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115TH CONGRESS
1ST SESSION

H. R. 2430

[Report No. 115–201]

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.

IN THE HOUSE OF REPRESENTATIVES

MAY 16, 2017

Mr. WALDEN (for himself, Mr. PALLONE, Mr. BURGESS, and Mr. GENE GREEN of Texas) introduced the following bill; which was referred to the Committee on Energy and Commerce

JULY 11, 2017

Reported with an amendment, committed to the Committee of the Whole House on the State of the Union, and ordered to be printed

[Strike out all after the enacting clause and insert the part printed in *italie*]

[For text of introduced bill, see copy of bill as introduced on May 16, 2017]

A BILL

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,*

3 **SECTION 1. SHORT TITLE.**

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

6 **SEC. 2. TABLE OF CONTENTS.**

7 *The table of contents for this Act is as follows:*

Sec. 1. Short title.

Sec. 2. Table of contents.

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Sec. 302. Definitions.

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

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TITLE IV—FEES RELATING TO BIOSIMILAR BIOLOGICAL PRODUCTS

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Sec. 402. Definitions.

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TITLE V—REAUTHORIZATIONS AND IMPROVEMENTS RELATED TO DRUGS

- Sec. 501. Reauthorization of provision relating to exclusivity of certain drugs containing single enantiomers.*
Sec. 502. Reauthorization of orphan grants program.
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Sec. 504. Protecting and strengthening the drug supply chain.
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TITLE VI—DEVICE INSPECTION AND REGULATORY IMPROVEMENTS

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- Sec. 611. Reauthorization of pediatric humanitarian device exceptions.*
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Sec. 614. Report on ensuring quality, safety, and continued effectiveness of devices that have been serviced.
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Sec. 616. Risk-based classification of accessories.

TITLE VII—GENERIC DRUG ACCESS AND COMPETITION

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

TITLE VIII—FOSTERING INNOVATION IN MEDICAL IMAGING

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

TITLE IX—ADDITIONAL PROVISIONS

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

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 author-*
7 *ized by the amendments made in this title will be dedicated*
8 *toward expediting the drug development process and the*
9 *process for the review of human drug applications, includ-*
10 *ing postmarket drug safety activities, as set forth in the*
11 *goals identified for purposes of part 2 of subchapter C of*
12 *chapter VII of the Federal Food, Drug, and Cosmetic Act,*
13 *in the letters from the Secretary of Health and Human*
14 *Services to the Chairman of the Committee on Health, Edu-*
15 *cation, Labor, and Pensions of the Senate and the Chair-*
16 *man of the Committee on Energy and Commerce of the*
17 *House of Representatives, as set forth in the Congressional*
18 *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 Federal*
22 *Food, Drug, and Cosmetic Act (21 U.S.C. 379h(a)) is*
23 *amended—*

1 (A) in the matter preceding paragraph (1),
2 by striking “fiscal year 2013” and inserting “fis-
3 cal 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 ei-
8 ther 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 safety
19 or effectiveness are not required for ap-
20 proval.”;

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 fol-
12 lows: “Except as provided in subparagraphs (B)
13 and (C), each person who is named as the appli-
14 cant in a human drug application, and who,
15 after September 1, 1992, had pending before the
16 Secretary a human drug application or supple-
17 ment, shall pay the annual prescription drug
18 program fee established for a fiscal year under
19 subsection (c)(5) for each prescription drug prod-
20 uct that is identified in such a human drug ap-
21 plication approved as of October 1 of such fiscal
22 year.”;

23 (K) in subparagraph (B) of such paragraph
24 (2)—

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

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

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

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

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

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

1 *(b) FEE REVENUE AMOUNTS.—Subsection (b) of sec-*
 2 *tion 736 of the Federal Food, Drug, and Cosmetic Act (21*
 3 *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, ex-*
 7 *cept as provided in subsections (c), (d), (f), and (g),*
 8 *be established to generate a total revenue amount*
 9 *under such subsection that is equal to the sum of—*

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

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

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

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

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

1 “(F) additional dollar amounts for each fis-
2 cal 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 2020.

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

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

8 “(2) TYPES OF FEES.—Of the total revenue
9 amount determined for a fiscal year under paragraph
10 (1)—

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

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

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

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

21 “(B) for fiscal years 2019 through 2022, the
22 dollar amount of the total revenue amount estab-
23 lished under paragraph (1) for the previous fis-
24 cal year, not including any adjustments made
25 under subsection (c)(3) or (c)(4).”.

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

5 “(c) *ADJUSTMENTS; ANNUAL FEE SETTING.*—

6 “(1) *INFLATION ADJUSTMENT.*—

7 “(A) *IN GENERAL.*—For purposes of sub-
 8 section (b)(1)(B), the dollar amount of the infla-
 9 tion adjustment to the annual base revenue for
 10 each fiscal year shall be equal to the product
 11 of—

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

14 “(ii) the inflation adjustment percent-
 15 age under subparagraph (B).

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

20 “(i) the average annual percent change
 21 in the cost, per full-time equivalent position
 22 of the Food and Drug Administration, of all
 23 personnel compensation and benefits paid
 24 with respect to such positions for the first 3
 25 years of the preceding 4 fiscal years, multi-

1 *plied by the proportion of personnel com-*
2 *pensation and benefits costs to total costs of*
3 *the process for the review of human drug*
4 *applications (as defined in section 735(6))*
5 *for the first 3 years of the preceding 4 fiscal*
6 *years; and*

7 *“(ii) the average annual percent*
8 *change that occurred in the Consumer Price*
9 *Index for urban consumers (Washington-*
10 *Baltimore, DC–MD–VA–WV; Not Season-*
11 *ally Adjusted; All items; Annual Index) for*
12 *the first 3 years of the preceding 4 years of*
13 *available data multiplied by the proportion*
14 *of all costs other than personnel compensa-*
15 *tion and benefits costs to total costs of the*
16 *process for the review of human drug appli-*
17 *cations (as defined in section 735(6)) for the*
18 *first 3 years of the preceding 4 fiscal years.*

19 *“(2) CAPACITY PLANNING ADJUSTMENT.—*

20 *“(A) IN GENERAL.—For each fiscal year,*
21 *after the annual base revenue established in sub-*
22 *section (b)(1)(A) is adjusted for inflation in ac-*
23 *cordance with paragraph (1), such revenue shall*
24 *be adjusted further for such fiscal year, in ac-*
25 *cordance with this paragraph, to reflect changes*

1 *in the resource capacity needs of the Secretary*
2 *for the process for the review of human drug ap-*
3 *plications.*

4 “(B) *INTERIM METHODOLOGY.*—

5 “(i) *IN GENERAL.*—*Until the capacity*
6 *planning methodology described in subpara-*
7 *graph (C) is effective, the adjustment under*
8 *this paragraph for a fiscal year shall be*
9 *based on the product of—*

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

13 “(II) *the adjustment percentage*
14 *under clause (ii).*

15 “(ii) *ADJUSTMENT PERCENTAGE.*—*The*
16 *adjustment percentage under this clause for*
17 *a fiscal year is the weighted change in the*
18 *3-year average ending in the most recent*
19 *year for which data are available, over the*
20 *3-year average ending in the previous year,*
21 *for—*

22 “(I) *the total number of human*
23 *drug applications, efficacy supple-*
24 *ments, and manufacturing supple-*
25 *ments submitted to the Secretary;*

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

4 “(III) the total number of formal
5 meetings scheduled by the Secretary,
6 and written responses issued by the
7 Secretary in lieu of such formal meet-
8 ings, as identified in section I.H of the
9 letters described in section 101(b) of the
10 Prescription Drug User Fee Amend-
11 ments of 2017.

12 “(C) CAPACITY PLANNING METHODOLOGY.—

13 “(i) DEVELOPMENT; EVALUATION AND
14 REPORT.—The Secretary shall obtain,
15 through a contract with an independent ac-
16 counting or consulting firm, a report evalu-
17 ating options and recommendations for a
18 new methodology to accurately assess
19 changes in the resource and capacity needs
20 of the process for the review of human drug
21 applications. The capacity planning meth-
22 odological options and recommendations
23 presented in such report shall utilize and be
24 informed by personnel time reporting data
25 as an input. The report shall be published

1 *for public comment no later than the end of*
2 *fiscal year 2020.*

3 “(ii) *ESTABLISHMENT AND IMPLEMEN-*
4 *TATION.—After review of the report de-*
5 *scribed in clause (i) and any public com-*
6 *ments thereon, the Secretary shall establish*
7 *a capacity planning methodology for pur-*
8 *poses of this paragraph, which shall—*

9 “(I) *replace the interim method-*
10 *ology under subparagraph (B);*

11 “(II) *incorporate such approaches*
12 *and attributes as the Secretary deter-*
13 *mines appropriate; and*

14 “(III) *be effective beginning with*
15 *the first fiscal year for which fees are*
16 *set after such capacity planning meth-*
17 *odology is established.*

18 “(D) *LIMITATION.—Under no circumstances*
19 *shall an adjustment under this paragraph result*
20 *in fee revenue for a fiscal year that is less than*
21 *the sum of the amounts under subsections*
22 *(b)(1)(A) (the annual base revenue for the fiscal*
23 *year) and (b)(1)(B) (the dollar amount of the in-*
24 *flation adjustment for the fiscal year).*

1 “(E) *PUBLICATION IN FEDERAL REG-*
2 *ISTER.—The Secretary shall publish in the Fed-*
3 *eral Register notice under paragraph (5) the fee*
4 *revenue and fees resulting from the adjustment*
5 *and the methodologies under this paragraph.*

6 “(3) *OPERATING RESERVE ADJUSTMENT.—*

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

15 “(B) *DECREASE.—If the Secretary has car-*
16 *ryover balances for such process in excess of 14*
17 *weeks of such operating reserves, the Secretary*
18 *shall decrease such fee revenue and fees to pro-*
19 *vide for not more than 14 weeks of such oper-*
20 *ating reserves.*

21 “(C) *NOTICE OF RATIONALE.—If an adjust-*
22 *ment under subparagraph (A) or (B) is made,*
23 *the rationale for the amount of the increase or*
24 *decrease (as applicable) in fee revenue and fees*
25 *shall be contained in the annual Federal Reg-*

1 *ister notice under paragraph (5) establishing fee*
 2 *revenue and fees for the fiscal year involved.*

3 *“(4) ADDITIONAL DIRECT COST ADJUSTMENT.—*

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

8 *“(i) for fiscal year 2018, by*
 9 *\$8,730,000; and*

10 *“(ii) for fiscal year 2019 and subse-*
 11 *quent fiscal years, by the amount deter-*
 12 *mined under subparagraph (B).*

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

15 *“(i) \$8,730,000, multiplied by*

16 *“(ii) the Consumer Price Index for*
 17 *urban consumers (Washington-Baltimore,*
 18 *DC–MD–VA–WV; Not Seasonally Adjusted;*
 19 *All Items; Annual Index) for the most re-*
 20 *cent year of available data, divided by such*
 21 *Index for 2016.*

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

1 “(A) establish, for the next fiscal year,
 2 human drug application fees and prescription
 3 drug program fees under subsection (a), based on
 4 the revenue amounts established under subsection
 5 (b) and the adjustments provided under this sub-
 6 section; and

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

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

14 (d) FEE WAIVER OR REDUCTION.—Section 736(d) of
 15 the Federal Food, Drug, and Cosmetic Act (21 U.S.C.
 16 379h(d)) is amended—

17 (1) in paragraph (1)—

18 (A) by inserting “or” at the end of subpara-
 19 graph (B);

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

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

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

1 (3) by redesignating paragraph (4) as para-
2 graph (3); and

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

4 (A) in subparagraphs (A) and (B), by strik-
5 ing “paragraph (1)(D)” and inserting “para-
6 graph (1)(C)”; and

7 (B) in subparagraph (B)—

8 (i) by striking clause (ii);

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

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

14 (e) *EFFECT OF FAILURE TO PAY FEES.*—Section
15 736(e) of the Federal Food, Drug, and Cosmetic Act (21
16 U.S.C. 379h(e)) is amended by striking “all fees” and in-
17 serting “all such fees”.

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

23 (g) *CREDITING AND AVAILABILITY OF FEES.*—Section
24 736(g) of the Federal Food, Drug, and Cosmetic Act (21
25 U.S.C. 379h(g)) is amended—

1 (1) in paragraph (3)—

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

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

6 (2) by striking paragraph (4).

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

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

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

15 (1) in subsection (a)(1)—

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

18 (B) in subparagraph (A), by striking “Pre-
19 scription Drug User Fee Amendments of 2012”
20 and inserting “Prescription Drug User Fee
21 Amendments of 2017”;

22 (2) in subsection (b), by striking “2013” and in-
23 serting “2018”; and

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

1 **SEC. 104. SUNSET DATES.**

2 (a) *AUTHORIZATION.*—Sections 735 and 736 of the
3 Federal Food, Drug, and Cosmetic Act (21 U.S.C. 379g;
4 379h) shall cease to be effective October 1, 2022.

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

8 (c) *PREVIOUS SUNSET PROVISION.*—Effective October
9 1, 2017, subsections (a) and (b) of section 105 of the Food
10 and Drug Administration Safety and Innovation Act (Pub-
11 lic Law 112–144) are repealed.

12 **SEC. 105. EFFECTIVE DATE.**

13 The amendments made by this title shall take effect
14 on October 1, 2017, or the date of the enactment of this
15 Act, whichever is later, except that fees under part 2 of sub-
16 chapter C of chapter VII of the Federal Food, Drug, and
17 Cosmetic Act shall be assessed for all human drug applica-
18 tions received on or after October 1, 2017, regardless of the
19 date of the enactment of this Act.

20 **SEC. 106. SAVINGS CLAUSE.**

21 Notwithstanding the amendments made by this title,
22 part 2 of subchapter C of chapter VII of the Federal Food,
23 Drug, and Cosmetic Act, as in effect on the day before the
24 date of the enactment of this title, shall continue to be in
25 effect with respect to human drug applications and supple-
26 ments (as defined in such part as of such day) that on or

1 *after October 1, 2012, but before October 1, 2017, were ac-*
 2 *cepted by the Food and Drug Administration for filing with*
 3 *respect to assessing and collecting any fee required by such*
 4 *part for a fiscal year prior to fiscal year 2018.*

5 ***TITLE II—FEES RELATING TO***
 6 ***DEVICES***

7 ***SEC. 201. SHORT TITLE; FINDINGS.***

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

10 (b) *FINDINGS.*—*The Congress finds that the fees au-*
 11 *thorized under the amendments made by this title will be*
 12 *dedicated toward expediting the process for the review of*
 13 *device applications and for assuring the safety and effec-*
 14 *tiveness of devices, as set forth in the goals identified for*
 15 *purposes of part 3 of subchapter C of chapter VII of the*
 16 *Federal Food, Drug, and Cosmetic Act in the letters from*
 17 *the Secretary of Health and Human Services to the Chair-*
 18 *man of the Committee on Health, Education, Labor, and*
 19 *Pensions of the Senate and the Chairman of the Committee*
 20 *on Energy and Commerce of the House of Representatives,*
 21 *as set forth in the Congressional Record.*

22 ***SEC. 202. DEFINITIONS.***

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

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

3 (2) by inserting after paragraph (7) the fol-
4 lowing new paragraph:

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

8 (3) in subparagraph (D) of paragraph (10) (as
9 redesignated by paragraph (1)), by striking “and sub-
10 missions” and inserting “submissions, and de novo
11 classification requests”; and

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

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

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

18 (1) in paragraph (1), by striking “fiscal year
19 2013” and inserting “fiscal year 2018”; and

20 (2) in paragraph (2)—

21 (A) in subparagraph (A)—

22 (i) in the matter preceding clause (i),
23 by striking “October 1, 2012” and inserting
24 “October 1, 2017”;

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

3 (iii) by adding at the end the following
4 new clause:

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

8 (B) in subparagraph (B)(v)(I), by striking
9 “or premarket notification submission” and in-
10 serting “premarket notification submission, or de
11 novo classification request”.

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

15 “(b) *FEE AMOUNTS*.—

16 “(1) *IN GENERAL*.—Subject to subsections (c),
17 (d), (e), and (h), for each of fiscal years 2018 through
18 2022, fees under subsection (a) shall be derived from
19 the base fee amounts specified in paragraph (2), to
20 generate the total revenue amounts specified in para-
21 graph (3).

22 “(2) *BASE FEE AMOUNTS SPECIFIED*.—For pur-
23 poses of paragraph (1), the base fee amounts specified
24 in this paragraph are as follows:

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

1 “(3) *TOTAL REVENUE AMOUNTS SPECIFIED.—*

2 *For purposes of paragraph (1), the total revenue*
3 *amounts specified in this paragraph are as follows:*

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

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

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

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

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

9 (c) *ANNUAL FEE SETTING; ADJUSTMENTS.—Section*
10 *738(c) of the Federal Food, Drug, and Cosmetic Act (21*
11 *U.S.C. 379j(c)) is amended—*

12 (1) *in paragraph (1), by striking “2012” and in-*
13 *serting “2017”;*

14 (2) *in paragraph (2)—*

15 (A) *in subparagraph (A), by striking*
16 *“2014” and inserting “2018”;*

17 (B) *by striking subparagraph (B) and in-*
18 *serting the following new subparagraph:*

19 “(B) *APPLICABLE INFLATION ADJUST-*
20 *MENT.—The applicable inflation adjustment for*
21 *fiscal year 2018 and each subsequent fiscal year*
22 *is the product of—*

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

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

8 (C) in subparagraph (C), in the heading, by
9 striking “TO TOTAL REVENUE AMOUNTS”; and
10 (D) by amending subparagraph (D) to read
11 as follows:

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

15 “(i) adjust the base fee amounts speci-
16 fied in subsection (b)(2) for such fiscal year
17 by multiplying such amounts by the appli-
18 cable inflation adjustment under subpara-
19 graph (B) for such year; and

20 “(ii) if the Secretary determines nec-
21 essary, increase (in addition to the adjust-
22 ment under clause (i)) such base fee
23 amounts, on a uniform proportionate basis,
24 to generate the total revenue amounts under

1 subsection (b)(3), as adjusted for inflation
 2 under subparagraph (A).”; and

3 (3) in paragraph (3)—

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

6 (B) by striking “further adjusted” and in-
 7 serting “increased”.

8 (d) *SMALL BUSINESSES; FEE WAIVER AND FEE RE-*
 9 *DUCTION REGARDING PREMARKET APPROVAL FEES.*—Sec-
 10 *tion 738(d) of the Federal Food, Drug, and Cosmetic Act*
 11 *(21 U.S.C. 379j(d)) is amended—*

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

16 (2) in paragraph (2)(C)—

17 (A) by striking “supplement, or” and in-
 18 serting “supplement,”; and

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

21 (e) *SMALL BUSINESSES; FEE REDUCTION REGARDING*
 22 *PREMARKET NOTIFICATION SUBMISSIONS.*—Section
 23 *738(e)(2)(C) of the Federal Food, Drug, and Cosmetic Act*
 24 *(21 U.S.C. 379j(e)(2)(C)) is amended by striking “50” and*
 25 *inserting “25”.*

1 (f) *FEE WAIVER OR REDUCTION.*—

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

5 (2) *CONFORMING CHANGES.*—

6 (A) Section 515(c)(4)(A) of the Federal
7 Food, Drug, and Cosmetic Act (21 U.S.C.
8 360e(c)(4)(A)) is amended by striking “738(h)”
9 and inserting “738(g)”.

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

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

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

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

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

23 (1) by striking “or periodic reporting concerning
24 a class III device” and inserting “periodic reporting

1 concerning a class III device, or de novo classification
2 request”; and

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

5 (h) *CONDITIONS*.—Subsection (g)(1)(A), as redesign-
6 nated, of section 738 of the Federal Food, Drug, and Cos-
7 metic Act (21 U.S.C. 379j) is amended by striking
8 “\$280,587,000” and inserting “\$320,825,000”.

9 (i) *CREDITING AND AVAILABILITY OF FEES*.—Sub-
10 section (h), as redesignated, of section 738 of the Federal
11 Food, Drug, and Cosmetic Act (21 U.S.C. 379j) is amend-
12 ed—

13 (1) in paragraph (3)—

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

16 (B) by striking “subsection (c)” and all that
17 follows through the period at the end and insert-
18 ing “subsection (c).”; and

19 (2) by striking paragraph (4).

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

21 (a) *PERFORMANCE REPORTS*.—Section 738A(a) of the
22 Federal Food, Drug, and Cosmetic Act (21 U.S.C. 379j–
23 1(a)) is amended—

24 (1) in paragraph (1)—

25 (A) in subparagraph (A)—

1 (i) by striking “2013” and inserting
2 “2018”; and

3 (ii) by striking “the Medical Device
4 User Fee Amendments of 2012” and insert-
5 ing “the Medical Device User Fee Amend-
6 ments of 2017”; and

7 (B) in subparagraph (B), by striking “the
8 Medical Device User Fee Amendments Act of
9 2012” and inserting “the Medical Device User
10 Fee Amendments of 2017”; and

11 (2) in paragraph (2), by striking “2013 through
12 2017” and inserting “2018 through 2022”.

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

16 (1) in paragraph (1), by striking “2017” and in-
17 serting “2022”; and

18 (2) in paragraph (5), by striking “2017” and in-
19 serting “2022”.

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

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

24 “(d) *PILOT ACCREDITATION SCHEME FOR CON-*
25 *FORMITY ASSESSMENT*.—

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

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

8 “(B) *subject to paragraph (2), determina-*
9 *tions by testing laboratories so accredited that a*
10 *device conforms with such standard or standards*
11 *shall be accepted by the Secretary for purposes of*
12 *demonstrating such conformity under this sec-*
13 *tion unless the Secretary finds that a particular*
14 *such determination shall not be so accepted.*

15 “(2) *SECRETARIAL REVIEW OF ACCREDITED LAB-*
16 *ORATORY DETERMINATIONS.*—*The Secretary may—*

17 “(A) *review determinations by testing lab-*
18 *oratories accredited pursuant to this subsection,*
19 *including by conducting periodic audits of such*
20 *determinations or processes of accredited bodies*
21 *or testing laboratories and, following such re-*
22 *view, taking additional measures under this Act,*
23 *such as suspension or withdrawal of accredita-*
24 *tion of such testing laboratory under paragraph*
25 *(1)(A) or requesting additional information with*

1 *respect to such device, as the Secretary deter-*
 2 *mines appropriate; and*

3 *“(B) if the Secretary becomes aware of in-*
 4 *formation materially bearing on safety or effec-*
 5 *tiveness of a device assessed for conformity by a*
 6 *testing laboratory so accredited, take such addi-*
 7 *tional measures under this Act as the Secretary*
 8 *determines appropriate, such as suspension or*
 9 *withdrawal of accreditation of such testing lab-*
 10 *oratory under paragraph (1)(A), or requesting*
 11 *additional information with regard to such de-*
 12 *vice.*

13 *“(3) IMPLEMENTATION AND REPORTING.—*

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

22 *“(B) PILOT PROGRAM GUIDANCE.—The Sec-*
 23 *retary shall—*

24 *“(i) not later than September 30, 2019,*
 25 *issue draft guidance regarding the goals*

1 *and implementation of the pilot program*
2 *under this subsection; and*

3 “(ii) *not later than September 30,*
4 *2021, issue final guidance with respect to*
5 *the implementation of such program.*

6 “(C) *PILOT PROGRAM INITIATION.—Not*
7 *later than September 30, 2020, the Secretary*
8 *shall initiate the pilot program under this sub-*
9 *section.*

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

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

15 “(A) *the authority for accreditation bodies*
16 *to accredit testing laboratories pursuant to para-*
17 *graph (1)(A) shall cease to have force or effect;*

18 “(B) *the Secretary—*

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

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

24 “(C) *except for purposes of accepting a de-*
25 *termination described in subparagraph (B)(ii),*

the Secretary shall not continue to recognize the accreditation of testing laboratories accredited under paragraph (1)(A); and

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

SEC. 206. REAUTHORIZATION OF REVIEW.

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

(1) in subsection (a)(3)—

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

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

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

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

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

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

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

8 “(II) whether the device type, or
9 subset of such device type, is perma-
10 nently implantable, life sustaining, or
11 life supporting;

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

15 “(iii) beginning on the date such guid-
16 ance is finalized, designate and post on the
17 internet website of the Food and Drug Ad-
18 ministration, an updated list of class I and
19 class II device types, or subsets of such de-
20 vice types, and the Secretary’s determina-
21 tion with respect to whether each such de-
22 vice type, or subset of a device type, is eligi-
23 ble or not eligible for review by an accred-
24 ited person under this section based on the
25 factors described in clause (i).”; and

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

2 “(C) *INTERIM RULE.*—Until the date on
3 which the updated list is designated and posted
4 in accordance with subparagraph (B)(iii), the
5 list in effect on the date of enactment the Medical
6 Device User Fee Amendments of 2017 shall be in
7 effect.”;

8 (2) in subsection (b)—

9 (A) in paragraph (2)—

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

11 (ii) by redesignating subparagraph (E)

12 as subparagraph (D); and

13 (B) in paragraph (3)—

14 (i) by redesignating subparagraph (E)

15 as subparagraph (F);

16 (ii) in subparagraph (F) (as so reded-

17 ignated), by striking “The operations of”

18 and all that follows through “it will—” and

19 inserting “Such person shall agree, at a

20 minimum, to include in its request for ac-

21 creditation a commitment to, at the time of

22 accreditation, and at any time it is per-

23 forming any review pursuant to this sec-

24 tion—”; and

1 (iii) by inserting after subparagraph
2 (D) the following new subparagraph:

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

6 (3) in subsection (c), by striking “2017” and in-
7 serting “2022”.

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

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

12 “(3) *PRESUBMISSIONS AND SUBMISSIONS SOLELY*
13 *IN ELECTRONIC FORMAT.*—

14 “(A) *IN GENERAL.*—Beginning on such date
15 as the Secretary specifies in final guidance
16 issued under subparagraph (C), presubmissions
17 and submissions for devices described in para-
18 graph (1) (and any appeals of action taken by
19 the Secretary with respect to such presubmissions
20 or submissions) shall be submitted solely in such
21 electronic format as specified by the Secretary in
22 such guidance.

23 “(B) *DRAFT GUIDANCE.*—The Secretary
24 shall, not later than October 1, 2019, issue draft
25 guidance providing for—

1 “(i) any further standards for the sub-
 2 mission by electronic format required under
 3 subparagraph (A);

4 “(ii) a timetable for the establishment
 5 by the Secretary of such further standards;
 6 and

7 “(iii) criteria for waivers of and ex-
 8 emptions from the requirements of this sub-
 9 section.

10 “(C) *FINAL GUIDANCE.*—The Secretary
 11 shall, not later than 12 months after the close of
 12 the public comment period on the draft guidance
 13 issued under subparagraph (B), issue final guid-
 14 ance described in clauses (i) through (iii) of such
 15 subparagraph.”.

16 **SEC. 208. SAVINGS CLAUSE.**

17 Notwithstanding the amendments made by this title,
 18 part 3 of subchapter C of chapter VII of the Federal Food,
 19 Drug, and Cosmetic Act (21 U.S.C. 379i et seq.), as in effect
 20 on the day before the date of the enactment of this title,
 21 shall continue to be in effect with respect to the submissions
 22 listed in section 738(a)(2)(A) of such Act (as defined in such
 23 part as of such day) that on or after October 1, 2012, but
 24 before October 1, 2017, were accepted by the Food and Drug
 25 Administration for filing with respect to assessing and col-

1 *lecting any fee required by such part for a fiscal year prior*
 2 *to fiscal year 2018.*

3 **SEC. 209. EFFECTIVE DATE.**

4 *The amendments made by this title shall take effect*
 5 *on October 1, 2017, or the date of the enactment of this*
 6 *Act, whichever is later, except that fees under part 3 of sub-*
 7 *chapter C of chapter VII of the Federal Food, Drug, and*
 8 *Cosmetic Act shall be assessed for all submissions listed in*
 9 *section 738(a)(2)(A) of such Act received on or after October*
 10 *1, 2017, regardless of the date of the enactment of this Act.*

11 **SEC. 210. SUNSET CLAUSE.**

12 *(a) AUTHORIZATION.—Sections 737 and 738 of the*
 13 *Federal Food, Drug, and Cosmetic Act (21 U.S.C. 739i;*
 14 *739j) shall cease to be effective October 1, 2022.*

15 *(b) REPORTING REQUIREMENTS.—Section 738A (21*
 16 *U.S.C. 739j–1) of the Federal Food, Drug, and Cosmetic*
 17 *Act (regarding reauthorization and reporting requirements)*
 18 *shall cease to be effective January 31, 2023.*

19 *(c) PREVIOUS SUNSET PROVISION.—Effective October*
 20 *1, 2017, section 207(a) of the Medical Device User Fee*
 21 *Amendments of 2012 (Public Law 112–144) is repealed.*

1 ***TITLE III—FEES RELATING TO***
2 ***GENERIC DRUGS***

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

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

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

16 ***SEC. 302. DEFINITIONS.***

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

19 *(1) in paragraph (1)(B), by striking “applica-*
20 *tion for a positron emission tomography drug.” and*
21 *inserting “application—*

22 *“(i) for a positron emission tomog-*
23 *raphy drug; or*

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

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

6 (3) by inserting after paragraph (4) the fol-
7 lowing:

8 “(5) The term ‘contract manufacturing organiza-
9 tion facility’ means a manufacturing facility of a fin-
10 ished dosage form of a drug approved pursuant to an
11 abbreviated new drug application, where such manu-
12 facturing facility is not identified in an approved ab-
13 breviated new drug application held by the owner of
14 such facility or an affiliate of such owner or facil-
15 ity.”.

16 **SEC. 303. AUTHORITY TO ASSESS AND USE HUMAN GE-**
17 **NERIC DRUG FEES.**

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

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

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

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

3 (3) *in paragraph (2)*—

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

6 “(C) *NOTICE.*—*Not later than 60 days be-*
7 *fore the start of each of fiscal years 2018 through*
8 *2022, the Secretary shall publish in the Federal*
9 *Register the amount of the drug master file fee*
10 *established by this paragraph for such fiscal*
11 *year.*”; and

12 (B) *in subparagraph (E)*—

13 (i) *in clause (i)*—

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

17 *“(I) the date”;*

18 (II) *by striking the period and in-*
19 *serting “; or”;* and

20 (III) *by adding at the end the fol-*
21 *lowing:*

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

1 (ii) in clause (ii), by striking “notice
 2 provided for in clause (i) or (ii) of subpara-
 3 graph (C), as applicable” and inserting
 4 “notice provided for in subparagraph (C)”;
 5 (4) in paragraph (3)—

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

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

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

13 “(B) NOTICE.—Not later than 60 days be-
 14 fore the start of each of fiscal years 2018 through
 15 2022, the Secretary shall publish in the Federal
 16 Register the amount of the fees under subpara-
 17 graph (A) for such fiscal year.

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

23 (D) in subparagraph (D)—

24 (i) in the heading, by inserting “, IS
 25 WITHDRAWN PRIOR TO BEING RECEIVED, OR

1 *IS NO LONGER RECEIVED” after “RE-*
2 *CEIVED”; and*

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

6 *“(i) APPLICATIONS NOT CONSIDERED*
7 *TO HAVE BEEN RECEIVED AND APPLICA-*
8 *TIONS WITHDRAWN PRIOR TO BEING RE-*
9 *CEIVED.—The Secretary shall refund 75*
10 *percent of the fee paid under subparagraph*
11 *(A) for any abbreviated new drug applica-*
12 *tion that the Secretary considers not to have*
13 *been received within the meaning of section*
14 *505(j)(5)(A) for a cause other than failure*
15 *to pay fees, or that has been withdrawn*
16 *prior to being received within the meaning*
17 *of section 505(j)(5)(A).*

18 *“(ii) APPLICATIONS NO LONGER RE-*
19 *CEIVED.—The Secretary shall refund 100*
20 *percent of the fee paid under subparagraph*
21 *(A) for any abbreviated new drug applica-*
22 *tion if the Secretary initially receives the*
23 *application under section 505(j)(5)(A) and*
24 *subsequently determines that an exclusivity*
25 *period for a listed drug should have pre-*

1 *vented the Secretary from receiving such*
 2 *application, such that the abbreviated new*
 3 *drug application is no longer received with-*
 4 *in the meaning of section 505(j)(5)(A).”;*

5 *(E) in subparagraph (E), by striking “or*
 6 *prior approval supplement”; and*

7 *(F) in the matter preceding clause (i) of*
 8 *subparagraph (F)—*

9 *(i) by striking “2012” and inserting*
 10 *“2017”; and*

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

13 *(5) in paragraph (4)—*

14 *(A) in subparagraph (A)—*

15 *(i) in the matter preceding clause (i)*
 16 *and in clause (iii), by striking “, or in-*
 17 *tended to be identified, in at least one ge-*
 18 *neric drug submission that is pending or”*
 19 *and inserting “in at least one generic drug*
 20 *submission that is”;*

21 *(ii) in clause (i), by striking “or in-*
 22 *tended to be identified in at least one ge-*
 23 *neric drug submission that is pending or”*
 24 *and inserting “in at least one generic drug*
 25 *submission that is”;*

1 (iii) in clause (ii), by striking “pro-
 2 duces,” and all that follows through “such
 3 a” and inserting “is identified in at least
 4 one generic drug submission in which the
 5 facility is approved to produce one or more
 6 active pharmaceutical ingredients or in a
 7 Type II active pharmaceutical ingredient
 8 drug master file referenced in at least one
 9 such”; and

10 (iv) in clause (iii), by striking “to fees
 11 under both such clauses” and inserting
 12 “only to the fee attributable to the manufac-
 13 ture of the finished dosage forms”; and

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

16 “(C) NOTICE.—Within the timeframe speci-
 17 fied in subsection (d)(1), the Secretary shall pub-
 18 lish in the Federal Register the amount of the
 19 fees under subparagraph (A) for such fiscal year.

20 “(D) FEE DUE DATE.—For each of fiscal
 21 years 2018 through 2022, the fees under subpara-
 22 graph (A) for such fiscal year shall be due on the
 23 later of—

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

1 “(ii) the first business day after the en-
 2 actment of an appropriations Act providing
 3 for the collection and obligation of fees for
 4 such year under this section for such year.”;

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

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

9 “(5) *GENERIC DRUG APPLICANT PROGRAM*
 10 *FEE.*—

11 “(A) *IN GENERAL.*—A generic drug appli-
 12 cant program fee shall be assessed annually as
 13 described in subsection (b)(2)(E).

14 “(B) *AMOUNT.*—The amount of fees estab-
 15 lished under subparagraph (A) shall be estab-
 16 lished under subsection (d).

17 “(C) *NOTICE.*—Within the timeframe speci-
 18 fied in subsection (d)(1), the Secretary shall pub-
 19 lish in the Federal Register the amount of the
 20 fees under subparagraph (A) for such fiscal year.

21 “(D) *FEE DUE DATE.*—For each of fiscal
 22 years 2018 through 2022, the fees under subpara-
 23 graph (A) for such fiscal year shall be due on the
 24 later of—

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

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

8 (b) *FEE REVENUE AMOUNTS*.—Section 744B(b) of the
9 *Federal Food, Drug, and Cosmetic Act* (21 U.S.C. 379j–
10 *42(b)*) is amended—

11 (1) in paragraph (1)—

12 (A) in subparagraph (A)—

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

15 (ii) by striking “2013” and inserting
16 “2018”;

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

19 (iv) by striking “Of that amount” and
20 all that follows through the end of clause
21 (ii); and

22 (B) in subparagraph (B)—

23 (i) in the heading, by striking “2014
24 THROUGH 2017” and inserting “2019
25 THROUGH 2022”;

1 (ii) by striking “2014 through 2017”
2 and inserting “2019 through 2022”;

3 (iii) by striking “paragraphs (2)
4 through (4)” and inserting “paragraphs (2)
5 through (5)”; and

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

8 (2) in paragraph (2)—

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

11 (i) by striking “paragraph (1)(A)(ii)
12 for fiscal year 2013 and paragraph (1)(B)
13 for each of fiscal years 2014 through 2017”
14 and inserting “such paragraph for a fiscal
15 year”; and

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

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

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

22 “(B) Thirty-three percent shall be derived
23 from fees under subsection (a)(3) (relating to ab-
24 breviated new drug applications).

1 “(C) Twenty percent shall be derived from
 2 fees under subsection (a)(4)(A)(i) (relating to ge-
 3 neric drug facilities). The amount of the fee for
 4 a contract manufacturing organization facility
 5 shall be equal to one-third the amount of the fee
 6 for a facility that is not a contract manufac-
 7 turing organization facility. The amount of the
 8 fee for a facility located outside the United
 9 States and its territories and possessions shall be
 10 \$15,000 higher than the amount of the fee for a
 11 facility located in the United States and its ter-
 12 ritories and possessions.”;

13 (D) in subparagraph (D)—

14 (i) by striking “Fourteen percent” and
 15 inserting “Seven percent”;

16 (ii) by striking “not less than \$15,000
 17 and not more than \$30,000” and inserting
 18 “\$15,000”; and

19 (iii) by striking “, as determined” and
 20 all that follows through the period at the
 21 end and inserting a period; and

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

23 “(E)(i) Thirty-five percent shall be derived
 24 from fees under subsection (a)(5) (relating to ge-
 25 neric drug applicant program fees). For pur-

1 poses of this subparagraph, if a person has affili-
2 ates, a single program fee shall be assessed with
3 respect to that person, including its affiliates,
4 and may be paid by that person or any one of
5 its affiliates. The Secretary shall determine the
6 fees as follows:

7 “(I) If a person (including its affili-
8 ates) owns at least one but not more than
9 5 approved abbreviated new drug applica-
10 tions on the due date for the fee under this
11 subsection, the person (including its affili-
12 ates) shall be assessed a small business ge-
13 neric drug applicant program fee equal to
14 one-tenth of the large size operation generic
15 drug applicant program fee.

16 “(II) If a person (including its affili-
17 ates) owns at least 6 but not more than 19
18 approved abbreviated new drug applications
19 on the due date for the fee under this sub-
20 section, the person (including its affiliates)
21 shall be assessed a medium size operation
22 generic drug applicant program fee equal to
23 two-fifths of the large size operation generic
24 drug applicant program fee.

1 “(III) If a person (including its affili-
 2 ates) owns 20 or more approved abbreviated
 3 new drug applications on the due date for
 4 the fee under this subsection, the person (in-
 5 cluding its affiliates) shall be assessed a
 6 large size operation generic drug applicant
 7 program fee.

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

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

17 (1) in paragraph (1)—

18 (A) by striking “2014” and inserting
 19 “2019”;

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

24 (C) by striking the flush text following sub-
 25 paragraph (C); and

1 (2) in paragraph (2)—

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

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

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

9 (d) ANNUAL FEE SETTING.—Section 744B(d) of the
10 Federal Food, Drug, and Cosmetic Act (21 U.S.C. 379j–
11 42(d)) is amended—

12 (1) by striking paragraphs (1) and (2) and in-
13 serting the following:

14 “(1) FISCAL YEARS 2018 THROUGH 2022.—Not
15 more than 60 days before the first day of each of fis-
16 cal years 2018 through 2022, the Secretary shall es-
17 tablish the fees described in paragraphs (2) through
18 (5) of subsection (a), based on the revenue amounts
19 established under subsection (b) and the adjustments
20 provided under subsection (c).”;

21 (2) by redesignating paragraph (3) as para-
22 graph (2); and

23 (3) in paragraph (2) (as so redesignated), in the
24 matter preceding subparagraph (A), by striking “fees

1 under paragraphs (1) and (2)” and inserting “fee
2 under paragraph (1)”.

3 (e) *IDENTIFICATION OF FACILITIES*.—Section 744B(f)
4 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C.
5 379j–42(f)) is amended—

6 (1) by striking paragraph (1);

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

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

10 (A) by striking “paragraph (4)” and insert-
11 ing “paragraph (3)”; and

12 (B) by striking “Such information shall”
13 and all that follows through the end of subpara-
14 graph (B) and inserting “Such information
15 shall, for each fiscal year, be submitted, updated,
16 or reconfirmed on or before June 1 of the pre-
17 vious fiscal year.”; and

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

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

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

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

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

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

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

8 “(F) whether the facility is a contract man-
9 ufacturing organization facility.”.

10 (f) *EFFECT OF FAILURE TO PAY FEES.*—Section
11 744B(g) of the Federal Food, Drug, and Cosmetic Act (21
12 U.S.C. 379–42(g)) is amended—

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

16 (2) in paragraph (2)(C)(ii), by striking “of
17 505(j)(5)(A)” and inserting “of section 505(j)(5)(A)”;
18 and

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

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

22 “(A) *IN GENERAL.*—A person who fails to
23 pay a fee as required under subsection (a)(5) by
24 the date that is 20 calendar days after the due

1 *date, as specified in subparagraph (D) of such*
 2 *subsection, shall be subject to the following:*

3 *“(i) The Secretary shall place the per-*
 4 *son on a publicly available arrears list.*

5 *“(ii) Any abbreviated new drug appli-*
 6 *cation submitted by the generic drug appli-*
 7 *cant or an affiliate of such applicant shall*
 8 *not be received, within the meaning of sec-*
 9 *tion 505(j)(5)(A).*

10 *“(iii) All drugs marketed pursuant to*
 11 *any abbreviated new drug application held*
 12 *by such applicant or an affiliate of such ap-*
 13 *plicant shall be deemed misbranded under*
 14 *section 502(aa).*

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

19 (g) *LIMITATIONS.—Section 744B(h)(2) of the Federal*
 20 *Food, Drug, and Cosmetic Act (21 U.S.C. 379–42(h)(2)) is*
 21 *amended by striking “for Type II active pharmaceutical in-*
 22 *gredient drug master files, abbreviated new drug applica-*
 23 *tions and prior approval supplements, and generic drug fa-*
 24 *cilities and active pharmaceutical ingredient facilities”.*

1 (h) *CREDITING AND AVAILABILITY OF FEES.*—Section
 2 744B(i) of the Federal Food, Drug, and Cosmetic Act (21
 3 U.S.C. 379–42(i)) is amended—

4 (1) in paragraph (2)—

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

7 (B) in subparagraph (D)—

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

10 (ii) by striking “(after fiscal year
 11 2013)”; and

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

14 (2) in paragraph (3), by striking “fiscal years
 15 2013 through 2017” and inserting “fiscal years 2018
 16 through 2022”.

17 (i) *INFORMATION ON ABBREVIATED NEW DRUG APPLI-*
 18 *CATIONS OWNED BY APPLICANTS AND THEIR AFFILI-*
 19 *ATES.*—Section 744B of the Federal Food, Drug, and Cos-
 20 metic Act (21 U.S.C. 379–42) is amended by adding at the
 21 end the following:

22 “(o) *INFORMATION ON ABBREVIATED NEW DRUG AP-*
 23 *PLICATIONS OWNED BY APPLICANTS AND THEIR AFFILI-*
 24 *ATES.*—

1 “(1) *IN GENERAL.*—By April 1 of each year,
 2 each person that owns an abbreviated new drug ap-
 3 plication, or any affiliate of such person, shall sub-
 4 mit, on behalf of the person and its affiliates, to the
 5 Secretary a list of—

6 “(A) all approved abbreviated new drug ap-
 7 plications owned by such person; and

8 “(B) if any affiliate of such person also
 9 owns an abbreviated new drug application, all
 10 affiliates that own any such abbreviated new
 11 drug applications and all approved abbreviated
 12 new drug applications owned by any such affil-
 13 iate.

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

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

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

20 (1) in subsection (a)—

21 (A) by striking “2013” and inserting
 22 “2018”; and

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

1 (2) in subsection (b), by striking “2013” and in-
 2 serting “2018”; and

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

5 **SEC. 305. SUNSET DATES.**

6 (a) *AUTHORIZATION*.—Sections 744A and 744B of the
 7 *Federal Food, Drug, and Cosmetic Act* (21 U.S.C. 379j–
 8 41; 379j–42) shall cease to be effective October 1, 2022.

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

12 (c) *PREVIOUS SUNSET PROVISION*.—Effective October
 13 1, 2017, subsections (a) and (b) of section 304 of the *Food*
 14 *and Drug Administration Safety and Innovation Act* (Pub-
 15 *lic Law 112–144*) are repealed.

16 **SEC. 306. EFFECTIVE DATE.**

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

1 **SEC. 307. SAVINGS CLAUSE.**

2 *Notwithstanding the amendments made by this title,*
 3 *part 7 of subchapter C of chapter VII of the Federal Food,*
 4 *Drug, and Cosmetic Act, as in effect on the day before the*
 5 *date of the enactment of this title, shall continue to be in*
 6 *effect with respect to abbreviated new drug applications (as*
 7 *defined in such part as of such day) that on or after October*
 8 *1, 2012, but before October 1, 2017, were received by the*
 9 *Food and Drug Administration within the meaning of sec-*
 10 *tion 505(j)(5)(A) of such Act (21 U.S.C. 355(j)(5)(A)), prior*
 11 *approval supplements that were submitted, and drug mas-*
 12 *ter files for Type II active pharmaceutical ingredients that*
 13 *were first referenced with respect to assessing and collecting*
 14 *any fee required by such part for a fiscal year prior to fiscal*
 15 *year 2018.*

16 **TITLE IV—FEES RELATING TO**
 17 **BIOSIMILAR BIOLOGICAL**
 18 **PRODUCTS**

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

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

22 (b) *FINDING.*—*The Congress finds that the fees author-*
 23 *ized by the amendments made in this title will be dedicated*
 24 *to expediting the process for the review of biosimilar biologi-*
 25 *cal product applications, including postmarket safety ac-*
 26 *tivities, as set forth in the goals identified for purposes of*

1 *part 8 of subchapter C of chapter VII of the Federal Food,*
 2 *Drug, and Cosmetic Act, in the letters from the Secretary*
 3 *of Health and Human Services to the Chairman of the*
 4 *Committee on Health, Education, Labor, and Pensions of*
 5 *the Senate and the Chairman of the Committee on Energy*
 6 *and Commerce of the House of Representatives, as set forth*
 7 *in the Congressional Record.*

8 **SEC. 402. DEFINITIONS.**

9 (a) *ADJUSTMENT FACTOR.*—Section 744G(1) of the
 10 *Federal Food, Drug, and Cosmetic Act (21 U.S.C. 379j–*
 11 *51(1)) is amended to read as follows:*

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

18 (b) *BIOSIMILAR BIOLOGICAL PRODUCT.*—Section
 19 744G(3) of the *Federal Food, Drug, and Cosmetic Act (21*
 20 *U.S.C. 379j–51(3)) is amended by striking “means a prod-*
 21 *uct” and inserting “means a specific strength of a biological*
 22 *product in final dosage form”.*

1 **SEC. 403. AUTHORITY TO ASSESS AND USE BIOSIMILAR**
2 **FEES.**

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

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

9 (2) in the heading of paragraph (1), by striking
10 “BIOSIMILAR” and inserting “BIOSIMILAR BIOLOGI-
11 CAL PRODUCT”;

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

14 (4) in paragraph (1)(B)(i), by striking
15 “(b)(1)(B) for biosimilar biological product develop-
16 ment” and inserting “(c)(5) for the biosimilar biologi-
17 cal product development program”;

18 (5) in paragraph (1)(B)(ii), by striking “annual
19 biosimilar biological product development program
20 fee” and inserting “annual biosimilar biological prod-
21 uct development fee”;

22 (6) in paragraph (1)(B)(iii), by striking “an-
23 nual biosimilar development program fee” and insert-
24 ing “annual biosimilar biological product develop-
25 ment fee”;

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

3 “(iv) *REFUND*.—If a person submits a
4 marketing application for a biosimilar bio-
5 logical product before October 1 of a fiscal
6 year and such application is accepted for
7 filing on or after October 1 of such fiscal
8 year, the person may request a refund equal
9 to the annual biosimilar development fee
10 paid by the person for the product for such
11 fiscal year. To qualify for consideration for
12 a refund under this clause, a person shall
13 submit to the Secretary a written request
14 for such refund not later than 180 days
15 after the marketing application is accepted
16 for filing.”;

17 (8) in paragraph (1)(C), by striking “for a prod-
18 uct effective October 1 of a fiscal year by,” and insert-
19 ing “for a product, effective October 1 of a fiscal year,
20 by,”;

21 (9) in paragraph (1)(D)—

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

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

4 (C) in clause (i)(II), by inserting after “dis-
 5 continued)” the following: “by such person”;

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

8 (11) in paragraph (1)(F)—

9 (A) in the subparagraph heading, by strik-
 10 ing “BIOSIMILAR DEVELOPMENT PROGRAM” be-
 11 fore “FEES”; and

12 (B) by amending clause (i) to read as fol-
 13 lows:

14 “(i) REFUNDS.—Except as provided in
 15 subparagraph (B)(iv), the Secretary shall
 16 not refund any initial or annual biosimilar
 17 biological product development fee paid
 18 under subparagraph (A) or (B), or any re-
 19 activation fee paid under subparagraph
 20 (D).”;

21 (12) in paragraph (2)—

22 (A) in the paragraph heading, by striking
 23 “AND SUPPLEMENT”;

24 (B) by amending subparagraphs (A) and
 25 (B) to read as follows:

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

5 “(i) *A fee established under subsection*
6 *(c)(5) for a biosimilar biological product*
7 *application for which clinical data (other*
8 *than comparative bioavailability studies)*
9 *with respect to safety or effectiveness are re-*
10 *quired for approval.*

11 “(ii) *A fee established under subsection*
12 *(c)(5) for a biosimilar biological product*
13 *application for which clinical data (other*
14 *than comparative bioavailability studies)*
15 *with respect to safety or effectiveness are not*
16 *required for approval. Such fee shall be*
17 *equal to half of the amount of the fee de-*
18 *scribed in clause (i).*

19 “(B) *RULE OF APPLICABILITY; TREATMENT*
20 *OF CERTAIN PREVIOUSLY PAID FEES.*—*Any per-*
21 *son who pays a fee under subparagraph (A), (B),*
22 *or (D) of paragraph (1) for a product before Oc-*
23 *tober 1, 2017, but submits a biosimilar biological*
24 *product application for that product after such*
25 *date, shall—*

1 “(i) be subject to any biosimilar bio-
 2 logical product application fees that may be
 3 assessed at the time when such biosimilar
 4 biological product application is submitted;
 5 and

6 “(ii) be entitled to no reduction of such
 7 application fees based on the amount of fees
 8 paid for that product before October 1,
 9 2017, under such subparagraphs (A), (B),
 10 or (D).”;

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

13 (D) in subparagraphs (C) through (F), by
 14 striking “or supplement” each place it appears;
 15 and

16 (E) in subparagraph (D), by striking “or a
 17 supplement”;

18 (13) by amending paragraph (3) to read as fol-
 19 lows:

20 “(3) BIOSIMILAR BIOLOGICAL PRODUCT PRO-
 21 GRAM FEE.—

22 “(A) IN GENERAL.—Each person who is
 23 named as the applicant in a biosimilar biologi-
 24 cal product application shall pay the annual
 25 biosimilar biological product program fee estab-

1 *lished for a fiscal year under subsection (c)(5)*
2 *for each biosimilar biological product that—*

3 *“(i) is identified in such a biosimilar*
4 *biological product application approved as*
5 *of October 1 of such fiscal year; and*

6 *“(ii) as of October 1 of such fiscal*
7 *year, does not appear on a list, developed*
8 *and maintained by the Secretary, of discon-*
9 *tinued biosimilar biological products.*

10 *“(B) DUE DATE.—The biosimilar biological*
11 *product program fee for a 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 year; or*

15 *“(ii) the first business day after the en-*
16 *actment of an appropriations Act providing*
17 *for the collection and obligation of fees for*
18 *such year under this section.*

19 *“(C) ONE FEE PER PRODUCT PER YEAR.—*
20 *The biosimilar biological product program fee*
21 *shall be paid only once for each product for each*
22 *fiscal year.*

23 *“(D) LIMITATION.—A person who is named*
24 *as the applicant in a biosimilar biological prod-*
25 *uct application shall not be assessed more than*

1 5 biosimilar biological product program fees for
 2 a fiscal year for biosimilar biological products
 3 identified in such biosimilar biological product
 4 application.”.

5 (b) *FEE REVENUE AMOUNTS*.—Subsection (b) of sec-
 6 tion 744H of the Federal Food, Drug, and Cosmetic Act
 7 (21 U.S.C. 379j–52) is amended to read as follows:

8 “(b) *FEE REVENUE AMOUNTS*.—

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

12 “(A) \$45,000,000; and

13 “(B) the dollar amount equal to the fiscal
 14 year 2018 adjustment (as determined under sub-
 15 section (c)(4)).

16 “(2) *SUBSEQUENT FISCAL YEARS*.—For each of
 17 the fiscal years 2019 through 2022, fees under sub-
 18 section (a) shall, except as provided in subsection (c),
 19 be established to generate a total revenue amount
 20 equal to the sum of—

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

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

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

4 “(D) the dollar amount equal to the oper-
 5 ating reserve adjustment for the fiscal year, if
 6 applicable (as determined under subsection
 7 (c)(3)).

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

10 “(A) ALLOCATION.—The Secretary shall de-
 11 termine the percentage of the total revenue
 12 amount for a fiscal year to be derived from, re-
 13 spectively—

14 “(i) initial and annual biosimilar de-
 15 velopment fees and reactivation fees under
 16 subsection (a)(1);

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

19 “(iii) biosimilar biological product
 20 program fees under subsection (a)(3).

21 “(B) LIMITATIONS ON FEE AMOUNTS.—
 22 Until the first fiscal year for which the capacity
 23 planning adjustment under subsection (c)(2) is
 24 effective, the amount of any fee under subsection
 25 (a) for a fiscal year after fiscal year 2018 shall

1 *not exceed 125 percent of the amount of such fee*
 2 *for fiscal year 2018.*

3 “(C) *BIOSIMILAR BIOLOGICAL PRODUCT DE-*
 4 *VELOPMENT FEES.*—*The initial biosimilar bio-*
 5 *logical product development fee under subsection*
 6 *(a)(1)(A) for a fiscal year shall be equal to the*
 7 *annual biosimilar biological product develop-*
 8 *ment fee under subsection (a)(1)(B) for that fis-*
 9 *cal year.*

10 “(D) *REACTIVATION FEE.*—*The reactivation*
 11 *fee under subsection (a)(1)(D) for a fiscal year*
 12 *shall be equal to twice the amount of the annual*
 13 *biosimilar biological product development fee*
 14 *under subsection (a)(1)(B) for that fiscal year.*

15 “(4) *ANNUAL BASE REVENUE.*—*For purposes of*
 16 *paragraph (2), the dollar amount of the annual base*
 17 *revenue for a fiscal year shall be the dollar amount*
 18 *of the total revenue amount for the previous fiscal*
 19 *year, excluding any adjustments to such revenue*
 20 *amount under subsection (c)(3).”.*

21 “(c) *ADJUSTMENTS; ANNUAL FEE SETTING.*—*Section*
 22 *744H of the Federal Food, Drug, and Cosmetic Act (21*
 23 *U.S.C. 379j–52) is amended—*

24 *(1) by redesignating subsections (c) through (h)*
 25 *as subsections (d) through (i), respectively;*

(2) in subsections (a)(2)(F) and (h) (as redesignated by paragraph (1)), by striking “subsection (c)” and inserting “subsection (d)”;

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

and

(4) by inserting after subsection (b) the following:

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

“(1) *INFLATION ADJUSTMENT.*—

“(A) *IN GENERAL.*—For purposes of subsection (b)(2)(B), the dollar amount of the inflation adjustment to the annual base revenue for each fiscal year shall be equal to the product of—

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

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

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

“(i) the average annual percent change in the cost, per full-time equivalent position

1 *of the Food and Drug Administration, of all*
2 *personnel compensation and benefits paid*
3 *with respect to such positions for the first 3*
4 *years of the preceding 4 fiscal years, multi-*
5 *plied by the proportion of personnel com-*
6 *ensation and benefits costs to total costs of*
7 *the process for the review of biosimilar bio-*
8 *logical product applications (as defined in*
9 *section 744G(13)) for the first 3 years of the*
10 *preceding 4 fiscal years; and*

11 “(ii) *the average annual percent*
12 *change that occurred in the Consumer Price*
13 *Index for urban consumers (Washington-*
14 *Baltimore, DC–MD–VA–WV; Not Season-*
15 *ally Adjusted; All items; Annual Index) for*
16 *the first 3 years of the preceding 4 years of*
17 *available data multiplied by the proportion*
18 *of all costs other than personnel compensa-*
19 *tion and benefits costs to total costs of the*
20 *process for the review of biosimilar biologi-*
21 *cal product applications (as defined in sec-*
22 *tion 744G(13)) for the first 3 years of the*
23 *preceding 4 fiscal years.*

24 “(2) *CAPACITY PLANNING ADJUSTMENT.—*

1 “(A) *IN GENERAL.*—Beginning with the fis-
2 cal year described in subparagraph (B)(ii)(II),
3 the Secretary shall, in addition to the adjust-
4 ment under paragraph (1), further increase the
5 fee revenue and fees under this section for a fis-
6 cal year to reflect changes in the resource capac-
7 ity needs of the Secretary for the process for the
8 review of biosimilar biological product applica-
9 tions.

10 “(B) *CAPACITY PLANNING METHODOLOGY.*—

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

1 “(i) *ESTABLISHMENT AND IMPLEMEN-*
2 *TATION.*—After review of the report de-
3 scribed in clause (i) and receipt and review
4 of public comments thereon, the Secretary
5 shall establish a capacity planning method-
6 ology for purposes of this paragraph, which
7 shall—

8 “(I) incorporate such approaches
9 and attributes as the Secretary deter-
10 mines appropriate; and

11 “(II) be effective beginning with
12 the first fiscal year for which fees are
13 set after such capacity planning meth-
14 odology is established.

15 “(C) *LIMITATION.*—Under no circumstances
16 shall an adjustment under this paragraph result
17 in fee revenue for a fiscal year that is less than
18 the sum of the amounts under subsections
19 (b)(2)(A) (the annual base revenue for the fiscal
20 year) and (b)(2)(B) (the dollar amount of the in-
21 flation adjustment for the fiscal year).

22 “(D) *PUBLICATION IN FEDERAL REG-*
23 *ISTER.*—The Secretary shall publish in the Fed-
24 eral Register notice under paragraph (5) the fee

1 *revenue and fees resulting from the adjustment*
2 *and the methodologies under this paragraph.*

3 *“(3) OPERATING RESERVE ADJUSTMENT.—*

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

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

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

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

1 *fees for the process for the review of bio-*
2 *similar biological product applications.*

3 “(C) *FEDERAL REGISTER NOTICE.—If an*
4 *adjustment 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 Federal*
8 *Register notice under paragraph (5) establishing*
9 *fee revenue and fees for the fiscal year involved.*

10 “(4) *FISCAL YEAR 2018 ADJUSTMENT.—*

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

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

23 “(C) *LIMITATION.—No adjustment under*
24 *this paragraph shall result in an increase in fee*

1 *revenue and fees under this section in excess of*
2 *\$9,000,000.*

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

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

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

18 “(6) *LIMIT.*—*The total amount of fees assessed*
19 *for a fiscal year under this section may not exceed the*
20 *total costs for such fiscal year for the resources allo-*
21 *cated for the process for the review of biosimilar bio-*
22 *logical product applications.”.*

23 “(d) *APPLICATION FEE WAIVER FOR SMALL BUSI-*
24 *NESS.*—*Subsection (d)(1) of section 744H of the Federal*

1 *Food, Drug, and Cosmetic Act (21 U.S.C. 379j–52), as re-*
 2 *designated by subsection (c)(1), is amended—*

3 *(1) by striking subparagraph (B);*

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

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

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

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

18 *(1) in paragraph (2)—*

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

22 *“(C) COMPLIANCE.—The Secretary shall be*
 23 *considered to have met the requirements of sub-*
 24 *paragraph (B) in any fiscal year if the costs de-*
 25 *scribed in such subparagraph are not more than*

1 15 percent below the level specified in such sub-
2 paragraph.”; and

3 (B) in subparagraph (D)—

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

6 (ii) by striking “(after fiscal year
7 2013)”; and

8 (2) in paragraph (3), by striking “2013 through
9 2017” and inserting “2018 through 2022”.

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

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

13 (1) in subsection (a)—

14 (A) by striking “2013” and inserting
15 “2018”; and

16 (B) by striking “Biosimilar User Fee Act of
17 2012” and inserting “Biosimilar User Fee
18 Amendments of 2017”;

19 (2) in subsection (b), by striking “2013” and in-
20 serting “2018”;

21 (3) by striking subsection (d);

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

1 (5) *in subsection (d), as so redesignated, by*
 2 *striking “2017” each place it appears and inserting*
 3 *“2022”.*

4 **SEC. 405. SUNSET DATES.**

5 (a) *AUTHORIZATION.—Sections 744G and 744H of the*
 6 *Federal Food, Drug, and Cosmetic Act, as amended by sec-*
 7 *tion 403 of this Act, shall cease to be effective October 1,*
 8 *2022.*

9 (b) *REPORTING REQUIREMENTS.—Section 744I of the*
 10 *Federal Food, Drug, and Cosmetic Act, as amended by sec-*
 11 *tion 404 of this Act, shall cease to be effective January 31,*
 12 *2023.*

13 (c) *PREVIOUS SUNSET PROVISION.—*

14 (1) *IN GENERAL.—Effective October 1, 2017, sec-*
 15 *tion 404 of the Food and Drug Administration Safety*
 16 *and Innovation Act (Public Law 112–144) is re-*
 17 *pealed.*

18 (2) *CONFORMING AMENDMENT.—The Food and*
 19 *Drug Administration Safety and Innovation Act*
 20 *(Public Law 112–144) is amended in the table of con-*
 21 *tents in section 2 by striking the item relating to sec-*
 22 *tion 404.*

23 **SEC. 406. EFFECTIVE DATE.**

24 *The amendments made by this title shall take effect*
 25 *on October 1, 2017, or the date of the enactment of this*

1 *Act, whichever is later, except that fees under part 8 of sub-*
2 *chapter C of chapter VII of the Federal Food, Drug, and*
3 *Cosmetic Act shall be assessed for all biosimilar biological*
4 *product applications received on or after October 1, 2017,*
5 *regardless of the date of the enactment of this Act.*

6 **SEC. 407. SAVINGS CLAUSE.**

7 *Notwithstanding the amendments made by this title,*
8 *part 8 of subchapter C of chapter VII of the Federal Food,*
9 *Drug, and Cosmetic Act, as in effect on the day before the*
10 *date of the enactment of this title, shall continue to be in*
11 *effect with respect to biosimilar biological product applica-*
12 *tions and supplements (as defined in such part as of such*
13 *day) that were accepted by the Food and Drug Administra-*
14 *tion for filing on or after October 1, 2012, but before October*
15 *1, 2017, with respect to assessing and collecting any fee re-*
16 *quired by such part for a fiscal year prior to fiscal year*
17 *2018.*

1 **TITLE V—REAUTHORIZATIONS**
 2 **AND IMPROVEMENTS RE-**
 3 **LATED TO DRUGS**

4 **SEC. 501. REAUTHORIZATION OF PROVISION RELATING TO**
 5 **EXCLUSIVITY OF CERTAIN DRUGS CON-**
 6 **TAINING SINGLE ENANTIOMERS.**

7 *Section 505(u)(4) of the Federal Food, Drug, and Cos-*
 8 *metic Act (21 U.S.C. 355(u)(4)) is amended by striking*
 9 *“2017” and inserting “2022”.*

10 **SEC. 502. REAUTHORIZATION OF ORPHAN GRANTS PRO-**
 11 **GRAM.**

12 *Section 5(c) of the Orphan Drug Act (21 U.S.C.*
 13 *360ee(c)) is amended by striking “2013 through 2017” and*
 14 *inserting “2018 through 2022”.*

15 **SEC. 503. REAUTHORIZATION OF PEDIATRIC STUDY OF**
 16 **DRUGS.**

17 *Section 409I(e)(1) of the Public Health Service Act (42*
 18 *U.S.C. 284m(e)(1)) is amended by striking “2013 through*
 19 *2017” and inserting “2018 through 2022”.*

20 **SEC. 504. PROTECTING AND STRENGTHENING THE DRUG**
 21 **SUPPLY CHAIN.**

22 *(a) DIVERTED DRUGS.—Paragraph (1) of section*
 23 *801(d) of the Federal Food, Drug, and Cosmetic Act (21*
 24 *U.S.C. 381(d)) is amended—*

1 (1) by striking “(d)(1) *Except as*” and inserting
 2 “(d)(1)(A) *Except as*”; and

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

4 “(B) *Except as authorized by the Secretary in the case*
 5 *of a drug that appears on the drug shortage list in effect*
 6 *under section 506E, no drug that would be subject to section*
 7 *503(b), and which is manufactured outside the United*
 8 *States and intended by the manufacturer or labeled to be*
 9 *marketed outside the United States, may be imported into*
 10 *the United States for sale or commercial use.”.*

11 (b) *COUNTERFEIT DRUGS.*—Subsection (b) of section
 12 303 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C.
 13 333) is amended by adding at the end the following:

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

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

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

1 (1) *will lower the cost of prescription drugs for*
 2 *consumers and reduce the burden of such cost on tax-*
 3 *payers; 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 ***TITLE VI—DEVICE INSPECTION***
 13 ***AND REGULATORY IMPROVE-***
 14 ***MENTS***

15 ***Subtitle A—Improving the Process***
 16 ***for Inspections of Device Estab-***
 17 ***lishments***

18 ***SEC. 601. RISK-BASED INSPECTIONS FOR DEVICES.***

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

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

23 “(A) *IN GENERAL.—The Secretary, acting*
 24 *through one or more officers or employees duly*
 25 *designated by the Secretary, shall inspect estab-*

lishments described in paragraph (1) that are engaged in the manufacture, propagation, compounding, or processing of a device or devices (referred to in this subsection as ‘device establishments’) in accordance with a risk-based schedule established by the Secretary.

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

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

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

SEC. 602. RECOGNITION OF FOREIGN GOVERNMENT INSPECTIONS.

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

1 **SEC. 603. IMPROVEMENTS TO INSPECTIONS PROCESS FOR**
2 **DEVICE ESTABLISHMENTS.**

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

6 “(h)(1) *In the case of inspections other than for-cause*
7 *inspections, the Secretary shall review processes and stand-*
8 *ards applicable to inspections of domestic and foreign de-*
9 *vice establishments in effect as of the date of the enactment*
10 *of this subsection, and update such processes and standards*
11 *through the adoption of uniform processes and standards*
12 *applicable to such inspections. Such processes and stand-*
13 *ards shall provide for—*

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

16 “(B) *announcing the inspection of the establish-*
17 *ment within a reasonable time before such inspection*
18 *occurs, including by providing to the owner, operator,*
19 *or agent in charge of the establishment a notification*
20 *regarding the type and nature of the inspection;*

21 “(C) *a reasonable estimate of the timeframe for*
22 *the inspection, an opportunity for advance commu-*
23 *nications between the officers or employees carrying*
24 *out the inspection under subsection (a)(1) and the*
25 *owner, operator, or agent in charge of the establish-*
26 *ment concerning appropriate working hours during*

1 *the inspection, and, to the extent feasible, advance no-*
2 *tice of some records that will be requested in order to*
3 *expedite the inspection; and*

4 “(D) *regular communications during the inspec-*
5 *tion with the owner, operator, or agent in charge of*
6 *the establishment regarding inspection status, which*
7 *may be recorded by either party with advance notice*
8 *and mutual consent.*

9 “(2)(A) *The Secretary shall, with respect to a request*
10 *described in subparagraph (B), provide nonbinding feed-*
11 *back with respect to such request not later than 45 days*
12 *after the Secretary receives such request.*

13 “(B) *A request described in this subparagraph is a re-*
14 *quest for feedback—*

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

18 “(ii) *with respect to actions proposed to be taken*
19 *by a device establishment in a response to a report re-*
20 *ceived by such establishment pursuant to subsection*
21 *(b) that involve a public health priority, that impli-*
22 *cate systemic or major actions, or relate to emerging*
23 *safety issues (as determined by the Secretary).*

24 “(3) *Nothing in this subsection limits the authority of*
25 *the Secretary to conduct inspections otherwise permitted*

1 *under this Act in order to ensure compliance with this*
2 *Act.”.*

3 *(b) GUIDANCE.—*

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

8 *(A) specifies how the Food and Drug Ad-*
9 *ministration will implement the process de-*
10 *scribed in paragraph (1) of subsection (h) of sec-*
11 *tion 704 of the Federal Food, Drug, and Cos-*
12 *metic Act (21 U.S.C. 374), as added by sub-*
13 *section (a), and the requirements described in*
14 *paragraph (2) of such subsection;*

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

17 *(C) establishes, with respect to inspections*
18 *of both domestic and foreign device establish-*
19 *ments (as referred to in section 510(h)(2) of the*
20 *Federal Food, Drug, and Cosmetic Act, as*
21 *amended by subsection (a)), a standard time-*
22 *frame for such inspections—*

23 *(i) that occurs over consecutive days;*

24 *and*

1 (ii) to which each investigator con-
 2 ducting such an inspection shall adhere un-
 3 less the investigator identifies to the estab-
 4 lishment involved a reason that more time
 5 is needed to conduct such investigation; and
 6 (D) identifies practices for investigators and
 7 device establishments to facilitate the continuity
 8 of inspections of such establishments.

9 (2) *FINAL GUIDANCE*.—Not later than 1 year
 10 after providing notice and opportunity for public
 11 comment on the draft guidance issued under para-
 12 graph (1), the Secretary of Health and Human Serv-
 13 ices shall issue final guidance to implement subsection
 14 (h) of section 704 of the Federal Food, Drug, and Cos-
 15 metic Act (21 U.S.C. 374), as added by subsection
 16 (a).

17 **SEC. 604. CERTIFICATES TO FOREIGN GOVERNMENTS FOR**
 18 **DEVICES.**

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

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

23 “(E)(i) If the Secretary denies a request made under
 24 subparagraph (A)(ii) for certification with respect to a de-
 25 vice, the Secretary shall provide, in writing, to the person

1 *seeking such certification the basis for such denial, and spe-*
2 *cifically identify the finding upon which such denial is*
3 *based.*

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

6 “(I) *grounds other than an injunction pro-*
7 *ceeding pursuant to section 302, seizure action pursu-*
8 *ant to section 304, or a recall designated Class I or*
9 *Class II pursuant to part 7, title 21, Code of Federal*
10 *Regulations, and*

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

14 *the Secretary shall provide a substantive summary of the*
15 *specific grounds for noncompliance so identified, if such*
16 *grounds have not been previously communicated to the*
17 *manufacturer.*

18 “(iii) *With respect to a device manufactured in an es-*
19 *tablishment that has received a report under section 704(b),*
20 *the Secretary shall not deny a request for certification*
21 *under subparagraph (A)(ii) based exclusively on the*
22 *issuance of that report if the owner, operator, or agent in*
23 *charge of such establishment has agreed to a plan of correc-*
24 *tion in response to such report.*

1 “(F)(i) *The Secretary shall provide a process for a per-*
2 *son who is denied a certification as described in subpara-*
3 *graph (E)(i) to request a review that conforms to the stand-*
4 *ards of section 517A(b).*

5 “(ii) *Notwithstanding any previous review conducted*
6 *pursuant to clause (i), a person who has been denied a cer-*
7 *tification for a device as described in subparagraph (E)(i)*
8 *may, at any time, request a review of that denial in order*
9 *to present new information relating to actions taken by*
10 *such person to address the reasons identified by the Sec-*
11 *retary for such denial, including evidence that corrective*
12 *actions are being or have been implemented to address the*
13 *grounds for noncompliance identified by the Secretary*
14 *under subparagraph (E)(ii).*

15 “(G)(i) *This paragraph applies to requests for certifi-*
16 *cation on behalf of any device establishment registered*
17 *under section 510, whether the establishment is located in*
18 *the United States or another country.*

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

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

1 (b) *GUIDANCE.*—Not later than 1 year after date of
 2 the enactment of this section, the Secretary of Health and
 3 Human Services shall issue guidance providing for a proc-
 4 ess to carry out subparagraph (F) of section 801(e)(4) of
 5 the Federal Food, Drug, and Cosmetic Act (21 U.S.C.
 6 381(e)(4)), as added by subsection (a). Not later than 12
 7 months after the comment period closes for the draft guid-
 8 ance, the Secretary shall issue final guidance.

9 **SEC. 605. FACILITATING INTERNATIONAL HARMONIZATION.**

10 Section 704(g) of the Federal Food, Drug, and Cos-
 11 metic Act (21 U.S.C. 374(g)) is amended by adding at the
 12 end the following:

13 “(15) Notwithstanding any other provision of this sub-
 14 section, for purposes of conducting inspections of establish-
 15 ments that manufacture, prepare, propagate, compound, or
 16 process devices except types of devices licensed under section
 17 351 of the Public Health Service Act, which inspections are
 18 required under section 510(h) or are inspections of such es-
 19 tablishments required to register pursuant to section 510(i),
 20 the Secretary may recognize auditing organizations that
 21 are recognized by organizations established by governments
 22 to facilitate international harmonization. Nothing in this
 23 paragraph affects the authority of the Secretary to inspect
 24 any device establishment pursuant to this Act. Nothing in

1 *this paragraph affects the authority of the Secretary to de-*
 2 *termine the official classification of an inspection.”.*

3 **SEC. 606. REAUTHORIZATION OF INSPECTION PROGRAM.**

4 *Section 704(g)(11) of the Federal Food, Drug, and Cos-*
 5 *metic Act (21 U.S.C. 374(g)(11)) is amended by striking*
 6 *“October 1, 2017” and inserting “October 1, 2022”.*

7 ***Subtitle B—Other Provisions***

8 **SEC. 611. REAUTHORIZATION OF PEDIATRIC HUMANI-**
 9 **TARIAN DEVICE EXCEPTIONS.**

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

13 **SEC. 612. REAUTHORIZATION OF PEDIATRIC DEVICE CON-**
 14 **SORTIA.**

15 *Section 305(e) of the Pediatric Medical Device Safety*
 16 *and Improvement Act of 2007 (Public Law 110–85; 42*
 17 *U.S.C. 282 note)) is amended by striking “2013 through*
 18 *2017” and inserting “2018 through 2022”.*

19 **SEC. 613. REGULATION OF OVER-THE-COUNTER HEARING**
 20 **AIDS.**

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

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

1 “(1) *DEFINITION.*—

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

4 “(i) *that uses the same fundamental*
5 *scientific technology as air conduction hear-*
6 *ing aids (as defined in section 874.3300 of*
7 *title 21, Code of Federal Regulations) (or*
8 *any successor regulation) or wireless air*
9 *conduction hearing aids (as defined in sec-*
10 *tion 874.3305 of title 21, Code of Federal*
11 *Regulations) (or any successor regulation);*

12 “(ii) *that is intended to be used by*
13 *adults over the age of 18 to compensate for*
14 *perceived mild to moderate hearing impair-*
15 *ment;*

16 “(iii) *that, through tools, tests, or soft-*
17 *ware, allows the user to control the over-the-*
18 *counter hearing aid and customize it to the*
19 *user’s hearing needs;*

20 “(iv) *that may—*

21 “(I) *use wireless technology; or*

22 “(II) *include tests for self-assess-*
23 *ment of hearing loss; and*

24 “(v) *that is available over-the-counter,*
25 *without the supervision, prescription, or*

1 other order, involvement, or intervention of
2 a licensed person, to consumers through in-
3 person transactions, by mail, or online.

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

8 “(2) *REGULATION*.—An over-the-counter hearing
9 aid shall be subject to the regulations promulgated in
10 accordance with section 613(b) of the *FDA Reauthor-*
11 *ization Act of 2017* and shall be exempt from sections
12 801.420 and 801.421 of title 21, *Code of Federal Reg-*
13 *ulations (or any successor regulations).*”.

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

15 (1) *IN GENERAL*.—The Secretary of Health and
16 Human Services (referred to in this section as the
17 “Secretary”), not later than 3 years after the date of
18 enactment of this Act, shall promulgate proposed reg-
19 ulations to establish a category of over-the-counter
20 hearing aids, as defined in subsection (p) of section
21 520 of the *Federal Food, Drug, and Cosmetic Act* (21
22 U.S.C. 360j) as amended by subsection (a), and, not
23 later than 180 days after the date on which the public
24 comment period on the proposed regulations closes,
25 shall issue such final regulations.

1 (2) *REQUIREMENTS.*—*In promulgating the regu-*
2 *lations under paragraph (1), the Secretary shall—*

3 (A) *include requirements that provide rea-*
4 *sonable assurances of the safety and efficacy of*
5 *over-the-counter hearing aids;*

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

9 (C) *include requirements for appropriate la-*
10 *beling of the over-the-counter hearing aid, in-*
11 *cluding requirements that such labeling include*
12 *a conspicuous statement that the device is only*
13 *intended for adults over the age of 18, informa-*
14 *tion on how consumers may report adverse*
15 *events, information on any contraindications,*
16 *conditions, or symptoms of medically treatable*
17 *causes of hearing loss, and advisements to con-*
18 *sult promptly with a licensed physician; and*

19 (D) *describe the requirements under which*
20 *the sale of over-the-counter hearing aids is per-*
21 *mitted, without the supervision, prescription, or*
22 *other order, involvement, or intervention of a li-*
23 *icensed person, to consumers through in-person*
24 *transactions, by mail, or online.*

1 (3) *PREMARKET NOTIFICATION.*—*The Secretary*
2 *shall make findings under section 510(m) of the Fed-*
3 *eral Food, Drug, and Cosmetic Act (21 U.S.C.*
4 *360(m)) to determine whether over-the-counter hear-*
5 *ing aids (as defined in section 520(p) of the Federal*
6 *Food, Drug, and Cosmetic Act (21 U.S.C. 360j), as*
7 *amended by subsection (a)) require a report under*
8 *section 510(k) to provide reasonable assurance of safe-*
9 *ty and effectiveness.*

10 (4) *EFFECT ON STATE LAW.*—*No State or local*
11 *government shall establish or continue in effect any*
12 *law, regulation, order, or other requirement specifi-*
13 *cally related to hearing products that would restrict*
14 *or interfere with the servicing, marketing, sale, dis-*
15 *persing, use, customer support, or distribution of*
16 *over-the-counter hearing aids (as defined in section*
17 *520(p) of the Federal Food, Drug, and Cosmetic Act*
18 *(21 U.S.C. 360j), as amended by subsection (a))*
19 *through in-person transactions, by mail, or online,*
20 *that is different from, in addition to, or otherwise not*
21 *identical to, the regulations promulgated under this*
22 *subsection, including any State or local requirement*
23 *for the supervision, prescription, or other order, in-*
24 *volvement, or intervention of a licensed person for*
25 *consumers to access over-the-counter hearing aids.*

1 (5) *NO EFFECT ON PRIVATE REMEDIES.*—*Nothing*
2 *in this section shall be construed to modify or oth-*
3 *erwise affect the ability of any person to exercise a*
4 *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 date*
8 *on which final regulations are issued under subsection (b),*
9 *the Secretary shall update and finalize the draft guidance*
10 *of the Department of Health and Human Services entitled*
11 *“Regulatory Requirements for Hearing Aid Devices and*
12 *Personal Sound Amplification Products”, issued on Novem-*
13 *ber 7, 2013. Such updated and finalized guidance shall*
14 *clarify which products, on the basis of claims or other mar-*
15 *keting, advertising, or labeling material, meet the definition*
16 *of a device in section 201 of the Federal Food, Drug, and*
17 *Cosmetic Act (21 U.S.C. 321) and which products meet the*
18 *definition of a personal sound amplification product, as set*
19 *forth in such guidance.*

20 (d) *REPORT.*—*Not later than 2 years after the date*
21 *on which the final regulations described in subsection (b)(1)*
22 *are issued, the Secretary of Health and Human Services*
23 *shall submit to Congress a report analyzing any adverse*
24 *events relating to over-the-counter hearing aids (as defined*

1 *in subsection (p)(1) of section 520 of the Federal Food,*
 2 *Drug, and Cosmetic Act (21 U.S.C. 360j)).*

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

6 *(a) IN GENERAL.—Not later than 180 days after the*
 7 *date of enactment of this Act, the Secretary of Health and*
 8 *Human Services, acting through the Commissioner of Food*
 9 *and Drugs, shall submit to the Committee on Energy and*
 10 *Commerce of the House of Representatives and the Com-*
 11 *mittee on Health, Education, Labor and Pensions of the*
 12 *Senate a report on how the Food and Drug Administration*
 13 *intends to ensure the quality, safety, and continued effec-*
 14 *tiveness of devices (as defined in section 201(h) of the Fed-*
 15 *eral Food, Drug, and Cosmetic Act (21 U.S.C. 301(h))) with*
 16 *respect to which servicing (as defined in subsection (c)) has*
 17 *been performed by any entity engaging in such servicing.*

18 *(b) CONTENTS.—The report submitted under sub-*
 19 *section (a) shall contain—*

20 *(1) the status of, and findings to date with re-*
 21 *spect to, the notice entitled “Refurbishing, Recondi-*
 22 *tioning, Rebuilding, Remarketing, Remanufacturing,*
 23 *and Servicing of Medical Devices Performed by*
 24 *Third-Party Entities and Original Equipment Manu-*
 25 *facturers; Request for Comments” published by the*

1 *Food and Drug Administration on April 25, 2016 (81*
2 *Fed. Reg. 24041 et seq.), including how the Food and*
3 *Drug Administration intends to define the specific ac-*
4 *tivities performed on a device by the manufacturer of*
5 *the device or other entities;*

6 *(2) a description of the statutory or regulatory*
7 *authority of the Food and Drug Administration used*
8 *to oversee and regulate servicing conducted with re-*
9 *spect to devices;*

10 *(3) details on how the Food and Drug Adminis-*
11 *tration intends to protect the public health by ensur-*
12 *ing consistent quality, safety, and continued effective-*
13 *ness of devices with respect to which servicing has*
14 *been performed by any entity engaging in such serv-*
15 *icing;*

16 *(4) information on how the Food and Drug Ad-*
17 *ministration can better understand the device serv-*
18 *icing industry, including the size, scope, location, and*
19 *composition of entities performing such servicing and*
20 *the rate of adverse events related to such servicing;*

21 *(5) information regarding the current regulation*
22 *by States, the Joint Commission, or other regulatory*
23 *bodies of servicing conducted with respect to devices*
24 *by all entities, including original equipment manu-*
25 *facturers, third-party entities, and hospitals; and*

1 (6) *any additional information determined by*
 2 *the Secretary (acting through the Commissioner) to be*
 3 *relevant to ensuring the quality, safety, and contin-*
 4 *ued effectiveness of devices with respect to which serv-*
 5 *icing has been performed, including whether addi-*
 6 *tional Federal statutory authority is necessary to en-*
 7 *sure such quality, safety, and continued effectiveness.*

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

13 **SEC. 615. DEVICE PILOT PROJECTS TO GENERATE RELI-**
 14 **ABLE AND TIMELY SAFETY AND ACTIVE SUR-**
 15 **VEILLANCE DATA.**

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

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

21 “(1) *IN GENERAL.*—*The Secretary shall, not*
 22 *later than one year after the date of the enactment of*
 23 *the FDA Reauthorization Act of 2017, initiate one or*
 24 *more pilot projects relating to providing timely and*
 25 *reliable information on the safety and effectiveness of*

1 *devices approved under section 515, cleared under sec-*
2 *tion 510(k), or classified under section 513(f)(2), in*
3 *which a manufacturer or manufacturers of a device or*
4 *device type voluntarily participate. Any such project*
5 *shall meet each of the following criteria:*

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

11 *“(B) The project informs, to the extent ap-*
12 *plicable, the development of methods, systems,*
13 *data criteria, and programs that could be used*
14 *to support safety and active surveillance activi-*
15 *ties for any device.*

16 *“(C) The project shall be designed and con-*
17 *ducted in coordination with a comprehensive*
18 *system for evaluating device technology that op-*
19 *erates under a governing board with appropriate*
20 *representation of stakeholders, including patient*
21 *groups and device manufacturers.*

22 *“(D) The project uses electronic health data*
23 *including, as appropriate, claims data, patient*
24 *survey data, and any other data, as the Sec-*
25 *retary determines appropriate.*

1 “(E) The project prioritizes devices and de-
2 vice types that meet one or more of the following
3 criteria:

4 “(i) Devices and device types for which
5 the collection and analysis of real world evi-
6 dence regarding a device’s safety and effec-
7 tiveness is likely to advance public health.

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

10 “(iii) Devices and device types, the
11 failure of which has significant health con-
12 sequences.

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

15 “(I) has received public rec-
16 ommendations in accordance with
17 paragraph (2)(B); and

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

22 “(2) PARTICIPATION.—The Secretary shall estab-
23 lish the conditions and processes—

1 “(A) under which a manufacturer of a de-
 2 vice may voluntarily participate in a pilot
 3 project described in paragraph (1); and

4 “(B) for facilitating public recommenda-
 5 tions for devices to be prioritized under such a
 6 pilot project, including requirements for the data
 7 necessary to support such a recommendation.

8 “(3) CONTINUATION OF ONGOING PROJECTS.—
 9 The Secretary may continue or expand projects, with
 10 respect to providing timely and reliable information
 11 on the safety and effectiveness of devices approved
 12 under section 515, cleared under section 510(k), or
 13 classified under section 513(f)(2), that are being car-
 14 ried out as of the date of the enactment of the FDA
 15 Reauthorization Act of 2017. The Secretary shall, be-
 16 ginning on such date of enactment, take such steps as
 17 may be necessary—

18 “(A) to ensure such projects meet the re-
 19 quirements of subparagraphs (A) through (E) of
 20 paragraph (1); and

21 “(B) to increase the voluntary participation
 22 in such projects of manufacturers of devices and
 23 facilitate public recommendations for any de-
 24 vices prioritized under such a project.

25 “(4) IMPLEMENTATION.—

1 “(A) *CONTRACTING AUTHORITY.*—*The Sec-*
2 *retary may carry out a pilot project meeting the*
3 *criteria specified in subparagraphs (A) through*
4 *(E) of paragraph (1) or a project continued or*
5 *expanded under paragraph (3) by entering into*
6 *contracts, cooperative agreements, grants, or*
7 *other appropriate agreements with public or pri-*
8 *vate entities that have a significant presence in*
9 *the United States and meet the following condi-*
10 *tions:*

11 “(i) *If such an entity is a component*
12 *of another organization, the entity and the*
13 *organization have established an agreement*
14 *under which appropriate security measures*
15 *are implemented to maintain the confiden-*
16 *tiality and privacy of the data described in*
17 *paragraph (1)(D) and such agreement en-*
18 *sures that the entity will not make an un-*
19 *authorized disclosure of such data to the*
20 *other components of the organization in*
21 *breach of requirements with respect to con-*
22 *fidentiality and privacy of such data estab-*
23 *lished under such security measures.*

24 “(ii) *In the case of the termination or*
25 *nonrenewal of such a contract, cooperative*

1 *agreement, grant, or other appropriate*
2 *agreement, the entity or entities involved*
3 *shall comply with each of the following:*

4 “(I) *The entity or entities shall*
5 *continue to comply with the require-*
6 *ments with respect to confidentiality*
7 *and privacy referred to in clause (i)*
8 *under this subparagraph with respect*
9 *to all data disclosed to the entity under*
10 *such an agreement.*

11 “(II) *The entity or entities shall*
12 *return any data disclosed to such enti-*
13 *ty pursuant to this subsection and to*
14 *which it would not otherwise have ac-*
15 *cess or, if returning such data is not*
16 *practicable, destroy the data.*

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

19 “(I) *research, statistical, epi-*
20 *demiologic, or clinical capability and*
21 *expertise to conduct and complete the*
22 *activities under this subsection, includ-*
23 *ing the capability and expertise to pro-*
24 *vide the Secretary access to de-identi-*

1 *fied data consistent with the require-*
2 *ments of this subsection;*

3 *“(II) an information technology*
4 *infrastructure to support electronic*
5 *data and operational standards to pro-*
6 *vide security for such data, as appro-*
7 *priate;*

8 *“(III) experience with, and exper-*
9 *tise on, the development of research on,*
10 *and surveillance of, device safety and*
11 *effectiveness using electronic health*
12 *data; or*

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

16 *“(B) REVIEW OF CONTRACT IN THE EVENT*
17 *OF A MERGER OR ACQUISITION.—The Secretary*
18 *shall review any contract, cooperative agreement,*
19 *grant, or other appropriate agreement entered*
20 *into under this paragraph with an entity meet-*
21 *ing the conditions specified in subparagraph (A)*
22 *in the event of a merger or acquisition of the en-*
23 *tity in order to ensure that the requirements*
24 *specified in this subsection will continue to be*
25 *met.*

1 “(5) *COMPLIANCE WITH REQUIREMENTS FOR*
2 *RECORDS OR REPORTS ON DEVICES.*—*The participa-*
3 *tion of a manufacturer in pilot projects under this*
4 *subsection shall not affect the eligibility of such man-*
5 *ufacturer to participate in any quarterly reporting*
6 *program with respect to devices carried out under sec-*
7 *tion 519 or 522. The Secretary may determine that,*
8 *for a specified time period to be determined by the*
9 *Secretary, a manufacturer’s participation in a pilot*
10 *project under this subsection or a project continued or*
11 *expanded under paragraph (3) may meet the applica-*
12 *ble requirements of section 519 or 522, if—*

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

16 “(B) *the Secretary has established proce-*
17 *dures for making adverse event and safety infor-*
18 *mation collected from such project public, to the*
19 *extent possible.*

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

23 “(A) *individually identifiable health infor-*
24 *mation so collected shall not be disclosed when*

1 *presenting any information from such project;*
 2 *and*

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

9 *“(7) LIMITATIONS.—*

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

18 *“(B) NO USE OF FEES.—Pilot projects ini-*
 19 *tiated under this subsection may not primarily*
 20 *utilize funds collected pursuant to the Medical*
 21 *Device User Fee Amendments of 2017.*

22 *“(8) OTHER PROJECTS REQUIRED TO COMPLY.—*
 23 *Paragraphs (1)(B), (4)(A)(i), (4)(A)(ii), (5), and (6)*
 24 *shall apply with respect to any pilot program under-*
 25 *taken in coordination with the comprehensive system*

1 *described in paragraph (1)(C) that relates to the use*
2 *of real world evidence for devices in the same manner*
3 *and to the same extent as such paragraphs apply*
4 *with respect to pilot projects conducted under this*
5 *subsection.*

6 “(9) *REPORT TO CONGRESS.*—*Not later than 18*
7 *months after the date of enactment of this Act, and*
8 *annually thereafter, the Secretary shall submit to the*
9 *Committee on Energy and Commerce of the House of*
10 *Representatives and the Committee on Health, Edu-*
11 *cation, Labor and Pensions of the Senate a report*
12 *containing a description of the pilot projects being*
13 *conducted under this subsection and projects contin-*
14 *ued or expanded pursuant to paragraph (3), includ-*
15 *ing for each such project—*

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

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

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

1 “(D) the devices or device categories in-
2 volved in such project;

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

5 “(F) the findings of the project in relation
6 to device safety, including adverse events, mal-
7 functions, and other safety information.

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

11 (b) REPORT.—Not later than January 31, 2021, the
12 Secretary of Health and Human Services, acting through
13 the Commissioner of Food and Drugs, may conduct a re-
14 view through an independent third party to evaluate the
15 strengths, limitations, and appropriate use of evidence col-
16 lected pursuant to real world evidence pilot projects de-
17 scribed in the letters described in section 201(b) of the Med-
18 ical Device User Fee Amendments of 2017 and subsection
19 (i) of section 519 of the Federal Food, Drug, and Cosmetic
20 Act (21 U.S.C. 360i), as added by subsection (a)—

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

24 (2) to determine whether the methods, systems,
25 and programs carried out through such pilot projects

1 *efficiently generate reliable and timely evidence about*
2 *the effectiveness of the surveillance of devices with re-*
3 *spect to safety.*

4 **SEC. 616. RISK-BASED CLASSIFICATION OF ACCESSORIES.**

5 *(a) IN GENERAL.—Subsection (f) of section 513 of the*
6 *Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360c)*
7 *is amended by adding at the end the following new para-*
8 *graph:*

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

17 *“(B) The classification of any accessory distinct from*
18 *another device by regulation or written order issued prior*
19 *to December 13, 2016, shall continue to apply unless and*
20 *until the accessory is reclassified by the Secretary, notwith-*
21 *standing the classification of any other device with which*
22 *such accessory is intended to be used. Nothing in this section*
23 *shall preclude the Secretary’s ability to initiate the classi-*
24 *fication of an accessory through regulation or written order,*
25 *as appropriate.*

1 “(C)(i) *In the case of an accessory that has been grant-*
2 *ed marketing authorization as part of a submission under*
3 *section 515(c), 510(k), or paragraph (2) of this subsection*
4 *with another device with which such accessory is intended*
5 *to be used, and with respect to which the Secretary has*
6 *issued a written order classifying such accessory type dis-*
7 *tinct from another device in accordance with subparagraph*
8 *(A), the manufacturer or importer of such accessory may,*
9 *in lieu of submitting a request for classification of such ac-*
10 *cessory, submit a written request to the Secretary identi-*
11 *fying such classification. A request under this clause shall*
12 *include such information to support the request as may be*
13 *specified by the Secretary.*

14 “(ii) *A request under clause (i) shall include a rec-*
15 *ommendation for the proper classification of the accessory*
16 *pursuant to subparagraph (A), and shall include such in-*
17 *formation as may be necessary for the Secretary to evaluate,*
18 *based on the least burdensome approach, the appropriate*
19 *class for the accessory under subsection (a).*

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

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

1 “(v) A written notification that the Secretary disagrees
2 with the classification recommended in a request pursuant
3 to clause (ii) shall include a detailed description and jus-
4 tification for the determination to disagree.

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

14 “(I) may include a written request for the proper
15 classification of the accessory pursuant to subpara-
16 graph (A);

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

22 “(III) shall, if the request under subclause (I) is
23 requesting classification of the accessory in class II,
24 include in the application an initial draft proposal

1 *for special controls, if special controls would be re-*
2 *quired pursuant to subsection (a)(1)(B).*

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

8 *“(iii) The Secretary’s evaluation of an accessory under*
9 *clause (i) shall constitute an order establishing a new classi-*
10 *fication for such accessory for the specified intended use or*
11 *uses of such accessory and for any accessory with the same*
12 *intended use or uses as such accessory.*

13 *“(E) For accessories that have been granted marketing*
14 *authorization as part of a submission for another device*
15 *with which the accessory involved is intended to be used,*
16 *through an application for such other device under section*
17 *515(c), a report under section 510(k), or a request for classi-*
18 *fication under paragraph (2) of this subsection, and that*
19 *have not been classified by the Secretary based on the risks*
20 *and appropriate level of regulatory controls in accordance*
21 *with subparagraph (A):*

22 *“(i) Not later than the date that is one year after*
23 *the date of enactment of the FDA Reauthorization Act*
24 *of 2017 and at least once every 5 years thereafter, and*
25 *as the Secretary otherwise deems appropriate, pursu-*

1 *ant to this paragraph, the Secretary shall publish in*
2 *the Federal Register a notice proposing a list of such*
3 *accessories that the Secretary believes may be suitable*
4 *for a distinct classification in class I and the pro-*
5 *posed regulations for such classifications. In devel-*
6 *oping such lists, the Secretary shall consider rec-*
7 *ommendations from sponsors of device submissions*
8 *and other stakeholders for accessories to be included*
9 *on such lists. The notices shall provide for a period*
10 *of not less than 60 calendar days for public comment.*
11 *Within 180 days after the end of the comment period,*
12 *the Secretary shall publish in the Federal Register a*
13 *final action classifying such suitable accessories into*
14 *class I.*

15 *“(ii) A manufacturer or importer of an accessory*
16 *that has been granted such marketing authorization*
17 *may submit to the Secretary a written request for the*
18 *appropriate classification of the accessory based on*
19 *the risks and appropriate level of regulatory controls*
20 *as described in subparagraph (A) or (C), and shall,*
21 *if the request is requesting classification of the acces-*
22 *sory in class II, include in the submission an initial*
23 *draft proposal for special controls, if special controls*
24 *would be required pursuant to subsection (a)(1)(B).*
25 *Such request shall include such information as may*

1 *be necessary for the Secretary to evaluate, based on*
2 *the least burdensome approach, the appropriate class*
3 *for the accessory under subsection (a). The Secretary*
4 *shall provide an opportunity for a manufacturer or*
5 *importer to meet with appropriate personnel of the*
6 *Food and Drug Administration to discuss the appro-*
7 *priate classification of such accessory prior to submit-*
8 *ting a written request under this clause for classifica-*
9 *tion of the accessory.*

10 “(iii) *The Secretary shall respond to a request*
11 *made under clause (ii) not later than 90 calendar*
12 *days after receiving such submission by granting or*
13 *denying the request for classification of the accessory,*
14 *and the Secretary shall by written order classify such*
15 *accessory or deny the request. If the Secretary does*
16 *not agree with the recommendation for classification*
17 *submitted by the manufacturer or importer, the re-*
18 *sponse shall include a detailed description and jus-*
19 *tification for such determination. Within 30 calendar*
20 *days after granting such a request, the Secretary shall*
21 *publish a notice in the Federal Register announcing*
22 *such response.*

23 “(F) *Nothing in this paragraph may be construed as*
24 *precluding a manufacturer of an accessory of a new type*
25 *from using the classification process described in subsection*

1 (f)(2) to obtain classification of such accessory in accord-
 2 ance with the criteria and requirements set forth in that
 3 subsection.”.

4 (b) *CONFORMING CHANGE.*—Section 513(b) of the Fed-
 5 eral Food, Drug, and Cosmetic Act (21 U.S.C. 360c(b)) is
 6 amended by striking paragraph (9) (relating to classifica-
 7 tion of an accessory).

8 (c) *EFFECTIVE DATE.*—The amendments made by sub-
 9 sections (a) and (b) shall take effect on the date that is 60
 10 days after the date of enactment of this Act.

11 **TITLE VII—GENERIC DRUG** 12 **ACCESS AND COMPETITION**

13 **SEC. 701. COMPETITIVE GENERIC THERAPIES.**

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

17 **“SEC. 506H. COMPETITIVE GENERIC THERAPIES.**

18 “(a) *IN GENERAL.*—The Secretary shall, at the request
 19 of the sponsor of a drug that is designated as a competitive
 20 generic therapy pursuant to subsection (b), expedite the de-
 21 velopment and review of such drug pursuant to section
 22 505(j).

23 “(b) *DESIGNATION PROCESS.*—

1 “(1) *REQUEST.*—The sponsor of a drug may re-
2 quest the Secretary to designate the drug as a com-
3 petitive generic therapy.

4 “(2) *TIMING.*—A request under paragraph (1)
5 may be made concurrently with, or at any time prior
6 to, the submission of an abbreviated new drug appli-
7 cation for the drug under section 505(j).

8 “(3) *CRITERIA.*—A drug is eligible for designa-
9 tion as a competitive generic therapy under this sec-
10 tion if the Secretary determines that there is inad-
11 equate generic competition.

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

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

18 “(B) if the Secretary finds that the drug
19 meets such criteria, designate the drug as a com-
20 petitive generic therapy.

21 “(c) *ACTIONS.*—In expediting the development and re-
22 view of a drug under subsection (a), the Secretary shall,
23 as requested by the sponsor, take actions including the fol-
24 lowing:

1 “(1) *Hold meetings with the sponsor and the re-*
2 *view team throughout the development of the drug*
3 *prior to submission of the application for such drug*
4 *under section 505(j).*

5 “(2) *Provide timely advice to, and interactive*
6 *communication with, the sponsor regarding the devel-*
7 *opment of the drug to ensure that the development*
8 *program to gather the data necessary for approval is*
9 *as efficient as practicable.*

10 “(3) *Involve senior managers and experienced re-*
11 *view staff, as appropriate, in a collaborative, coordi-*
12 *nated review, including with respect to drug-device*
13 *combination products and other complex products.*

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

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

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

21 “(d) *DEFINITIONS.—In this section:*

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

24 “(2) *The term ‘inadequate generic competition’*
25 *means, with respect to a product, there is not more*

1 *than one approved drug product on the list of prod-*
 2 *ucts described in section 505(j)(7)(A) (not including*
 3 *products on the discontinued section of such list) that*
 4 *is—*

5 *“(A) the reference listed drug; or*

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

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

12 *(b) GUIDANCE; AMENDED REGULATIONS.—*

13 *(1) IN GENERAL.—*

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

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

21 *(ii) not later than 1 year after the close*
 22 *of the comment period for the draft guid-*
 23 *ance, issue final guidance on such provi-*
 24 *sions.*

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

3 (i) *specify the process and criteria by*
4 *which the Secretary makes a designation*
5 *under section 506H of the Federal Food,*
6 *Drug, and Cosmetic Act, as added by sub-*
7 *section (a);*

8 (ii) *specify the actions the Secretary*
9 *will take to expedite the development and*
10 *review of a competitive generic therapy pur-*
11 *suant to such a designation; and*

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

14 (2) AMENDED REGULATIONS.—

15 (A) IN GENERAL.—*If the Secretary of*
16 *Health and Human Services determines that it*
17 *is necessary to amend the regulations under title*
18 *21, Code of Federal Regulations, in order to im-*
19 *plement section 506H of the Federal Food, Drug,*
20 *and Cosmetic Act, as added by subsection (a),*
21 *the Secretary shall amend such regulations not*
22 *later than 2 years after the date of enactment of*
23 *this Act.*

24 (B) PROCEDURE.—*In carrying out sub-*
25 *paragraph (A), and in issuing any other regula-*

1 *tions to implement such section 506H, the Sec-*
2 *retary shall—*

3 *(i) issue a notice of proposed rule-*
4 *making that includes the proposed regula-*
5 *tion;*

6 *(ii) provide a period of not less than*
7 *60 days for comments on the proposed regu-*
8 *lation; and*

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

12 **SEC. 702. ENHANCING REGULATORY TRANSPARENCY TO**
13 **ENHANCE GENERIC COMPETITION.**

14 *Section 505(j) of the Federal Food, Drug, and Cos-*
15 *metic Act (21 U.S.C. 355) is amended by adding at the*
16 *end the following:*

17 *“(11) Upon the request of an applicant regarding one*
18 *or more specified pending applications under this sub-*
19 *section, the Secretary shall—*

20 *“(A) by telephone or electronic mail, provide re-*
21 *view status updates; and*

22 *“(B) indicate in such updates the categorical*
23 *status of the applications by each relevant review dis-*
24 *cipline.”.*

1 **SEC. 703. INCENTIVIZING COMPETITIVE GENERIC THERAPY**
 2 **DEVELOPMENT.**

3 *Section 505(j)(5) of the Federal Food, Drug, and Cos-*
 4 *metic Act (21 U.S.C. 355(j)(5)) is amended—*

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

7 *“(v) 180-DAY EXCLUSIVITY PERIOD FOR COM-*
 8 *PETITIVE GENERIC THERAPIES.—*

9 *“(I) EFFECTIVENESS OF APPLICATION.—*
 10 *Subject to subparagraph (D)(iv), if the applica-*
 11 *tion is for a drug that is the same as a competi-*
 12 *tive generic therapy for which any first approved*
 13 *applicant has commenced commercial marketing,*
 14 *the application shall be made effective on the*
 15 *date that is 180 days after the date of the first*
 16 *commercial marketing of the competitive generic*
 17 *therapy (including the commercial marketing of*
 18 *the listed drug) by any first approved applicant.*

19 *“(II) LIMITATION.—The exclusivity period*
 20 *under subclause (I) shall not apply with respect*
 21 *to a competitive generic therapy that has pre-*
 22 *viously received an exclusivity period under sub-*
 23 *clause (I).*

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

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

3 “(AA) *that is designated as a*
4 *competitive generic therapy under sec-*
5 *tion 506H; and*

6 “(BB) *for which there are no un-*
7 *expired patents or blocking*
8 *exclusivities on the list of products de-*
9 *scribed in section 505(j)(7)(A) at the*
10 *time of approval.*

11 “(bb) *The term ‘first approved appli-*
12 *cant’ means any applicant that has sub-*
13 *mitted an application that—*

14 “(AA) *is for a competitive generic*
15 *therapy that is approved on the first*
16 *day on which any application for such*
17 *competitive generic therapy is ap-*
18 *proved;*

19 “(BB) *is not eligible for a 180-*
20 *day exclusivity period under clause*
21 *(iv) for the drug that is the subject of*
22 *the application for the competitive ge-*
23 *neric therapy; and*

24 “(CC) *is not for a drug for which*
25 *all drug versions have forfeited eligi-*

1 *bility for a 180-day exclusivity period*
 2 *under clause (iv) pursuant to subpara-*
 3 *graph (D).’; and*

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

6 *“(iv) SPECIAL FORFEITURE RULE FOR*
 7 *COMPETITIVE GENERIC THERAPY.—The 180-*
 8 *day exclusivity period described in subpara-*
 9 *graph (B)(v) shall be forfeited by a first ap-*
 10 *proved applicant if the applicant fails to*
 11 *market the competitive generic therapy*
 12 *within 75 days after the date on which the*
 13 *approval of the first approved applicant’s*
 14 *application for the competitive generic ther-*
 15 *apy is made effective.”.*

16 **SEC. 704. TROPICAL DISEASE PRODUCT APPLICATION.**

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

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

22 *(2) by adding at the end the following:*

23 *“(iii) that contains reports of one or*
 24 *more new clinical investigations (other than*
 25 *bioavailability studies) that are essential to*

1 the approval of the application and con-
 2 ducted or sponsored by the sponsor of such
 3 application; and

4 “(iv) that contains an attestation from
 5 the sponsor of the application that such re-
 6 ports were not submitted as part of an ap-
 7 plication for marketing approval or licen-
 8 sure by a regulatory authority in India,
 9 Brazil, Thailand, or any country that is a
 10 member of the Pharmaceutical Inspection
 11 Convention or the Pharmaceutical Inspec-
 12 tion Cooperation Scheme prior to Sep-
 13 tember 27, 2007.”.

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

16 (a) *STUDY BY GAO.*—The Comptroller General of the
 17 United States shall conduct a study to determine the fol-
 18 lowing:

19 (1) *The rate of first cycle approvals and ten-*
 20 *tative approvals for generic drug applications sub-*
 21 *mitted during the period beginning on October 1,*
 22 *2012, and ending on September 30, 2017. The rate of*
 23 *first cycle approvals and tentative approvals shall be*
 24 *determined and reported per each GDUFA cohort*
 25 *year during this period.*

1 (2) *If the rate determined pursuant to para-*
2 *graph (1) for any GDUFA cohort year is lower than*
3 *20 percent, the reasons contributing to the relatively*
4 *low rate of first cycle approvals and tentative approv-*
5 *als for generic drug applications shall be itemized, as-*
6 *sessed, and reported. In making the assessment re-*
7 *quired by this paragraph, the Comptroller General*
8 *shall consider, among other things, the role played*
9 *by—*

10 (A) *the Food and Drug Administration’s*
11 *implementation of approval standards for ge-*
12 *neric drug applications;*

13 (B) *the extent to which those approval*
14 *standards are communicated clearly to industry*
15 *and applied consistently during the review proc-*
16 *ess;*

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

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

23 (E) *the processes and practices for commu-*
24 *nication between the Food and Drug Adminis-*

1 *tration and sponsors of generic drug applica-*
2 *tions; and*

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

6 *(3) Taking into account the determinations made*
7 *pursuant to paragraphs (1) and (2) and any review*
8 *process improvements implemented pursuant to this*
9 *Act, whether there are ways the review process for ge-*
10 *neric drugs could be improved to increase the rate of*
11 *first cycle approvals and tentative approvals for ge-*
12 *neric drug applications. In making this determina-*
13 *tion, the Comptroller General shall consider, among*
14 *other things, options for increasing review efficiency*
15 *and communication effectiveness.*

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

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

1 (1) *The term “GDUFA cohort year” means a fis-*
2 *cal year.*

3 (2) *The term “generic drug” means a drug that*
4 *is approved or is seeking approval under section*
5 *505(j) of the Federal Food, Drug, and Cosmetic Act*
6 *(21 U.S.C. 355(j)).*

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

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

13 (5)(A) *The term “first cycle approvals and ten-*
14 *tative approvals” means the approval or tentative ap-*
15 *proval of a generic drug application after the Food*
16 *and Drug Administration’s complete review of the ap-*
17 *plication and without issuance of one or more com-*
18 *plete response letters.*

19 (B) *For purposes of this paragraph, the term*
20 *“complete response letter” means a written commu-*
21 *nication to the sponsor of a generic drug application*
22 *or holder of a drug master file (DMF) from the Food*
23 *and Drug Administration describing all of the defi-*
24 *ciencies that the Administration has identified in the*
25 *generic drug application (including pending amend-*

1 *ments) or drug master file that must be satisfactorily*
 2 *addressed before the generic drug application can be*
 3 *approved.*

4 ***TITLE VIII—FOSTERING INNOVA-***
 5 ***TION IN MEDICAL IMAGING***

6 ***SEC. 801. APPROVAL OF APPLICATIONS FOR CERTAIN DIAG-***
 7 ***NOSTIC MEDICAL IMAGING DEVICES.***

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

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

13 “(1) *The Secretary may, subject to the succeeding*
 14 *provisions of this subsection, approve an application*
 15 *(or a supplement to such an application) submitted*
 16 *under section 515 with respect to an applicable med-*
 17 *ical imaging device, or, in the case of an applicable*
 18 *medical imaging device for which a notification is*
 19 *submitted under section 510(k), may make a substan-*
 20 *tial equivalence determination with respect to an ap-*
 21 *plicable medical imaging device, or may grant a re-*
 22 *quest submitted under section 513(f)(2) for an appli-*
 23 *cable medical imaging device, if the indications and*
 24 *conditions of use proposed in such application, notifi-*

1 *cation, or request involve the use of a contrast agent*
2 *that is not—*

3 *“(A) in a concentration, rate of administra-*
4 *tion, or route of administration that is different*
5 *from those described in the approved labeling of*
6 *the contrast agent, except that the Secretary may*
7 *approve such application, make such substantial*
8 *equivalence determination, or grant such request*
9 *if the Secretary determines that such differences*
10 *in concentration, rate of administration, or*
11 *route of administration exist but do not ad-*
12 *versely affect the safety and effectiveness of the*
13 *contrast agent when used with the device;*

14 *“(B) in a region, organ, or system of the*
15 *body that is different from those described in the*
16 *approved labeling of the contrast agent, except*
17 *that the Secretary may approve such applica-*
18 *tion, make such substantial equivalence deter-*
19 *mination, or grant such request if the Secretary*
20 *determines that such differences in region, organ,*
21 *or system of the body exist but do not adversely*
22 *affect the safety and effectiveness of the contrast*
23 *agent when used with the device;*

24 *“(C) in a patient population that is dif-*
25 *ferent from those described in the approved label-*

1 *ing of the contrast agent, except that the Sec-*
2 *retary may approve such application, make such*
3 *substantial equivalence determination, or grant*
4 *such request if the Secretary determines such dif-*
5 *ferences in patient population exist but do not*
6 *adversely affect the safety and effectiveness of the*
7 *contrast agent when used with the device; or*

8 *“(D) in an imaging modality (such as an*
9 *ultrasound, an x-ray, diagnostic radiopharma-*
10 *ceutical-based technologies, fluorescent imaging*
11 *technology, or magnetic resonance) that is dif-*
12 *ferent from those described in the approved label-*
13 *ing of the contrast agent.*

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

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

22 *“(B) review information and data provided*
23 *to the Secretary by the sponsor of a contrast*
24 *agent in an application submitted under section*
25 *505 of this Act or section 351 of the Public*

1 *Health Service Act, so long as the sponsor of*
2 *such contrast agent has provided to the sponsor*
3 *of the applicable medical imaging device that is*
4 *the subject of such review a right of reference and*
5 *the application is submitted in accordance with*
6 *this subsection.*

7 “(3) *An application submitted under section*
8 *515, a notification submitted under section 510(k), or*
9 *a request submitted under section 513(f)(2), as de-*
10 *scribed in paragraph (1), with respect to an applica-*
11 *ble medical imaging device shall be subject to the re-*
12 *quirements of such respective section. Such applica-*
13 *tion, notification, or request shall only be subject to*
14 *the requirements of this Act applicable to devices.*

15 “(4) *For purposes of this subsection and section*
16 *505(y)—*

17 “(A) *the term ‘applicable medical imaging*
18 *device’ means a device intended to be used in*
19 *conjunction with a contrast agent (or class of*
20 *contrast agents) for an imaging use that is not*
21 *described in the approved labeling of such con-*
22 *trast agent (or the approved labeling of any con-*
23 *trast agent in the same class as such contrast*
24 *agent); and*

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

6 “(i) is a diagnostic radiopharma-
 7 ceutical, as defined in section 315.2 and
 8 601.31 of title 21, Code of Federal Regula-
 9 tions (or any successor regulations); or

10 “(ii) is a diagnostic agent that im-
 11 proves the visualization of structure or func-
 12 tion within the body by increasing the rel-
 13 ative difference in signal intensity within
 14 the target tissue, structure, or fluid.”.

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

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

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

23 “(1) The sponsor of a contrast agent for which
 24 an application has been approved under this section
 25 may submit a supplement to the application seeking

1 *approval for the use of the contrast agent for a new*
2 *indication and conditions of use following the author-*
3 *ization of a premarket submission for an applicable*
4 *medical imaging device for that use with the contrast*
5 *agent pursuant to section 520(q)(1).*

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

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

11 “(B) *review information and data sub-*
12 *mitted to the Secretary by the sponsor of an ap-*
13 *plicable medical imaging device pursuant to sec-*
14 *tion 515, 510(k), or 513(f)(2) so long as the*
15 *sponsor of such applicable medical imaging de-*
16 *vice has provided to the sponsor of the contrast*
17 *agent a right of reference.*

18 “(3) *For purposes of this subsection—*

19 “(A) *the term ‘new indication’ means a use*
20 *of a contrast agent that is described in the ap-*
21 *proved labeling of an applicable medical imag-*
22 *ing device described in section 520(q), but that*
23 *is not described in the approved labeling of the*
24 *contrast agent; and*

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

4 ***TITLE IX—ADDITIONAL***
5 ***PROVISIONS***

6 ***SEC. 901. TECHNICAL CORRECTIONS.***

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

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

12 (2) in paragraph (2), by striking “section
13 2074(1)(C)” and inserting “section 3102(1)(C)”.

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

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

20 (d) Section 505F(d) of the Federal Food, Drug, and
21 Cosmetic Act (21 U.S.C. 355g(d)) is amended by striking
22 “2” and inserting “3”.

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

1 (1) *section 3051(a) of such Act is amended by*
 2 *striking “by inserting after section 515B” and insert-*
 3 *ing “by inserting after section 515A”; and*

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

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

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

17 **SEC. 902. REAUTHORIZATION OF THE CRITICAL PATH PUB-**
 18 **LIC-PRIVATE PARTNERSHIPS.**

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

Union Calendar No. 138

115TH CONGRESS
1ST Session

H. R. 2430

[Report No. 115-201]

A BILL

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.

JULY 11, 2017

Reported with an amendment, committed to the Committee of the Whole House on the State of the Union, and ordered to be printed