC THERAPY.—The
20 180-day exclusivity period described in
21 subparagraph (B)(v) shall be forfeited by a
22 first approved applicant if the applicant
23 fails to market the competitive generic
24 therapy within 75 days after the date on
25 which the approval of the first approved

1 applicant's application for the competitive
2 generic therapy is made effective.”.

3 **SEC. 809. GAO STUDY OF ISSUES REGARDING FIRST CYCLE**
4 **APPROVALS OF GENERIC MEDICINES.**

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

8 (1) The rate of first cycle approvals and ten-
9 tative approvals for applications submitted under
10 section 505(j) of the Federal Food, Drug, and Cos-
11 metic Act (21 U.S.C. 355(j)) during the period be-
12 ginning on October 1, 2012, and ending on Sep-
13 tember 30, 2017. The rate of first cycle approvals
14 and tentative approvals shall be determined and re-
15 ported per each GDUFA cohort year during this pe-
16 riod.

17 (2) If the rate determined pursuant to para-
18 graph (1) for any GDUFA cohort year is lower than
19 20 percent, the reasons contributing to the relatively
20 low rate of first cycle approvals and tentative ap-
21 provals for generic drug applications shall be
22 itemized, assessed, and reported. In making the as-
23 sessment required by this paragraph, the Comp-
24 troller General shall consider, among other things,
25 the role played by—

1 (A) the Food and Drug Administration's
2 implementation of approval standards for ge-
3 neric drug applications;

4 (B) the extent to which those approval
5 standards are communicated clearly to industry
6 and applied consistently during the review pro-
7 cess;

8 (C) the procedures for reviewing generic
9 drug applications, including timelines for review
10 activities by the Food and Drug Administra-
11 tion;

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

15 (E) the processes and practices for com-
16 munication between the Food and Drug Admin-
17 istration and sponsors of generic drug applica-
18 tions; and

19 (F) the completeness and quality of origi-
20 nal generic drug applications submitted to the
21 Food and Drug Administration.

22 (3) Taking into account the determinations
23 made pursuant to paragraphs (1) and (2) and any
24 review process improvements implemented pursuant
25 to this Act, whether there are ways the review proc-

1 ess for generic drugs could be improved to increase
2 the rate of first cycle approvals and tentative ap-
3 provals for generic drug applications. In making this
4 determination, the Comptroller General shall con-
5 sider, among other things, options for increasing re-
6 view efficiency and communication effectiveness.

7 (b) COMPLETION DATE.—Not later than the expira-
8 tion of the 2-year period beginning on the date of enact-
9 ment of this Act, the Comptroller General shall complete
10 the study under subsection (a) and submit a report de-
11 scribing the findings and conclusions of the study to the
12 Secretary, the Committee on Energy and Commerce of the
13 House of Representatives, and the Committee on Health,
14 Education, Labor, and Pensions of the Senate.

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

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

18 (2) The term “generic drug” means a drug that
19 is approved or is seeking approval under section
20 505(j) of the Federal Food, Drug, and Cosmetic Act
21 (21 U.S.C. 355(j)).

22 (3) The term “generic drug application” means
23 an abbreviated new drug application for the approval
24 of a generic drug under section 505(j) of the Fed-

1 eral Food, Drug, and Cosmetic Act (21 U.S.C.
2 355(j)).

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

5 (5)(A) The term “first cycle approvals and ten-
6 tative approvals” means the approval or tentative
7 approval of a generic drug application after the
8 Food and Drug Administration’s complete review of
9 the application and without issuance of one or more
10 complete response letters.

11 (B) For purposes of this paragraph, the term
12 “complete response letter” means a written commu-
13 nication to the sponsor of a generic drug application
14 or holder of a drug master file from the Food and
15 Drug Administration describing all of the defi-
16 ciencies that the Administration has identified in the
17 generic drug application (including pending amend-
18 ments) or drug master file that must be satisfac-
19 torily addressed before the generic drug application
20 can be approved.

21 **TITLE IX—ADDITIONAL** 22 **PROVISIONS**

23 **SEC. 901. TECHNICAL CORRECTIONS.**

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

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

4 (2) in paragraph (2), by striking “section
5 2074(1)(C)” and inserting “section 3102(1)(C)”.

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

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

12 (d) Section 505F(d) of the Federal Food, Drug, and
13 Cosmetic Act (21 U.S.C. 355g(d)) is amended by striking
14 “2” and inserting “3”.

15 (e) Section 510(h)(6) of the Federal Food, Drug, and
16 Cosmetic Act (21 U.S.C. 360(h)(6)) is amended by strik-
17 ing “February 1” and replacing with “May 1”.

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

20 (1) section 3051(a) of such Act is amended by
21 striking “by inserting after section 515B” and in-
22 serting “by inserting after section 515A”; and

23 (2) section 515C of the Federal Food, Drug,
24 and Cosmetic Act (21 U.S.C. 360e–3), as inserted

1 by such section 3051(a), is redesignated as section
2 515B.

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

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

13 **SEC. 902. ANNUAL REPORT ON INSPECTIONS.**

14 Not later than March 1 of each year, the Secretary
15 of Health and Human Services shall post on the internet
16 website of the Food and Drug Administration information
17 related to inspections of facilities necessary for approval
18 of a drug under section 505 of the Federal Food, Drug,
19 and Cosmetic Act (21 U.S.C. 355), approval of a device
20 under section 515 of such Act (21 U.S.C. 360e), or clear-
21 ance of a device under section 510(k) of such Act (21
22 U.S.C. 360(k)) that were conducted during the previous
23 calendar year. Such information shall include the fol-
24 lowing:

1 (1) The median time following a request from
2 staff of the Food and Drug Administration review-
3 ing an application or report to the beginning of the
4 inspection, and the median time from the beginning
5 of an inspection to the issuance of a report pursuant
6 to section 704(b) of the Federal Food, Drug, and
7 Cosmetic Act (21 U.S.C. 374(b)).

8 (2) The median time from the issuance of a re-
9 port pursuant to such section 704(b) to the sending
10 of a warning letter, issuance of an import alert, or
11 holding of a regulatory meeting for inspections for
12 which the Secretary concluded that regulatory or en-
13 forcement action was indicated.

14 (3) The median time from the sending of a
15 warning letter, issuance of an import alert, or hold-
16 ing of a regulatory meeting to resolution of the regu-
17 latory or enforcement action indicated for inspec-
18 tions for which the Secretary concluded that such
19 action was indicated.

20 (4) The number of times that a facility was
21 issued a report pursuant to such section 704(b) and
22 approval of an application was delayed due to the
23 issuance of a withhold recommendation.

1 **SEC. 903. STREAMLINING AND IMPROVING CONSISTENCY**
2 **IN PERFORMANCE REPORTING.**

3 (a) PDUFA.—Section 736B(a) of the Federal Food,
4 Drug, and Cosmetic Act (21 U.S.C. 379h–2(a)), as
5 amended by section 103, is further amended by inserting
6 after paragraph (2) the following:

7 “(3) REAL TIME REPORTING.—

8 “(A) IN GENERAL.—Not later than 30 cal-
9 endar days after the end of the second quarter
10 of fiscal year 2018, and not later than 30 cal-
11 endar days after the end of each quarter of
12 each fiscal year thereafter, the Secretary shall
13 post the data described in subparagraph (B) on
14 the internet website of the Food and Drug Ad-
15 ministration for such quarter and on a cumu-
16 lative basis for such fiscal year, and may re-
17 move duplicative data from the annual perform-
18 ance report under this subsection.

19 “(B) DATA.—The Secretary shall post the
20 following data in accordance with subparagraph
21 (A):

22 “(i) The number and titles of draft
23 and final guidance on topics related to the
24 process for the review of human drug ap-
25 plications, and whether such guidances
26 were issued as required by statute or pur-

1 suant to a commitment under the letters
2 described in section 101(b) of the Prescrip-
3 tion Drug User Fee Amendments of 2017.

4 “(ii) The number and titles of public
5 meetings held on topics related to the proc-
6 ess for the review of human drug applica-
7 tions, and whether such meetings were re-
8 quired by statute or pursuant to a commit-
9 ment under the letters described in section
10 101(b) of the Prescription Drug User Fee
11 Amendments of 2017.

12 “(iii) The number of new drug appli-
13 cations and biological licensing applications
14 approved.

15 “(iv) The number of new drug appli-
16 cations and biological licensing applications
17 filed.

18 “(4) RATIONALE FOR PDUFA PROGRAM
19 CHANGES.—Beginning with fiscal year 2020, the
20 Secretary shall include in the annual report under
21 paragraph (1)—

22 “(A) data, analysis, and discussion of the
23 changes in the number of full-time equivalents
24 hired as agreed upon in the letters described in
25 section 101(b) of the Prescription Drug User

1 Fee Amendments of 2017 and the number of
2 full time equivalents funded by budget authority
3 at the Food and Drug Administration by each
4 division within the Center for Drug Evaluation
5 and Research, the Center for Biologics Evalua-
6 tion and Research, the Office of Regulatory Af-
7 fairs, and the Office of the Commissioner;

8 “(B) data, analysis, and discussion of the
9 changes in the fee revenue amounts and costs
10 for the process for the review of human drugs,
11 including identifying drivers of such changes;
12 and

13 “(C) for each of the Center for Drug Eval-
14 uation and Research, the Center for Biologics
15 Evaluation and Research, the Office of Regu-
16 latory Affairs, and the Office of the Commis-
17 sioner, the number of employees for whom time
18 reporting is required and the number of em-
19 ployees for whom time reporting is not re-
20 quired.”.

21 (b) MDUFA.—Section 738A(a)(1)(A) of the Federal
22 Food, Drug, and Cosmetic Act (21 U.S.C. 379j–
23 1(a)(1)(A)), as amended by section 204, is further amend-
24 ed—

1 (1) by striking “Beginning with” and inserting
2 the following:

3 “(i) GENERAL REQUIREMENTS.—Be-
4 ginning with”; and

5 (2) by adding at the end the following:

6 “(ii) ADDITIONAL INFORMATION.—
7 Beginning with fiscal year 2018, the an-
8 nual report under this subparagraph shall
9 include the progress of the Center for De-
10 vices and Radiological Health in achieving
11 the goals, and future plans for meeting the
12 goals, including—

13 “(I) the number of premarket ap-
14 plications filed under section 515 per
15 fiscal year for each review division;

16 “(II) the number of reports sub-
17 mitted under section 510(k) per fiscal
18 year for each review division; and

19 “(III) the number of expedited
20 development and priority review des-
21 ignations under section 515C per fis-
22 cal year.

23 “(iii) REAL TIME REPORTING.—

24 “(I) IN GENERAL.—Not later
25 than 30 calendar days after the end of

1 the second quarter of fiscal year
2 2018, and not later than 30 calendar
3 days after the end of each quarter of
4 each fiscal year thereafter, the Sec-
5 retary shall post the data described in
6 subclause (II) on the internet website
7 of the Food and Drug Administration
8 for such quarter and on a cumulative
9 basis for such fiscal year, and may re-
10 move duplicative data from the annual
11 report under this subparagraph.

12 “(II) DATA.—The Secretary shall
13 post the following data in accordance
14 with subclause (I):

15 “(aa) The number and titles
16 of draft and final guidance on
17 topics related to the process for
18 the review of devices, and wheth-
19 er such guidances were issued as
20 required by statute or pursuant
21 to the letters described in section
22 201(b) of the Medical Device
23 User Fee Amendments of 2017;
24 and

1 “(bb) The number and titles
2 of public meetings held on topics
3 related to the process for the re-
4 view of devices, and if such meet-
5 ings were required by statute or
6 pursuant to a commitment under
7 the letters described in section
8 201(b) of the Medical Device
9 User Fee Amendments of 2017.

10 “(iv) RATIONALE FOR MDUFA PRO-
11 GRAM CHANGES.—Beginning with fiscal
12 year 2020, the Secretary shall include in
13 the annual report under paragraph (1)—

14 “(I) data, analysis, and discus-
15 sion of the changes in the number of
16 full-time equivalents hired as agreed
17 upon in the letters described in sec-
18 tion 201(b) of the Medical Device
19 User Fee Amendments of 2017 and
20 the number of full time equivalents
21 funded by budget authority at the
22 Food and Drug Administration by
23 each division within the Center for
24 Devices and Radiological Health, the
25 Center for Biologics Evaluation and

1 Research, the Office of Regulatory Af-
2 fairs, and the Office of the Commis-
3 sioner;

4 “(II) data, analysis, and discus-
5 sion of the changes in the fee revenue
6 amounts and costs for the process for
7 the review of devices, including identi-
8 fying drivers of such changes; and

9 “(III) for each of the Center for
10 Devices and Radiological Health, the
11 Center for Biologics Evaluation and
12 Research, the Office of Regulatory Af-
13 fairs, and the Office of the Commis-
14 sioner, the number of employees for
15 whom time reporting is required and
16 the number of employees for whom
17 time reporting is not required.”.

18 (c) GDUFA.—Section 744C(a) of the Federal Food,
19 Drug, and Cosmetic Act (21 U.S.C. 379j–43(a)), as
20 amended by section 304, is further amended—

21 (1) by striking “Beginning with” and inserting
22 the following:

23 “(1) GENERAL REQUIREMENTS.—Beginning
24 with”; and

25 (2) by adding at the end the following:

1 “(2) REAL TIME REPORTING.—

2 “(A) IN GENERAL.—Not later than 30 cal-
3 endar days after the end of the second quarter
4 of fiscal year 2018, and not later than 30 cal-
5 endar days after the end of each quarter of
6 each fiscal year thereafter, the Secretary shall
7 post the data described in subparagraph (B) on
8 the internet website of the Food and Drug Ad-
9 ministration, and may remove duplicative data
10 from the annual report under this subsection.

11 “(B) DATA.—The Secretary shall post the
12 following data in accordance with subparagraph
13 (A):

14 “(i) The number and titles of draft
15 and final guidance on topics related to
16 human generic drug activities and whether
17 such guidances were issued as required by
18 statute or pursuant to a commitment
19 under the letters described in section
20 301(b) of the Generic Drug User Fee
21 Amendments of 2017.

22 “(ii) The number and titles of public
23 meetings held on topics related to human
24 generic drug activities and whether such
25 meetings were required by statute or pur-

1 suant to a commitment under the letters
2 described in section 301(b) of the Generic
3 Drug User Fee Amendments of 2017.

4 “(3) RATIONALE FOR GDUFA PROGRAM
5 CHANGES.—Beginning with fiscal year 2020, the
6 Secretary shall include in the annual report under
7 paragraph (1)—

8 “(A) data, analysis, and discussion of the
9 changes in the number of full-time equivalents
10 hired as agreed upon in the letters described in
11 section 301(b) of the Generic Drug User Fee
12 Amendments of 2017 and the number of full
13 time equivalents funded by budget authority at
14 the Food and Drug Administration by each di-
15 vision within the Center for Drug Evaluation
16 and Research, the Center for Biologics Evalua-
17 tion and Research, the Office of Regulatory Af-
18 fairs, and the Office of the Commissioner;

19 “(B) data, analysis, and discussion of the
20 changes in the fee revenue amounts and costs
21 for human generic drug activities, including
22 identifying drivers of such changes; and

23 “(C) for each of the Center for Drug Eval-
24 uation and Research, the Center for Biologics
25 Evaluation and Research, the Office of Regu-

1 latory Affairs, and the Office of the Commis-
2 sioner, the number of employees for whom time
3 reporting is required and the number of em-
4 ployees for whom time reporting is not re-
5 quired.”.

6 (d) BsUFA.—Section 744I(a) of the Federal Food,
7 Drug, and Cosmetic Act (21 U.S.C. 379j–53(a)), as
8 amended by section 404, is further amended—

9 (1) by striking “Beginning with” and inserting
10 the following:

11 “(1) GENERAL REQUIREMENTS.—Beginning
12 with”; and

13 (2) by adding at the end the following:

14 “(2) ADDITIONAL INFORMATION.—Beginning
15 with fiscal year 2018, the report under this sub-
16 section shall include the progress of the Food and
17 Drug Administration in achieving the goals, and fu-
18 ture plans for meeting the goals, including—

19 “(A) information on all previous cohorts
20 for which the Secretary has not given a com-
21 plete response on all biosimilar biological prod-
22 uct applications and supplements in the cohort;

23 “(B) the number of original biosimilar bio-
24 logical product applications filed per fiscal year,

1 and the number of approvals issued by the
2 agency for such applications; and

3 “(C) the number of resubmitted original
4 biosimilar biological product applications filed
5 per fiscal year and the number of approvals let-
6 ters issued by the agency for such applications.

7 “(3) REAL TIME REPORTING.—

8 “(A) IN GENERAL.—Not later than 30 cal-
9 endar days after the end of the second quarter
10 of fiscal year 2018, and not later than 30 cal-
11 endar days after the end of each quarter of
12 each fiscal year thereafter, the Secretary shall
13 post the data described in subparagraph (B) for
14 such quarter and on a cumulative basis for the
15 fiscal year on the internet website of the Food
16 and Drug Administration, and may remove du-
17 plicative data from the annual report under this
18 subsection.

19 “(B) DATA.—The Secretary shall post the
20 following data in accordance with subparagraph
21 (A):

22 “(i) The number and titles of draft
23 and final guidance on topics related to the
24 process for the review of biosimilars, and
25 whether such guidances were required by

1 statute or pursuant to a commitment
2 under the letters described in section
3 401(b) of the Biosimilar User Fee Amend-
4 ments of 2017.

5 “(ii) The number and titles of public
6 meetings held on topics related to the proc-
7 ess for the review of biosimilars, and
8 whether such meetings were required by
9 statute or pursuant to a commitment
10 under the letters described in section
11 401(b) of the Biosimilar User Fee Amend-
12 ments of 2017.

13 “(4) RATIONALE FOR BSUFA PROGRAM
14 CHANGES.—Beginning with fiscal year 2020, the
15 Secretary shall include in the annual report under
16 paragraph (1)—

17 “(A) data, analysis, and discussion of the
18 changes in the number of full-time equivalents
19 hired as agreed upon in the letters described in
20 section 401(b) of the Biosimilar User Fee
21 Amendments of 2017 and the number of full
22 time equivalents funded by budget authority at
23 the Food and Drug Administration by each di-
24 vision within the Center for Drug Evaluation
25 and Research, the Center for Biologics Evalua-

1 tion and Research, the Office of Regulatory Af-
2 fairs, and the Office of the Commissioner;

3 “(B) data, analysis, and discussion of the
4 changes in the fee revenue amounts and costs
5 for the process for the review of biosimilar bio-
6 logical product applications, including identi-
7 fying drivers of such changes; and

8 “(C) for each of the Center for Drug Eval-
9 uation and Research, the Center for Biologics
10 Evaluation and Research, the Office of Regu-
11 latory Affairs, and the Office of the Commis-
12 sioner, the number of employees for whom time
13 reporting is required and the number of em-
14 ployees for whom time reporting is not re-
15 quired.”.

16 **SEC. 904. ANALYSIS OF USE OF FUNDS.**

17 (a) PDUFA REPORTS.—

18 (1) ANALYSIS IN PDUFA PERFORMANCE RE-
19 PORTS.—Section 736B(a) of the Federal Food,
20 Drug, and Cosmetic Act (21 U.S.C. 379h–2(a)), as
21 amended by section 903(a), is further amended by
22 adding at the end the following:

23 “(5) ANALYSIS.—For each fiscal year, the Sec-
24 retary shall include in the report under paragraph
25 (1) an analysis of the following:

1 “(A) The difference between the aggregate
2 number of human drug applications filed and
3 the aggregate number of approvals, accounting
4 for—

5 “(i) such applications filed during one
6 fiscal year for which a decision is not
7 scheduled to be made until the following
8 fiscal year;

9 “(ii) the aggregate number of applica-
10 tions for each fiscal year that did not meet
11 the goals identified in the letters described
12 in section 101(b) of the Prescription Drug
13 User Fee Amendments of 2017 for the ap-
14 plicable fiscal year.

15 “(B) Relevant data to determine whether
16 the Center for Drug Evaluation and Research
17 and the Center for Biologics Evaluation and
18 Research have met performance enhancement
19 goals identified in the letters described in sec-
20 tion 101(b) of the Prescription Drug User Fee
21 Amendments of 2017 for the applicable fiscal
22 year.

23 “(C) The most common causes and trends
24 of external or other circumstances affecting the
25 ability of the Center for Drug Evaluation and

1 Research, the Center for Biologics Evaluation
2 and Research, Office of Regulatory Affairs, and
3 the Food and Drug Administration to meet the
4 review time and performance enhancement
5 goals identified in the letters described in sec-
6 tion 101(b) of the Prescription Drug User Fee
7 Amendments of 2017.”.

8 (2) ISSUANCE OF CORRECTIVE ACTION RE-
9 PORTS.—Section 736B of the Federal Food, Drug,
10 and Cosmetic Act (21 U.S.C. 379h–2) is amended—

11 (A) by redesignating subsections (e) and
12 (d) as subsections (e) and (f), respectively; and

13 (B) by inserting after subsection (b) the
14 following:

15 “(c) CORRECTIVE ACTION REPORT.—Beginning with
16 fiscal year 2018, for each fiscal year for which fees are
17 collected under this part, the Secretary shall prepare and
18 submit a corrective action report to the Committee on En-
19 ergy and Commerce and the Committee on Appropriations
20 of the House of Representatives and the Committee on
21 Health, Education, Labor, and Pensions and the Com-
22 mittee on Appropriations of the Senate. The report shall
23 include the following information, as applicable:

24 “(1) GOALS MET.—For each fiscal year, if the
25 Secretary determines, based on the analysis under

1 subsection (a)(5), that each of the goals identified in
2 the letters described in section 101(b) of the Pre-
3 scription Drug User Fee Amendments of 2017 for
4 the applicable fiscal year have been met, the correc-
5 tive action report shall include recommendations on
6 ways in which the Secretary can improve and
7 streamline the human drug application review pro-
8 cess.

9 “(2) GOALS MISSED.—For any of the goals
10 identified in the letters described in section 101(b)
11 of the Prescription Drug User Fee Amendments of
12 2017 for the applicable fiscal year that the Secretary
13 determines to not have been met, the corrective ac-
14 tion report shall include—

15 “(A) a detailed justification for such deter-
16 mination and a description, as applicable, of the
17 types of circumstances and trends under which
18 human drug applications that missed the review
19 goal time were approved during the first cycle
20 review, or application review goals were missed;
21 and

22 “(B) with respect to performance enhance-
23 ment goals that were not achieved, a description
24 of efforts the Food and Drug Administration
25 has put in place for the fiscal year in which the

1 report is submitted to improve the ability of
2 such agency to meet each such goal for the
3 such fiscal year.

4 “(d) ENHANCED COMMUNICATION.—

5 “(1) COMMUNICATIONS WITH CONGRESS.—

6 Each fiscal year, as applicable and requested, rep-
7 resentatives from the Centers with expertise in the
8 review of human drugs shall meet with representa-
9 tives from the Committee on Health, Education,
10 Labor, and Pensions of the Senate and the Com-
11 mittee on Energy and Commerce of the House of
12 Representatives to report on the contents described
13 in the reports under this section.

14 “(2) PARTICIPATION IN CONGRESSIONAL HEAR-

15 ING.—Each fiscal year, as applicable and requested,
16 representatives from the Food and Drug Adminis-
17 tration shall participate in a public hearing before
18 the Committee on Health, Education, Labor, and
19 Pensions of the Senate and the Committee on En-
20 ergy and Commerce of the House of Representa-
21 tives, to report on the contents described in the re-
22 ports under this section. Such hearing shall occur
23 not later than 120 days after the end of each fiscal
24 year for which fees are collected under this part.”.

25 (b) MDUFA REPORTS.—

1 (1) ANALYSIS IN MDUFA PERFORMANCE RE-
2 PORTS.—Section 738A(a)(1)(A) of the Federal
3 Food, Drug, and Cosmetic Act (21 U.S.C. 379j-
4 1(a)(1)(A)), as amended by section 903(b), is fur-
5 ther amended by adding at the end the following:

6 “(iv) ANALYSIS.—For each fiscal
7 year, the Secretary shall include in the re-
8 port under clause (i) an analysis of the fol-
9 lowing:

10 “(I) The difference between the
11 aggregate number of premarket appli-
12 cations filed under section 515 and
13 aggregate reports submitted under
14 section 510(k) and the aggregate
15 number of major deficiency letters,
16 not approvable letters, and denials for
17 such applications issued by the agen-
18 cy, accounting for—

19 “(aa) the number of applica-
20 tions filed and reports submitted
21 during one fiscal year for which a
22 decision is not scheduled to be
23 made until the following fiscal
24 year; and

1 “(bb) the aggregate number
2 of applications for each fiscal
3 year that did not meet the goals
4 as identified by the letters de-
5 scribed in section 201(b) of the
6 Medical Device User Fee Amend-
7 ments of 2017 for the applicable
8 fiscal year.

9 “(II) Relevant data to determine
10 whether the Center for Devices and
11 Radiological Health has met perform-
12 ance enhancement goals identified by
13 the letters described in section 201(b)
14 of the Medical Device User Fee
15 Amendments of 2017 for the applica-
16 ble fiscal year.

17 “(III) The most common causes
18 and trends for external or other cir-
19 cumstances affecting the ability of the
20 Center for Devices and Radiological
21 Health, the Office of Regulatory Af-
22 fairs, or the Food and Drug Adminis-
23 tration to meet review time and per-
24 formance enhancement goals identi-
25 fied by the letters described in section

1 201(b) of the Medical Device User
2 Fee Amendments of 2017.”.

3 (2) ISSUANCE OF CORRECTIVE ACTION RE-
4 PORTS.—Section 738A(a) of the Federal Food,
5 Drug, and Cosmetic Act (21 U.S.C. 379j–1(a)) is
6 amended—

7 (A) by redesignating paragraphs (2) and
8 (3) as paragraphs (4) and (5), respectively; and

9 (B) by inserting after paragraph (1) the
10 following:

11 “(2) CORRECTIVE ACTION REPORT.—Beginning
12 with fiscal year 2018, for each fiscal year for which
13 fees are collected under this part, the Secretary shall
14 prepare and submit a corrective action report to the
15 Committee on Energy and Commerce and the Com-
16 mittee on Appropriations of the House of Represent-
17 atives and the Committee on Health, Education,
18 Labor, and Pensions and the Committee on Appro-
19 priations of the Senate. The report shall include the
20 following information, as applicable:

21 “(A) GOALS MET.—For each fiscal year, if
22 the Secretary determines, based on the analysis
23 under paragraph (1)(A)(iv), that each of the
24 goals identified by the letters described in sec-
25 tion 201(b) of the Medical Device User Fee

1 Amendments of 2017 for the applicable fiscal
2 year have been met, the corrective action report
3 shall include recommendations on ways in which
4 the Secretary can improve and streamline the
5 medical device application review process.

6 “(B) GOALS MISSED.—For each of the
7 goals identified by the letters described in sec-
8 tion 201(b) of the Medical Device User Fee
9 Amendments of 2017 for the applicable fiscal
10 year that the Secretary determines to not have
11 been met, the corrective action report shall in-
12 clude—

13 “(i) a justification for such determina-
14 tion;

15 “(ii) a description of the types of cir-
16 cumstances, in the aggregate, under which
17 applications or reports submitted under
18 section 515 or notifications submitted
19 under section 510(k) missed the review
20 goal times but were approved during the
21 first cycle review, as applicable;

22 “(iii) a summary and any trends with
23 regard to the circumstances for which a re-
24 view goal was missed; and

1 “(iv) the performance enhancement
2 goals that were not achieved during the
3 previous fiscal year and a description of ef-
4 forts the Food and Drug Administration
5 has put in place for the fiscal year in
6 which the report is submitted to improve
7 the ability of such agency to meet each
8 such goal for the such fiscal year.

9 “(3) ENHANCED COMMUNICATION.—

10 “(A) COMMUNICATIONS WITH CON-
11 GRESS.—Each fiscal year, as applicable and re-
12 quested, representatives from the Centers with
13 expertise in the review of devices shall meet
14 with representatives from the Committee on
15 Health, Education, Labor, and Pensions of the
16 Senate and the Committee on Energy and Com-
17 merce of the House of Representatives to report
18 on the contents described in the reports under
19 this section.

20 “(B) PARTICIPATION IN CONGRESSIONAL
21 HEARING.—Each fiscal year, as applicable and
22 requested, representatives from the Food and
23 Drug Administration shall participate in a pub-
24 lic hearing before the Committee on Health,
25 Education, Labor, and Pensions of the Senate

1 and the Committee on Energy and Commerce
2 of the House of Representatives, to report on
3 the contents described in the reports under this
4 section. Such hearing shall occur not later than
5 120 days after the end of each fiscal year for
6 which fees are collected under this part.”.

7 (c) GDUFA REPORTS.—

8 (1) ANALYSIS IN GDUFA PERFORMANCE RE-
9 PORTS.—Section 744C(a) of the Federal Food,
10 Drug, and Cosmetic Act (21 U.S.C. 379j–43(a)), as
11 amended by section 903(c) is further amended by
12 adding at the end the following:

13 “(4) ANALYSIS.—For each fiscal year, the Sec-
14 retary shall include in the report an analysis of the
15 following:

16 “(A) The difference between the aggregate
17 number of abbreviated new drug applications
18 filed and the aggregate number of approvals or
19 aggregate number of complete response letters
20 issued by the agency, accounting for—

21 “(i) such applications filed during one
22 fiscal year for which a decision is not
23 scheduled to be made until the following
24 fiscal year; and

1 “(ii) the aggregate number of applica-
2 tions for each fiscal year that did not meet
3 the goals identified by the letters described
4 in section 301(b) of the Generic Drug User
5 Fee Amendments of 2017 for the applica-
6 ble fiscal year.

7 “(B) Relevant data to determine whether
8 the Food and Drug Administration has met the
9 performance enhancement goals identified by
10 the letters described in section 301(b) of the
11 Generic Drug User Fee Amendments of 2017
12 for the applicable fiscal year.

13 “(C) The most common causes and trends
14 for external or other circumstances that af-
15 fected the ability of the Secretary to meet re-
16 view time and performance enhancement goals
17 identified by the letters described in section
18 301(b) of the Generic Drug User Fee Amend-
19 ments of 2017.”.

20 (2) ISSUANCE OF CORRECTIVE ACTION RE-
21 PORTS.—Section 744C of the Federal Food, Drug,
22 and Cosmetic Act (21 U.S.C. 379j–43) is amend-
23 ed—

24 (A) by redesignating subsections (c) and
25 (d) as subsections (e) and (f), respectively; and

1 (B) by inserting after subsection (b) the
2 following:

3 “(c) CORRECTIVE ACTION REPORT.—Beginning with
4 fiscal year 2018, for each fiscal year for which fees are
5 collected under this part, the Secretary shall prepare and
6 submit a corrective action report to the Committee on En-
7 ergy and Commerce and the Committee on Appropriations
8 of the House of Representatives and the Committee on
9 Health, Education, Labor, and Pensions and the Com-
10 mittee on Appropriations of the Senate. The report shall
11 include the following information, as applicable:

12 “(1) GOALS MET.—For each fiscal year, if the
13 Secretary determines, based on the analysis under
14 subsection (a)(4), that each of the goals identified by
15 the letters described in section 301(b) of the Generic
16 Drug User Fee Amendments of 2017 for the appli-
17 cable fiscal year have been met, the corrective action
18 report shall include recommendations on ways in
19 which the Secretary can improve and streamline the
20 abbreviated new drug application review process.

21 “(2) GOALS MISSED.—For each of the goals
22 identified by the letters described in section 301(b)
23 of the Generic Drug User Fee Amendments of 2017
24 for the applicable fiscal year that the Secretary de-

1 termines to not have been met, the corrective action
2 report shall include—

3 “(A) a detailed justification for such deter-
4 mination and a description, as applicable, of the
5 types of circumstances and trends under which
6 abbreviated new drug applications missed the
7 review goal times but were approved during the
8 first cycle review, or review goals were missed;
9 and

10 “(B) with respect to performance enhance-
11 ment goals that were not achieved, a detailed
12 description of efforts the Food and Drug Ad-
13 ministration has put in place for the fiscal year
14 in which the report is submitted to improve the
15 ability of such agency to meet each such goal
16 for the such fiscal year.

17 “(d) ENHANCED COMMUNICATION.—

18 “(1) COMMUNICATIONS WITH CONGRESS.—
19 Each fiscal year, as applicable and requested, rep-
20 resentatives from the Centers with expertise in the
21 review of human drugs shall meet with representa-
22 tives from the Committee on Health, Education,
23 Labor, and Pensions of the Senate and the Com-
24 mittee on Energy and Commerce of the House of

1 Representatives to report on the contents described
2 in the reports under this section.

3 “(2) PARTICIPATION IN CONGRESSIONAL HEAR-
4 ING.—Each fiscal year, as applicable and requested,
5 representatives from the Food and Drug Adminis-
6 tration shall participate in a public hearing before
7 the Committee on Health, Education, Labor, and
8 Pensions of the Senate and the Committee on En-
9 ergy and Commerce of the House of Representa-
10 tives, to report on the contents described in the re-
11 ports under this section. Such hearing shall occur
12 not later than 120 days after the end of each fiscal
13 year for which fees are collected under this part.”.

14 (d) BSUFA REPORTS.—

15 (1) ANALYSIS IN BSUFA PERFORMANCE RE-
16 PORTS.—Section 744I(a) of the Federal Food, Drug,
17 and Cosmetic Act (21 U.S.C. 379j–53(a)) as amend-
18 ed by section 903(d) is further amended by adding
19 at the end the following:

20 “(5) ANALYSIS.—For each fiscal year, the Sec-
21 retary shall include in the report an analysis of the
22 following:

23 “(A) The difference between the aggregate
24 number of biosimilar biological product applica-
25 tions and supplements filed and the aggregate

1 number of approvals issued by the agency, ac-
2 counting for—

3 “(i) such applications filed during one
4 fiscal year for which a decision is not
5 scheduled to be made until the following
6 fiscal year; and

7 “(ii) the aggregate number of applica-
8 tions for each fiscal year that did not meet
9 the goals identified by the letters described
10 in section 401(b) of the Biosimilar User
11 Fee Amendments of 2017 for the applica-
12 ble fiscal year.

13 “(B) Relevant data to determine whether
14 the Center for Drug Evaluation and Research
15 and the Center for Biologics Evaluation and
16 Research have met the performance enhance-
17 ment goals identified by the letters described in
18 section 401(b) of the Biosimilar User Fee
19 Amendments of 2017 for the applicable fiscal
20 year.

21 “(C) The most common causes and trends
22 for external or other circumstances affecting
23 the ability of the Secretary to meet review time
24 and performance enhancement goals identified

1 by the letters described in section 401(b) of the
2 Biosimilar User Fee Amendments of 2017.”.

3 (2) ISSUANCE OF CORRECTIVE ACTION RE-
4 PORTS.—Section 744I of the Federal Food, Drug,
5 and Cosmetic Act (21 U.S.C. 379j–53), as amended
6 by section 404, is further amended—

7 (A) by redesignating subsections (e) and
8 (d) as subsections (e) and (f), respectively; and

9 (B) by inserting after subsection (b) the
10 following:

11 “(c) CORRECTIVE ACTION REPORT.—Beginning with
12 fiscal year 2018, and for each fiscal year for which fees
13 are collected under this part, the Secretary shall prepare
14 and submit a corrective action report to the Committee
15 on Energy and Commerce and Committee on Appropria-
16 tions of the House of Representatives and the Committee
17 on Health, Education, Labor, and Pensions and Com-
18 mittee on Appropriations of the Senate. The report shall
19 include the following information, as applicable:

20 “(1) GOALS MET.—For each fiscal year, if the
21 Secretary determines, based on the analysis under
22 subsection (a)(5), that each of the goals identified by
23 the letters described in section 401(b) of the Bio-
24 similar User Fee Amendments of 2017 for the appli-
25 cable fiscal year have been met, the corrective action

1 report shall include recommendations on ways in
2 which the Secretary can improve and streamline the
3 biosimilar biological product application review pro-
4 cess.

5 “(2) GOALS MISSED.—For each of the goals
6 identified by the letters described in section 401(b)
7 of the Biosimilar User Fee Amendments of 2017 for
8 the applicable fiscal year that the Secretary deter-
9 mines to not have been met, the corrective action re-
10 port shall include—

11 “(A) a justification for such determination
12 and a description of the types of circumstances
13 and trends, as applicable, under which bio-
14 similar biological product applications missed
15 the review goal times but were approved during
16 the first cycle review, or review goals were
17 missed; and

18 “(B) with respect to performance enhance-
19 ment goals that were not achieved, a description
20 of efforts the Food and Drug Administration
21 has put in place for the fiscal year in which the
22 report is submitted to improve the ability of
23 such agency to meet each such goal for the
24 such fiscal year.

25 “(d) ENHANCED COMMUNICATION.—

1 “(1) COMMUNICATIONS WITH CONGRESS.—
2 Each fiscal year, as applicable and requested, rep-
3 resentatives from the Centers with expertise in the
4 review of human drugs shall meet with representa-
5 tives from the Committee on Health, Education,
6 Labor, and Pensions of the Senate and the Com-
7 mittee on Energy and Commerce of the House of
8 Representatives to report on the contents described
9 in the reports under this section.

10 “(2) PARTICIPATION IN CONGRESSIONAL HEAR-
11 ING.—Each fiscal year, as applicable and requested,
12 representatives from the Food and Drug Adminis-
13 tration shall participate in a public hearing before
14 the Committee on Health, Education, Labor, and
15 Pensions of the Senate and the Committee on En-
16 ergy and Commerce of the House of Representa-
17 tives, to report on the contents described in the re-
18 ports under this section. Such hearing shall occur
19 not later than 120 days after the end of each fiscal
20 year for which fees are collected under this part.”.

21 **SEC. 905. FACILITIES MANAGEMENT.**

22 (a) EVALUATION.—

23 (1) STUDY.—The Comptroller General of the
24 United States shall conduct a study on the expenses
25 incurred by the Food and Drug Administration re-

1 lated to facility maintenance and renovation in fiscal
2 years 2012 through 2019. The study under this
3 paragraph shall include the following:

4 (A) A review of purchases and expenses
5 differentiated by appropriated funds, and re-
6 sources authorized by the Food and Drug Ad-
7 ministration Safety and Innovation Act (Public
8 Law 112–144) and this Act, as applicable, that
9 contributed to—

10 (i) the maintenance of scientific equip-
11 ment and any existing facility plan or
12 plans to maintain previously purchased sci-
13 entific equipment;

14 (ii) the renovation of facilities in the
15 Center for Drug Evaluation and Research,
16 the Center for Biologics Evaluation and
17 Research, and the Center for Devices and
18 Radiological Health, and the purpose of
19 such renovation including the need for the
20 renovation;

21 (iii) the assets purchased or repaired
22 under the “repair of facilities and acquisi-
23 tion” authority under parts 2, 3, 7, and 8
24 of subchapter C of chapter VII of the Fed-

1 eral Food, Drug, and Cosmetic Act (21
2 U.S.C. 379f et seq.);

3 (iv) the maintenance and repair of fa-
4 cilities and fixtures, including a description
5 of any unanticipated repairs and mainte-
6 nance as well as scheduled repairs mainte-
7 nance, and the budget plan for the sched-
8 uled or anticipated maintenance;

9 (v) the acquisition of furniture, a de-
10 scription of the furniture purchased, and
11 the purpose of the furniture including pur-
12 chases for the Center for Drug Evaluation
13 and Research, the Center for Biologics
14 Evaluation and Research, and the Center
15 for Devices and Radiological Health; and

16 (vi) the acquisition of other necessary
17 materials and supplies by product category
18 under the authority under parts 2, 3, 7,
19 and 8 of subchapter C of chapter VII of
20 the Federal Food, Drug, and Cosmetic Act
21 (21 U.S.C. 379f et seq.).

22 (B) An analysis of the Food and Drug Ad-
23 ministration's ability to further its public health
24 mission and review medical products by incur-
25 ring the expenses listed in clauses (i) through

1 (vi) of subparagraph (A). In conducting the
2 analysis, the Comptroller General shall request
3 information from and consult with appropriate
4 employees, including staff and those responsible
5 for the fiscal decisions regarding facility main-
6 tenance and renovation for the agency.

7 (2) REPORT.—

8 (A) IN GENERAL.—The Comptroller Gen-
9 eral shall issue a report to the Committee on
10 Health, Education, Labor, and Pensions of the
11 Senate and the Committee on Energy and Com-
12 merce of the House of Representatives not later
13 than July 30, 2020, containing the results of
14 the study under paragraph (1).

15 (B) RECOMMENDATIONS.—As part of the
16 report under this paragraph, the Comptroller
17 General may provide recommendations, as ap-
18 plicable, on methods through which the Food
19 and Drug Administration may improve plan-
20 ning for—

21 (i) the maintenance, renovation, and
22 repair of facilities;

23 (ii) the purchase of furniture or other
24 acquisitions; and

1 (iii) ways the Food and Drug Admin-
2 istration may allocate the expenses de-
3 scribed in clauses (i) and (ii) of paragraph
4 (1)(A), as informed by the analysis under
5 paragraph (1)(B).

6 (b) ADMINISTRATION.—

7 (1) PDUFA.—Section 736(f) of the Federal
8 Food, Drug, and Cosmetic Act (21 U.S.C. 379h(f))
9 is amended by adding at the end the following:

10 “(3) LIMITATION.—Beginning on October 1,
11 2023, the authorities under section 735(7)(C) shall
12 include only expenditures for leasing and necessary
13 scientific equipment.”.

14 (2) MDUFA.—Section 738(h) of the Federal
15 Food, Drug, and Cosmetic Act (21 U.S.C. 379j(h))
16 is amended by adding at the end the following:

17 “(3) LIMITATION.—Beginning on October 1,
18 2023, the authorities under section 737(9)(C) shall
19 include only leasing and necessary scientific equip-
20 ment.”.

21 (3) GDUFA.—Section 744B(e) of the Federal
22 Food, Drug, and Cosmetic Act (21 U.S.C. 379j-
23 42(e)) is amended—

24 (A) in the subsection heading, by striking
25 “LIMIT” and inserting “LIMITATIONS”;

1 (B) by striking “The total amount” and
2 inserting the following:

3 “(1) IN GENERAL.—The total amount”; and

4 (C) by adding at the end the following:

5 “(2) LEASING AND NECESSARY EQUIPMENT.—

6 Beginning on October 1, 2023, the authorities under
7 section 744A(11)(C) shall include only leasing and
8 necessary scientific equipment.”.

9 (4) BSUFA.—Section 744H(e)(2)(B) of the
10 Federal Food, Drug, and Cosmetic Act (21 U.S.C.
11 379j–52(e)(2)(B)) is amended—

12 (A) in the subparagraph heading, by strik-
13 ing “LIMITATION” and inserting “LIMITA-
14 TIONS”;

15 (B) by striking “The fees authorized” and
16 inserting the following:

17 “(i) IN GENERAL.—The fees author-
18 ized”; and

19 (C) by adding at the end the following:

20 “(ii) LEASING AND NECESSARY

21 EQUIPMENT.—Beginning on October 1,

22 2023, the authorities under section

1 744G(9)(C) shall include only leasing and
2 necessary scientific equipment.”.

Passed the House of Representatives July 12, 2017.

Attest:

Clerk.

115TH CONGRESS
1ST SESSION

H. R. 2430

AN ACT

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.