

Calendar No. 76

115TH CONGRESS
1ST SESSION

S. 934

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 SENATE OF THE UNITED STATES

APRIL 25, 2017

Mr. ALEXANDER (for himself and Mrs. MURRAY) introduced the following bill; which was read twice and referred to the Committee on Health, Education, Labor, and Pensions

MAY 11, 2017

Reported by Mr. ALEXANDER, with an amendment

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

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,*

1 **SECTION 1. SHORT TITLE.**

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

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

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

Sec. 1. Short title.

Sec. 2. Table of contents.

TITLE I—FEES RELATING TO DRUGS

Sec. 101. Short title; finding.

Sec. 102. Authority to assess and use drug fees.

Sec. 103. Reauthorization; reporting requirements.

Sec. 104. Sunset dates.

Sec. 105. Effective date.

Sec. 106. Savings clause.

TITLE H—FEES RELATING TO DEVICES

Sec. 201. Short title; findings.

Sec. 202. Definitions.

Sec. 203. Authority to assess and use device fees.

Sec. 204. Reauthorization; reporting requirements.

Sec. 205. Conformity assessment pilot program.

Sec. 206. Reauthorization of review.

Sec. 207. Electronic format for submissions.

Sec. 208. Savings clause.

Sec. 209. Effective date.

Sec. 210. Sunset clause.

TITLE III—FEES RELATING TO GENERIC DRUGS

Sec. 301. Short title; finding.

Sec. 302. Definitions.

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

Sec. 304. Reauthorization; reporting requirements.

Sec. 305. Sunset dates.

Sec. 306. Effective date.

Sec. 307. Savings clause.

**TITLE IV—FEES RELATING TO BIOSIMILAR BIOLOGICAL
PRODUCTS**

Sec. 401. Short title; finding.

Sec. 402. Definitions.

Sec. 403. Authority to assess and use biosimilar fees.

Sec. 404. Reauthorization; reporting requirements.

Sec. 405. Sunset dates.

Sec. 406. Effective date.

Sec. 407. Savings clause.

TITLE V—REAUTHORIZATION OF OTHER PROGRAMS

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

Sec. 502. Reauthorization of pediatric humanitarian device exceptions.

Sec. 503. Reauthorization of the critical path public-private partnerships.

Sec. 504. Reauthorization of pediatric device consortia.

Sec. 505. Reauthorization of orphan grants program.

TITLE I—FEES RELATING TO DRUGS

SEC. 101. SHORT TITLE; FINDING.

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

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

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

(a) **TYPES OF FEES.**—

1 ~~(1) IN GENERAL.—~~Section 736(a) of the Fed-
 2 eral Food, Drug, and Cosmetic Act (21 U.S.C.
 3 379h(a)) is amended—

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

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

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

12 ~~(D)~~ in paragraph (1)(A)—

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

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

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

1 ~~(F)~~ in paragraph ~~(1)~~~~(F)~~—

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

4 (ii) by striking the second sentence;

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

7 ~~(H)~~ by redesignating paragraph ~~(3)~~ as
8 paragraph ~~(2)~~;

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

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

1 ~~(K)~~ in subparagraph ~~(B)~~ of such para-
 2 graph ~~(2)~~—

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

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

12 ~~(L)~~ by adding at the end of such para-
 13 graph ~~(2)~~ the following:

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

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

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

4 (b) FEE REVENUE AMOUNTS.—Subsection (b) of sec-
5 tion 736 of the Federal Food, Drug, and Cosmetic Act
6 (21 U.S.C. 379h) is amended to read as follows:

7 “(b) FEE REVENUE AMOUNTS.—

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

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

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

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

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

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

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

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

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

8 “(iii) \$16,953,329 for fiscal year
 9 2020;

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

11 and

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

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

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

19 “(B) 80 percent shall be derived from pre-
 20 scription drug program fees under subsection
 21 (a)(2).

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

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

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

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

12 ~~“(c) ADJUSTMENTS; ANNUAL FEE SETTING.—~~

13 ~~“(1) INFLATION ADJUSTMENT.—~~

14 ~~“(A) IN GENERAL.—For purposes of sub-~~
15 ~~section (b)(1)(B), the dollar amount of the in-~~
16 ~~flation adjustment to the annual base revenue~~
17 ~~for each fiscal year shall be equal to the prod-~~
18 ~~uct of—~~

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

21 ~~“(ii) the inflation adjustment percent-~~
22 ~~age under subparagraph (B).~~

23 ~~“(B) INFLATION ADJUSTMENT PERCENT-~~
24 ~~AGE.—The inflation adjustment percentage~~

under this subparagraph for a fiscal year is equal to the sum of—

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

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

1 section 735(6)) for the first 3 years of the
2 preceding 4 fiscal years.

3 ~~“(2) CAPACITY PLANNING ADJUSTMENT.—~~

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

13 ~~“(B) INTERIM METHODOLOGY.—~~

14 ~~“(i) IN GENERAL.—~~Until the capacity
15 planning methodology described in sub-
16 paragraph (C) is effective, the adjustment
17 under this paragraph for a fiscal year shall
18 be based on the product of—

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

22 ~~“(H) the adjustment percentage~~
23 under clause (ii).

24 ~~“(ii) ADJUSTMENT PERCENTAGE.—~~

25 The adjustment percentage under this

1 clause for a fiscal year is the weighted
 2 change in the 3-year average ending in the
 3 most recent year for which data are avail-
 4 able, over the 3-year average ending in the
 5 previous year, for—

6 “(I) the total number of human
 7 drug applications, efficacy supple-
 8 ments, and manufacturing supple-
 9 ments submitted to the Secretary;

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

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

21 “(C) CAPACITY PLANNING METHOD-
 22 OLOGY.—

23 “(i) DEVELOPMENT, EVALUATION
 24 AND REPORT.—The Secretary shall obtain,
 25 through a contract with an independent ac-

counting or consulting firm; a report evaluating options and recommendations for a new methodology to accurately assess changes in the resource and capacity needs of the process for the review of human drug applications. The capacity planning methodological options and recommendations presented in such report shall utilize and be informed by personnel time reporting data as an input. The report shall be published for public comment no later than the end of fiscal year 2020.

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

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

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

“(III) be effective beginning with the first fiscal year for which fees are

1 set after such capacity planning meth-
2 odology is established.

3 “(D) LIMITATION.—Under no cir-
4 cumstances shall an adjustment under this
5 paragraph result in fee revenue for a fiscal year
6 that is less than the sum of the amounts under
7 subsections (b)(1)(A) (the annual base revenue
8 for the fiscal year) and (b)(1)(B) (the dollar
9 amount of the inflation adjustment for the fis-
10 cal year).

11 “(E) PUBLICATION IN FEDERAL REG-
12 ISTER.—The Secretary shall publish in the Fed-
13 eral Register notice under paragraph (5) the fee
14 revenue and fees resulting from the adjustment
15 and the methodologies under this paragraph.

16 “(3) OPERATING RESERVE ADJUSTMENT.—

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

1 “(B) DECREASE.—If the Secretary has
 2 carryover balances for such process in excess of
 3 14 weeks of such operating reserves, the Sec-
 4 retary shall decrease such fee revenue and fees
 5 to provide for not more than 14 weeks of such
 6 operating reserves.

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

15 “(4) ADDITIONAL DIRECT COST ADJUST-
 16 MENT.—

17 “(A) IN GENERAL.—The Secretary shall,
 18 in addition to adjustments under paragraphs
 19 (1), (2), and (3), further increase the fee rev-
 20 enue and fees—

21 “(i) for fiscal year 2018, by
 22 \$8,730,000; and

23 “(ii) for fiscal year 2019 and subse-
 24 quent fiscal years, by the amount deter-
 25 mined under subparagraph (B).

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

3 “(i) \$8,730,000, multiplied by

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

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

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

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

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

1 (d) FEE WAIVER OR REDUCTION.—Section 726(d) of
 2 the Federal Food, Drug, and Cosmetic Act (21 U.S.C.
 3 379h(d)) is amended—

4 (1) in paragraph (1)—

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

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

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

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

12 (3) by redesignating paragraph (4) as para-
 13 graph (3); and

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

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

18 (B) in subparagraph (B)—

19 (i) by striking clause (ii);

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

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

1 (e) EFFECT OF FAILURE TO PAY FEES.—Section
 2 736(e) of the Federal Food, Drug, and Cosmetic Act (21
 3 U.S.C. 379h(e)) is amended by striking “all fees” and in-
 4 serting “all such fees”.

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

10 (g) CREDITING AND AVAILABILITY OF FEES.—Sec-
 11 tion 736(g) of the Federal Food, Drug, and Cosmetic Act
 12 (21 U.S.C. 379h(g)) is amended—

13 (1) in paragraph (3)—

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

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

18 (2) by striking paragraph (4).

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

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

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

4 (1) in subsection (a)(1)—

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

7 (B) in subparagraph (A), by striking “Pre-
8 scription Drug User Fee Amendments of 2012”
9 and inserting “Prescription Drug User Fee
10 Amendments of 2017”;

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

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

15 **SEC. 104. SUNSET DATES.**

16 (a) **AUTHORIZATION.**—Sections 735 and 736 of the
17 Federal Food, Drug, and Cosmetic Act (21 U.S.C. 379g;
18 379h) shall cease to be effective October 1, 2022.

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

22 (c) **PREVIOUS SUNSET PROVISION.**—Effective Octo-
23 ber 1, 2017, subsections (a) and (b) of section 105 of the
24 Food and Drug Administration Safety and Innovation Act
25 (Public Law 112-144) are repealed.

1 **SEC. 105. EFFECTIVE DATE.**

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

9 **SEC. 106. SAVINGS CLAUSE.**

10 Notwithstanding the amendments made by this title,
 11 part 2 of subchapter C of chapter VII of the Federal Food,
 12 Drug, and Cosmetic Act, as in effect on the day before
 13 the date of the enactment of this title, shall continue to
 14 be in effect with respect to human drug applications and
 15 supplements (as defined in such part as of such day) that
 16 on or after October 1, 2012, but before October 1, 2017,
 17 were accepted by the Food and Drug Administration for
 18 filing with respect to assessing and collecting any fee re-
 19 quired by such part for a fiscal year prior to fiscal year
 20 2018.

21 **TITLE II—FEES RELATING TO**
 22 **DEVICES**

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

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

1 (b) FINDINGS.—The Congress finds that the fees au-
 2 thorized under the amendments made by this title will be
 3 dedicated toward expediting the process for the review of
 4 device applications and for assuring the safety and effec-
 5 tiveness of devices, as set forth in the goals identified for
 6 purposes of part 3 of subchapter C of chapter VII of the
 7 Federal Food, Drug, and Cosmetic Act in the letters from
 8 the Secretary of Health and Human Services to the Chair-
 9 man of the Committee on Health, Education, Labor, and
 10 Pensions of the Senate and the Chairman of the Com-
 11 mittee on Energy and Commerce of the House of Rep-
 12 resentatives, as set forth in the Congressional Record.

13 **SEC. 202. DEFINITIONS.**

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

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

18 (2) by inserting after paragraph (7) the fol-
 19 lowing new paragraph:

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

23 (3) in subparagraph (D) of paragraph (10) (as
 24 redesignated by paragraph (1)), by striking “and

1 submissions” and inserting “submissions, and de
2 novo classification requests”; and

3 (4) in paragraph (11) (as redesignated by para-
4 graph (1)), by striking “2011” and inserting
5 “2016”.

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

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

10 (1) in paragraph (1), by striking “fiscal year
11 2013” and inserting “fiscal year 2018”; and

12 (2) in paragraph (2)—

13 (A) in subparagraph (A)—

14 (i) in the matter preceding clause (i),
15 by striking “October 1, 2012” and insert-
16 ing “October 1, 2017”;

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

19 (iii) by adding at the end the fol-
20 lowing new clause:

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

24 (B) in subparagraph (B)(v)(I), by striking
25 “or premarket notification submission” and in-

1 serting “premarket notification submission, or
2 de novo classification request”.

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

6 “(b) FEE AMOUNTS.—

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

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

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

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

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

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

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

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

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

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

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

6 (2) in paragraph (2)—

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

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

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

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

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

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

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

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

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

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

(3) in paragraph (3)—

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

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

(d) SMALL BUSINESSES; FEE WAIVER AND FEE REDUCTION REGARDING PREMARKET APPROVAL FEES.—

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

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

7 (2) in paragraph (2)(C)—

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

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

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

17 (f) ~~FEE WAIVER OR REDUCTION.~~—

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

21 (2) ~~CONFORMING CHANGES.~~—

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

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

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

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

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

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

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

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

(h) CONDITIONS.—Subsection (g)(1)(A), as redesignated, of section 738 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 379j) is amended by striking “\$280,587,000” and inserting “\$220,825,000”.

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

5 (1) in paragraph (3)—

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

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

11 (2) by striking paragraph (4).

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

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

16 (1) in paragraph (1)—

17 (A) in subparagraph (A)—

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

8 “(3) IMPLEMENTATION AND REPORTING.—

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

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

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

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

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

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

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

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

15 “(B) the Secretary—

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

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

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

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

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

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

10 (1) in subsection (a)(3)—

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

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

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

19 (B) by striking subparagraph (B) and in-
 20 serting the following:

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

23 “(i) issue draft guidance on the fac-
 24 tors the Secretary will use in determining
 25 whether a class I or class II device type, or

1 subset of such device types, is eligible for
2 review by an accredited person, includ-
3 ing—

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

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

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

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

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

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

7 (2) in subsection (b)—

8 (A) in paragraph (2)—

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

10 (ii) by redesignating subparagraph
 11 (E) as subparagraph (D); and

12 (B) in paragraph (3)—

13 (i) by redesignating subparagraph (E)
 14 as subparagraph (F);

15 (ii) in subparagraph (F) (as so redes-
 16 ignated), by striking “The operations of”
 17 and all that follows through “it will—”
 18 and inserting “Such person shall agree, at
 19 a minimum, to include in its request for
 20 accreditation a commitment to, at the time
 21 of accreditation, and at any time it is per-
 22 forming any review pursuant to this sec-
 23 tion—”; and

24 (iii) by inserting after subparagraph
 25 (D) the following new subparagraph:

1 “(E) The operations of such person shall
 2 be in accordance with generally accepted profes-
 3 sional and ethical business practices.”; and
 4 (3) in subsection (c), by striking “2017” and
 5 inserting “2022”.

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

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

10 “(3) PRESUBMISSIONS AND SUBMISSIONS SOLE-
 11 LY IN ELECTRONIC FORMAT.—

12 “(A) IN GENERAL.—Beginning on October
 13 1, 2021 (or such later date as may be specified
 14 by the Secretary under subparagraph (B)),
 15 presubmissions and submissions for devices de-
 16 scribed in paragraph (1) (and any appeals of
 17 action taken by the Secretary with respect to
 18 such presubmissions or submissions) shall be
 19 submitted solely in such electronic format as
 20 specified by the Secretary in guidance issued
 21 under subparagraph (C).

22 “(B) EXTENSION.—The Secretary may, if
 23 the Secretary determines an extension of the
 24 date specified in subparagraph (A) is necessary
 25 for the development and adoption of the elec-

1 tronic format referred to in such paragraph, ex-
 2 tend such date until such later date as the Sec-
 3 retary may specify, but in no event later than
 4 April 1, 2023.

5 “(C) GUIDANCE.—The Secretary shall, not
 6 later than January 1, 2021, or such later date
 7 as may be specified by the Secretary under sub-
 8 paragraph (B), issue guidance providing for—

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

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

15 “(iii) set forth criteria for waivers of
 16 and exemptions from the requirements of
 17 this subsection.”.

18 **SEC. 208. SAVINGS CLAUSE.**

19 Notwithstanding the amendments made by this title,
 20 part 3 of subchapter C of chapter VII of the Federal Food,
 21 Drug, and Cosmetic Act (21 U.S.C. 379i et seq.), as in
 22 effect on the day before the date of the enactment of this
 23 title, shall continue to be in effect with respect to the sub-
 24 missions listed in section 738(a)(2)(A) of such Act (as de-
 25 fined in such part as of such day) that on or after October

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

5 **SEC. 209. EFFECTIVE DATE.**

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

14 **SEC. 210. SUNSET CLAUSE.**

15 (a) **AUTHORIZATION.**—Sections ~~737 and 738 of the~~
 16 ~~Federal Food, Drug, and Cosmetic Act (21 U.S.C. 739i;~~
 17 ~~739j) shall cease to be effective October 1, 2022.~~

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

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

23 (1) **IN GENERAL.**—Effective ~~October 1, 2017,~~
 24 ~~section 207(a) of the Medical Device User Fee~~

1 Amendments of 2012 (Public Law 112–144) is re-
 2 pealed.

3 ~~(2) CONFORMING AMENDMENT.—~~The Food and
 4 Drug Administration Safety and Innovation Act
 5 (Public Law 112–144) is amended in the table of
 6 contents in section 2 by striking the item relating to
 7 section 207.

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

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

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

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

1 **SEC. 302. DEFINITIONS.**

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

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

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

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

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

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

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

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

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

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

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

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

13 (3) in paragraph (2)—

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

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

22 (B) in subparagraph (E)—

23 (i) in clause (i)—

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

1 “(I) the date”;

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

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

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

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

13 (4) in paragraph (3)—

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

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

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

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

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

6 (D) in subparagraph (D)—

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

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

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

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

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

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

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

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

21 (5) in paragraph (4)—

22 (A) in subparagraph (A)—

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

23 (1) in paragraph (1)—

24 (A) in subparagraph (A)—

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

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

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

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

10 (B) in subparagraph (B)—

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

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

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

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

21 (2) in paragraph (2)—

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

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

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

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

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

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

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

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

25 (D) in subparagraph (D)—

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

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

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

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

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

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

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

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

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

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

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

4 (1) in paragraph (1)—

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

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

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

13 (2) in paragraph (2)—

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

16 (B) by striking “2018” and inserting
 17 “2023”.

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

21 (1) in subsection (e)(2), by striking “Such fees
 22 may only be used in fiscal year 2018.”; and

23 (2) in subsection (d)—

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

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

8 (B) by redesignating paragraph (3) as
 9 paragraph (2); and

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

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

17 (1) by striking paragraph (1);

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

13 (1) in paragraph (2)—

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

16 (B) in subparagraph (D)—

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

19 (ii) by striking “(after fiscal year
20 2013)”; and

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

23 (2) in paragraph (3), by striking “fiscal years
24 2013 through 2017” and inserting “fiscal years
25 2018 through 2022”.

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

6 “(o) INFORMATION ON ABBREVIATED NEW DRUG
 7 APPLICATIONS OWNED BY APPLICANTS AND THEIR AF-
 8 FILIATES.—

9 “(1) IN GENERAL.—By April 1 of each year,
 10 each person that owns an abbreviated new drug ap-
 11 plication, or any affiliate of such person, shall sub-
 12 mit to the Secretary a list of—

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

15 “(B) if any affiliate of such person also
 16 owns an abbreviated new drug application, all
 17 approved abbreviated new drug applications
 18 owned by any such affiliate.

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

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

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

25 (1) in subsection (a)—

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

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

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

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

10 **SEC. 305. SUNSET DATES.**

11 (a) **AUTHORIZATION.**—Sections 744A and 744B of
12 the Federal Food, Drug, and Cosmetic Act (21 U.S.C.
13 379j–41; 379j–42) shall cease to be effective October 1,
14 2022.

15 (b) **REPORTING REQUIREMENTS.**—Section 744C of
16 the Federal Food, Drug, and Cosmetic Act (21 U.S.C.
17 379j–43) shall cease to be effective January 31, 2023.

18 (c) **PREVIOUS SUNSET PROVISION.**—Effective Octo-
19 ber 1, 2017, subsections (a) and (b) of section 304 of the
20 Food and Drug Administration Safety and Innovation Act
21 (Public Law 112–144) are repealed.

22 **SEC. 306. EFFECTIVE DATE.**

23 The amendments made by this title shall take effect
24 on October 1, 2017, or the date of the enactment of this
25 Act, whichever is later, except that fees under part 7 of

1 subchapter C of chapter VII of the Federal Food, Drug,
 2 and Cosmetic Act shall be assessed for all abbreviated new
 3 drug applications received on or after October 1, 2017,
 4 regardless of the date of the enactment of this Act.

5 **SEC. 307. SAVINGS CLAUSE.**

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

20 **TITLE IV—FEES RELATING TO**
 21 **BIOSIMILAR BIOLOGICAL**
 22 **PRODUCTS**

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

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

1 (b) **FINDING.**—The Congress finds that the fees au-
 2 thorized by the amendments made in this title will be dedi-
 3 cated to expediting the process for the review of biosimilar
 4 biological product applications, including postmarket safe-
 5 ty activities, as set forth in the goals identified for pur-
 6 poses of part 8 of subchapter C of chapter VII of the Fed-
 7 eral Food, Drug, and Cosmetic Act, in the letters from
 8 the Secretary of Health and Human Services to the Chair-
 9 man of the Committee on Health, Education, Labor, and
 10 Pensions of the Senate and the Chairman of the Com-
 11 mittee on Energy and Commerce of the House of Rep-
 12 resentatives, as set forth in the Congressional Record.

13 **SEC. 402. DEFINITIONS.**

14 (a) **ADJUSTMENT FACTOR.**—Section 744G(1) of the
 15 Federal Food, Drug, and Cosmetic Act (21 U.S.C. 379j–
 16 51(1)) is amended to read as follows:

17 “(1) The term ‘adjustment factor’ applicable to
 18 a fiscal year is the Consumer Price Index for all
 19 urban consumers (all items; United States city aver-
 20 age) for October of the preceding fiscal year divided
 21 by such Index for October 2011.”.

22 (b) **BIOSIMILAR BIOLOGICAL PRODUCT.**—Section
 23 744G(3) of the Federal Food, Drug, and Cosmetic Act
 24 (21 U.S.C. 379j–51(3)) is amended by striking “means

1 a product” and inserting “means a specific strength of
2 a biological product in final dosage form”.

3 **SEC. 403. AUTHORITY TO ASSESS AND USE BIOSIMILAR**
4 **FEES.**

5 (a) TYPES OF FEES.—Section 744H(a) of the Fed-
6 eral Food, Drug, and Cosmetic Act (21 U.S.C. 379j-
7 52(a)) is amended—

8 (1) in the matter preceding paragraph (1), by
9 striking “fiscal year 2013” and inserting “fiscal year
10 2018”;

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

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

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

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

24 (6) in paragraph (1)(B)(iii), by striking “an-
25 nual biosimilar development program fee” and in-

1 serting “annual biosimilar biological product devel-
2 opment fee”;

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

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

19 (8) in paragraph (1)(C), by striking “for a
20 product effective October 1 of a fiscal year by,” and
21 inserting “for a product, effective October 1 of a fis-
22 cal year, by,”;

23 (9) in paragraph (1)(D)—

24 (A) in clause (i) in the matter preceding
25 subclause (I), by inserting “, if the person seeks

1 to resume participation in such program,” be-
 2 fore “pay a fee”;

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

6 (C) in clause (i)(II), by inserting after
 7 “discontinued)” the following: “by such per-
 8 son”;

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

11 (11) in the heading of subparagraph (F) of
 12 paragraph (1), by striking “BIOSIMILAR DEVELOP-
 13 MENT PROGRAM FEES” and inserting “BIOSIMILAR
 14 BIOLOGICAL PRODUCT DEVELOPMENT FEES”;

15 (12) in paragraph (1)(F)—

16 (A) in the heading of subparagraph (F), by
 17 striking “BIOSIMILAR DEVELOPMENT PRO-
 18 GRAM” before “FEES”; and

19 (B) by amending clause (i) to read as fol-
 20 lows:

21 “(i) REFUNDS.—Except as provided
 22 in subparagraph (B)(iv), the Secretary
 23 shall not refund any initial or annual bio-
 24 similar biological product development fee
 25 paid under subparagraph (A) or (B), or

1 any reactivation fee paid under subpara-
2 graph (D).”;

3 ~~(13) in paragraph (2)—~~

4 ~~(A) in the heading of paragraph (2), by~~
5 ~~striking “AND SUPPLEMENT”;~~

6 ~~(B) by amending subparagraphs (A) and~~
7 ~~(B) to read as follows:~~

8 ~~“(A) IN GENERAL.—Each person that sub-~~
9 ~~mits, on or after October 1, 2017, a biosimilar~~
10 ~~biological product application shall be subject to~~
11 ~~the following fees:~~

12 ~~“(i) A fee established under sub-~~
13 ~~section (c)(5) for a biosimilar biological~~
14 ~~product application for which clinical data~~
15 ~~(other than comparative bioavailability~~
16 ~~studies) with respect to safety or effective-~~
17 ~~ness are required for approval.~~

18 ~~“(ii) A fee established under sub-~~
19 ~~section (c)(5) for a biosimilar biological~~
20 ~~product application for which clinical data~~
21 ~~(other than comparative bioavailability~~
22 ~~studies) with respect to safety or effective-~~
23 ~~ness are not required for approval. Such~~
24 ~~fee shall be equal to half of the amount of~~
25 ~~the fee described in clause (i).~~

1 “(B) RULE OF APPLICABILITY; TREAT-
2 MENT OF CERTAIN PREVIOUSLY PAID FEES.—

3 Any person who pays a fee under subparagraph
4 (A), (B), or (D) of paragraph (1) for a product
5 before October 1, 2017, but submits a bio-
6 similar biological product application for that
7 product after such date, shall—

8 “(i) be subject to any biosimilar bio-
9 logical product application fees that may
10 be assessed at the time when such bio-
11 similar biological product application is
12 submitted; and

13 “(ii) be entitled to no reduction of
14 such application fees based on the amount
15 of fees paid for that product before Octo-
16 ber 1, 2017, under such subparagraph (A),
17 (B), or (D).”;

18 (C) in the heading of subparagraph (D);
19 by striking “OR SUPPLEMENT”; and

20 (D) in subparagraphs (C) through (F)—

21 (i) by striking “or supplement” each
22 place it appears; and

23 (ii) in subparagraph (D), by striking
24 “or a supplement”; and

1 (14) by amending paragraph (3) to read as fol-
2 lows:

3 ~~“(3) BIOSIMILAR BIOLOGICAL PRODUCT PRO-~~
4 GRAM FEE.—

5 ~~“(A) IN GENERAL.—Each person who is~~
6 named as the applicant in a biosimilar biologi-
7 cal product application shall pay the annual bio-
8 similar biological product program fee estab-
9 lished for a fiscal year under subsection (c)(5)
10 for each biosimilar biological product that—

11 ~~“(i) is identified in such a biosimilar~~
12 biological product application approved as
13 of October 1 of such fiscal year; and

14 ~~“(ii) as of October 1 of such fiscal~~
15 year; does not appear on a list; developed
16 and maintained by the Secretary; of dis-
17 continued biosimilar biological products.

18 ~~“(B) DUE DATE.—The biosimilar biologi-~~
19 cal product program fee for a fiscal year shall
20 be due on the later of—

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

23 ~~“(ii) the first business day after the~~
24 enactment of an appropriations Act pro-

1 viding for the collection and obligation of
2 fees for such year under this section.

3 ~~“(C) ONE FEE PER PRODUCT PER YEAR.—~~

4 The biosimilar biological product program fee
5 shall be paid only once for each product for
6 each fiscal year.

7 ~~“(D) LIMITATION.—A person who is~~
8 named as the applicant in a biosimilar biologi-
9 cal product application shall not be assessed
10 more than 5 biosimilar biological product pro-
11 gram fees for a fiscal year for biosimilar bi-
12 ological products identified in such biosimilar bi-
13 ological product application.”.

14 ~~(b) FEE REVENUE AMOUNTS.—Subsection (b) of sec-~~
15 tion 744H of the Federal Food, Drug, and Cosmetic Act
16 ~~(21 U.S.C. 379j-52) is amended to read as follows:~~

17 ~~“(b) FEE REVENUE AMOUNTS.—~~

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

21 ~~“(A) \$45,000,000; and~~

22 ~~“(B) the dollar amount equal to the fiscal~~
23 year 2018 adjustment (as determined under
24 subsection (c)(4)).

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

6 ~~“(A) the annual base revenue for the fiscal~~
 7 year (as determined under paragraph (4));

8 ~~“(B) the dollar amount equal to the infla-~~
 9 tion adjustment for the fiscal year (as deter-
 10 mined under subsection (c)(1));

11 ~~“(C) the dollar amount equal to the capae-~~
 12 ity planning adjustment for the fiscal year (as
 13 determined under subsection (c)(2)); and

14 ~~“(D) the dollar amount equal to the oper-~~
 15 ating reserve adjustment for the fiscal year, if
 16 applicable (as determined under subsection
 17 (c)(3)).

18 ~~“(3) ALLOCATION OF REVENUE AMOUNT~~
 19 ~~AMONG FEES; LIMITATIONS ON FEE AMOUNTS.—~~

20 ~~“(A) ALLOCATION.—~~The Secretary shall
 21 determine the percentage of the total revenue
 22 amount for a fiscal year to be derived from, re-
 23 spectively—

1 “(i) initial and annual biosimilar de-
 2 velopment fees and reactivation fees under
 3 subsection (a)(1);

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

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

8 “(B) LIMITATIONS ON FEE AMOUNTS.—

9 Until the first fiscal year for which the capacity
 10 planning adjustment under subsection (c)(2) is
 11 effective, the amount of any fee under sub-
 12 section (a) for a fiscal year after fiscal year
 13 2018 shall not exceed 125 percent of the
 14 amount of such fee for fiscal year 2018.

15 “(C) BIOSIMILAR BIOLOGICAL PRODUCT
 16 DEVELOPMENT FEES.—The initial biosimilar bi-
 17 ological product development fee under sub-
 18 section (a)(1)(A) for a fiscal year shall be equal
 19 to the annual biosimilar biological product de-
 20 velopment fee under subsection (a)(1)(B) for
 21 that fiscal year.

22 “(D) REACTIVATION FEE.—The reactiva-
 23 tion fee under subsection (a)(1)(D) for a fiscal
 24 year shall be equal to twice the amount of the
 25 annual biosimilar biological product develop-

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

3 ~~“(4) ANNUAL BASE REVENUE.—For purposes~~
4 of paragraph (2), the dollar amount of the annual
5 base revenue for a fiscal year shall be the dollar
6 amount of the total revenue amount for the previous
7 fiscal year, excluding any adjustments to such rev-
8 enue amount under subsection (c)(3).”.

9 (c) ADJUSTMENTS; ANNUAL FEE SETTING.—Section
10 744H of the Federal Food, Drug, and Cosmetic Act (21
11 U.S.C. 379j–52) is amended—

12 (1) by redesignating subsections (e) through (h)
13 as subsections (d) through (i), respectively;

14 (2) in subsections (a)(2)(F) and (g), by striking
15 “subsection (e)” and inserting “subsection (d)”;

16 (3) in subsection (a)(4)(A), by striking “sub-
17 section (b)(1)(F)” and inserting “subsection (e)(5)”;
18 and

19 (4) by inserting after subsection (b) the fol-
20 lowing:

21 ~~“(c) ADJUSTMENTS; ANNUAL FEE SETTING.—~~

22 ~~“(1) INFLATION ADJUSTMENT.—~~

23 ~~“(A) IN GENERAL.—For purposes of sub-~~
24 ~~section (b)(2)(B), the dollar amount of the in-~~
25 ~~flation adjustment to the annual base revenue~~

for each fiscal year shall be equal to the product of—

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

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

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

“(i) the average annual percent change in the cost, per full-time equivalent position of the Food and Drug Administration, of all personnel compensation and benefits paid with respect to such positions for the first 3 years of the preceding 4 fiscal years; multiplied by the proportion of personnel compensation and benefits costs to total costs of the process for the review of biosimilar biological product applications (as defined in section 744G(13)) for the first 3 years of the preceding 4 fiscal years; and

“(ii) the average annual percent change that occurred in the Consumer

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

“(2) CAPACITY PLANNING ADJUSTMENT.—

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

“(B) CAPACITY PLANNING METHODOLOGY.—

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

16 “(ii) ESTABLISHMENT AND IMPLE-
 17 MENTATION.—After review of the report
 18 described in clause (i) and receipt and re-
 19 view of public comments thereon, the Sec-
 20 retary shall establish a capacity planning
 21 methodology for purposes of this para-
 22 graph, which shall—

23 “(I) incorporate such approaches
 24 and attributes as the Secretary deter-
 25 mines appropriate; and

1 “(H) be effective beginning with
 2 the first fiscal year for which fees are
 3 set after such capacity planning meth-
 4 odology is established.

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

13 “(D) PUBLICATION IN FEDERAL REG-
 14 ISTER.—The Secretary shall publish in the Fed-
 15 eral Register notice under paragraph (5) the fee
 16 revenue and fees resulting from the adjustment
 17 and the methodologies under this paragraph.

18 “(3) OPERATING RESERVE ADJUSTMENT.—

19 “(A) INTERIM APPLICATION; FEE REDUC-
 20 TION.—Until the first fiscal year for which the
 21 capacity planning adjustment under paragraph
 22 (2) is effective, the Secretary may, in addition
 23 to the adjustment under paragraph (1), reduce
 24 the fee revenue and fees under this section for
 25 a fiscal year as the Secretary determines appro-

1 appropriate for long-term financial planning pur-
2 poses.

3 “(B) ~~GENERAL APPLICATION AND METH-~~
4 ~~ODOLOGY.~~—Beginning with the first fiscal year
5 for which the capacity planning adjustment
6 under paragraph (2) is effective, the Secretary
7 may, in addition to the adjustments under
8 paragraphs (1) and (2)—

9 “(i) reduce the fee revenue and fees
10 under this section as the Secretary deter-
11 mines appropriate for long-term financial
12 planning purposes; or

13 “(ii) increase the fee revenue and fees
14 under this section if such an adjustment is
15 necessary to provide for not more than 24
16 weeks of operating reserves of carryover
17 user fees for the process for the review of
18 biosimilar biological product applications.

19 “(C) ~~FEDERAL REGISTER NOTICE.~~—If an
20 adjustment under subparagraph (A) or (B) is
21 made, the rationale for the amount of the in-
22 crease or decrease (as applicable) in fee revenue
23 and fees shall be contained in the annual Fed-
24 eral Register notice under paragraph (5) estab-

1 lishing fee revenue and fees for the fiscal year
2 involved.

3 ~~“(4) FISCAL YEAR 2018 ADJUSTMENT.—~~

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

10 ~~“(B) METHODOLOGY.—The Secretary shall~~
11 publish under paragraph (5) a description of
12 the methodology used to calculate the fiscal
13 year 2018 adjustment under this paragraph in
14 the Federal Register notice establishing fee rev-
15 enue and fees for fiscal year 2018.

16 ~~“(C) LIMITATION.—No adjustment under~~
17 this paragraph shall result in an increase in fee
18 revenue and fees under this section in excess of
19 \$9,000,000.

20 ~~“(5) ANNUAL FEE SETTING.—For fiscal year~~
21 2018 and each subsequent fiscal year, the Secretary
22 shall, not later than 60 days before the start of each
23 such fiscal year—

24 ~~“(A) establish, for the fiscal year, initial~~
25 and annual biosimilar biological product devel-

opment fees and reactivation fees under subsection (a)(1); biosimilar biological product application fees under subsection (a)(2); and biosimilar biological product program fees under subsection (a)(3), based on the revenue amounts established under subsection (b) and the adjustments provided under this subsection; and

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

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

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

(1) by striking subparagraph (B);

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

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

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

6 (f) CREDITING AND AVAILABILITY OF FEES.—Sub-
 7 section (f) of section 744H of the Federal Food, Drug,
 8 and Cosmetic Act (21 U.S.C. 379j–52), as redesignated
 9 by subsection (e)(1), is amended—

10 (1) in paragraph (2)—

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

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

20 (B) in subparagraph (D)—

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

23 (ii) by striking “(after fiscal year
 24 2013)”; and

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

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

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

6 (1) in subsection (a)—

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

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

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

14 ~~(3) by striking subsection (d);~~

15 ~~(4) by redesignating subsection (e) as sub-~~
 16 ~~section (d); and~~

17 ~~(5) in subsection (d), as so redesignated, by~~
 18 ~~striking “2017” each place it appears and inserting~~
 19 ~~“2022”.~~

20 **SEC. 405. SUNSET DATES.**

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

1 (b) ~~REPORTING REQUIREMENTS.—Section 744I of~~
 2 the Federal Food, Drug, and Cosmetic Act, as amended
 3 by section 404 of this Act, shall cease to be effective Janu-
 4 ary 31, 2023.

5 (c) ~~PREVIOUS SUNSET PROVISION.—~~

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

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

15 **SEC. 406. EFFECTIVE DATE.**

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

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

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

13 **TITLE V—REAUTHORIZATION OF**
 14 **OTHER PROGRAMS**

15 **SEC. 501. REAUTHORIZATION OF PROVISION RELATING TO**
 16 **EXCLUSIVITY OF CERTAIN DRUGS CON-**
 17 **TAINING SINGLE ENANTIOMERS.**

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

21 **SEC. 502. REAUTHORIZATION OF PEDIATRIC HUMANI-**
 22 **TARIAN DEVICE EXCEPTIONS.**

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

1 **SEC. 503. REAUTHORIZATION OF THE CRITICAL PATH PUB-**
 2 **LIC-PRIVATE PARTNERSHIPS.**

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

7 **SEC. 504. REAUTHORIZATION OF PEDIATRIC DEVICE CON-**
 8 **SORTIA.**

9 Section 305(e) of Pediatric Medical Device Safety
 10 and Improvement Act of 2007 (Public Law 110-85; 42
 11 U.S.C. 282 note) is amended by striking “2013 through
 12 2017” and inserting “2018 through 2022”.

13 **SEC. 505. REAUTHORIZATION OF ORPHAN GRANTS PRO-**
 14 **GRAM.**

15 Section 5(e) of the Orphan Drug Act (21 U.S.C.
 16 360ee(e)) is amended by striking “2013 through 2017”
 17 and inserting “2018 through 2022”.

18 **SECTION 1. SHORT TITLE.**

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

21 **SEC. 2. TABLE OF CONTENTS.**

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

Sec. 1. Short title.

Sec. 2. Table of contents.

TITLE I—FEES RELATING TO DRUGS

Sec. 101. Short title; finding.

Sec. 102. Authority to assess and use drug fees.

Sec. 103. Reauthorization; reporting requirements.

- Sec. 104. Sunset dates.*
- Sec. 105. Effective date.*
- Sec. 106. Savings clause.*

TITLE II—FEES RELATING TO DEVICES

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

TITLE III—FEES RELATING TO GENERIC DRUGS

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

TITLE IV—FEES RELATING TO BIOSIMILAR BIOLOGICAL PRODUCTS

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

TITLE V—PEDIATRIC DRUGS AND DEVICES

- Sec. 501. Pediatric devices.*
- Sec. 502. Pediatric drug development.*
- Sec. 503. Guidance on molecular targets in pediatric oncology.*
- Sec. 504. Best pharmaceuticals for children.*

TITLE VI—REAUTHORIZATIONS AND IMPROVEMENTS RELATED TO DRUGS

- Sec. 601. Reauthorization of provision relating to exclusivity of certain drugs containing single enantiomers.*
- Sec. 602. Reauthorization of the critical path public-private partnerships.*
- Sec. 603. Reauthorization of orphan grants program.*
- Sec. 604. Guidance regarding bioequivalence.*
- Sec. 605. Patient experience data.*
- Sec. 606. Communications plans.*
- Sec. 607. Protecting and strengthening the drug supply chain.*
- Sec. 608. Technical corrections.*

TITLE VII—DEVICE INSPECTION AND REGULATORY IMPROVEMENTS

- Sec. 701. Risk-based inspections for devices.*
Sec. 702. Improvements to inspections process.
Sec. 703. Reauthorization of inspection program.
Sec. 704. Certificates to foreign governments for devices.
Sec. 705. Facilitating international harmonization.
Sec. 706. Notification of guidance related to lab-developed tests.
Sec. 707. Diagnostic imaging devices intended for use with contrast agents.
Sec. 708. Diagnostic clarity.
Sec. 709. Appropriate classification of device accessories.
Sec. 710. Device pilot projects.
Sec. 711. Regulation of over-the-counter hearing aids.

TITLE VIII—ADDITIONAL PROVISIONS

- Sec. 801. GAO report.*
Sec. 802. Streamlining and improving consistency in performance reporting.
Sec. 803. Analysis of use of funds.
Sec. 804. Information on technology contracting.
Sec. 805. Facilities management.
Sec. 806. Expanded access.
Sec. 807. Technical corrections.

TITLE IX—GENERIC DRUG ACCESS

Subtitle A—Removing Regulatory Barriers to Competition

- Sec. 901. Improving access to generic drugs.*
Sec. 902. Reporting on pending generic drug applications, priority review applications, and inspections.

Subtitle B—Incentivizing Competition

- Sec. 911. Expediting generic competition.*
Sec. 912. List of generic drugs with limited competition.
Sec. 913. Suitability petitions.
Sec. 914. Inspections.

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*

1 *process for the review of human drug applications, includ-*
 2 *ing postmarket drug safety activities, as set forth in the*
 3 *goals identified for purposes of part 2 of subchapter C of*
 4 *chapter VII of the Federal Food, Drug, and Cosmetic Act,*
 5 *in the letters from the Secretary of Health and Human*
 6 *Services to the Chairman of the Committee on Health, Edu-*
 7 *cation, Labor, and Pensions of the Senate and the Chair-*
 8 *man of the Committee on Energy and Commerce of the*
 9 *House of Representatives, as set forth in the Congressional*
 10 *Record.*

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

12 (a) *TYPES OF FEES.—*

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

16 (A) *in the matter preceding paragraph (1),*
 17 *by striking “fiscal year 2013” and inserting “fis-*
 18 *cal year 2018”;*

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

21 (C) *in paragraph (1), by striking “or a*
 22 *supplement” and “or supplement” each place ei-*
 23 *ther appears;*

24 (D) *in paragraph (1)(A)—*

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

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

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

14 (F) in paragraph (1)(F)—

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

17 (ii) by striking the second sentence;

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

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

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

1 *(J) in subparagraph (A) of such paragraph*
 2 *(2), by amending the first sentence to read as fol-*
 3 *lows: “Except as provided in subparagraphs (B)*
 4 *and (C), each person who is named as the appli-*
 5 *cant in a human drug application, and who,*
 6 *after September 1, 1992, had pending before the*
 7 *Secretary a human drug application or supple-*
 8 *ment, shall pay the annual prescription drug*
 9 *program fee established for a fiscal year under*
 10 *subsection (c)(5) for each prescription drug prod-*
 11 *uct that is identified in such a human drug ap-*
 12 *plication approved as of October 1 of such fiscal*
 13 *year.”;*

14 *(K) in subparagraph (B) of such paragraph*
 15 *(2)—*

16 *(i) in the heading of subparagraph*
 17 *(B), by inserting after “EXCEPTION” the fol-*
 18 *lowing: “FOR CERTAIN PRESCRIPTION DRUG*
 19 *PRODUCTS”; and*

20 *(ii) by striking “A prescription drug*
 21 *product shall not be assessed a fee” and in-*
 22 *serting “A prescription drug program fee*
 23 *shall not be assessed for a prescription drug*
 24 *product”; and*

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

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

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

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

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

19 “(b) *FEE REVENUE AMOUNTS.*—

20 “(1) *IN GENERAL.*—For each of the fiscal years
21 2018 through 2022, fees under subsection (a) shall, ex-
22 cept as provided in subsections (c), (d), (f), and (g),
23 be established to generate a total revenue amount
24 under such subsection that is equal to the sum of—

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

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

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

9 “(D) the dollar amount equal to the oper-
10 ating reserve adjustment for the fiscal year, if
11 applicable (as determined under subsection
12 (c)(3));

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

16 “(F) additional dollar amounts for each fis-
17 cal year as follows:

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

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

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

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

22 and

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

1 “(2) *TYPES OF FEES.*—Of the total revenue
2 amount determined for a fiscal year under paragraph
3 (1)—

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

7 “(B) 80 percent shall be derived from pre-
8 scription drug program fees under subsection
9 (a)(2).

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

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

14 “(B) for fiscal years 2019 through 2022, the
15 dollar amount of the total revenue amount estab-
16 lished under paragraph (1) for the previous fis-
17 cal year, not including any adjustments made
18 under subsection (c)(3) or (c)(4).”.

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

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

24 “(1) *INFLATION ADJUSTMENT.*—

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

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

8 “(ii) the inflation adjustment percent-
 9 age under subparagraph (B).

10 “(B) *INFLATION ADJUSTMENT PERCENT-*
 11 *AGE.*—The inflation adjustment percentage
 12 under this subparagraph for a fiscal year is
 13 equal to the sum of—

14 “(i) the average annual percent change
 15 in the cost, per full-time equivalent position
 16 of the Food and Drug Administration, of all
 17 personnel compensation and benefits paid
 18 with respect to such positions for the first 3
 19 years of the preceding 4 fiscal years, multi-
 20 plied by the proportion of personnel com-
 21 pensation and benefits costs to total costs of
 22 the process for the review of human drug
 23 applications (as defined in section 735(6))
 24 for the first 3 years of the preceding 4 fiscal
 25 years; and

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

“(2) CAPACITY PLANNING ADJUSTMENT.—

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

“(B) INTERIM METHODOLOGY.—

“(i) IN GENERAL.—Until the capacity planning methodology described in subpara-

graph (C) is effective, the adjustment under this paragraph for a fiscal year shall be based on the product of—

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

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

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

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

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

“(III) the total number of formal meetings scheduled by the Secretary, and written responses issued by the

1 *Secretary in lieu of such formal meet-*
 2 *ings, as identified in section I.H of the*
 3 *letters described in section 101(b) of the*
 4 *Prescription Drug User Fee Amend-*
 5 *ments of 2017.*

6 “(C) *CAPACITY PLANNING METHODOLOGY.—*

7 *“(i) DEVELOPMENT; EVALUATION AND*
 8 *REPORT.—The Secretary shall obtain,*
 9 *through a contract with an independent ac-*
 10 *counting or consulting firm, a report evalu-*
 11 *ating options and recommendations for a*
 12 *new methodology to accurately assess*
 13 *changes in the resource and capacity needs*
 14 *of the process for the review of human drug*
 15 *applications. The capacity planning meth-*
 16 *odological options and recommendations*
 17 *presented in such report shall utilize and be*
 18 *informed by personnel time reporting data*
 19 *as an input. The report shall be published*
 20 *for public comment no later than the end of*
 21 *fiscal year 2020.*

22 *“(ii) ESTABLISHMENT AND IMPLEMEN-*
 23 *TATION.—After review of the report de-*
 24 *scribed in clause (i) and any public com-*
 25 *ments thereon, the Secretary shall establish*

1 *a capacity planning methodology for pur-*
 2 *poses of this paragraph, which shall—*

3 *“(I) replace the interim method-*
 4 *ology under subparagraph (B);*

5 *“(II) incorporate such approaches*
 6 *and attributes as the Secretary deter-*
 7 *mines appropriate; and*

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

12 *“(D) LIMITATION.—Under no circumstances*
 13 *shall an adjustment under this paragraph result*
 14 *in fee revenue for a fiscal year that is less than*
 15 *the sum of the amounts under subsections*
 16 *(b)(1)(A) (the annual base revenue for the fiscal*
 17 *year) and (b)(1)(B) (the dollar amount of the in-*
 18 *flation adjustment for the fiscal year).*

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

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

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

9 “(B) *DECREASE.*—If the Secretary has car-
 10 ryover balances for such process in excess of 14
 11 weeks of such operating reserves, the Secretary
 12 shall decrease such fee revenue and fees to pro-
 13 vide for not more than 14 weeks of such oper-
 14 ating reserves.

15 “(C) *NOTICE OF RATIONALE.*—If an adjust-
 16 ment under subparagraph (A) or (B) is made,
 17 the rationale for the amount of the increase or
 18 decrease (as applicable) in fee revenue and fees
 19 shall be contained in the annual Federal Reg-
 20 ister notice under paragraph (5) establishing fee
 21 revenue and fees for the fiscal year involved.

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

23 “(A) *IN GENERAL.*—The Secretary shall, in
 24 addition to adjustments under paragraphs (1),

1 (2), and (3), further increase the fee revenue and
2 fees—

3 “(i) for fiscal year 2018, by
4 \$8,730,000; and

5 “(ii) for fiscal year 2019 and subse-
6 quent fiscal years, by the amount deter-
7 mined under subparagraph (B).

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

10 “(i) \$8,730,000, multiplied by

11 “(ii) the Consumer Price Index for
12 urban consumers (Washington-Baltimore,
13 DC–MD–VA–WV; Not Seasonally Adjusted;
14 All Items; Annual Index) for the most re-
15 cent year of available data, divided by such
16 Index for 2016.

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

20 “(A) establish, for the next fiscal year,
21 human drug application fees and prescription
22 drug program fees under subsection (a), based on
23 the revenue amounts established under subsection
24 (b) and the adjustments provided under this sub-
25 section; and

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

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

8 (d) *FEE WAIVER OR REDUCTION*.—Section 736(d) of
9 the Federal Food, Drug, and Cosmetic Act (21 U.S.C.
10 379h(d)) is amended—

11 (1) in paragraph (1)—

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

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

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

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

19 (3) by redesignating paragraph (4) as para-
20 graph (3); and

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

22 (A) in subparagraphs (A) and (B), by strik-
23 ing “paragraph (1)(D)” and inserting “para-
24 graph (1)(C)”;

25 (B) in subparagraph (B)—

1 (i) by striking clause (ii);

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

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

7 (e) *EFFECT OF FAILURE TO PAY FEES.*—Section
8 736(e) of the Federal Food, Drug, and Cosmetic Act (21
9 U.S.C. 379h(e)) is amended by striking “all fees” and in-
10 serting “all such fees”.

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

16 (g) *CREDITING AND AVAILABILITY OF FEES.*—Section
17 736(g) of the Federal Food, Drug, and Cosmetic Act (21
18 U.S.C. 379h(g)) is amended—

19 (1) in paragraph (3)—

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

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

24 (2) by striking paragraph (4).

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

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

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

9 (1) in subsection (a)(1)—

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

12 (B) in subparagraph (A), by striking “Pre-
 13 scription Drug User Fee Amendments of 2012”
 14 and inserting “Prescription Drug User Fee
 15 Amendments of 2017”;

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

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

20 **SEC. 104. SUNSET DATES.**

21 (a) *AUTHORIZATION*.—Sections 735 and 736 of the
 22 *Federal Food, Drug, and Cosmetic Act* (21 U.S.C. 379g;
 23 379h) shall cease to be effective October 1, 2022.

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

4 (c) *PREVIOUS SUNSET PROVISION.*—Effective October
 5 1, 2017, subsections (a) and (b) of section 105 of the *Food*
 6 *and Drug Administration Safety and Innovation Act* (Pub-
 7 lic Law 112–144) are repealed.

8 **SEC. 105. EFFECTIVE DATE.**

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

16 **SEC. 106. SAVINGS CLAUSE.**

17 *Notwithstanding the amendments made by this title,*
 18 *part 2 of subchapter C of chapter VII of the Federal Food,*
 19 *Drug, and Cosmetic Act, as in effect on the day before the*
 20 *date of the enactment of this title, shall continue to be in*
 21 *effect with respect to human drug applications and supple-*
 22 *ments (as defined in such part as of such day) that on or*
 23 *after October 1, 2012, but before October 1, 2017, were ac-*
 24 *cepted by the Food and Drug Administration for filing with*

1 *respect to assessing and collecting any fee required by such*
 2 *part for a fiscal year prior to fiscal year 2018.*

3 ***TITLE II—FEES RELATING TO***
 4 ***DEVICES***

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

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

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

20 ***SEC. 202. DEFINITIONS.***

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

23 (1) *by redesignating paragraphs (8) through (13)*
 24 *as paragraphs (9) through (14), respectively;*

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

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

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

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

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

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

16 (1) in paragraph (1), by striking “fiscal year
 17 2013” and inserting “fiscal year 2018”; and

18 (2) in paragraph (2)—

19 (A) in subparagraph (A)—

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

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

1 (iii) by adding at the end the following
2 new clause:

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

6 (B) in subparagraph (B)(v)(I), by striking
7 “or premarket notification submission” and in-
8 serting “premarket notification submission, or *de*
9 *nov*o classification request”.

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

13 “(b) *FEE AMOUNTS*.—

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

20 “(2) *BASE FEE AMOUNTS SPECIFIED*.—For pur-
21 poses of paragraph (1), the base fee amounts specified
22 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>	\$294,000	\$300,000	\$310,000	\$328,000	\$329,000
<i>Establishment Registration</i>	\$4,375	\$4,548	\$4,760	\$4,975	\$4,978

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—

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

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

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

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

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

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

17 “(ii) if the Secretary determines nec-
18 essary, increase (in addition to the adjust-
19 ment under clause (i)) such base fee
20 amounts, on a uniform proportionate basis,
21 to generate the total revenue amounts under
22 subsection (b)(3), as adjusted for inflation
23 under subparagraph (A).”; and

24 (3) in paragraph (3)—

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

3 (B) by striking “further adjusted” and in-
 4 serting “increased”.

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

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

13 (2) in paragraph (2)(C)—

14 (A) by striking “supplement, or” and in-
 15 serting “supplement,”; and

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

18 (e) *SMALL BUSINESSES; FEE REDUCTION REGARDING*
 19 *PREMARKET NOTIFICATION SUBMISSIONS.*—*Section*
 20 *738(e)(2)(C) of the Federal Food, Drug, and Cosmetic Act*
 21 *(21 U.S.C. 379j(e)(2)(C)) is amended by striking “50” and*
 22 *inserting “25”.*

23 (f) *FEE WAIVER OR REDUCTION.*—

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

4 (2) *CONFORMING CHANGES*.—

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

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

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

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

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

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

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

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

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

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

11 (1) in paragraph (3)—

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

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

17 (2) by striking paragraph (4).

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

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

22 (1) in paragraph (1)—

23 (A) in subparagraph (A)—

24 (i) by striking “2013” and inserting
25 “2018”; and

1 (ii) by striking “the Medical Device
2 User Fee Amendments of 2012” and insert-
3 ing “Medical Device User Fee Amendments
4 of 2017”; and

5 (B) in subparagraph (B), by striking “the
6 Medical Device User Fee Amendments of 2012”
7 and inserting “Medical Device User Fee Amend-
8 ments of 2017”; and

9 (2) in paragraph (2), by striking “2013 through
10 2017” and inserting “2018 through 2022”.

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

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

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

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

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

22 “(d) *PILOT ACCREDITATION SCHEME FOR CON-*
23 *FORMITY ASSESSMENT*.—

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

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

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

13 “(2) SECRETARIAL REVIEW OF ACCREDITED LAB-
 14 ORATORY DETERMINATIONS.—The Secretary may—

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

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

11 “(3) IMPLEMENTATION AND REPORTING.—

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

20 “(B) PILOT PROGRAM GUIDANCE.—The Sec-
21 retary shall—

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

1 “(ii) not later than September 30,
2 2021, issue final guidance with respect to
3 the implementation of such program.

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

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

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

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

16 “(B) the Secretary—

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

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

22 “(C) except for purposes of accepting a de-
23 termination described in subparagraph (B)(ii),
24 the Secretary shall not continue to recognize the

1 *accreditation of testing laboratories accredited*
 2 *under paragraph (1)(A); and*

3 “(D) *the Secretary may take actions in ac-*
 4 *cordance with paragraph (2) with respect to the*
 5 *determinations made prior to such date and rec-*
 6 *ognition of the accreditation of testing labora-*
 7 *tories pursuant to determinations made prior to*
 8 *such date.”.*

9 **SEC. 206. REAUTHORIZATION OF REVIEW.**

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

12 *(1) in subsection (a)(3)—*

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

15 “(ii) *a device classified under section*
 16 *513(f)(2) or designated under section*
 17 *515C(d);*

18 “(iii) *a device that is intended to be*
 19 *life sustaining or life supporting, unless*
 20 *otherwise determined by the Secretary in*
 21 *accordance with subparagraph (B)(i)(II)*
 22 *and listed as eligible for review under sub-*
 23 *paragraph (B)(iii); or*

1 “(iv) a device that is of a type, or sub-
 2 set of a type, listed as not eligible for review
 3 under subparagraph (B)(iii).”;

4 (B) by striking subparagraph (B) and in-
 5 serting the following:

6 “(B) DESIGNATION FOR REVIEW.—The Sec-
 7 retary shall—

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

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

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

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

1 “(iii) beginning on the date such guid-
 2 ance is finalized, designate and post on the
 3 Internet website of the Food and Drug Ad-
 4 ministration, an updated list of class I and
 5 class II device types, or subsets of such de-
 6 vice types, and the Secretary’s determina-
 7 tion with respect to whether each such de-
 8 vice type, or subset of a device type, is eligi-
 9 ble or not eligible for review by an accred-
 10 ited person under this section based on the
 11 factors described in clause (i).”; and

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

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

19 (2) in subsection (b)—

20 (A) in paragraph (2)—

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

22 (ii) by redesignating subparagraph (E)

23 as subparagraph (D); and

24 (B) in paragraph (3)—

1 (i) by redesignating subparagraph (E)
2 as subparagraph (F);

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

12 (iii) by inserting after subparagraph
13 (D) the following new subparagraph:

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

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

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

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

23 “(3) PRESUBMISSIONS AND SUBMISSIONS SOLELY
24 IN ELECTRONIC FORMAT.—

1 “(A) *IN GENERAL.*—Beginning such date as
2 the Secretary specifies in final guidance issued
3 under subparagraph (C), presubmissions and
4 submissions for devices described in paragraph
5 (1) (and any appeals of action taken by the Sec-
6 retary with respect to such presubmissions or
7 submissions) shall be submitted solely in such
8 electronic format as specified by the Secretary in
9 such guidance.

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

13 “(i) any further standards for the sub-
14 mission by electronic format required under
15 subparagraph (A);

16 “(ii) a timetable for the establishment
17 by the Secretary of such further standards;
18 and

19 “(iii) set forth criteria for waivers of
20 and exemptions from the requirements of
21 this subsection.

22 “(C) *FINAL GUIDANCE.*—The Secretary
23 shall, not later than 1 year after the close of the
24 public comment period on the draft guidance

1 *issued under subparagraph (B), issue final guid-*
 2 *ance.”.*

3 **SEC. 208. SAVINGS CLAUSE.**

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

15 **SEC. 209. EFFECTIVE DATE.**

16 *The amendments made by this title shall take effect*
 17 *on October 1, 2017, or the date of the enactment of this*
 18 *Act, whichever is later, except that fees under part 3 of sub-*
 19 *chapter C of chapter VII of the Federal Food, Drug, and*
 20 *Cosmetic Act shall be assessed for all submissions listed in*
 21 *section 738(a)(2)(A) of such Act received on or after October*
 22 *1, 2017, regardless of the date of the enactment of this Act.*

1 **SEC. 210. SUNSET CLAUSE.**

2 (a) *AUTHORIZATION.*—Sections 737 and 738 of the
3 *Federal Food, Drug, and Cosmetic Act* (21 U.S.C. 739i;
4 739j) shall cease to be effective October 1, 2022.

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

9 (c) *PREVIOUS SUNSET PROVISION.*—

10 (1) *IN GENERAL.*—Effective October 1, 2017, sec-
11 tion 207(a) of the *Medical Device User Fee Amend-*
12 *ments of 2012* (Public Law 112–144) is repealed.

13 (2) *CONFORMING AMENDMENT.*—The *Food and*
14 *Drug Administration Safety and Innovation Act*
15 (Public Law 112–144) is amended in the table of con-
16 tents in section 2 by striking the item relating to sec-
17 tion 207.

18 **TITLE III—FEES RELATING TO**
19 **GENERIC DRUGS**

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

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

23 (b) *FINDING.*—The Congress finds that the fees author-
24 ized by the amendments made in this title will be dedicated
25 to human generic drug activities, as set forth in the goals
26 identified for purposes of part 7 of subchapter C of chapter

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

7 **SEC. 302. DEFINITIONS.**

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

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

13 *“(i) for a positron emission tomog-*
 14 *raphy drug; or*

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

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

20 *(3) by inserting after paragraph (4) the fol-*
 21 *lowing:*

22 *“(5) The term ‘contract manufacturing organiza-*
 23 *tion facility’ means a manufacturing facility of a fin-*
 24 *ished dosage form of a drug approved pursuant to an*
 25 *abbreviated new drug application, where such manu-*

1 *facturing facility is not identified in an approved ab-*
 2 *breiated new drug application held by the owner of*
 3 *such facility or an affiliate of such owner or facil-*
 4 *ity.”.*

5 **SEC. 303. AUTHORITY TO ASSESS AND USE HUMAN GE-**
 6 **NERIC DRUG FEES.**

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

10 *(1) in the matter preceding paragraph (1), by*
 11 *striking “fiscal year 2013” and inserting “fiscal year*
 12 *2018”;*

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

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

17 *(3) in paragraph (2)—*

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

20 *“(C) NOTICE.—Not later than 60 days be-*
 21 *fore the start of each of fiscal years 2018 through*
 22 *2022, the Secretary shall publish in the Federal*
 23 *Register the amount of the drug master file fee*
 24 *established by this paragraph for such fiscal*
 25 *year.”; and*

1 *(B) in subparagraph (E)—*

2 *(i) in clause (i)—*

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

6 *“(I) the date”;*

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

9 *(III) by adding at the end the fol-*
 10 *lowing:*

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

14 *(ii) in clause (ii), by striking “notice*
 15 *provided for in clause (i) or (ii) of subpara-*
 16 *graph (C), as applicable” and inserting*
 17 *“notice provided for in subparagraph (C)”;*

18 *(4) in paragraph (3)—*

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

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

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

1 “(B) *NOTICE.*—Not later than 60 days be-
 2 fore the start of each of fiscal years 2018 through
 3 2022, the Secretary shall publish in the Federal
 4 Register the amount of the fees under subpara-
 5 graph (A) for such fiscal year.

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

11 (D) in subparagraph (D)—

12 (i) in the heading, by inserting “, IS
 13 WITHDRAWN PRIOR TO BEING RECEIVED, OR
 14 IS NO LONGER RECEIVED” after “RE-
 15 CEIVED”; and

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

19 “(i) *APPLICATIONS NOT CONSIDERED*
 20 *TO HAVE BEEN RECEIVED AND APPLICA-*
 21 *TIONS WITHDRAWN PRIOR TO BEING RE-*
 22 *CEIVED.*—The Secretary shall refund 75
 23 percent of the fee paid under subparagraph
 24 (A) for any abbreviated new drug applica-
 25 tion that the Secretary considers not to have

1 *been received within the meaning of section*
 2 *505(j)(5)(A) for a cause other than failure*
 3 *to pay fees, or that has been withdrawn*
 4 *prior to being received within the meaning*
 5 *of section 505(j)(5)(A).*

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

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

20 *(F) in the matter preceding clause (i) of*
 21 *subparagraph (F)—*

22 *(i) by striking “2012” and inserting*
 23 *“2017”; and*

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

1 (5) in paragraph (4)—

2 (A) in subparagraph (A)—

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

9 (ii) in clause (i), by striking “or in-
10 tended to be identified in at least one ge-
11 neric drug submission that is pending or”
12 and inserting “in at least one generic drug
13 submission that is”;

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

23 (iv) in clause (iii), by striking “to fees
24 under both such clauses” and inserting

1 *“only to the fee attributable to the manufac-*
 2 *ture of the finished dosage forms”;* and

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

5 *“(C) NOTICE.—Within the timeframe speci-*
 6 *fied in subsection (d)(1), the Secretary shall pub-*
 7 *lish in the Federal Register the amount of the*
 8 *fees under subparagraph (A) for such fiscal*
 9 *year.”.*

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

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

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

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

22 *(7) by inserting after paragraph (4) the fol-*
 23 *lowing:*

24 *“(5) GENERIC DRUG APPLICANT PROGRAM*
 25 *FEE.—*

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

4 “(B) *AMOUNT.*—The amount of fees estab-
 5 lished under subparagraph (A) shall be estab-
 6 lished under subsection (d).

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

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

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

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

22 (b) *FEE REVENUE AMOUNTS.*—Section 744B(b) of the
 23 *Federal Food, Drug, and Cosmetic Act* (21 U.S.C. 379j–
 24 42(b)) is amended—

25 (1) in paragraph (1)—

1 (A) in subparagraph (A)—

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

4 (ii) by striking “2013” and inserting
5 “2018”;

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

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

11 (B) in subparagraph (B)—

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

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

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

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

22 (2) in paragraph (2)—

23 (A) in the matter preceding subparagraph

24 (A)—

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

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

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

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

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

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

1 *facility located in the United States and its ter-*
 2 *ritories and possessions.”;*

3 *(D) in subparagraph (D)—*

4 *(i) by striking “Fourteen percent” and*
 5 *inserting “Seven percent”;*

6 *(ii) by striking “not less than \$15,000*
 7 *and not more than \$30,000” and inserting*
 8 *“\$15,000”; and*

9 *(iii) by striking “, as determined” and*
 10 *all that follows through the period at the*
 11 *end and inserting a period; and*

12 *(E) by adding at the end the following:*

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

22 *“(I) If a person (including its affili-*
 23 *ates) owns at least one but not more than*
 24 *5 approved abbreviated new drug applica-*
 25 *tions on the due date for the fee under this*

1 subsection, the person (including its affili-
2 ates) shall be assessed a small business ge-
3 neric drug applicant program fee equal to
4 one-tenth of the large size operation generic
5 drug applicant program fee.

6 “(II) If a person (including its affili-
7 ates) owns at least 6 but not more than 19
8 approved abbreviated new drug applications
9 on the due date for the fee under this sub-
10 section, the person (including its affiliates)
11 shall be assessed a medium size operation
12 generic drug applicant program fee equal to
13 two-fifths of the large size operation generic
14 drug applicant program fee.

15 “(III) If a person (including its affili-
16 ates) owns 20 or more approved abbreviated
17 new drug applications on the due date for
18 the fee under this subsection, the person (in-
19 cluding its affiliates) shall be assessed a
20 large size operation generic drug applicant
21 program fee.

22 “(ii) For purposes of this subparagraph, an
23 abbreviated new drug application shall be
24 deemed not to be approved if the applicant has
25 submitted a written request for withdrawal of

1 *approval of such abbreviated new drug applica-*
 2 *tion by April 1 of the previous fiscal year.”.*

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

6 (1) *in paragraph (1)—*

7 (A) *by striking “2014” and inserting*
 8 *“2019”;*

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

13 (C) *by striking the flush text following sub-*
 14 *paragraph (C); and*

15 (2) *in paragraph (2)—*

16 (A) *by striking “2017” each place it ap-*
 17 *pears and inserting “2022”; and*

18 (B) *by striking “2018” and inserting*
 19 *“2023”.*

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

23 (1) *in subsection (c)(2), by striking “Such fees*
 24 *may only be used in fiscal year 2018.”; and*

25 (2) *in subsection (d)—*

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

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

10 (B) by redesignating paragraph (3) as
11 paragraph (2); and

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

16 (e) *IDENTIFICATION OF FACILITIES.*—Section 744B(f)
17 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C.
18 379j-42(f)) is amended—

19 (1) by striking paragraph (1);

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

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

23 (A) by striking “paragraph (4)” and insert-
24 ing “paragraph (3)”; and

1 (B) by striking “Such information shall”
 2 and all that follows through the end of subpara-
 3 graph (B) and inserting “Such information
 4 shall, for each fiscal year, be submitted, updated,
 5 or reconfirmed on or before June 1 of the pre-
 6 vious fiscal year.”; and

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

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

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

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

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

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

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

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

23 (f) *EFFECT OF FAILURE TO PAY FEES.*—Section
 24 744B(g) of the Federal Food, Drug, and Cosmetic Act (21
 25 U.S.C. 379–42(g)) is amended—

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

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

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

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

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

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

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

22 “(iii) All drugs marketed pursuant to
 23 any abbreviated new drug application held
 24 by such applicant or an affiliate of such ap-

1 *plicant shall be deemed misbranded under*
 2 *section 502(aa).*

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

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

13 (h) *CREDITING AND AVAILABILITY OF FEES.—Section*
 14 *744B(i) of the Federal Food, Drug, and Cosmetic Act (21*
 15 *U.S.C. 379–42(i)) is amended—*

16 (1) *in paragraph (2)—*

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

19 (B) *in subparagraph (D)—*

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

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

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

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

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

9 *“(o) INFORMATION ON ABBREVIATED NEW DRUG AP-*
 10 *PLICATIONS OWNED BY APPLICANTS AND THEIR AFFILI-*
 11 *ATES.—*

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

16 *“(A) all approved abbreviated new drug ap-*
 17 *plications owned by such person; and*

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

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

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

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

7 (1) in subsection (a)—

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

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

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

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

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

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

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

24 (c) *PREVIOUS SUNSET PROVISION.*—Effective October
 25 1, 2017, subsections (a) and (b) of section 304 of the Food

1 *and Drug Administration Safety and Innovation Act (Pub-*
2 *lic Law 112–144) are repealed.*

3 **SEC. 306. 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 7 of sub-*
7 *chapter C of chapter VII of the Federal Food, Drug, and*
8 *Cosmetic Act shall be assessed for all abbreviated new drug*
9 *applications received on or after October 1, 2017, regardless*
10 *of the date of the enactment of this Act.*

11 **SEC. 307. SAVINGS CLAUSE.**

12 *Notwithstanding the amendments made by this title,*
13 *part 7 of subchapter C of chapter VII of the Federal Food,*
14 *Drug, and Cosmetic Act, as in effect on the day before the*
15 *date of the enactment of this title, shall continue to be in*
16 *effect with respect to abbreviated new drug applications (as*
17 *defined in such part as of such day) that on or after October*
18 *1, 2012, but before October 1, 2017, were received by the*
19 *Food and Drug Administration within the meaning of*
20 *505(j)(5)(A) of such Act (21 U.S.C. 355(j)(5)(A)), prior ap-*
21 *proval supplements that were submitted, and drug master*
22 *files for Type II active pharmaceutical ingredients that*
23 *were first referenced with respect to assessing and collecting*
24 *any fee required by such part for a fiscal year prior to fiscal*
25 *year 2018.*

1 **TITLE IV—FEES RELATING TO**
 2 **BIOSIMILAR BIOLOGICAL**
 3 **PRODUCTS**

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

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

7 (b) *FINDING.*—The Congress finds that the fees author-
 8 ized by the amendments made in this title will be dedicated
 9 to expediting the process for the review of biosimilar biologi-
 10 cal product applications, including postmarket safety ac-
 11 tivities, as set forth in the goals identified for purposes of
 12 part 8 of subchapter C of chapter VII of the Federal Food,
 13 Drug, and Cosmetic Act, in the letters from the Secretary
 14 of Health and Human Services to the Chairman of the
 15 Committee on Health, Education, Labor, and Pensions of
 16 the Senate and the Chairman of the Committee on Energy
 17 and Commerce of the House of Representatives, as set forth
 18 in the Congressional Record.

19 **SEC. 402. DEFINITIONS.**

20 (a) *ADJUSTMENT FACTOR.*—Section 744G(1) of the
 21 Federal Food, Drug, and Cosmetic Act (21 U.S.C. 379j–
 22 51(1)) is amended to read as follows:

23 “(1) The term ‘adjustment factor’ applicable to a
 24 fiscal year is the Consumer Price Index for all urban
 25 consumers (all items; United States city average)

1 *(Washington-Baltimore, DC-MD, VA-WV; Not Sea-*
 2 *sonally Adjusted; All items) for October of the pre-*
 3 *ceding fiscal year divided by such Index for October*
 4 *2011 divided by such index for September 2011.”.*

5 **(b) BIOSIMILAR BIOLOGICAL PRODUCT.**—Section
 6 744G(3) of the Federal Food, Drug, and Cosmetic Act (21
 7 U.S.C. 379j–51(3)) is amended by striking “means a prod-
 8 uct” and inserting “means a specific strength of a biological
 9 product in final dosage form”.

10 **SEC. 403. AUTHORITY TO ASSESS AND USE BIOSIMILAR**
 11 **FEES.**

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

15 (1) in the matter preceding paragraph (1), by
 16 striking “fiscal year 2013” and inserting “fiscal year
 17 2018”;

18 (2) in the heading of paragraph (1), by striking
 19 “BIOSIMILAR” and inserting “BIOSIMILAR BIOLOGI-
 20 CAL PRODUCT”;

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

23 (4) in paragraph (1)(B)(i), by striking
 24 “(b)(1)(B) for biosimilar biological product develop-

1 *ment” and inserting “(c)(5) for the biosimilar biological*
2 *cal product development program”;*

3 *(5) in paragraph (1)(B)(ii), by striking “annual*
4 *biosimilar biological product development program*
5 *fee” and inserting “annual biosimilar biological prod-*
6 *uct development fee”;*

7 *(6) in paragraph (1)(B)(iii), by striking “an-*
8 *nual biosimilar development program fee” and insert-*
9 *ing “annual biosimilar biological product develop-*
10 *ment fee”;*

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

13 *“(iv) REFUND.—If a person submits a*
14 *marketing application for a biosimilar bio-*
15 *logical product before October 1 of a fiscal*
16 *year and such application is accepted for*
17 *filing on or after October 1 of such fiscal*
18 *year, the person may request a refund equal*
19 *to the annual biosimilar development fee*
20 *paid by the person for the product for such*
21 *fiscal year. To qualify for consideration for*
22 *a refund under this clause, a person shall*
23 *submit to the Secretary a written request*
24 *for such refund not later than 180 days*

1 *after the marketing application is accepted*
 2 *for filing.”;*

3 (8) *in paragraph (1)(C), by striking “for a prod-*
 4 *uct effective October 1 of a fiscal year by,” and insert-*
 5 *ing “for a product, effective October 1 of a fiscal year,*
 6 *by,”;*

7 (9) *in paragraph (1)(D)—*

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

12 (B) *in clause (i)(I), by inserting after*
 13 *“grants a request” the following: “by such per-*
 14 *son”;* *and*

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

17 (10) *in the heading of paragraph (1)(E), by*
 18 *striking “BIOSIMILAR DEVELOPMENT PROGRAM”;*

19 (11) *in the heading of subparagraph (F) of para-*
 20 *graph (1), by striking “BIOSIMILAR DEVELOPMENT*
 21 *PROGRAM FEES” and inserting “BIOSIMILAR BIOLOGI-*
 22 *CAL PRODUCT DEVELOPMENT FEES”;*

23 (12) *in paragraph (1)(F)—*

1 (A) in the heading of subparagraph (F), by
 2 striking “BIOSIMILAR DEVELOPMENT PROGRAM”
 3 before “FEES”; and

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

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

13 (13) in paragraph (2)—

14 (A) in the heading of paragraph (2), by
 15 striking “AND SUPPLEMENT”;

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

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

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

1 *with respect to safety or effectiveness are re-*
 2 *quired for approval.*

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

11 “(B) *RULE OF APPLICABILITY; TREATMENT*
 12 *OF CERTAIN PREVIOUSLY PAID FEES.—Any per-*
 13 *son who pays a fee under subparagraph (A), (B),*
 14 *or (D) of paragraph (1) for a product before Oc-*
 15 *tober 1, 2017, but submits a biosimilar biological*
 16 *product application for that product after such*
 17 *date, shall—*

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

23 “(ii) *be entitled to no reduction of such*
 24 *application fees based on the amount of fees*
 25 *paid for that product before October 1,*

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

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

5 (D) in subparagraphs (C) through (F)—

6 (i) by striking “or supplement” each
7 place it appears; and

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

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

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

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

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

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

1 *and maintained by the Secretary, of discon-*
 2 *tinued biosimilar biological products.*

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

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

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

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

16 “(D) *LIMITATION.*—*A person who is named*
 17 *as the applicant in a biosimilar biological prod-*
 18 *uct application shall not be assessed more than*
 19 *5 biosimilar biological product program fees for*
 20 *a fiscal year for biosimilar biological products*
 21 *identified in such biosimilar biological product*
 22 *application.”.*

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

1 “(b) *FEE REVENUE AMOUNTS.*—

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

5 “(A) \$45,000,000; and

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

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

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

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

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

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

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

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

7 “(i) *initial and annual biosimilar de-*
 8 *velopment fees and reactivation fees under*
 9 *subsection (a)(1);*

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

12 “(iii) *biosimilar biological product*
 13 *program fees under subsection (a)(3).*

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

21 “(C) *BIOSIMILAR BIOLOGICAL PRODUCT DE-*
 22 *VELOPMENT FEES.*—*The initial biosimilar bio-*
 23 *logical product development fee under subsection*
 24 *(a)(1)(A) for a fiscal year shall be equal to the*
 25 *annual biosimilar biological product develop-*

1 *ment fee under subsection (a)(1)(B) for that fis-*
 2 *cal year.*

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

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

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

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

19 (2) *in subsections (a)(2)(F) and (g), by striking*
 20 *“subsection (c)” and inserting “subsection (d)”;*

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

24 (4) *by inserting after subsection (b) the fol-*
 25 *lowing:*

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

2 “(1) *INFLATION ADJUSTMENT.*—

3 “(A) *IN GENERAL.*—*For purposes of sub-*
 4 *section (b)(2)(B), the dollar amount of the infla-*
 5 *tion adjustment to the annual base revenue for*
 6 *each fiscal year shall be equal to the product*
 7 *of—*

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

10 “(ii) *the inflation adjustment percent-*
 11 *age under subparagraph (B).*

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

16 “(i) *the average annual percent change*
 17 *in the cost, per full-time equivalent position*
 18 *of the Food and Drug Administration, of all*
 19 *personnel compensation and benefits paid*
 20 *with respect to such positions for the first 3*
 21 *years of the preceding 4 fiscal years, multi-*
 22 *plied by the proportion of personnel com-*
 23 *ensation and benefits costs to total costs of*
 24 *the process for the review of biosimilar bio-*
 25 *logical product applications (as defined in*

1 *section 744G(13)) for the first 3 years of the*
 2 *preceding 4 fiscal years; and*

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

16 “(2) CAPACITY PLANNING ADJUSTMENT.—

17 “(A) IN GENERAL.—Beginning with the fis-
 18 cal year described in subparagraph (B)(ii)(II),
 19 the Secretary shall, in addition to the adjust-
 20 ment under paragraph (1), further increase the
 21 fee revenue and fees under this section for a fis-
 22 cal year to reflect changes in the resource capac-
 23 ity needs of the Secretary for the process for the
 24 review of biosimilar biological product applica-
 25 tions.

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

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

17 “(ii) *ESTABLISHMENT AND IMPLEMEN-*
18 *TATION.*—*After review of the report de-*
19 *scribed in clause (i) and receipt and review*
20 *of public comments thereon, the Secretary*
21 *shall establish a capacity planning method-*
22 *ology for purposes of this paragraph, which*
23 *shall—*

1 “(I) incorporate such approaches
2 and attributes as the Secretary deter-
3 mines appropriate; and

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

8 “(C) *LIMITATION.*—Under no circumstances
9 shall an adjustment under this paragraph result
10 in fee revenue for a fiscal year that is less than
11 the sum of the amounts under subsections
12 (b)(2)(A) (the annual base revenue for the fiscal
13 year) and (b)(2)(B) (the dollar amount of the in-
14 flation adjustment for the fiscal year).

15 “(D) *PUBLICATION IN FEDERAL REG-*
16 *ISTER.*—The Secretary shall publish in the Fed-
17 eral Register notice under paragraph (5) the fee
18 revenue and fees resulting from the adjustment
19 and the methodologies under this paragraph.

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

21 “(A) *INTERIM APPLICATION; FEE REDUC-*
22 *TION.*—Until the first fiscal year for which the
23 capacity planning adjustment under paragraph
24 (2) is effective, the Secretary may, in addition to
25 the adjustment under paragraph (1), reduce the

1 *fee revenue and fees under this section for a fis-*
 2 *cal year as the Secretary determines appropriate*
 3 *for long-term financial planning purposes.*

4 “(B) *GENERAL APPLICATION AND METHOD-*
 5 *LOGY.—Beginning with the first fiscal year for*
 6 *which the capacity planning adjustment under*
 7 *paragraph (2) is effective, the Secretary may, in*
 8 *addition to the adjustments under paragraphs*
 9 *(1) and (2)—*

10 “(i) *reduce the fee revenue and fees*
 11 *under this section as the Secretary deter-*
 12 *mines appropriate for long-term financial*
 13 *planning purposes; or*

14 “(ii) *increase the fee revenue and fees*
 15 *under this section if such an adjustment is*
 16 *necessary to provide for not more than 21*
 17 *weeks of operating reserves of carryover user*
 18 *fees for the process for the review of bio-*
 19 *similar biological product applications.*

20 “(C) *FEDERAL REGISTER NOTICE.—If an*
 21 *adjustment under subparagraph (A) or (B) is*
 22 *made, the rationale for the amount of the in-*
 23 *crease or decrease (as applicable) in fee revenue*
 24 *and fees shall be contained in the annual Federal*

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

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

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

10 “(B) *METHODOLOGY.*—The Secretary shall
11 *publish under paragraph (5) a description of the*
12 *methodology used to calculate the fiscal year*
13 *2018 adjustment under this paragraph in the*
14 *Federal Register notice establishing fee revenue*
15 *and fees for fiscal year 2018.*

16 “(C) *LIMITATION.*—No adjustment under
17 *this paragraph shall result in an increase in fee*
18 *revenue and fees under this section in excess of*
19 *\$9,000,000.*

20 “(5) *ANNUAL FEE SETTING.*—For fiscal year
21 *2018 and each subsequent fiscal year, the Secretary*
22 *shall, not later than 60 days before the start of each*
23 *such fiscal year—*

24 “(A) *establish, for the fiscal year, initial*
25 *and annual biosimilar biological product devel-*

opment fees and reactivation fees under subsection (a)(1), biosimilar biological product application fees under subsection (a)(2), and biosimilar biological product program fees under subsection (a)(3), based on the revenue amounts established under subsection (b) and the adjustments provided under this subsection; and

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

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

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

(1) by striking subparagraph (B);

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

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

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

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

10 (1) in paragraph (2)—

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

14 “(C) *COMPLIANCE.*—The Secretary shall be
 15 considered to have met the requirements of sub-
 16 paragraph (B) in any fiscal year if the costs de-
 17 scribed in such subparagraph are not more than
 18 15 percent below the level specified in such sub-
 19 paragraph.”; and

20 (B) in subparagraph (D)—

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

23 (ii) by striking “(after fiscal year
 24 2013)”; and

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

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

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

6 (1) *in subsection (a)—*

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

9 (B) *by striking “Biosimilar User Fee Act of*
 10 *2012” and inserting “Biosimilar User Fee*
 11 *Amendments of 2017”;*

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

14 (3) *by striking subsection (d);*

15 (4) *by redesignating subsection (e) as subsection*
 16 *(d); and*

17 (5) *in subsection (d), as so redesignated, by*
 18 *striking “2017” each place it appears and inserting*
 19 *“2022”.*

20 **SEC. 405. SUNSET DATES.**

21 (a) *AUTHORIZATION.—Sections 744G and 744H of the*
 22 *Federal Food, Drug, and Cosmetic Act, as amended by sec-*
 23 *tion 403 of this Act, shall cease to be effective October 1,*
 24 *2022.*

1 (b) *REPORTING REQUIREMENTS.*—Section 744I of the
 2 *Federal Food, Drug, and Cosmetic Act*, as amended by sec-
 3 tion 404 of this Act, shall cease to be effective January 31,
 4 2023.

5 (c) *PREVIOUS SUNSET PROVISION.*—

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

10 (2) *CONFORMING AMENDMENT.*—The *Food and*
 11 *Drug Administration Safety and Innovation Act*
 12 (Public Law 112–144) is amended in the table of con-
 13 tents in section 2 by striking the item relating to sec-
 14 tion 404.

15 **SEC. 406. EFFECTIVE DATE.**

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

23 **SEC. 407. SAVINGS CLAUSE.**

24 *Notwithstanding the amendments made by this title,*
 25 *part 8 of subchapter C of chapter VII of the Federal Food,*

1 *Drug, and Cosmetic Act, as in effect on the day before the*
 2 *date of the enactment of this title, shall continue to be in*
 3 *effect with respect to biosimilar biological product applica-*
 4 *tions and supplements (as defined in such part as of such*
 5 *day) that were accepted by the Food and Drug Administra-*
 6 *tion for filing on or after October 1, 2012, but before October*
 7 *1, 2017, with respect to assessing and collecting any fee re-*
 8 *quired by such part for a fiscal year prior to fiscal year*
 9 *2018.*

10 ***TITLE V—PEDIATRIC DRUGS*** 11 ***AND DEVICES***

12 ***SEC. 501. PEDIATRIC DEVICES.***

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

16 *(1) in subsection (a)(3)—*

17 *(A) by redesignating subparagraphs (B)*
 18 *through (D) as subparagraphs (D) through (F),*
 19 *respectively;*

20 *(B) by inserting after subparagraph (A) the*
 21 *following:*

22 *“(B) an assessment of pediatric device label-*
 23 *ing needs based on a review of real world evi-*
 24 *dence collected on the off-label use of medical de-*

1 *vices in children, using data available to the*
 2 *Secretary;*

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

6 *(C) in subparagraph (E), as so redesign-*
 7 *ated, by striking “; and” and inserting “;”;*

8 *(D) in subparagraph (F) (as so redesign-*
 9 *ated), by striking “(B), and (C).” and inserting*
 10 *“(C), (D), and (E); and”; and*

11 *(E) by adding at the end the following:*

12 *“(G) the number of devices for which ex-*
 13 *trapolation was used to support the approval of*
 14 *pediatric labeling of such devices.*

15 *For the items described in this paragraph, such report*
 16 *shall disaggregate the number of devices by pediatric*
 17 *subpopulation.”;*

18 *(2) by redesignating subsection (c) as subsection*
 19 *(d); and*

20 *(3) by inserting after subsection (b), the fol-*
 21 *lowing:*

22 *“(c) PEDIATRIC DEVICE INNOVATION.—*

23 *“(1) IN GENERAL.—The Secretary shall, not*
 24 *later than 1 year after the date of enactment of the*
 25 *FDA Reauthorization Act of 2017, establish within*

1 *the Center for Devices and Radiological Health a*
2 *structure to—*

3 “(A) *provide assistance to device manufac-*
4 *turers that would result in the development, ap-*
5 *proval, and labeling of medical devices for chil-*
6 *dren;*

7 “(B) *oversee an internal pediatrics team*
8 *that—*

9 “(i) *is comprised of employees of the*
10 *Food and Drug Administration with exper-*
11 *tise in pediatrics and appropriate expertise*
12 *pertaining to the relevant devices under re-*
13 *view; and*

14 “(ii) *provides expertise and consulta-*
15 *tion, to all applicable divisions within the*
16 *Center for Devices and Radiological Health,*
17 *on—*

18 “(I) *the application of subsection*
19 *(b), section 520(m), section 510(k), and*
20 *section 522 of this Act and section 402*
21 *of the Public Health Service Act to pe-*
22 *diatric devices; and*

23 “(II) *pediatrics, as it pertains to*
24 *reviewing devices;*

1 “(C) coordinate pediatric activities within
 2 the Center for Devices and Radiological Health;
 3 and

4 “(D) collaborate with other programs, of-
 5 fices, and centers of the Food and Drug Adminis-
 6 tration, including the consortia program author-
 7 ized under section 305 of the Pediatric Medical
 8 Device Safety and Improvement Act of 2007.

9 “(2) STAFF.—Such structure shall include a
 10 chief pediatric medical officer and other appropriate
 11 individuals, as the Secretary determines necessary.”.

12 (b) HUMANITARIAN DEVICE EXEMPTION.—Section
 13 520(m) of the Federal Food, Drug, and Cosmetic Act (21
 14 U.S.C. 360j(m)) is amended—

15 (1) in paragraph (4)—

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

19 (B) in the matter following subparagraph
 20 (B), by inserting “or an appropriate local com-
 21 mittee” after “review committee” each place such
 22 term appears; and

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

1 (c) *DEMONSTRATION GRANTS FOR IMPROVING PEDI-*
 2 *ATRIC AVAILABILITY.*—Section 305 of the Pediatric Medical
 3 *Device Safety and Improvement Act of 2007 (Public Law*
 4 *110–85; 42 U.S.C. 282 note) is amended—*

5 (1) *in subsection (c)—*

6 (A) *in paragraph (4), by striking “and” at*
 7 *the end;*

8 (B) *in paragraph (5), by striking the period*
 9 *and inserting “; and”; and*

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

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

14 (2) *in subsection (e), by striking “2017” and in-*
 15 *serting “2022”.*

16 (d) *MEETING ON PEDIATRIC DEVICE DEVELOP-*
 17 *MENT.*—

18 (1) *IN GENERAL.*—Not later than 1 year after
 19 *the date of enactment of this Act, the Secretary of*
 20 *Health and Human Services shall convene a public*
 21 *meeting regarding opportunities and barriers to the*
 22 *development, approval, and labeling of pediatric med-*
 23 *ical devices. Such meeting shall include representa-*
 24 *tives from the medical device industry, academia, re-*
 25 *cipients of funding under section 305 of the Pediatric*

1 *Medical Device Safety and Improvement Act of 2007*
2 *(Public Law 110–85; 42 U.S.C. 282 note), medical*
3 *provider organizations, and organizations rep-*
4 *resenting patients and consumers.*

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

7 (A) *improve research infrastructure and re-*
8 *search networks to facilitate the conduct of clin-*
9 *ical studies of devices for children that would re-*
10 *sult in the approval and labeling of medical de-*
11 *vices for children;*

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

15 (C) *enhance the appropriate use of*
16 *postmarket registries and data to increase pedi-*
17 *atric medical device labeling;*

18 (D) *increase Food and Drug Administra-*
19 *tion assistance to medical device manufactures*
20 *in developing devices for children that are ap-*
21 *proved and labeled for their use; and*

22 (E) *identify current barriers to pediatric*
23 *device development and incentives to address*
24 *such barriers.*

1 (3) *REPORT*.—Not later than 6 months after the
 2 meeting described in paragraph (1), the Secretary of
 3 Health and Human Services shall submit to the Com-
 4 mittee on Energy and Commerce of the House of Rep-
 5 resentatives and the Committee on Health, Education,
 6 Labor, and Pensions of the Senate, and publish, in-
 7 cluding on the Internet website of the Food and Drug
 8 Administration, a report that summarizes and re-
 9 sponds to the recommendations raised in such meet-
 10 ing.

11 **SEC. 502. PEDIATRIC DRUG DEVELOPMENT.**

12 (a) *EARLY MEETING ON PEDIATRIC STUDY PLAN*.—

13 (1) *IN GENERAL*.—Clause (i) of section
 14 505B(e)(2)(C) of the Federal Food, Drug, and Cos-
 15 metic Act (21 U.S.C. 355c(e)(2)(C)) is amended to
 16 read as follows:

17 “(i) shall meet with the applicant—
 18 “(I) if requested by the applicant
 19 with respect to a drug that is intended
 20 to treat a serious or life-threatening
 21 disease or condition, to discuss prepa-
 22 ration of the initial pediatric study
 23 plan, not later than the end-of-Phase 1
 24 meeting (as such term is used in sec-
 25 tion 312.82(b) of title 21, Code of Fed-

1 *eral Regulations, or successor regula-*
 2 *tions) or within 30 calendar days of*
 3 *receipt of such request, whichever is*
 4 *later;*

5 *“(II) to discuss the initial pedi-*
 6 *atric study plan as soon as practicable,*
 7 *but not later than 90 calendar days*
 8 *after the receipt of such plan under*
 9 *subparagraph (A); and*

10 *“(III) to discuss any scientific or*
 11 *operational challenges that may be the*
 12 *basis of a deferral under subsection*
 13 *(a)(3) or a full or partial waiver under*
 14 *subsection (a)(4);”.*

15 (2) *CONFORMING CHANGES.*—Section 505B(e) of
 16 *the Federal Food, Drug, and Cosmetic Act (21 U.S.C.*
 17 *355c(e)) is amended—*

18 *(A) in the heading of paragraph (2), by*
 19 *striking “MEETING” and inserting “MEETINGS”;*

20 *(B) in the heading of paragraph (2)(C), by*
 21 *striking “MEETING” and inserting “MEETINGS”;*

22 *(C) in clauses (ii) and (iii) of paragraph*
 23 *(2)(C), by striking “no meeting” each place it*
 24 *appears and inserting “no meeting under clause*
 25 *(i)(II)”;* and

1 (D) in paragraph (3) by striking “meeting
2 under paragraph (2)(C)(i)” and inserting “meet-
3 ing under paragraph (2)(C)(i)(II)”.

4 (b) *INFORMING INTERNAL REVIEW COMMITTEE.*—Sec-
5 tion 505A(f) of the Federal Food, Drug, and Cosmetic Act
6 (21 U.S.C. 355a(f)) is amended by adding at the end the
7 following:

8 “(7) *INFORMING INTERNAL REVIEW COM-*
9 *MITTEE.*—The Secretary shall provide to the com-
10 mittee referred to in paragraph (1) any response
11 issued to an applicant or holder with respect to a
12 proposed pediatric study request.”.

13 (c) *ACTION ON SUBMISSIONS.*—

14 (1) *IN GENERAL.*—Section 505A(d) of the Fed-
15 eral Food, Drug, and Cosmetic Act (21 U.S.C.
16 355a(d)) is amended—

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

20 (B) by inserting after paragraph (2) the fol-
21 lowing:

22 “(3) *ACTION ON SUBMISSIONS.*—The Secretary
23 shall review and act upon a submission of a proposed
24 pediatric study request or a sponsor’s proposed

1 *amendment to a written request for pediatric studies*
 2 *within 120 calendar days of the submission.”.*

3 (2) *CONFORMING AMENDMENTS.—*

4 (A) *FFDCA.—Section 505A of the Federal*
 5 *Food, Drug, and Cosmetic Act (21 U.S.C. 355a),*
 6 *as amended by paragraph (1), is further amend-*
 7 *ed by striking subsection “(d)(3)” each place it*
 8 *appears and inserting “(d)(4)”.*

9 (B) *PHSA.—Paragraphs (2), (3), and (4)*
 10 *of section 351(m) of the Public Health Service*
 11 *Act (42 U.S.C. 262(m)) are amended by striking*
 12 *“section 505A(d)(3)” each place it appears and*
 13 *inserting “section 505A(d)(4)”.*

14 (d) *STUDY.—The Secretary of Health and Human*
 15 *Services, acting through the internal review committee es-*
 16 *tablished under section 505C of the Federal Food, Drug,*
 17 *and Cosmetic Act (21 U.S.C. 355d) shall, not later than*
 18 *one year after the date of enactment of this Act, develop*
 19 *and implement a plan to achieve, when appropriate, earlier*
 20 *submission of pediatric studies under section 505A of the*
 21 *Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355a)*
 22 *or section 351(m) of the Public Health Service Act (42*
 23 *U.S.C. 262(m)). Such plan shall include recommendations*
 24 *to achieve—*

1 (1) *earlier discussion of proposed pediatric study*
 2 *requests and written requests with sponsors, and if*
 3 *appropriate, at the meeting required under section*
 4 *505B(e)(2)(C) of the Federal Food, Drug, and Cos-*
 5 *metic Act (21 U.S.C. 355c(e)(2)(C)), as amended by*
 6 *subsection (a);*

7 (2) *earlier issuance of written requests for a pe-*
 8 *diatric study under such section 505A, including for*
 9 *investigational new drugs prior to the submission of*
 10 *an application under section 505(b)(1) of the Federal*
 11 *Food, Drug, and Cosmetic Act (21 U.S.C. 355(b)(1));*
 12 *and*

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

16 (e) *NEONATOLOGY EXPERTISE.—*

17 (1) *IN GENERAL.—Section 6(d) of the Best Phar-*
 18 *maceuticals for Children Act (21 U.S.C. 393a(d)) is*
 19 *amended by striking “For the 5-year period begin-*
 20 *ning on the date of enactment of this subsection, at”*
 21 *and inserting “At”.*

22 (2) *DRAFT GUIDANCE.—Not later than 2 years*
 23 *after the date of enactment of this Act, the Secretary*
 24 *shall issue draft guidance on clinical pharmacology*

1 *considerations for neonatal studies for drugs and bio-*
 2 *logical products.*

3 (f) *SUBMISSION OF ASSESSMENTS.*—Section
 4 *505B(d)(1) of the Federal Food, Drug, and Cosmetic Act*
 5 *(21 U.S.C. 355c(d)(1)) is amended by adding at the end*
 6 *the following: “The Secretary shall inform the Pediatric Ad-*
 7 *visory Committee of all letters and responses to such letters*
 8 *issued under this paragraph.”.*

9 (g) *INTERNAL COMMITTEE.*—Section 505C of the Fed-
 10 *eral Food, Drug, and Cosmetic Act (21 U.S.C. 355d) is*
 11 *amended by inserting “or pediatric rare diseases” after*
 12 *“psychiatry”.*

13 **SEC. 503. GUIDANCE ON MOLECULAR TARGETS IN PEDI-**
 14 **ATRIC ONCOLOGY.**

15 (a) *IN GENERAL.*—The Secretary of Health and
 16 *Human Services (referred to in this section as the “Sec-*
 17 *retary”), acting through the Commissioner of Food and*
 18 *Drugs, shall issue guidance on the development of oncology*
 19 *drugs or biological products directed at molecular targets,*
 20 *including for pediatric populations.*

21 (b) *COLLABORATION; PUBLIC MEETING.*—In devel-
 22 *oping the guidance under subsection (a), the Secretary, act-*
 23 *ing through the Commissioner of Food and Drugs and in*
 24 *collaboration with the Director of the National Cancer In-*
 25 *stitute, shall convene a public meeting not later than 180*

1 days after the date of enactment of this Act to solicit feed-
2 back from physicians and researchers (including pediatric
3 oncologists), patients, and other stakeholders to provide
4 input on development of the guidance. The Secretary shall
5 seek input at such meeting on—

6 (1) the scientific data necessary to determine
7 when an oncology drug or biological product directed
8 at a molecular target is sufficient to support pediatric
9 clinical development given the ethical, practical, and
10 other barriers to clinical investigations in the pedi-
11 atric population;

12 (2) how to determine relevancy of a molecular
13 target to the growth or progression of a pediatric can-
14 cer, including the clinical data necessary to make
15 such a determination;

16 (3) how to overcome the challenges related to pe-
17 diatric oncology drug development, including issues
18 related to conducting clinical trials in pediatric rare
19 cancers with small patient populations;

20 (4) the advantages and disadvantages of innova-
21 tive clinical trial designs in addressing the develop-
22 ment of oncology drugs or biological products directed
23 at molecular targets in pediatric cancer patients; and

24 (5) the ways in which the Secretary can improve
25 the current process outlined under sections 505A and

1 505B of the Federal Food, Drug, and Cosmetic Act
 2 (21 U.S.C. 355a, 355c) to encourage additional re-
 3 search and development of pediatric cancer treat-
 4 ments.

5 **SEC. 504. BEST PHARMACEUTICALS FOR CHILDREN.**

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

8 (1) in subsection (a)(2)(A)(ii), by inserting “and
 9 identification of biomarkers for such diseases, dis-
 10 orders, or conditions,” after “biologics,”;

11 (2) in subsection (c)—

12 (A) in paragraph (6)(B)—

13 (i) by striking “shall be assigned a
 14 docket number by the Commissioner of Food
 15 and Drugs” and inserting “, not later than
 16 90 days after submission, shall be posted on
 17 the Internet website of the Food and Drug
 18 Administration in an accessible manner”;
 19 and

20 (ii) by striking “become part of the
 21 docket file with respect to each of the drugs”
 22 and inserting “be posted on the Internet
 23 website of the Food and Drug Administra-
 24 tion”; and

25 (B) in paragraph (7)—

1 (i) in the matter preceding subpara-
 2 graph (A), by striking “submitted” and in-
 3 serting “posted”; and

4 (ii) in subparagraph (C), by striking
 5 “(i) place” and all that follows through the
 6 period at the end and inserting “publish
 7 through posting on the Internet website of
 8 the Food and Drug Administration a sum-
 9 mary of the report and a copy of any re-
 10 quested labeling changes.”;

11 (3) by striking subsection (d);

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

14 (5) in paragraph (1) of subsection (d), as so re-
 15 designated, by striking “2013 through 2017” and in-
 16 serting “2018 through 2022”.

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

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

23 Section 505(u)(4) of the Federal Food, Drug, and Cos-
 24 metic Act (21 U.S.C. 355(u)(4)) is amended by striking
 25 “2017” and inserting “2022”.

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

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

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

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

11 **SEC. 604. GUIDANCE REGARDING BIOEQUIVALENCE.**

12 *(a) IN GENERAL.—In accordance with subsection (b),*
 13 *the Secretary of Health and Human Services, acting*
 14 *through the Commissioner of Food and Drugs, shall issue*
 15 *product-specific guidance that—*

16 *(1) applies to complex non-biologic drugs; and*
 17 *(2) outlines how to demonstrate bioequivalence to*
 18 *the reference drug, in order to facilitate generic devel-*
 19 *opment for such drugs.*

20 *(b) DEADLINE FOR ISSUING GUIDANCE.—After the*
 21 *date of enactment of this Act, the Secretary of Health and*
 22 *Human Services, acting through the Commissioner of Food*
 23 *and Drugs, shall publish a guidance, for each complex non-*
 24 *biologic drug that is approved under section 505(b) of the*
 25 *Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(b)),*
 26 *not less than 2 years prior to the earliest date on which*

1 *an abbreviated new drug application may be submitted*
 2 *pursuant to section 505(j) of the Federal Food, Drug, and*
 3 *Cosmetic Act (21 U.S.C. 355(c)) that references such drug.*

4 *(c) APPLICABILITY.—This section applies to guidances*
 5 *for abbreviated new drug applications that reference new*
 6 *drug applications first approved on or after October 1,*
 7 *2017.*

8 **SEC. 605. PATIENT EXPERIENCE DATA.**

9 *Section 569C(c)(2)(A) of the Federal Food, Drug, and*
 10 *Cosmetic Act (21 U.S.C. 360bbb–8c(c)(2)(A)) is amended*
 11 *by striking “impact of such disease or condition, or a re-*
 12 *lated therapy,” and inserting “physical and psychosocial*
 13 *impacts of such disease or condition, related therapy, or*
 14 *clinical investigation”.*

15 **SEC. 606. COMMUNICATIONS PLANS.**

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

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

19 *(2) in subparagraph (C), by striking the period*
 20 *and inserting “; or”; and*

21 *(3) by adding at the end the following:*

22 *“(D) disseminating information to health*
 23 *care providers about the meaning of terms re-*
 24 *lated to drug formulations or properties that are*
 25 *described in the drug labeling, including infor-*

1 *mation about the limitations or patient care im-*
 2 *plications of such formulations or properties,*
 3 *and how such formulations or properties may be*
 4 *related to serious adverse drug events associated*
 5 *with use of the drug.”.*

6 **SEC. 607. PROTECTING AND STRENGTHENING THE DRUG**
 7 **SUPPLY CHAIN.**

8 (a) *DIVERTED DRUGS.*—Paragraph (1) of section
 9 *801(d) of the Federal Food, Drug, and Cosmetic Act (21*
 10 *U.S.C. 381(d)) is amended—*

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

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

14 *“(B) Except as authorized by the Secretary in the case*
 15 *of a drug that appears on the drug shortage list under sec-*
 16 *tion 506E or in the case of importation pursuant to section*
 17 *804(j), no drug that is subject to section 503(b)(1) may be*
 18 *imported into the United States for commercial use if such*
 19 *drug is manufactured outside the United States, the manu-*
 20 *facturer has not authorized the drug to be marketed in the*
 21 *United States, and the manufacturer has not caused the*
 22 *drug to be labeled to be marketed in the United States.”.*

23 (b) *COUNTERFEIT DRUGS.*—Subsection (b) of section
 24 *303 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C.*
 25 *333) is amended by adding at the end the following:*

1 “(8) *Notwithstanding subsection (a), any person who*
 2 *violates section 301(i)(3) by selling or dispensing, or hold-*
 3 *ing for sale or dispensing, a drug that is a counterfeit drug*
 4 *shall be fined under title 18, United States Code, impris-*
 5 *oned for not more than 10 years, or both, unless the person*
 6 *acted in good faith and had no reason to believe the drug*
 7 *was a counterfeit drug.”.*

8 **SEC. 608. TECHNICAL CORRECTIONS.**

9 *Section 527 of the Federal Food, Drug, and Cosmetic*
 10 *Act (21 U.S.C. 360cc) is amended—*

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

15 *(2) in subsection (b)—*

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

1 *by the Secretary, as the already approved drug*
 2 *for the same rare disease or condition if”;*

3 *(B) in paragraph (1), by striking “notice”*
 4 *and all that follows through “assure” and insert-*
 5 *ing “of exclusive approval or licensure notice*
 6 *and opportunity for the submission of views,*
 7 *that during such period the holder of the exclu-*
 8 *sive approval or licensure cannot ensure”;* and

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

12 *(3) by adding at the end the following:*

13 “(c) *CONDITION OF CLINICAL SUPERIORITY.—*

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

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

8 “(d) *REGULATIONS.*—The Secretary may promulgate
 9 regulations for the implementation of subsection (c). Until
 10 such time as the Secretary promulgates regulations in ac-
 11 cordance with this subsection, any definitions set forth in
 12 regulations implementing this section that were promul-
 13 gated prior to the date of enactment of the FDA Reauthor-
 14 ization Act of 2017 shall continue to apply.”.

15 **TITLE VII—DEVICE INSPECTION** 16 **AND REGULATORY IMPROVE-** 17 **MENTS**

18 **SEC. 701. RISK-BASED INSPECTIONS FOR DEVICES.**

19 (a) *IN GENERAL.*—Section 510(h) of the Federal Food,
 20 Drug, and Cosmetic Act (21 U.S.C. 360(h)) is amended—

21 (1) by striking paragraph (2) and inserting the
 22 following:

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

24 “(A) *IN GENERAL.*—The Secretary, acting
 25 through one or more officers or employees duly

1 *designated by the Secretary, shall inspect estab-*
 2 *lishments described in paragraph (1) that are*
 3 *engaged in the manufacture, propagation,*
 4 *compounding, or processing of a device or devices*
 5 *(referred to in this subsection as ‘device establish-*
 6 *ments’) in accordance with a risk-based schedule*
 7 *established by the Secretary.*

8 “(B) *FACTORS AND CONSIDERATIONS.*—*In*
 9 *establishing the risk-based schedule under sub-*
 10 *paragraph (A), the Secretary shall—*

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

14 “(ii) *consider the participation of the*
 15 *device establishment, as applicable, in inter-*
 16 *national device audit programs in which*
 17 *the United States participates or the United*
 18 *States recognizes.”; and*

19 (2) *in paragraph (4)—*

20 (A) *in the matter preceding subparagraph*
 21 *(A), by striking “paragraph (3)” and inserting*
 22 *“paragraph (2) or (3)”;* and

23 (B) *in subparagraph (C), by inserting “or*
 24 *device” after “drug”.*

1 (b) *FOREIGN INSPECTIONS*.—Section 809(a)(1) of the
 2 *Federal Food, Drug, and Cosmetic Act* (21 U.S.C.
 3 384e(a)(1)) is amended by striking “section 510(h)(3)” and
 4 inserting “paragraph (2) or (3) of section 510(h)”.

5 **SEC. 702. IMPROVEMENTS TO INSPECTIONS PROCESS.**

6 (a) *INSPECTION PROCEDURE*.—Section 704 of the *Fed-*
 7 *eral Food, Drug, and Cosmetic Act* (21 U.S.C. 374) is
 8 amended by adding at the end the following:

9 “(h)(1) *In the case of inspections that are not for-cause*
 10 *inspections, the Secretary shall review existing processes*
 11 *and standards for inspections of domestic and foreign device*
 12 *establishments, and update such processes and standards to*
 13 *ensure uniform processes and standards, with exceptions as*
 14 *appropriate. Such processes and standards shall include—*

15 “(A) *announcing the inspection to the establish-*
 16 *ment within a reasonable time before such inspection,*
 17 *which shall include notification to the owner, oper-*
 18 *ator, or agent in charge of the establishment regard-*
 19 *ing the type and nature of the inspection;*

20 “(B) *providing a reasonable estimate of the time-*
 21 *frame for the duration of the inspection, an oppor-*
 22 *tunity for advancing communications between the of-*
 23 *ficers or employees carrying out the inspection under*
 24 *subsection (a)(1) and the owner, operator, or agent in*
 25 *charge of the establishment concerning appropriate*

1 *working hours during the inspection, and, to the ex-*
 2 *tent feasible, advance notice of records that will be re-*
 3 *quested in order to expedite the inspection; and*

4 *“(C) providing for requirements with respect to*
 5 *the frequency and conditions of communications dur-*
 6 *ing the inspection with the owner, operator, or agent*
 7 *in charge of the establishment regarding inspection*
 8 *status, which may be recorded by either party with*
 9 *advance notice and mutual consent.*

10 *“(2) Nothing in this subsection affects the authority*
 11 *of the Secretary to conduct inspections otherwise permitted*
 12 *under this Act in order to ensure compliance.”.*

13 *(b) REPORT RESPONSES.—Section 704(b) of the Fed-*
 14 *eral Food, Drug, and Cosmetic Act (21 U.S.C. 374(b)) is*
 15 *amended—*

16 *(1) by striking “Upon completion” and inserting*
 17 *“(1) Upon completion”; and*

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

19 *“(2) In the case of establishments registered under sec-*
 20 *tion 510 that have received a report pursuant to paragraph*
 21 *(1), and for which the owner, operator, or agent in charge*
 22 *of such establishment submits a timely response to such re-*
 23 *port that includes a request for feedback to the actions pro-*
 24 *posed in such response, and which involves a public health*
 25 *priority, the Secretary shall provide nonbinding feedback*

1 *regarding such proposed actions within 45 days of receipt*
2 *of such request.”.*

3 *(c) GUIDANCE.—*

4 *(1) DRAFT GUIDANCE.—Not later than 1 year*
5 *after the date of enactment of this Act, the Secretary*
6 *of Health and Human Services shall issue draft guid-*
7 *ance that—*

8 *(A) specifies how the Food and Drug Ad-*
9 *ministration will implement the process de-*
10 *scribed in subsection (h) of section 704 of the*
11 *Federal Food, Drug, and Cosmetic Act (21*
12 *U.S.C. 374), as amended by this section, and the*
13 *requirements described in subsection (b)(2) of*
14 *such section;*

15 *(B) provides standard methods for commu-*
16 *nications described in such subsections;*

17 *(C) establishes standard timeframes over*
18 *consecutive days applicable to both domestic and*
19 *foreign inspections, to which each inspector shall*
20 *adhere unless an investigator can identify to the*
21 *establishment a reason that more time is needed;*
22 *and*

23 *(D) identifies practices for investigators and*
24 *device establishments to facilitate the continuity*
25 *of inspections.*

1 (2) *FINAL GUIDANCE*.—Not later than 18 months
 2 after the close of the comment period on the draft
 3 guidance under paragraph (1), the Secretary shall
 4 issue final guidance consistent with such paragraph.

5 **SEC. 703. REAUTHORIZATION OF INSPECTION PROGRAM.**

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

9 **SEC. 704. CERTIFICATES TO FOREIGN GOVERNMENTS FOR**
 10 **DEVICES.**

11 Subsection (e)(4) of section 801 of the Federal Food,
 12 Drug, and Cosmetic Act (21 U.S.C. 381(e)(4)) is amend-
 13 ed—

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

15 “(E)(i)(I) If the Secretary denies a request for certifi-
 16 cation under subparagraph (A)(ii) with respect to a device
 17 manufactured in an establishment (foreign or domestic)
 18 registered under section 510, the Secretary shall provide in
 19 writing to the person seeking such certification the basis
 20 for such denial, and specifically identify the finding upon
 21 which such denial is based.

22 “(II) If the denial of a request as described in sub-
 23 clause (I) is based on grounds other than an injunction pro-
 24 ceeding pursuant to section 302, seizure action pursuant
 25 to section 304, or a recall designated Class I or Class II

1 pursuant to part 7, title 21, Code of Federal Regulations,
2 the Secretary shall provide a substantive summary of the
3 specific grounds for noncompliance identified.

4 “(III) With respect to a device manufactured in an
5 establishment that has received a report under section
6 704(b), the Secretary shall not deny a request for certifi-
7 cation with respect to a device pursuant to subparagraph
8 (A)(ii) if the Secretary and the owner, operator, or agent
9 in charge of such establishment have agreed to a plan of
10 correction in response to such report.

11 “(ii)(I) The Secretary shall provide a process for a per-
12 son who is denied a certification as described in clause
13 (i)(I) to request a review that conforms to the standards
14 of section 517A(b).

15 “(II) Notwithstanding any previous review conducted
16 pursuant to subclause (I), a person who has been denied
17 a certification as described in clause (i)(I) may at any time
18 request a review in order to present new information relat-
19 ing to actions taken by such person to address the reasons
20 identified by the Secretary for the denial of certification,
21 including evidence that corrective actions are being or have
22 been implemented to address grounds for noncompliance
23 identified by the Secretary.

24 “(III) Not later than 1 year after date of enactment
25 of the FDA Reauthorization Act of 2017, the Secretary shall

1 *issue guidance providing for a process to carry out this sub-*
 2 *paragraph. Not later than 1 year after the close of the com-*
 3 *ment period for such guidance, the Secretary shall issue*
 4 *final guidance.”; and*

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

7 **SEC. 705. FACILITATING INTERNATIONAL HARMONIZATION.**

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

11 *“(15) Notwithstanding any other provision of*
 12 *this subsection, for purposes of conducting inspections*
 13 *of establishments that manufacture, prepare, propa-*
 14 *gate, compound, or process devices except types of de-*
 15 *vices licensed under section 351 of the Public Health*
 16 *Service Act, which inspections are required under sec-*
 17 *tion 510(h) or are inspections of such establishments*
 18 *required to register pursuant to section 510(i), the*
 19 *Secretary may recognize auditing organizations that*
 20 *are recognized by organizations established by govern-*
 21 *ments to facilitate international harmonization. Noth-*
 22 *ing in this paragraph affects the authority of the Sec-*
 23 *retary to inspect any device establishment pursuant*
 24 *to this Act. Nothing in this paragraph affects the au-*

1 *thority of the Secretary to determine the official clas-*
 2 *sification of an inspection.”.*

3 **SEC. 706. NOTIFICATION OF GUIDANCE RELATED TO LAB-**
 4 **DEVELOPED TESTS.**

5 *Section 1143 of the Food and Drug Administration*
 6 *Safety and Innovation Act (Public Law 112–144) is*
 7 *amended—*

8 *(1) in subsection (a), by striking “60” and in-*
 9 *serting “90”; and*

10 *(2) in subsection (b), by striking “5” and insert-*
 11 *ing “10”.*

12 **SEC. 707. DIAGNOSTIC IMAGING DEVICES INTENDED FOR**
 13 **USE WITH CONTRAST AGENTS.**

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

17 *“(p)(1) The Secretary may approve an application or*
 18 *supplement to an application under section 515 for an ap-*
 19 *plicable medical imaging device, may make a substantial*
 20 *equivalence determination as to an applicable medical im-*
 21 *aging device for which a report or a supplement to a report*
 22 *has been submitted under section 510(k), or may grant a*
 23 *request under section 513(f)(2) for an applicable medical*
 24 *imaging device if the requirements of this subsection and*
 25 *other applicable premarket requirements are met, and the*

1 *indications and conditions of use proposed in such applica-*
2 *tion or notification involve the use of a contrast agent that*
3 *is not—*

4 “(A) *in a concentration, rate of administration,*
5 *or route of administration that is different from those*
6 *described in the approved labeling of such contrast*
7 *agent, unless the Secretary determines, based on infor-*
8 *mation contained in the application or report, that*
9 *the difference does not adversely affect the safety or ef-*
10 *fectiveness of the contrast agent when used with the*
11 *device;*

12 “(B) *in a region, organ, or system of the body*
13 *that is different from those described in the approved*
14 *labeling of the contrast agent, unless the Secretary de-*
15 *termines, based on information contained in the de-*
16 *vice application, request, or report, that any dif-*
17 *ference does not affect the safety or effectiveness of the*
18 *contrast agent when used with the device;*

19 “(C) *in a patient population different from the*
20 *patient population in the approved labeling for such*
21 *contrast agent, unless the Secretary determines, based*
22 *on information contained in the application or re-*
23 *port, that the difference does not adversely affect the*
24 *safety or effectiveness of the contrast agent when used*
25 *with the device; or*

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

6 “(2) An applicable medical imaging device that is eli-
7 gible for approval under section 515, clearance under sec-
8 tion 510(k), or classification under section 513(f)(2), or ap-
9 proval, clearance, or classification as described in para-
10 graph (1) shall be subject only to such requirements of this
11 Act that are applicable to devices.

12 “(3) An application under section 515, report under
13 section 510(k), or classification under section 513(f)(2) for
14 an applicable medical imaging device intended for use in
15 conjunction with a contrast agent to which clause (ii) or
16 (iii) of section 505(c)(3)(E) applies shall refer to such con-
17 trast agent in such application, report, or request by trade
18 or brand name, rather than to the international nonpropri-
19 etary name.

20 “(4) In conducting a review of an application or re-
21 port submitted for an applicable medical imaging device,
22 the agency center charged with the premarket review of de-
23 vices center may consult with the agency center charged
24 with the premarket review of drugs and biological products.

25 “(5) For purposes of this subsection—

1 “(A) the term ‘applicable medical imaging de-
 2 vice’ means a device intended to be used in conjunc-
 3 tion with a contrast agent or class of contrast agents
 4 for a use that is not described in the indications and
 5 usage section of the approved labeling of such contrast
 6 agent or the approved labeling of any contrast agent
 7 in such class, as applicable; and

8 “(B) the term ‘contrast agent’ means a drug that
 9 is approved under section 505 or licensed under sec-
 10 tion 351 of the Public Health Service Act, is intended
 11 for use in conjunction with an applicable medical im-
 12 aging device, and—

13 “(i) is a diagnostic radiopharmaceutical, as
 14 defined in sections 315.2 and 601.30 of title 21,
 15 Code of Federal Regulations (or any successor
 16 regulations); or

17 “(ii) is a diagnostic agent that improves the
 18 visualization of structure or function within the
 19 body by increasing the relative difference in sig-
 20 nal intensity within the target tissue, structure,
 21 or fluid.”.

22 **SEC. 708. DIAGNOSTIC CLARITY.**

23 Not later than 18 months after the date of enactment
 24 of this Act, the Secretary of Health and Human Services
 25 (referred to in this section as the “Secretary”) shall update

1 *guidance with respect to the circumstances under which re-*
 2 *agents, new instruments, or new combinations of instru-*
 3 *ments may be added to groups of instruments that have*
 4 *been cleared under section 510(k) of the Federal Food, Drug,*
 5 *and Cosmetic Act (21 U.S.C. 360(k)). The updated guidance*
 6 *shall provide standard definitions and describe procedures*
 7 *for sponsors seeking to add a new instrument, reagent, or*
 8 *combination of instruments to a cleared group of instru-*
 9 *ments to submit information to the Secretary dem-*
 10 *onstrating that the new reagent, new instrument, or new*
 11 *combination of instruments does not alter the assay's per-*
 12 *formance, as applicable. The Secretary shall consult with*
 13 *affected entities and other stakeholders in updating the*
 14 *guidance.*

15 **SEC. 709. APPROPRIATE CLASSIFICATION OF DEVICE AC-**
 16 **CESSORIES.**

17 *Section 513(b)(9) of the Federal Food, Drug, and Cos-*
 18 *metic Act (21 U.S.C. 360c(b)(9)) is amended—*

19 *(1) by striking “(9) The Secretary” and insert-*
 20 *ing “(9)(A) The Secretary”; and*

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

22 *“(B) The classification of any accessory classified*
 23 *prior to December 13, 2016, based on the intended use or*
 24 *uses of such accessory, shall continue to apply, unless other-*
 25 *wise determined by the Secretary under section 515(e)(1).*

1 “(C)(i) *If an accessory has been cleared or approved*
2 *based on the classification of another device with which such*
3 *accessory is intended to be used and the Secretary has estab-*
4 *lished a classification for such accessory based on the in-*
5 *tended use or uses of the accessory, in accordance with sub-*
6 *paragraph (A), the manufacturer of such accessory may*
7 *identify the classification so established for such accessory*
8 *in a written notification to the Secretary.*

9 “(ii) *Unless the Secretary notifies a manufacturer*
10 *within 30 calendar days of receipt of a written notification*
11 *described in clause (i) that the Secretary does not agree that*
12 *the classification identified in such written notification is*
13 *appropriate for the accessory, the accessory shall be auto-*
14 *matically reclassified in accordance with the classification*
15 *identified in such written notification.*

16 “(iii) *A written notification that the Secretary dis-*
17 *agrees with the classification identified in a written notifi-*
18 *cation described in clause (ii) shall include a detailed de-*
19 *scription and justification for the determination to dis-*
20 *agree.*

21 “(D)(i) *A manufacturer of an accessory that has not*
22 *been classified by the Secretary based on the intended use*
23 *or uses of the accessory as described in subparagraph (A),*
24 *and for which the Secretary has not established a classifica-*
25 *tion for the accessory type as a stand-alone device, may sub-*

1 mit to the Secretary a written recommendation for the ap-
2 propriate classification of such accessory based on its in-
3 tended use or uses. Such submission shall include such in-
4 formation to support the recommendation as the Secretary
5 may require.

6 “(ii) The Secretary shall respond to a submission
7 under clause (i) within 60 calendar days of receiving the
8 submission by approving or denying the recommended clas-
9 sification of the accessory. If the Secretary does not agree
10 with the recommendation for classification submitted by the
11 sponsor, the response shall include a detailed description
12 and justification for such determination to disagree. The
13 Secretary shall provide an opportunity for a manufacturer
14 to meet with appropriate personnel to discuss appropriate
15 classification of such accessory prior to submitting a writ-
16 ten recommendation.

17 “(E)(i) At the time a sponsor submits an application
18 for premarket approval pursuant to section 515(c) or a re-
19 port pursuant to 510(k), the sponsor of such application
20 or report may include a recommendation and supporting
21 information for the proper classification of an accessory
22 pursuant to subparagraph (A), if applicable. If such acces-
23 sory type has not been classified by the Secretary based on
24 its intended use or uses as a stand-alone device as described
25 in subparagraph (A), the Secretary shall—

1 “(I) approve or deny such application pursuant
 2 to section 515(d), or find such report substantially
 3 equivalent or not substantially equivalent pursuant to
 4 section 510(k); and

5 “(II) approve or deny the classification of the ac-
 6 cessory proposed in such application or report.

7 “(F) A manufacturer may at any time use the classi-
 8 fication process described in section 513(f)(2) to obtain clas-
 9 sification of an accessory.”.

10 **SEC. 710. DEVICE PILOT PROJECTS.**

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

14 “(i) *PILOT PROJECTS*.—

15 “(1) *IN GENERAL*.—In order to provide timely
 16 and reliable information on the safety and effective-
 17 ness of cleared or approved devices, including re-
 18 sponses to adverse events and malfunctions, and to
 19 advance the objectives of part 803 of title 21, Code of
 20 Federal Regulations (or successor regulations), and
 21 advance the objectives of, and evaluate innovative new
 22 methods of compliance with, this section and section
 23 522, the Secretary shall, within one year of the date
 24 of enactment of the FDA Reauthorization Act of 2017,
 25 initiate one or more pilot projects for voluntary par-

1 *ticipation by a manufacturer or manufacturers of de-*
2 *vice or device type, or continue existing projects, in*
3 *accordance with paragraph (3), that meet all of the*
4 *following requirements:*

5 *“(A) Are designed to efficiently generate re-*
6 *liable and timely safety and active surveillance*
7 *data for use by the Secretary or manufacturers*
8 *of the devices that are involved in the pilot*
9 *project.*

10 *“(B) Inform the development of methods,*
11 *systems, data criteria, and programs that could*
12 *be used to support safety and active surveillance*
13 *activities for devices not included in such project.*

14 *“(C) Are designed and conducted in coordi-*
15 *nation with a comprehensive system for evalu-*
16 *ating medical device technology that operates*
17 *under a governing board with appropriate rep-*
18 *resentation of stakeholders, including consumer*
19 *groups and device manufacturers.*

20 *“(D) Use electronic health data including*
21 *claims data, patient survey data, and any other*
22 *data, as the Secretary determines appropriate.*

23 *“(E) Prioritize devices and device types*
24 *that meet one or more of the following criteria:*

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

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

7 “(iii) *Devices and device types, the*
8 *failure of which has significant health con-*
9 *sequences.*

10 “(iv) *Devices and device types for*
11 *which the Secretary has received public rec-*
12 *ommendations in accordance with para-*
13 *graph (2)(B) and has determined to meet*
14 *one of the criteria under clauses (i) through*
15 *(iii) and is appropriate for a project under*
16 *this subsection.*

17 “(2) *PARTICIPATION.—The Secretary shall estab-*
18 *lish the conditions and processes for—*

19 “(A) *authorizing voluntary participation of*
20 *a manufacturer of a device in the pilot project*
21 *described in paragraph (1); and*

22 “(B) *facilitating public recommendations*
23 *for devices to be prioritized under the pilot*
24 *project described in paragraph (1), including re-*

1 *quirements for the data necessary to support*
2 *such recommendation.*

3 “(3) *IMPLEMENTATION.—The Secretary may sat-*
4 *isfy the requirements of paragraphs (1) and (2) by*
5 *continuing or expanding existing projects, or by be-*
6 *ginning new projects, that meet the criteria of sub-*
7 *paragraphs (A) through (E) of paragraph (1) or by*
8 *entering into contracts, cooperative agreements,*
9 *grants, or other appropriate agreements with public*
10 *or private entities that have a significant presence in*
11 *the United States, and meet the following additional*
12 *conditions:*

13 “(A) *If such public or private entities are a*
14 *component of another organization, the entities*
15 *have established appropriate security measures*
16 *to maintain the confidentiality and privacy of*
17 *the data described in paragraph (1)(D) and the*
18 *entity shall not make an unauthorized disclosure*
19 *of such data to the other components of the orga-*
20 *nization in breach of such confidentiality and*
21 *privacy requirements.*

22 “(B) *In the case of the termination or non-*
23 *renewal of such contracts, cooperative agree-*
24 *ments, grants, or other appropriate agreements,*

1 *the entities shall comply with each of the fol-*
2 *lowing:*

3 *“(i) Continue to comply with the con-*
4 *fidentiality and privacy requirements under*
5 *this subsection with respect to all data dis-*
6 *closed to the entity.*

7 *“(ii) Return any data disclosed to such*
8 *entity under this subsection to which it*
9 *would not otherwise have access or, if re-*
10 *turning the data is not practicable, destroy*
11 *the data.*

12 *“(C) Have at least one of the following*
13 *qualifications:*

14 *“(i) Research, statistical, epidemio-*
15 *logic, or clinical capability and expertise to*
16 *conduct and complete the activities under*
17 *this subsection, including the capability and*
18 *expertise to provide the Secretary access to*
19 *de-identified data consistent with the re-*
20 *quirements of this subsection.*

21 *“(ii) An information technology infra-*
22 *structure in place to support electronic data*
23 *and operational standards to provide secu-*
24 *rity for such data, as appropriate.*

1 “(iii) *Experience with, and expertise*
 2 *on, the development of device safety and ef-*
 3 *fectiveness research and surveillance using*
 4 *electronic health data.*

5 “(iv) *Other expertise which the Sec-*
 6 *retary determines necessary to fulfill the ac-*
 7 *tivities under this subsection.*

8 “(4) *REVIEW OF CONTRACT IN THE EVENT OF A*
 9 *MERGER OR ACQUISITION.—The Secretary shall re-*
 10 *view a contract with a qualified entity under this*
 11 *subsection in the event of a merger or acquisition of*
 12 *the entity in order to ensure that the requirements*
 13 *under this subsection will continue to be met.*

14 “(5) *REPORT TO CONGRESS.—Not later than 18*
 15 *months after the date of enactment of the FDA Reau-*
 16 *thorization Act of 2017, and annually thereafter, the*
 17 *Secretary shall submit to the Committee on Health,*
 18 *Education, Labor, and Pensions of the Senate and the*
 19 *Committee on Energy and Commerce of the House of*
 20 *Representatives a report containing a description of*
 21 *the pilot projects being conducted pursuant to this*
 22 *subsection, including for each pilot project—*

23 “(A) *how the project is being implemented*
 24 *in accordance with paragraph (3) and the con-*
 25 *tractor or grantee as applicable;*

1 “(B) the number of manufacturers that have
2 agreed to participate;

3 “(C) the data sources used;

4 “(D) the devices or device categories in-
5 volved; and

6 “(E) the number of patients involved.

7 “(6) COMPLIANCE WITH REQUIREMENTS FOR
8 RECORDS OR REPORTS ON DEVICES.—The participa-
9 tion of a manufacturer in a pilot project under this
10 subsection shall not affect the eligibility of such man-
11 ufacturer to participate in any quarterly reporting
12 program implemented under this Act. The Secretary
13 may determine that, for the specified time period to
14 be determined by the Secretary, a manufacturer’s
15 participation in a pilot project under this subsection
16 may meet certain other requirements of this section or
17 section 522 if—

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

21 “(B) the Secretary has established proce-
22 dures for making adverse event and safety infor-
23 mation collected from the pilot public, to the ex-
24 tent possible, if collected pursuant to this section
25 or section 522.

1 “(7) *PRIVACY REQUIREMENTS.*—*With respect to*
 2 *the pilot projects conducted pursuant to this sub-*
 3 *section—*

4 “(A) *individual identifiable health informa-*
 5 *tion shall not be disclosed when presenting any*
 6 *information from such project; and*

7 “(B) *such projects shall comply with section*
 8 *264(c) of the Health Insurance Portability and*
 9 *Accountability Act of 1996 (42 U.S.C. 1320d–2*
 10 *note) and sections 552 and 552a of title 5,*
 11 *United States Code.*

12 “(8) *OTHER COMPLIANCE.*—*Any pilot program*
 13 *undertaken in coordination with the comprehensive*
 14 *system described in paragraph (1)(C), including pilot*
 15 *projects under this subsection, that relates to the use*
 16 *of real world evidence for devices shall comply with*
 17 *paragraph (1)(B), the conditions listed in subpara-*
 18 *graphs (A) and (B) of paragraph (3), and para-*
 19 *graphs (4), (5), (6), and (7).*

20 “(9) *SUNSET.*—*This subsection shall cease to*
 21 *have force or effect on October 1, 2022.”.*

22 (b) *REPORT.*—*Not later than January 31, 2021, the*
 23 *Secretary of Health and Human Services, acting through*
 24 *the Commissioner of Food and Drugs, shall conduct a re-*
 25 *view through an independent third party to evaluate the*

1 *strengths, limitations, and appropriate use of evidence col-*
 2 *lected pursuant to real world evidence pilot projects de-*
 3 *scribed in the letters described in section 201(b) of the Med-*
 4 *ical Device User Fee Amendments of 2017 and subsection*
 5 *(i) of section 519 of the Federal Food, Drug, and Cosmetic*
 6 *Act (21 U.S.C. 360i), as amended by subsection (a), for in-*
 7 *forming premarket and postmarket decisionmaking for*
 8 *multiple device types, and to determine whether the meth-*
 9 *ods, systems, and programs in such pilot projects efficiently*
 10 *generate reliable and timely evidence about the effectiveness*
 11 *or safety surveillance of devices.*

12 **SEC. 711. REGULATION OF OVER-THE-COUNTER HEARING**
 13 **AIDS.**

14 (a) *IN GENERAL.*—Section 520 of the Federal Food,
 15 Drug, and Cosmetic Act (21 U.S.C. 360j), as amended by
 16 section 707, is further amended by adding at the end the
 17 following:

18 “(q) *REGULATION OF OVER-THE-COUNTER HEARING*
 19 *AIDS.*—

20 “(1) *DEFINITION.*—In this subsection, the term
 21 ‘over-the-counter hearing aid’ means a device that—

22 “(A) *uses the same fundamental scientific*
 23 *technology as air conduction hearing aids (as de-*
 24 *defined in section 874.3300 of title 21, Code of*
 25 *Federal Regulations) (or any successor regula-*

tion) or wireless air conduction hearing aids (as defined in section 874.3305 of title 21, Code of Federal Regulations) (or any successor regulation);

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

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

“(D) may—

“(i) use wireless technology; or

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

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

“(2) *REGULATION.*—An over-the-counter hearing aid shall be subject to the regulations promulgated in accordance with section 711(b) of the *FDA Reauthorization Act of 2017* and shall be exempt from sections 801.420 and 801.421 of title 21, Code of Federal Regulations (or any successor regulations).”.

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

2 (1) *IN GENERAL.*—*The Secretary of Health and*
3 *Human Services (referred to in this section as the*
4 *“Secretary”), not later than 3 years after the date of*
5 *enactment of this Act, shall promulgate proposed reg-*
6 *ulations to establish a category of over-the-counter*
7 *hearing aids, as defined in subsection (q) of section*
8 *520 of the Federal Food, Drug, and Cosmetic Act (21*
9 *U.S.C. 360j) as amended by subsection (a), and, not*
10 *later than 180 days after the date on which the public*
11 *comment period on the proposed regulations closes,*
12 *shall issue such final regulations.*

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

15 (A) *include requirements that provide rea-*
16 *sonable assurances of the safety and efficacy of*
17 *over-the-counter hearing aids;*

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

21 (C) *include requirements for appropriate la-*
22 *beling of the over-the-counter hearing aid, in-*
23 *cluding how consumers may report adverse*
24 *events, any conditions or contraindications, and*

1 *any advisements to consult promptly with a li-*
 2 *censed physician; and*

3 *(D) describe the requirements under which*
 4 *the sale of over-the-counter hearing aids is per-*
 5 *mitted, without the supervision, prescription, or*
 6 *other order, involvement, or intervention of a li-*
 7 *censed person, to consumers through in-person*
 8 *transactions, by mail, or online.*

9 *(3) PREMARKET NOTIFICATION.—The Secretary*
 10 *shall make findings under section 510(m) of the Fed-*
 11 *eral Food, Drug, and Cosmetic Act (21 U.S.C.*
 12 *360(m)) to determine whether over-the-counter hear-*
 13 *ing aids (as defined in section 520(q) of the Federal*
 14 *Food, Drug, and Cosmetic Act (21 U.S.C. 360j), as*
 15 *amended by subsection (a)) require a report under*
 16 *section 510(k) to provide reasonable assurance of safe-*
 17 *ty and effectiveness.*

18 *(4) EFFECT ON STATE LAW.—No State or local*
 19 *government shall establish or continue in effect any*
 20 *law, regulation, or order specifically applicable to*
 21 *hearing products that would restrict or interfere with*
 22 *the servicing, marketing, sale, dispensing, use, cus-*
 23 *tomers support, or distribution of over-the-counter*
 24 *hearing aids (as defined in section 520(q) of the Fed-*
 25 *eral Food, Drug, and Cosmetic Act (21 U.S.C. 360j),*

1 as amended by subsection (a)) through in-person
2 transactions, by mail, or online, that is different
3 from, in addition to, or otherwise not identical to, the
4 regulations promulgated under this subsection, in-
5 cluding any State or local requirement for the super-
6 vision, prescription, or other order, involvement, or
7 intervention of a licensed person for consumers to ac-
8 cess over-the-counter hearing aids.

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

22 (d) *STUDY.*—Not later than 3 years after the date of
23 enactment of this Act, the Comptroller General of the United
24 States shall submit to Congress a report evaluating con-
25 sumer experience with hearing health care, hearing screen-

1 *ing in the primary care setting, and consumer adoption,*
 2 *usage, and outcomes related to hearing technology. The*
 3 *Comptroller General shall update such report not later than*
 4 *2 years after the final regulations described in subsection*
 5 *(b) are issued, and shall evaluate how implementation of*
 6 *such regulations has impacted hearing health care, includ-*
 7 *ing recommendations for improving consumer access to ap-*
 8 *propriate hearing health care.*

9 ***TITLE VIII—ADDITIONAL*** 10 ***PROVISIONS***

11 ***SEC. 801. GAO REPORT.***

12 *(a) IN GENERAL.—Not later than September 30, 2018,*
 13 *the Comptroller General of the United States shall issue a*
 14 *report, after consultation with patients and drug and med-*
 15 *ical device manufacturers, regarding the implementation of*
 16 *sections 569A and 569B of the Federal Food, Drug, and*
 17 *Cosmetic Act (21 U.S.C. 360bbb–8a, 360bbb–8b). Such re-*
 18 *port shall assess the progress the Food and Drug Adminis-*
 19 *tration has made on—*

20 *(1) working with other regulatory authorities of*
 21 *similar standing to foster and encourage uniform, sci-*
 22 *entifically driven clinical trial standards with respect*
 23 *to medical products around the world;*

24 *(2) providing consistent parallel scientific advice*
 25 *to manufacturers seeking simultaneous global develop-*

1 *ment and approval of new medical products, in co-*
 2 *ordination with regulatory authorities of similar*
 3 *standing; and*

4 *(3) facilitating the use of foreign clinical trial*
 5 *data to minimize duplicative clinical trials.*

6 *(b) ADDITIONAL REQUIREMENTS.—The report under*
 7 *subsection (a) shall include specific examples, if possible*
 8 *and available, and a list of activities at the Food and Drug*
 9 *Administration regarding the harmonization of premarket*
 10 *medical product requirements.*

11 **SEC. 802. STREAMLINING AND IMPROVING CONSISTENCY IN**
 12 **PERFORMANCE REPORTING.**

13 *(a) PDUFA.—Section 736B(a) of the Federal Food,*
 14 *Drug, and Cosmetic Act (21 U.S.C. 379h–2(a)) is amend-*
 15 *ed—*

16 *(1) in paragraph (1)(B)—*

17 *(A) in clause (vi), by inserting “and the*
 18 *number of designations and denials issued by the*
 19 *agency for such applications” before the semi-*
 20 *colon;*

21 *(B) in clause (vii), by striking “; and” and*
 22 *inserting “and the number of designations and*
 23 *denials issued by the agency for such applica-*
 24 *tions; and”; and*

1 (C) in clause (viii) by striking the period
 2 and inserting “and the number of designations
 3 and denials issued by the agency for such appli-
 4 cations.”; and

5 (2) by inserting after paragraph (2) the fol-
 6 lowing:

7 “(3) *REAL TIME REPORTING.*—

8 “(A) *IN GENERAL.*—Beginning with fiscal
 9 year 2018, every 30 calendar days, the Secretary
 10 shall post the data described in subparagraph
 11 (B) on the Internet website of the Food and Drug
 12 Administration and remove duplicative data
 13 from the annual performance report.

14 “(B) *DATA.*—The following data is required
 15 to be posted in accordance with subparagraph
 16 (A):

17 “(i) The number and titles of draft and
 18 final guidance issued by the Center for
 19 Drug Evaluation and Research or the Cen-
 20 ter for Biologics Evaluation and Research,
 21 and the justification for the issuance and fi-
 22 nalization of each such guidance.

23 “(ii) The number and titles of public
 24 meetings held by the Center for Drug Eval-
 25 uation and Research and the Center for

1 *Biologics Evaluation and Research each fis-*
 2 *cal year.*

3 “(iii) *The list of standard new drug*
 4 *applications and biologics license applica-*
 5 *tions, by fiscal year of receipt.*

6 “(iv) *The number of filed applications*
 7 *by each review division.*

8 “(4) *CAPACITY PLANNING AND IMPROVED TIME*
 9 *REPORTING.—Beginning with fiscal year 2020, the*
 10 *Secretary shall include in the annual report under*
 11 *paragraph (1)—*

12 “(A) *the number of full-time equivalents*
 13 *agreed upon in the letters described in section*
 14 *101(b) of the Prescription Drug User Fee*
 15 *Amendments of 2017 and the number of appro-*
 16 *priated full time equivalents at the Food and*
 17 *Drug Administration by each division within the*
 18 *Center for Drug Evaluation and Research, the*
 19 *Center for Biologics Evaluation and Research,*
 20 *the Office of Regulatory Affairs, and the Office*
 21 *of the Commissioner;*

22 “(B) *identification by name of all time re-*
 23 *porting categories that Food and Drug Adminis-*
 24 *tration uses for capacity planning and time re-*
 25 *porting with respect to the Center for Drug Eval-*

1 *uation and Research, the Center for Biologics*
2 *Evaluation and Research, the Office of Regu-*
3 *latory Affairs, and the Office of the Commis-*
4 *sioner, pursuant to the ‘resource capacity plan-*
5 *ning and modernized time reporting implemen-*
6 *tation plan’ in the letters described in section*
7 *101(b) of the Prescription Drug User Fee*
8 *Amendments of 2017;*

9 *“(C) the processes by which the Center for*
10 *Drug Evaluation and Research, the Center for*
11 *Biologics Evaluation and Research, the Office of*
12 *Regulatory Affairs, and the Office of the Com-*
13 *missioner require reporting on the amount of an*
14 *employee’s time that is dedicated to the review of*
15 *human drug applications, as required by the let-*
16 *ters described in section 101(b) of the Prescrip-*
17 *tion Drug User Fee Amendments of 2017, in-*
18 *cluding information regarding employees dedi-*
19 *cated to such activities on a full-time basis, and*
20 *employees dedicated to such activities on a part-*
21 *time basis; and*

22 *“(D) for each of the Center for Drug Eval-*
23 *uation and Research, the Center for Biologics*
24 *Evaluation and Research, the Office of Regu-*
25 *latory Affairs, and the Office of the Commis-*

sioner, the number of employees described in subparagraph (C) (both full-time equivalents and employees dedicated to such activities on a part-time basis) for whom time reporting is required as described in subparagraph (C), and the number of such employees required to estimate time dedicated to the review of human drug applications.”.

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

(1) by striking “Beginning with” and inserting the following:

“(i) GENERAL REQUIREMENTS.—Beginning with”; and

(2) by adding at the end the following:

“(ii) ADDITIONAL INFORMATION.—Beginning with fiscal year 2018, the annual report under this subparagraph shall include the progress of the Center for Devices and Radiological Health in achieving the goals, and future plans for meeting the goals, including, for each review division—

“(I) the number of premarket applications filed under section 515 per

1 *fiscal year for each review division,*
2 *and the number of approvable letters,*
3 *major deficiency letters, not approvable*
4 *letters, and denials for such applica-*
5 *tions;*

6 “(II) *the number of reports filed*
7 *under section 510(k) per fiscal year for*
8 *each review division and the number of*
9 *devices cleared or not substantially*
10 *equivalent for such reports; and*

11 “(III) *the number of expedited ac-*
12 *cess pathway designations for a fiscal*
13 *year for each review division and the*
14 *number of cleared or approved devices*
15 *or denials for such applications.*

16 “(iii) *REAL TIME REPORTING.—*

17 “(I) *IN GENERAL.—Beginning*
18 *with fiscal year 2018, the Secretary*
19 *shall, every 30 calendar days, post the*
20 *data described in subclause (II) on the*
21 *Internet website of the Food and Drug*
22 *Administration and remove duplicative*
23 *data from the annual report under this*
24 *subparagraph.*

1 “(II) *DATA.*—*The following data*
 2 *is required to be posted in accordance*
 3 *with subclause (I):*

4 “(aa) *The number and titles*
 5 *of draft and final guidance issued*
 6 *by the Center for Devices and Ra-*
 7 *diological Health and the jus-*
 8 *tification for the issuance and fi-*
 9 *nalization of such guidance.*

10 “(bb) *The number and titles*
 11 *of public meetings held by the*
 12 *Center for Devices and Radio-*
 13 *logical Health each fiscal year.”.*

14 (c) *GDUFA.*—*Section 744C(a) of the Federal Food,*
 15 *Drug, and Cosmetic Act (21 U.S.C. 379j–43(a)) is amend-*
 16 *ed—*

17 (1) *by striking “Beginning with” and inserting*
 18 *the following:*

19 “(1) *GENERAL REQUIREMENTS.*—*Beginning*
 20 *with”; and*

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

22 “(2) *ADDITIONAL INFORMATION.*—*Beginning*
 23 *with fiscal year 2018, the report under this subsection*
 24 *shall include the progress of the Office of Generic*

1 *Drugs in achieving the goals, and future plans for*
 2 *meeting the goals, including—*

3 “(A) *the number of original abbreviated*
 4 *new drug applications filed per fiscal year;*

5 “(B) *the number of amendments to abbrevi-*
 6 *ated new drug applications filed per fiscal*
 7 *year; and*

8 “(C) *the number of actions taken delineated*
 9 *by the type of action, including final approvals,*
 10 *tentative approvals, complete response letters,*
 11 *and the number of ‘refuse to receive’ letters*
 12 *issued by the Food and Drug Administration per*
 13 *fiscal year.*

14 “(3) *REAL TIME REPORTING.—*

15 “(A) *IN GENERAL.—Beginning with fiscal*
 16 *year 2018, the Secretary shall, every 30 calendar*
 17 *days, post the data described in subparagraph*
 18 *(B) on the Internet website of the Food and Drug*
 19 *Administration and remove duplicative data*
 20 *from the annual report under this subsection.*

21 “(B) *DATA.—The following data is required*
 22 *to be posted in accordance with subparagraph*
 23 *(A):*

24 “(i) *The number and titles of draft and*
 25 *final guidance issued by the Office of Ge-*

1 *neric Drugs and the justification for the*
 2 *issuance and finalization of such guidance.*

3 *“(ii) The number and titles of public*
 4 *meetings held by the Office of Generic Drugs*
 5 *each fiscal year.”.*

6 *(d) BsUFA.—Section 744I(a) of the Federal Food,*
 7 *Drug, and Cosmetic Act (21 U.S.C. 379j–53(a)) is amend-*
 8 *ed—*

9 *(1) by striking “Beginning with” and inserting*
 10 *the following:*

11 *“(1) GENERAL REQUIREMENTS.—Beginning*
 12 *with”; and*

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

14 *“(2) ADDITIONAL INFORMATION.—Beginning*
 15 *with fiscal year 2018, the report under this subsection*
 16 *shall include the progress of the Center for Biologics*
 17 *Evaluation and Research in achieving the goals, and*
 18 *future plans for meeting the goals, including—*

19 *“(A) information on all previous cohorts for*
 20 *which the Secretary has not given a complete re-*
 21 *sponse on all biosimilar biological product appli-*
 22 *cations and supplements in the cohort;*

23 *“(B) the number of original biosimilar bio-*
 24 *logical product applications filed per fiscal year,*
 25 *and the number of approvals or complete re-*

1 *sponse letters issued by the agency for such ap-*
2 *plications; and*

3 *“(C) the number of resubmitted original*
4 *biosimilar biological product applications filed*
5 *per fiscal year and the number of approvals or*
6 *complete response letters issued by the agency for*
7 *such applications.*

8 *“(3) REAL TIME REPORTING.—*

9 *“(A) IN GENERAL.—Beginning with fiscal*
10 *year 2018, the Secretary shall, every 30 calendar*
11 *days, post the data described in subparagraph*
12 *(B) on the Internet website of the Food and Drug*
13 *Administration and remove duplicative data*
14 *from the annual report under this subsection.*

15 *“(B) DATA.—The following data is required*
16 *to be posted in accordance with subparagraph*
17 *(A):*

18 *“(i) The number and titles of draft and*
19 *final guidance issued by the Center for*
20 *Drug Evaluation and Research and the*
21 *Center for Biologics Evaluation and Re-*
22 *search and the justification for the issuance*
23 *and finalization of such guidance.*

24 *“(ii) The number and titles of public*
25 *meetings held by the Center for Drug Eval-*

1 *uation and Research and the Center for*
2 *Biologic Evaluation and Research each fis-*
3 *cal year.”.*

4 “(4) *CAPACITY PLANNING AND TIME REPORT-*
5 *ING.—Beginning with fiscal year 2020, the Secretary*
6 *shall include in the annual report under paragraph*
7 *(1)—*

8 “(A) *the number of full-time equivalents*
9 *agreed upon in the letters described in section*
10 *401(b) of the Biosimilar User Fee Amendments*
11 *of 2017 and the number of appropriated full*
12 *time equivalents at the Food and Drug Adminis-*
13 *tration by each division within the Center for*
14 *Drug Evaluation and Research, the Center for*
15 *Biologics Evaluation and Research, the Office of*
16 *Regulatory Affairs, and the Office of the Com-*
17 *missioner;*

18 “(B) *identification by name of all time re-*
19 *porting categories that the Food and Drug Ad-*
20 *ministration uses for capacity planning and*
21 *time reporting under the ‘resource capacity plan-*
22 *ning and modernized time reporting implemen-*
23 *tation plan’ in the letters described in section*
24 *401(b) of the Biosimilar User Fee Amendments*
25 *of 2017 for the Center for Drug Evaluation and*

1 *Research, the Center for Biologics Evaluation*
2 *and Research, the Office of Regulatory Affairs*
3 *and the Office of the Commissioner;*

4 “(C) *the process by which the Center for*
5 *Drug Evaluation and Research, the Center for*
6 *Biologics Evaluation and Research, the Office of*
7 *Regulatory Affairs, and the Office of the Com-*
8 *missioner require reporting on the amount of an*
9 *employee’s time that is dedicated to the review of*
10 *biosimilar biological product applications, re-*
11 *quired pursuant to the letters described in sec-*
12 *tion 401(b) of the Biosimilar User Fee Amend-*
13 *ments of 2017, including information regarding*
14 *both employees dedicated to such activities on a*
15 *full-time basis, and employees dedicated to such*
16 *activities on a part-time basis; and*

17 “(D) *for each of the Center for Drug Eval-*
18 *uation and Research, the Center for Biologics*
19 *Evaluation and Research, the Office of Regu-*
20 *latory Affairs, and the Office of the Commis-*
21 *sioner, the actual number of employees described*
22 *in subparagraph (C) (both full-time equivalents*
23 *and employees dedicated to such activities on a*
24 *part-time basis) for whom time reporting is re-*
25 *quired as described in subparagraph (C), and the*

1 *number of such employees required to estimate*
 2 *time dedicated to the review of biosimilar bio-*
 3 *logical product applications.”.*

4 **SEC. 803. ANALYSIS OF USE OF FUNDS.**

5 *(a) PDUFA REPORTS.—*

6 *(1) ANALYSIS IN PDUFA PERFORMANCE RE-*
 7 *PORTS.—Section 736B(a) of the Federal Food, Drug,*
 8 *and Cosmetic Act (21 U.S.C. 379h–2(a)), as amended*
 9 *by section 802(a), is further amended by adding at*
 10 *the end the following:*

11 *“(5) ANALYSIS.—For each fiscal year, the Sec-*
 12 *retary shall include in the report under paragraph*
 13 *(1) an analysis of the following:*

14 *“(A) The difference between the number of*
 15 *human drug applications filed and the number*
 16 *of approvals or complete response letters issued*
 17 *by the agency, accounting for—*

18 *“(i) such applications filed during one*
 19 *fiscal year for which a decision is not sched-*
 20 *uled to be made until the following fiscal*
 21 *year;*

22 *“(ii) such applications pending with*
 23 *the Center for Drug Evaluation and Re-*
 24 *search and the Center for Biologics Evalua-*
 25 *tion and Research that did not meet the*

1 goals identified in the letters described in
2 section 101(b) of the Prescription Drug
3 User Fee Amendments of 2017 for the cor-
4 responding fiscal year and the future plans
5 of the Food and Drug Administration to
6 meet these goals; and

7 “(iii) the most common causes within
8 the agency for missing such goals.

9 “(B) Relevant data to determine whether
10 the Center for Drug Evaluation and Research
11 and the Center for Biologics Evaluation and Re-
12 search have met performance enhancement goals
13 identified in the letters described in section
14 101(b) of the Prescription Drug User Fee
15 Amendments of 2017 for the corresponding fiscal
16 year.

17 “(C) External or other circumstances im-
18 pacting the Center for Drug Evaluation and Re-
19 search, the Center for Biologics Evaluation and
20 Research, or the Food and Drug Administration,
21 that impacted the ability of the agency to meet
22 the review time and performance enhancement
23 goals identified in the letters described in section
24 101(b) of the Prescription Drug User Fee
25 Amendments of 2017.”.

1 (2) *ISSUANCE OF CORRECTIVE ACTION RE-*
 2 *PORTS.*—Section 736B of the Federal Food, Drug,
 3 and Cosmetic Act (21 U.S.C. 379h–2) is amended—

4 (A) by redesignating subsections (c) and (d)
 5 as subsections (e) and (f), respectively; and

6 (B) inserting after subsection (b) the fol-
 7 lowing:

8 “(c) *CORRECTIVE ACTION REPORT.*—Beginning with
 9 fiscal year 2018, and for each fiscal year for which fees are
 10 collected under this part, the Secretary shall prepare and
 11 submit a corrective action report to the Committee on En-
 12 ergy and Commerce and the Committee on Appropriations
 13 of the House of Representatives and the Committee on
 14 Health, Education, Labor, and Pensions and the Committee
 15 on Appropriations of the Senate upon submission of the
 16 performance report in subsection (a) for the corresponding
 17 fiscal year. The report shall include the following informa-
 18 tion, as applicable:

19 “(1) *GOALS MET.*—For each fiscal year, if the
 20 Secretary determines, based on the analysis under
 21 subsection (a)(5), that each of the goals identified in
 22 the letters described in section 101(b) of the Prescrip-
 23 tion Drug User Fee Amendments of 2017 for the cor-
 24 responding fiscal year have been met, the corrective
 25 action report shall include a summary of goals met,

1 *and recommendations on ways in which the Secretary*
 2 *can improve and streamline the human drug applica-*
 3 *tion review process.*

4 “(2) *GOALS MISSED.—For each of the goals iden-*
 5 *tified in the letters described in section 101(b) of the*
 6 *Prescription Drug User Fee Amendments of 2017 for*
 7 *the corresponding fiscal year that the Secretary deter-*
 8 *mines to not have been met, the corrective action re-*
 9 *port shall include a detailed justification for such de-*
 10 *termination and—*

11 “(A) *a detailed description of the cir-*
 12 *cumstances under which each drug application*
 13 *that missed the review goal time was approved*
 14 *during the first cycle review, as applicable;*

15 “(B) *aggregate data on the circumstances*
 16 *for all unapproved drug applications for which*
 17 *the review goal time was missed; and*

18 “(C) *the performance enhancement goals*
 19 *that were not achieved during the previous fiscal*
 20 *year and a detailed description of efforts the*
 21 *agency has put in place for the current fiscal*
 22 *year to improve the ability of the agency to meet*
 23 *each such goal, while maintaining standards of*
 24 *approval, for the current fiscal year.*

25 “(d) *ENHANCED COMMUNICATION.—*

1 “(1) *COMMUNICATIONS WITH CONGRESS.*—Each
2 *fiscal year, as applicable, representatives from the*
3 *Center for Drug Evaluation and Research and the*
4 *Center for Biologics Evaluation and Research shall*
5 *meet with representatives from the Committee on*
6 *Health, Education, Labor, and Pensions of the Senate*
7 *and the Committee on Energy and Commerce of the*
8 *House of Representatives to report on the contents de-*
9 *scribed in the reports under this section.*

10 “(2) *PARTICIPATION IN CONGRESSIONAL HEAR-*
11 *ING.*—Each *fiscal year, as applicable, representatives*
12 *from the Center for Drug Evaluation and Research*
13 *and the Center for Biologics Evaluation and Research*
14 *shall participate in a public hearing before the Com-*
15 *mittee on Health, Education, Labor, and Pensions of*
16 *the Senate and the Committee on Energy and Com-*
17 *merce of the House of Representatives, to report on*
18 *the contents described in the reports under this sec-*
19 *tion. Such hearing shall occur not later than 120*
20 *days after the end of each fiscal year for which fees*
21 *are collected under this part.*

22 “(3) *PUBLICLY AVAILABLE UPDATES.*—The *Sec-*
23 *retary shall provide an update on progress made for*
24 *the corrective action report during the following fiscal*
25 *year on the publically available Internet website of*

1 *the Food and Drug Administration every 30 business*
 2 *days.”.*

3 ***(b) MDUFA REPORTS.—***

4 ***(1) ANALYSIS IN MDUFA PERFORMANCE RE-***
 5 ***PORTS.—Section 738A(a)(1)(A) of the Federal Food,***
 6 ***Drug, and Cosmetic Act (21 U.S.C. 379j–1(a)(1)(A)),***
 7 *as amended by section 802(b), is further amended by*
 8 *adding at the end the following:*

9 ***“(iv) ANALYSIS.—For each fiscal year,***
 10 *the Secretary shall include in the report*
 11 *under clause (i) an analysis of the fol-*
 12 *lowing:*

13 ***“(I) The difference between the***
 14 *number of premarket applications filed*
 15 *under section 515 and applications*
 16 *filed under section 510(k) and the*
 17 *number of major deficiency letters, not*
 18 *approvable letters, and denials for such*
 19 *applications issued by the agency, ac-*
 20 *counting for—*

21 ***“(aa) such applications filed***
 22 *during one fiscal year for which a*
 23 *decision is not scheduled to be*
 24 *made until the following fiscal*
 25 *year;*

1 “(bb) such applications pend-
2 ing with the Center for Devices
3 and Radiological Health that did
4 not meet the goals as identified by
5 the letters described in section
6 201(b) of the Medical Device User
7 Fee Amendments of 2017 for the
8 corresponding fiscal year and the
9 future plans of the Food and Drug
10 Administration to meet these
11 goals; and

12 “(cc) the most common
13 causes within the agency for miss-
14 ing such goals.

15 “(II) Relevant data to determine
16 whether the Center Devices and Radio-
17 logical Health have met performance
18 enhancement goals identified by the let-
19 ters described in section 201(b) of the
20 Medical Device User Fee Amendments
21 of 2017 for the corresponding fiscal
22 year.

23 “(III) External or other cir-
24 cumstances impacting the Center De-
25 vices and Radiological Health or the

1 *Food and Drug Administration that*
 2 *impacted the ability of the agency to*
 3 *meet review time and performance en-*
 4 *hancement goals identified by the let-*
 5 *ters described in section 201(b) of the*
 6 *Medical Device User Fee Amendments*
 7 *of 2017.”.*

8 (2) *ISSUANCE OF CORRECTIVE ACTION RE-*
 9 *PORTS.—Section 738A(a) of the Federal Food, Drug,*
 10 *and Cosmetic Act (21 U.S.C. 379j–1(a)) is amend-*
 11 *ed—*

12 (A) *by redesignating paragraphs (2) and*
 13 (3) *as paragraphs (4) and (5), respectively; and*
 14 (B) *by inserting after paragraph (1) the fol-*
 15 *lowing:*

16 “(2) *CORRECTIVE ACTION REPORT.—Beginning*
 17 *with fiscal year 2018, and for each fiscal year for*
 18 *which fees are collected under this part, the Secretary*
 19 *shall prepare and submit a corrective action report to*
 20 *the Committee on Energy and Commerce and the*
 21 *Committee on Appropriations of the House of Rep-*
 22 *resentatives and the Committee on Health, Education,*
 23 *Labor, and Pensions and the Committee on Appro-*
 24 *priations of the Senate upon submission of the per-*
 25 *formance report in paragraph (1)(A) for the cor-*

1 *responding fiscal year. The report shall include the*
2 *following information, as applicable:*

3 *“(A) GOALS MET.—For each fiscal year, if*
4 *the Secretary determines, based on the analysis*
5 *under paragraph (1)(A)(iv), that each of the*
6 *goals identified by the letters described in section*
7 *201(b) of the Medical Device User Fee Amend-*
8 *ments of 2017 for the corresponding fiscal year*
9 *have been met, the corrective action report shall*
10 *include a summary of goals met, and rec-*
11 *ommendations on ways in which the Secretary*
12 *can improve and streamline the medical device*
13 *application review process.*

14 *“(B) GOALS MISSED.—For each of the goals*
15 *identified by the letters described in section*
16 *201(b) of the Medical Device User Fee Amend-*
17 *ments of 2017 for the corresponding fiscal year*
18 *that the Secretary determines to not have been*
19 *met, the corrective action report shall include a*
20 *detailed justification for such determination*
21 *and—*

22 *“(i) a detailed description of the cir-*
23 *cumstances under which each application or*
24 *report submitted under section 515 or sec-*
25 *tion 510(k) missed the review goal time but*

1 *was approved during the first cycle review,*
 2 *as applicable;*

3 “(ii) aggregate data on the cir-
 4 *cumstances for all unapproved medical de-*
 5 *vice applications for which the review goal*
 6 *time was missed; and*

7 “(iii) the performance enhancement
 8 *goals that were not achieved during the pre-*
 9 *vious fiscal year and a detailed description*
 10 *of efforts the agency has put in place for the*
 11 *current fiscal year to improve the ability of*
 12 *the agency to meet each such goal, while*
 13 *maintaining standards of approval, for the*
 14 *current fiscal year.*

15 “(3) *ENHANCED COMMUNICATION.—*

16 “(A) *COMMUNICATIONS WITH CONGRESS.—*
 17 *Each fiscal year, as applicable, representatives*
 18 *from the Center for Devices and Radiological*
 19 *Health shall meet with representatives from the*
 20 *Committee on Health, Education, Labor, and*
 21 *Pensions of the Senate and the Committee on*
 22 *Energy and Commerce of the House of Rep-*
 23 *resentatives to report on the contents described in*
 24 *the reports under this section.*

1 “(B) *PARTICIPATION IN CONGRESSIONAL*
 2 *HEARING.*—Each fiscal year, as applicable, rep-
 3 resentatives from the Center for Devices and Ra-
 4 diological Health shall participate in a public
 5 hearing before the Committee on Health, Edu-
 6 cation, Labor, and Pensions of the Senate and
 7 the Committee on Energy and Commerce of the
 8 House of Representatives, to report on the con-
 9 tents described in the reports under this section.
 10 Such hearing shall occur not later than 120 days
 11 after the end of each fiscal year for which fees
 12 are collected under this part.

13 “(C) *PUBLICLY AVAILABLE UPDATES.*—The
 14 Secretary shall provide an update on progress
 15 made for the corrective action report during the
 16 following fiscal year on the publically available
 17 Internet website of the Food and Drug Adminis-
 18 tration every 30 business days.”.

19 (c) *GDUFA REPORTS.*—

20 (1) *ANALYSIS IN GDUFA PERFORMANCE RE-*
 21 *PORTS.*—Section 744C(a) of the Federal Food, Drug,
 22 and Cosmetic Act (21 U.S.C. 379j–43(a)), as amended
 23 by section 802(c) is further amended by adding at the
 24 end the following:

1 “(4) *ANALYSIS.*—For each fiscal year, the Sec-
2 retary shall include in the report an analysis of the
3 following:

4 “(A) *The difference between the number of*
5 *abbreviated new drug applications filed and the*
6 *number of approvals or complete response letters*
7 *issued by the agency, accounting for —*

8 “(i) *such applications filed during one*
9 *fiscal year for which a decision is not sched-*
10 *uled to be made until the following fiscal*
11 *year;*

12 “(ii) *such applications pending with*
13 *the Office of Generic Drugs that did not*
14 *meet the goals identified by the letters de-*
15 *scribed in section 301(b) of the Generic*
16 *Drug User Fee Amendments of 2017 for the*
17 *corresponding fiscal year and the future*
18 *plans of the Food and Drug Administration*
19 *to meet these goals; and*

20 “(iii) *the most common causes within*
21 *the agency for missing such goals.*

22 “(B) *Relevant data to determine whether*
23 *the Office of Generic Drugs has met the perform-*
24 *ance enhancement goals identified by the letters*
25 *described in section 301(b) of the Generic Drug*

1 *User Fee Amendments of 2017 for the cor-*
 2 *responding fiscal year.*

3 “(C) *External or other circumstances im-*
 4 *pacting the Office of Generic Drugs or the Food*
 5 *and Drug Administration that impacted the*
 6 *ability of the agency to meet review time and*
 7 *performance enhancement goals identified by the*
 8 *letters described in section 301(b) of the Generic*
 9 *Drug User Fee Amendments of 2017.”.*

10 (2) *ISSUANCE OF CORRECTIVE ACTION RE-*
 11 *PORTS.—Section 744C of the Federal Food, Drug,*
 12 *and Cosmetic Act (21 U.S.C. 379j–43) is amended—*

13 (A) *by redesignating subsections (c) and (d)*
 14 *as subsections (e) and (f), respectively; and*

15 (B) *inserting after subsection (b) the fol-*
 16 *lowing:*

17 “(c) *CORRECTIVE ACTION REPORT.—Beginning with*
 18 *fiscal year 2018, and for each fiscal year for which fees are*
 19 *collected under this part, the Secretary shall prepare and*
 20 *submit a corrective action report to the Committee on En-*
 21 *ergy and Commerce and the Committee on Appropriations*
 22 *of the House of Representatives and the Committee on*
 23 *Health, Education, Labor, and Pensions and the Committee*
 24 *on Appropriations of the Senate upon submission of the*
 25 *performance report in subsection (a) for the corresponding*

1 *fiscal year. The report shall include the following informa-*
2 *tion, as applicable:*

3 “(1) *GOALS MET.*—*For each fiscal year, if the*
4 *Secretary determines, based on the analysis under*
5 *subsection (a)(4), that each of the goals identified by*
6 *the letters described in section 301(b) of the Generic*
7 *Drug User Fee Amendments of 2017 for the cor-*
8 *responding fiscal year have been met, the corrective*
9 *action report shall include a summary of goals met,*
10 *and recommendations on ways in which the Secretary*
11 *can improve and streamline the abbreviated new drug*
12 *application review process.*

13 “(2) *GOALS MISSED.*—*For each of the goals iden-*
14 *tified by the letters described in section 301(b) of the*
15 *Generic Drug User Fee Amendments of 2017 for the*
16 *corresponding fiscal year that the Secretary deter-*
17 *mines to not have been met, the corrective action re-*
18 *port shall include a detailed justification for such de-*
19 *termination and—*

20 “(A) *a detailed description of the cir-*
21 *cumstances under which each abbreviated new*
22 *drug application missed the review goal time but*
23 *was approved during the first cycle review, as*
24 *applicable;*

1 “(B) aggregate data on the circumstances
2 for all unapproved abbreviated new drug appli-
3 cations for which the review goal time was
4 missed; and

5 “(C) the performance enhancement goals
6 that were not achieved during the previous fiscal
7 year and a detailed description of efforts the
8 agency has put in place for the current fiscal
9 year to improve the ability of the agency to meet
10 each such goal for the current fiscal year.

11 “(d) *ENHANCED COMMUNICATION.*—

12 “(1) *COMMUNICATIONS WITH CONGRESS.*—Each
13 fiscal year, as applicable, representatives from the Of-
14 fice of Generic Drugs shall meet with representatives
15 from the Committee on Health, Education, Labor,
16 and Pensions of the Senate and the Committee on
17 Energy and Commerce of the House of Representa-
18 tives to report on the contents described in the reports
19 under this section.

20 “(2) *PARTICIPATION IN CONGRESSIONAL HEAR-*
21 *ING.*—Each fiscal year, as applicable, representatives
22 from the Center for Drug Evaluation and Research
23 shall participate in a public hearing before the Com-
24 mittee on Health, Education, Labor, and Pensions of
25 the Senate and the Committee on Energy and Com-

merce of the House of Representatives, to report on the contents described in the reports under this section. Such hearing shall occur not later than 120 days after the end of each fiscal year for which fees are collected under this part.

“(3) *PUBLICLY AVAILABLE UPDATES.*—The Secretary shall provide an update on progress made for the corrective action report during the following fiscal year on the publically available Internet website of the Food and Drug Administration every 30 business days.”.

(d) *BSUFA REPORTS.*—

(1) *ANALYSIS IN BSUFA PERFORMANCE REPORTS.*—Section 744I(a) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 379j–53(a)) as amended by section 802(d) is further amended by adding at the end the following:

“(5) *ANALYSIS.*—For each fiscal year, the Secretary shall include in the report an analysis of the following:

“(A) The difference between the number of biosimilar biological product applications and supplements filed and the number of approvals or complete response letters issued by the agency, accounting for—

1 “(i) such applications filed during one
2 fiscal year for which a decision is not sched-
3 uled to be made until the following fiscal
4 year;

5 “(ii) such applications pending with
6 the Center for Drug Evaluation and Re-
7 search or the Center for Biologics Evalua-
8 tion and Research that did not meet the
9 goals identified by the letters described in
10 section 401(b) of the Biosimilar User Fee
11 Amendments of 2017 for the corresponding
12 fiscal year and the future plans of the Food
13 and Drug Administration to meet these
14 goals; and

15 “(iii) the most common causes within
16 the agency for missing such goals.

17 “(B) Relevant data to determine whether
18 the Center for Drug Evaluation and Research
19 and the Center for Biologics Evaluation and Re-
20 search have met the performance enhancement
21 goals identified by the letters described in section
22 401(b) of the Biosimilar User Fee Amendments
23 of 2017 for the corresponding fiscal year.

24 “(C) External or other circumstances im-
25 pacting the Center for Drug Evaluation and Re-

1 *search, the Center for Biologics Evaluation and*
 2 *Research, and the Food and Drug Administra-*
 3 *tion that impacted the ability of the agency to*
 4 *meet review time and performance enhancement*
 5 *goals identified by the letters described in section*
 6 *401(b) of the Biosimilar User Fee Amendments*
 7 *of 2017.”.*

8 (2) *ISSUANCE OF CORRECTIVE ACTION RE-*
 9 *PORTS.—Section 744I of the Federal Food, Drug, and*
 10 *Cosmetic Act (21 U.S.C. 379j–53), as amended by sec-*
 11 *tion 404, is further amended—*

12 *(A) by redesignating subsections (c) and (d)*
 13 *as subsections (e) and (f), respectively; and*

14 *(B) inserting after subsection (b) the fol-*
 15 *lowing:*

16 “(c) *CORRECTIVE ACTION REPORT.—Beginning with*
 17 *fiscal year 2018, and for each fiscal year for which fees are*
 18 *collected under this part, the Secretary shall prepare and*
 19 *submit a corrective action report to the Committee on En-*
 20 *ergy and Commerce and Committee on Appropriations of*
 21 *the House of Representatives and the Committee on Health,*
 22 *Education, Labor, and Pensions and Committee on Appro-*
 23 *priations of the Senate upon submission of the performance*
 24 *report in subsection (a) for the corresponding fiscal year.*

1 *The report shall include the following information, as ap-*
2 *plicable:*

3 “(1) *GOALS MET.*—*For each fiscal year, if the*
4 *Secretary determines, based on the analysis under*
5 *subsection (a)(5), that each of the goals identified by*
6 *the letters described in section 401(b) of the Bio-*
7 *similar User Fee Amendments of 2017 for the cor-*
8 *responding fiscal year have been met, the corrective*
9 *action report shall include a summary of goals met,*
10 *and recommendations on ways in which the Secretary*
11 *can improve and streamline the biosimilar biological*
12 *product application review process.*

13 “(2) *GOALS MISSED.*—*For each of the goals iden-*
14 *tified by the letters described in section 401(b) of the*
15 *Biosimilar User Fee Amendments of 2017 for the cor-*
16 *responding fiscal year that the Secretary determines*
17 *to not have been met, the corrective action report shall*
18 *include a detailed justification for such determination*
19 *and—*

20 “(A) *a detailed description of the cir-*
21 *cumstances under which each biosimilar biologi-*
22 *cal product application missed the review goal*
23 *time but was approved during the first cycle re-*
24 *view, as applicable;*

1 “(B) aggregate data on the circumstances
2 for all biosimilar biological product applications
3 for which the review goal time was missed; and

4 “(C) the performance enhancement goals
5 that were not achieved during the previous fiscal
6 year and a detailed description of efforts the
7 agency has put in place for the current fiscal
8 year to improve the ability of the agency to meet
9 each such goal for the current fiscal year.

10 “(d) *ENHANCED COMMUNICATION.*—

11 “(1) *COMMUNICATIONS WITH CONGRESS.*—Each
12 fiscal year, as applicable, representatives from the
13 Center for Drug Evaluation and Research and the
14 Center for Biologics Evaluation and Research shall
15 meet with representatives from the Committee on
16 Health, Education, Labor, and Pensions of the Senate
17 and the Committee on Energy and Commerce of the
18 House of Representatives to report on the contents de-
19 scribed in the reports under this section.

20 “(2) *PARTICIPATION IN CONGRESSIONAL HEAR-*
21 *ING.*—Each fiscal year, as applicable, representatives
22 from the Center for Drug Evaluation and Research
23 and the Center for Biologics Evaluation and Research
24 shall participate in a public hearing before the Com-
25 mittee on Health, Education, Labor, and Pensions of

1 *the Senate and the Committee on Energy and Com-*
 2 *merce of the House of Representatives, to report on*
 3 *the contents described in the reports under this sec-*
 4 *tion. Such hearing shall occur not later than 120*
 5 *days after the end of each fiscal year for which fees*
 6 *are collected under this part.*

7 “(3) *PUBLICLY AVAILABLE UPDATES.*—*The Sec-*
 8 *retary shall provide an update on progress made for*
 9 *the corrective action report during the following fiscal*
 10 *year on the publically available Internet website of*
 11 *the Food and Drug Administration every 30 business*
 12 *days.”.*

13 **SEC. 804. INFORMATION ON TECHNOLOGY CONTRACTING.**

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

16 (1) *by striking “report on the” and inserting*
 17 *“report on—*

18 *“(1) the”;*

19 (2) *by striking the period at the end and insert-*
 20 *ing “; and”;*

21 (3) *by adding at the end the following:*

22 *“(2) the amount of the fees collected that are in-*
 23 *vested in the information technology infrastructure of*
 24 *the Food and Drug Administration, the entities re-*
 25 *ceiving contracts to develop such infrastructure, the*

1 *length of such contracts (including renewals), and the*
 2 *progress such entities have made toward meeting the*
 3 *goals described in such contracts.”.*

4 **SEC. 805. FACILITIES MANAGEMENT.**

5 (a) *EVALUATION.*—

6 (1) *STUDY.*—*The Comptroller General of the*
 7 *United States shall conduct a study on the expenses*
 8 *incurred by the Food and Drug Administration re-*
 9 *lated to facility maintenance and renovation in fiscal*
 10 *years 2012 through 2019. The study shall include the*
 11 *following:*

12 (A) *A review of purchases and expenses dif-*
 13 *ferentiated by appropriated funds, and resources*
 14 *authorized by the Food and Drug Administra-*
 15 *tion Safety and Innovation Act (Public Law*
 16 *112–144) and this Act, as applicable, that con-*
 17 *tributed to—*

18 (i) *the maintenance of scientific equip-*
 19 *ment and any existing facility plan or*
 20 *plans to maintain previously purchased sci-*
 21 *entific equipment;*

22 (ii) *the renovation of facilities in the*
 23 *Center for Drug Evaluation and Research,*
 24 *the Center for Biologics Evaluation and Re-*
 25 *search, and the Center for Devices and Ra-*

1 *diological Health, and the purpose of such*
2 *renovation including the need for the ren-*
3 *ovation;*

4 *(iii) the assets purchased or repaired*
5 *under the “repair of facilities and acquisi-*
6 *tion” authority under parts 2, 3, 7, and 8*
7 *of subchapter C of chapter VII of the Fed-*
8 *eral Food, Drug, and Cosmetic Act (21*
9 *U.S.C. 379f et seq.);*

10 *(iv) the maintenance and repair of fa-*
11 *cilities and fixtures, including a description*
12 *of any unanticipated repairs and mainte-*
13 *nance as well as scheduled repairs mainte-*
14 *nance, and the budget plan for the scheduled*
15 *or anticipated maintenance;*

16 *(v) the acquisition of furniture, a de-*
17 *scription of the furniture purchased, and*
18 *the purpose of the furniture including pur-*
19 *chases for the Center for Drug Evaluation*
20 *and Research, the Center for Biologics Eval-*
21 *uation and Research, and the Center for*
22 *Devices and Radiological Health; and*

23 *(vi) the acquisition of other necessary*
24 *materials and supplies by product category*
25 *under the authority under parts 2, 3, 7,*

1 *and 8 of subchapter C of chapter VII of the*
2 *Federal Food, Drug, and Cosmetic Act (21*
3 *U.S.C. 379f et seq.).*

4 *(B) An analysis of the Food and Drug Ad-*
5 *ministration's ability to further its public health*
6 *mission and review medical products by incur-*
7 *ring the expenses listed in clauses (i) through*
8 *(vi) of subparagraph (A). In conducting the*
9 *analysis, the Comptroller General shall request*
10 *information from and consult with appropriate*
11 *employees, including staff and those responsible*
12 *for the fiscal decisions regarding facility mainte-*
13 *nance and renovation for the agency.*

14 *(C) RECOMMENDATIONS.—The Comptroller*
15 *General may provide recommendations, as appli-*
16 *cable, on methods through which the Food and*
17 *Drug Administration may improve planning*
18 *for—*

19 *(i) the maintenance, renovation, and*
20 *repair of facilities;*

21 *(ii) the purchase of furniture or other*
22 *acquisitions; and*

23 *(iii) ways the agency may allocate the*
24 *expenses described in clauses (i) and (ii), as*

1 informed by the analysis under subpara-
2 graph (B).

3 (2) *REPORT.*—*The Comptroller General shall*
4 *issue a report to the Committee on Health, Edu-*
5 *cation, Labor, and Pensions of the Senate and the*
6 *Committee on Energy and Commerce of the House of*
7 *Representatives not later than September 30, 2020,*
8 *containing the results of the study under paragraph*
9 *(1).*

10 (b) *ADMINISTRATION.*—

11 (1) *PDUFA.*—*Section 736(f) of the Federal*
12 *Food, Drug, and Cosmetic Act (21 U.S.C. 379h(f)) is*
13 *amended by adding at the end the following:*

14 “(3) *LIMITATION.*—*Beginning on October 1,*
15 *2023, the authorities under section 735(7)(C) shall*
16 *only include expenditures for leasing and necessary*
17 *scientific equipment.”.*

18 (2) *MDUFA.*—*Section 738(h) of the Federal*
19 *Food, Drug, and Cosmetic Act (21 U.S.C. 379j(h)) is*
20 *amended by adding at the end the following:*

21 “(3) *LIMITATION.*—*Beginning on October 1,*
22 *2023, the authorities under section 737(9)(C) shall*
23 *only include leasing and necessary scientific equip-*
24 *ment.”.*

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

4 (A) in the subsection heading, by striking
 5 “*LIMIT*” and inserting “*LIMITATIONS*”;

6 (B) by striking “The total amount” and in-
 7 serting the following:

8 “(1) *IN GENERAL*.—The total amount”; and

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

10 “(2) *LEASING AND NECESSARY EQUIPMENT*.—Be-
 11 ginning on October 1, 2023, the authorities under sec-
 12 tion 744A(11)(C) shall only include leasing and nec-
 13 essary scientific equipment.”.

14 (4) *BSUFA*.—Section 744H(e)(2)(B) of the Fed-
 15 eral Food, Drug, and Cosmetic Act (21 U.S.C. 379j–
 16 52(e)(2)(B)) is amended—

17 (A) in the subparagraph heading, by strik-
 18 ing “*LIMITATION*” and inserting “*LIMITATIONS*”;

19 (B) by striking “The fees authorized” and
 20 inserting the following:

21 “(i) *IN GENERAL*.—The fees author-
 22 ized”; and

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

24 “(ii) *LEASING AND NECESSARY EQUIP-*
 25 *MENT*.—Beginning on October 1, 2023, the

1 *authorities under section 744G(9)(C) shall*
2 *only include leasing and necessary scientific*
3 *equipment.”.*

4 **SEC. 806. EXPANDED ACCESS.**

5 *(a) PATIENT ACCESS TO EXPERIMENTAL TREAT-*
6 *MENTS.—*

7 *(1) PUBLIC MEETING.—*

8 *(A) IN GENERAL.—The Secretary of Health*
9 *and Human Services (referred to in this section*
10 *as the “Secretary”), acting through the Commis-*
11 *sioner of Food and Drugs, in coordination with*
12 *the Director of the National Institutes of Health,*
13 *and in consultation with patients, health care*
14 *providers, drug sponsors, bioethicists, and other*
15 *stakeholders, shall, not later than 180 days after*
16 *the date of enactment of this Act, convene a pub-*
17 *lic meeting to discuss clinical trial inclusion and*
18 *exclusion criteria to inform the guidance under*
19 *paragraph (3). The Secretary shall inform the*
20 *Comptroller General of the United States of the*
21 *date when the public meeting will take place.*

22 *(B) TOPICS.—The Secretary shall provide a*
23 *publicly available report on the topics discussed*
24 *at the meeting described in subparagraph (A)*

1 *within 30 days of such meeting. Such topics*
2 *shall include discussion of—*

3 *(i) the rationale for, and potential bar-*
4 *riers for patients created by, clinical trial*
5 *inclusion and exclusion criteria;*

6 *(ii) how patient populations most like-*
7 *ly to be affected by a drug can benefit from*
8 *the results of trials that employ alternative*
9 *designs, as well as potential risks associated*
10 *with alternative clinical trial designs;*

11 *(iii) barriers to participation in clin-*
12 *ical trials, including—*

13 *(I) information regarding any po-*
14 *tential risks and benefits of participa-*
15 *tion;*

16 *(II) regulatory, geographical, and*
17 *socioeconomic barriers; and*

18 *(III) the impact of exclusion cri-*
19 *teria on the enrollment in clinical*
20 *trials of infants and children, pregnant*
21 *and lactating women, seniors, individ-*
22 *uals with advanced disease, and indi-*
23 *viduals with co-morbid conditions;*

24 *(iv) clinical trial designs and methods*
25 *that increase enrollment of more diverse pa-*

1 *tient populations while facilitating the col-*
 2 *lection of data to support substantial evi-*
 3 *dence of safety and effectiveness; and*

4 *(v) how changes to clinical trial inclu-*
 5 *sion and exclusion criteria may impact the*
 6 *complexity of the clinical trial design and*
 7 *length of clinical trials, and potential ap-*
 8 *proaches to mitigating those impacts to en-*
 9 *sure that the ability to demonstrate safety*
 10 *and effectiveness is not hindered through po-*
 11 *tential changes in eligibility criteria.*

12 *(2) REPORT.—Not later than 1 year after the*
 13 *Secretary issues a report on the topics discussed at*
 14 *the public meeting under paragraph (1)(B), the*
 15 *Comptroller General of the United States shall report*
 16 *to the Committee on Health, Education, Labor, and*
 17 *Pensions of the Senate and the Committee on Energy*
 18 *and Commerce of the House of Representatives on in-*
 19 *dividual access to investigational drugs through the*
 20 *expanded access program under section 561(b) of the*
 21 *Federal Food, Drug, and Cosmetic Act (21 U.S.C.*
 22 *360bbb(b)). The report shall include—*

23 *(A) a description of actions taken by manu-*
 24 *facturers under section 561A of the Federal Food,*
 25 *Drug, and Cosmetic Act (21 U.S.C. 360bbb–0);*

1 (B) consideration of whether Form FDA
2 3926 and the guidance document entitled “Ex-
3 panded Access to Investigational Drugs for
4 Treatment Use—Questions and Answers”, issued
5 by the Food and Drug Administration in June
6 2016, has reduced application burden with re-
7 spect to individuals and physicians seeking ac-
8 cess to investigational new drugs pursuant to
9 section 561(b) of the Federal Food, Drug, and
10 Cosmetic Act (21 U.S.C. 360bbb) and improved
11 clarity for patients, physicians, and drug manu-
12 facturers about such process;

13 (C) consideration of whether the guidance or
14 regulations released or updated under section
15 561 of the Federal Food, Drug, and Cosmetic Act
16 (21 U.S.C. 360bbb) have improved access for in-
17 dividual patients who do not qualify for clinical
18 trials of such investigational drugs, and what
19 barriers to such access remain;

20 (D) an assessment of how patients and
21 health care providers navigate different avenues
22 to engage with the Food and Drug Administra-
23 tion or drug sponsors on expanded access; and

24 (E) an analysis of the Secretary’s report
25 under paragraph (1)(B).

1 (3) *GUIDANCE*.—

2 (A) *IN GENERAL*.—Not later than 180 days
3 after the publication of the report under para-
4 graph (1), the Secretary, acting through the
5 Commissioner of Food and Drugs, shall issue one
6 or more draft guidances regarding eligibility cri-
7 teria for clinical trials. Not later than 18 months
8 after the public comment period on each such
9 draft guidance ends, the Secretary shall issue a
10 revised draft guidance or final guidance.

11 (B) *CONTENTS*.—The guidance documents
12 described in subparagraph (A) shall address
13 methodological approaches that a manufacturer
14 or sponsor of an investigation of a new drug
15 may take to—

16 (i) broaden eligibility criteria for clin-
17 ical trials, especially with respect to drugs
18 for the treatment of serious and life-threat-
19 ening conditions or diseases for which there
20 is an unmet medical need; and

21 (ii) develop eligibility criteria for, and
22 increase trial recruitment to, clinical trials
23 so that enrollment in such trials more accu-
24 rately reflects the patients most likely to re-
25 ceive the drug, as applicable and as appro-

1 *priate, while supporting findings of sub-*
2 *stantial evidence of safety and effectiveness.*

3 *(b) IMPROVING INSTITUTIONAL REVIEW BOARD RE-*
4 *VIEW OF SINGLE PATIENT EXPANDED ACCESS PRO-*
5 *TOCOL.—Not later than 1 year after the date of enactment*
6 *of this Act, the Secretary, acting through the Commissioner*
7 *of Food and Drugs, shall issue guidance or regulations, or*
8 *revise existing guidance or regulations, to streamline the*
9 *institutional review board review for individual pediatric*
10 *and adult patient expanded access protocol under 561(b)*
11 *of the Federal Food, Drug, and Cosmetic Act (21 U.S.C.*
12 *360bbb(b)). Such guidance or regulation may include a de-*
13 *scription of the conditions under which an institutional re-*
14 *view board chair (or designee) may review individual pa-*
15 *tient expanded access protocol submitted under section*
16 *505(i) of the Federal Food, Drug, and Cosmetic Act (21*
17 *U.S.C. 355(i)) for a drug and how centralized institutional*
18 *review boards may facilitate the use of expanded access pro-*
19 *ocols. The Secretary shall update any relevant forms asso-*
20 *ciated with individual patient expanded access protocol as*
21 *necessary.*

22 *(c) EXPANDED ACCESS POLICY TRANSPARENCY.—Sec-*
23 *tion 561A(f) of the Federal Food, Drug, and Cosmetic Act*
24 *(21 U.S.C. 360bbb–0(f)) is amended—*

1 (1) *in the matter preceding paragraph (1), by*
 2 *striking “later” and inserting “earlier”;*

3 (2) *by striking paragraph (1);*

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

6 (4) *in paragraph (1) as so redesignated, by strik-*
 7 *ing the period at the end and inserting “; or”; and*

8 (5) *by adding at the end the following:*

9 “(2) *as applicable, 15 days after the drug re-*
 10 *ceives a designation as a breakthrough therapy, fast*
 11 *track product, or regenerative advanced therapy*
 12 *under subsection (a), (b), or (g), respectively, of sec-*
 13 *tion 506.”.*

14 **SEC. 807. TECHNICAL CORRECTIONS.**

15 (a) *CROSS-REFERENCE.*—Section 3075(a) of the 21st
 16 *Century Cures Act (Public Law 114–255) is amended—*

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

20 (2) *in paragraph (2), by striking “section*
 21 *2074(1)(C)” and inserting “section 3102(1)(C)”.*

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

1 **TITLE IX—GENERIC DRUG**
 2 **ACCESS**
 3 **Subtitle A—Removing Regulatory**
 4 **Barriers to Competition**

5 **SEC. 901. IMPROVING ACCESS TO GENERIC DRUGS.**

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

9 “(11)(A) *The Secretary shall prioritize the review of,*
 10 *and act within 240 calendar days of the date of the submis-*
 11 *sion of, an original abbreviated new drug application sub-*
 12 *mitted for review under this subsection, or on a supplement*
 13 *to such an application, that is for a drug—*

14 “(i) *for which there are not more than 3 ap-*
 15 *proved drugs listed under paragraph (7), except that*
 16 *the review of an application submitted more than 30*
 17 *months in advance of the last applicable expiration*
 18 *date for a patent for which a certification under*
 19 *paragraph (2)(A)(vii)(III) has been submitted, or of*
 20 *the expiration date for an applicable period of exclu-*
 21 *sivity under this Act, will not be expedited; or*

22 “(ii) *that has been included on the list under sec-*
 23 *tion 506E.*

24 “(B) *The Secretary shall require the applicant, not*
 25 *later than 60 days prior to the submission of an application*

1 *described in subparagraph (A), to provide complete, accu-*
2 *rate information regarding facilities involved in manufac-*
3 *turing processes and testing, including facilities in cor-*
4 *responding Type II active pharmaceutical ingredients drug*
5 *master files submitted with an application and sites or or-*
6 *ganizations involved in bioequivalence and clinical studies*
7 *used to support the application, in order to make a deter-*
8 *mination regarding whether an inspection of an establish-*
9 *ment is necessary.*

10 “(C) *The Secretary may expedite an inspection or re-*
11 *inspection under section 704 of an establishment that pro-*
12 *poses to manufacture a drug described in subparagraph (A).*

13 “(D) *Nothing in this paragraph shall prevent the Sec-*
14 *retary from prioritizing the review of other applications as*
15 *the Secretary determines appropriate.*

16 “(12) *The Secretary shall provide review status up-*
17 *dates to applicants regarding applications under this sub-*
18 *section, as appropriate, including when the application is*
19 *awaiting final regulatory action by the office charged with*
20 *review.*

21 “(13) *The Secretary shall publish on the Internet*
22 *website of the Food and Drug Administration a list of all*
23 *drugs approved under subsection (b) for which all patents*
24 *and periods of exclusivity under this Act have expired. Such*
25 *list shall be updated at least once every 180 days.”.*

1 **SEC. 902. REPORTING ON PENDING GENERIC DRUG APPLI-**
2 **CATIONS, PRIORITY REVIEW APPLICATIONS,**
3 **AND INSPECTIONS.**

4 (a) *IN GENERAL.*—Not later than 180 calendar days
5 after the date of enactment of this Act, and quarterly there-
6 after until October 1, 2022, the Secretary of Health and
7 Human Services (referred to in this section as the “Sec-
8 retary”) shall post on the Internet website of the Food and
9 Drug Administration a report that provides—

10 (1) *the number of applications filed under sec-*
11 *tion 505(j) of the Federal Food, Drug, and Cosmetic*
12 *Act (21 U.S.C. 355(j)) awaiting action by the appli-*
13 *cant, including such applications that were filed*
14 *prior to October 1, 2014;*

15 (2) *the number of applications filed under sec-*
16 *tion 505(j) of the Federal Food, Drug, and Cosmetic*
17 *Act (21 U.S.C. 355(j)) awaiting action by the Sec-*
18 *retary, including such applications that were filed*
19 *prior to October 1, 2014;*

20 (3) *the number of applications filed under sec-*
21 *tion 505(j) of the Federal Food, Drug, and Cosmetic*
22 *Act (21 U.S.C. 355(j)) and prior approval supple-*
23 *ments withdrawn in each month covered by the re-*
24 *port;*

25 (4) *the mean and median approval and tentative*
26 *approval times for applications covered by the report;*

1 (5) *the number of applications described in*
 2 *paragraphs (1), (2), and (3) that are subject to pri-*
 3 *ority review; and*

4 (6) *the number of such applications on which the*
 5 *Secretary has taken action pursuant to section*
 6 *506H(b) of the Federal Food, Drug, and Cosmetic*
 7 *Act, as added by section 911.*

8 (b) *ANNUAL REPORT ON PRIORITY REVIEW APPLICA-*
 9 *TIONS.—*

10 (1) *IN GENERAL.—The Secretary shall submit to*
 11 *the Committee on Health, Education, Labor, and*
 12 *Pensions and the Special Committee on Aging of the*
 13 *Senate and the Committee on Energy and Commerce*
 14 *of the House of Representatives an annual report, not*
 15 *later than March 31 of each year, on the following:*

16 (A) *The number of applications filed under*
 17 *section 505(j) of the Federal Food, Drug, and*
 18 *Cosmetic Act (21 U.S.C. 355(j)) that are subject*
 19 *to priority review during the most recent cal-*
 20 *endar year and are awaiting action by the ap-*
 21 *plicant.*

22 (B) *The number of applications filed under*
 23 *section 505(j) of the Federal Food, Drug, and*
 24 *Cosmetic Act (21 U.S.C. 355(j)) that are subject*
 25 *to priority review during the most recent cal-*

1 *endar year and are awaiting action by the Sec-*
 2 *retary.*

3 *(C) The number of applications filed under*
 4 *section 505(j) of the Federal Food, Drug, and*
 5 *Cosmetic Act (21 U.S.C. 355(j)) that are subject*
 6 *to priority review during the most recent cal-*
 7 *endar year and have been approved by the Sec-*
 8 *retary.*

9 *(D) For each of subparagraphs (A) through*
 10 *(C), the number of such applications—*

11 *(i) for which there are not more than*
 12 *3 approved drugs listed under section*
 13 *505(j)(7) of the Federal Food, Drug, and*
 14 *Cosmetic Act (21 U.S.C. 355(j)(7)); and*

15 *(ii) the number of such applications*
 16 *that are for a drug on the drug shortage list*
 17 *under section 506E of the Federal Food,*
 18 *Drug, and Cosmetic Act (21 U.S.C. 356e).*

19 *(c) ANNUAL REPORT ON INSPECTIONS.—Not later than*
 20 *March 1 of each year, the Secretary shall post on the Inter-*
 21 *net website of the Food and Drug Administration—*

22 *(1) the average and median amount of time, fol-*
 23 *lowing a request by staff of the Food and Drug Ad-*
 24 *ministration reviewing an application or report sub-*
 25 *mitted under an applicable section described in sub-*

paragraph (A), (B), or (C), to schedule and complete inspections of facilities necessary for—

(A) approval of a drug under section 505 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355);

(B) approval of a device under section 515 of such Act (21 U.S.C. 360e); and

(C) clearance of a device under section 510(k) of such Act (21 U.S.C. 360(k)); and

(2) the average and median amount of time to schedule and complete for-cause inspections of facilities of drugs and devices.

Subtitle B—Incentivizing Competition

SEC. 911. EXPEDITING GENERIC COMPETITION.

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

“SEC. 506H. EXPEDITING GENERIC DRUG DEVELOPMENT.

“(a) *IN GENERAL.*—The Secretary shall, at the request of an applicant, expedite the development and review of an application under subsection (j) of section 505 for a drug—

“(1) for which there are not more than 3 approved drug products listed under section 505(j)(7);

or

1 “(2) that is included on the list under section
2 506E.

3 “(b) *REQUEST FROM SPONSORS.*—A request to expedite the development and review of an application under
4 subsection (a) shall be submitted by the applicant prior to
5 the submission of such application.

6 “(c) *OTHER APPLICATIONS.*—Nothing in this section
7 shall prevent the Secretary from expediting the development
8 and review of other applications as the Secretary determines appropriate.

9 “(d) *ADDITIONAL COMMUNICATION.*—The Secretary
10 shall take such actions as are appropriate to expedite the
11 development and review of the application for approval of
12 a drug described in subsection (a), including, as appropriate—
13

14 “(1) holding meetings with the sponsor and the
15 review team throughout the development of the drug
16 prior to submission of the application;

17 “(2) providing timely advice to, and interactive
18 communication with, the sponsor regarding the development of the application to ensure that the collection
19 of nonclinical and clinical data necessary for approval is as efficient as practicable;

20 “(3) in the case of a complex product, assigning
21 a cross-disciplinary project lead for the review team
22

1 to facilitate an efficient review of the development
 2 program and application, including manufacturing
 3 inspections; and

4 “(4) in the case of a complex product, including
 5 drug-device combinations, involving senior managers
 6 and experienced review staff, as appropriate, in a col-
 7 laborative, cross- disciplinary review.

8 “(e) *REPORTING REQUIREMENT.*—A sponsor of a drug
 9 expedited under this section shall report to the Secretary,
 10 one year following approval of an application under section
 11 505(j), on whether the approved drug has been marketed
 12 in interstate commerce since approval.”.

13 **SEC. 912. LIST OF GENERIC DRUGS WITH LIMITED COM-**
 14 **PETITION.**

15 Chapter V of the Federal Food, Drug, and Cosmetic
 16 Act (21 U.S.C. 351 et seq.) is amended by inserting after
 17 section 506H, as added by section 911, the following:

18 **“SEC. 506I. DRUG LISTING.**

19 “(a) *REMOVAL, WITHDRAWAL, OR TRANSFER.*—The
 20 holder of an application approved under subsection (b) or
 21 (j) of section 505 shall notify the Secretary within 180 days
 22 of removing the drug that is the subject of such application
 23 from interstate commerce, withdrawing such approved ap-
 24 plication, or transferring such approved application, and
 25 a reason for such removal, withdrawal, or transfer. If com-

1 *pliance with this subsection within such 180-day period is*
 2 *not practicable, then the holder shall comply as soon as*
 3 *practicable. The Secretary shall cross-reference information*
 4 *listed pursuant to section 506C where applicable to avoid*
 5 *duplicative reporting.*

6 “(b) *DRUGS WITH LIMITED COMPETITION.*—

7 “(1) *INFORMATION.*—*The Secretary shall—*

8 “(A) *maintain information with respect to*
 9 *applications approved under section 505(j); and*

10 “(B) *publish on the Internet website of the*
 11 *Food and Drug Administration such informa-*
 12 *tion under subparagraph (A) with respect to*
 13 *drugs for which there are 3 or fewer application*
 14 *holders; and*

15 “(C) *update the information published pur-*
 16 *suant to subparagraph (B) every 180 days.*

17 “(2) *CONTENTS.*—*The public information main-*
 18 *tained and published under paragraph (1)(B) shall*
 19 *include—*

20 “(A) *the name of the drug, name of the*
 21 *holder of the approved application, and the mar-*
 22 *keting status for each drug; and*

23 “(B) *an indication of whether the Secretary*
 24 *considers the drug to be for the treatment or pre-*
 25 *vention of a serious disease or medical condition,*

1 *for which there is no alternative drug that is*
 2 *judged by medical professionals to be an ade-*
 3 *quate substitute available in adequate supply.*

4 “(c) *PUBLIC HEALTH EXCEPTION.*—*The Secretary*
 5 *may choose not to make information collected under this*
 6 *section publicly available if the Secretary determines that*
 7 *disclosure of such information would adversely affect the*
 8 *public health.*

9 “(d) *NOTIFICATION.*—*When the Secretary first pub-*
 10 *lishes the information under subsection (b), the Secretary*
 11 *shall notify relevant Federal agencies, including the Centers*
 12 *for Medicare & Medicaid Services and the Federal Trade*
 13 *Commission, that the information has been published and*
 14 *will be updated regularly.”.*

15 **SEC. 913. SUITABILITY PETITIONS.**

16 (a) *IN GENERAL.*—*It is the sense of the Senate that*
 17 *the Food and Drug Administration shall meet the require-*
 18 *ment under section 505(j)(2)(C) of the Federal Food, Drug,*
 19 *and Cosmetic Act (21 U.S.C. 355(j)(2)(C)) and section*
 20 *314.93(e) of title 21, Code of Federal Regulations, of re-*
 21 *sponding to suitability petitions within 90 days of submis-*
 22 *sion.*

23 (b) *REPORT.*—*The Secretary of Health and Human*
 24 *Services shall include in the annual reports under section*
 25 *902(b)—*

1 (1) *the number of pending petitions under sec-*
 2 *tion 505(j)(2)(C) of the Federal Food, Drug, and Cos-*
 3 *metic Act (21 U.S.C. 355(j)(2)(C)); and*

4 (2) *the number of such petitions pending a sub-*
 5 *stantive response for more than 180 days from the*
 6 *date of receipt.*

7 **SEC. 914. INSPECTIONS.**

8 *Section 505(j) of the Federal Food, Drug, and Cos-*
 9 *metic Act (21 U.S.C. 355(j)), as amended by section 901,*
 10 *is further amended by adding at the end the following:*

11 “(14) *If the Secretary issues feedback pursuant to sec-*
 12 *tion 704(b)(2) with respect to information submitted in re-*
 13 *sponse to a report under section 704(b)(1), and a report*
 14 *that was issued under section 704(b)(1) is the only obstacle*
 15 *to approval of an application under this subsection or the*
 16 *Secretary determines that the public health benefit of ap-*
 17 *proving an application under this subsection outweighs any*
 18 *risk to public health, the Secretary shall, within 45 days*
 19 *of notification by the applicant that necessary changes have*
 20 *been made to the establishment to address any findings or*
 21 *deficiencies identified previously by the Secretary—*

22 “(A) *re-inspect the establishment with respect to*
 23 *which the report was issued; or*

1 “(B) make a determination regarding the re-
2 sponse to such report and review of such applica-
3 tion.”.

Calendar No. 76

115TH CONGRESS
1ST Session

S. 934

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.

May 11, 2017

Reported with an amendment