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(Original Signature of Member)

115TH CONGRESS
1ST SESSION

H. R.

To amend the Federal Food, Drug, and Cosmetic Act to revise and extend the user-fee programs for prescription drugs, medical devices, generic drugs, and biosimilar biological products, and for other purposes.

IN THE HOUSE OF REPRESENTATIVES

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

A BILL

To amend the Federal Food, Drug, and Cosmetic Act to revise and extend the user-fee programs for prescription drugs, medical devices, generic drugs, and biosimilar biological products, and for other purposes.

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

3 **SECTION 1. SHORT TITLE.**

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

1 SEC. 2. TABLE OF CONTENTS.

2 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.
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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—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.

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 capaci-
20 ty 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

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

3 “(i) the average annual percent
4 change in the cost, per full-time equivalent
5 position of the Food and Drug Administra-
6 tion, of all personnel compensation and
7 benefits paid with respect to such positions
8 for the first 3 years of the preceding 4 fis-
9 cal years, multiplied by the proportion of
10 personnel compensation and benefits costs
11 to total costs of the process for the review
12 of human drug applications (as defined in
13 section 735(6)) for the first 3 years of the
14 preceding 4 fiscal years; and

15 “(ii) the average annual percent
16 change that occurred in the Consumer
17 Price Index for urban consumers (Wash-
18 ington-Baltimore, DC–MD–VA–WV; Not
19 Seasonally Adjusted; All items; Annual
20 Index) for the first 3 years of the pre-
21 ceding 4 years of available data multiplied
22 by the proportion of all costs other than
23 personnel compensation and benefits costs
24 to total costs of the process for the review
25 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 “(II) 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-

1 counting or consulting firm, a report evalu-
2 ating options and recommendations for a
3 new methodology to accurately assess
4 changes in the resource and capacity needs
5 of the process for the review of human
6 drug applications. The capacity planning
7 methodological options and recommenda-
8 tions presented in such report shall utilize
9 and be informed by personnel time report-
10 ing data as an input. The report shall be
11 published for public comment no later than
12 the end of fiscal year 2020.

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

19 “(I) replace the interim method-
20 ology under subparagraph (B);

21 “(II) incorporate such ap-
22 proaches and attributes as the Sec-
23 retary determines appropriate; and

24 “(III) be effective beginning with
25 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 Adjusted;
7 All Items; Annual Index) for the most re-
8 cent year of available data, divided by such
9 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 736(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(c) of the Federal Food, Drug, and Cosmetic Act (21
3 U.S.C. 379j(c)) is amended—

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

6 (2) in paragraph (2)—

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

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

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

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

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

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

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

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

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

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

18 (3) in paragraph (3)—

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

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

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

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

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

7 (2) in paragraph (2)(C)—

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

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

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

17 (f) FEE WAIVER OR REDUCTION.—

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

21 (2) CONFORMING CHANGES.—

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

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

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

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

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

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

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

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

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

1 (i) CREDITING AND AVAILABILITY OF FEES.—Sub-
2 section (h), as 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 (e)” and all
9 that follows through the period at the end and
10 inserting “subsection (e).”; and

11 (2) by striking paragraph (4).

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

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

16 (1) in paragraph (1)—

17 (A) in subparagraph (A)—

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

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

16 signed), 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 (e), 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 such
13 date as the Secretary specifies in final guidance
14 issued under subparagraph (C), presubmissions
15 and submissions for devices described in para-
16 graph (1) (and any appeals of action taken by
17 the Secretary with respect to such
18 presubmissions or submissions) shall be sub-
19 mitted solely in such electronic format as speci-
20 fied by the Secretary in such guidance.

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

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

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

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

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

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

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

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

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

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

12 **SEC. 210. SUNSET CLAUSE.**

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

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

20 (c) PREVIOUS SUNSET PROVISION.—

21 (1) IN GENERAL.—Effective October 1, 2017,
22 section 207(a) of the Medical Device User Fee
23 Amendments of 2012 (Public Law 112–144) is re-
24 pealed.

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

6 **TITLE III—FEES RELATING TO**
7 **GENERIC DRUGS**

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

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

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

22 **SEC. 302. DEFINITIONS.**

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

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

4 “(i) for a positron emission tomog-
5 raphy drug; or

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

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

12 (3) by inserting after paragraph (4) the fol-
13 lowing:

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

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

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

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

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

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

13 (3) in paragraph (2)—

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

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

22 (B) in subparagraph (E)—

23 (i) in clause (i)—

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

1 “(I) the date”;

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

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

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

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

13 (4) in paragraph (3)—

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

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

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

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

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

6 (D) in subparagraph (D)—

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

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 generic 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 produces,” and all that follows through “such
11 a” and inserting “is identified in at least
12 one generic drug submission in which the
13 facility is approved to produce one or more
14 active pharmaceutical ingredients or in a
15 Type II active pharmaceutical ingredient
16 drug master file referenced in at least one
17 such”; and

18 (iv) in clause (iii), by striking “to fees
19 under both such clauses” and inserting
20 “only to the fee attributable to the manu-
21 facture of the finished dosage forms”; and
22 (B) by amending subparagraphs (C) and
23 (D) to read as follows:

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

23 (1) in paragraph (1)—

24 (A) in subparagraph (A)—

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

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

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

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

10 (B) in subparagraph (B)—

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

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

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

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

21 (2) in paragraph (2)—

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

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

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

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

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

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

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

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

25 (D) in subparagraph (D)—

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

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

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

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

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

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

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

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

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

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

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

4 (1) in paragraph (1)—

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

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

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

13 (2) in paragraph (2)—

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

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

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

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

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

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

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

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

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

17 (1) by striking paragraph (1);

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

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

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

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

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

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

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

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

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

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

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

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

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

20 (f) EFFECT OF FAILURE TO PAY FEES.—Section
21 744B(g) of the Federal Food, Drug, and Cosmetic Act
22 (21 U.S.C. 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 PPLICATIONS OWNED 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, on behalf of the person and its affiliates, to the
13 Secretary a list of —

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

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

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

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

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

4 (1) in subsection (a)—

5 (A) by striking “2013” and inserting
6 “2018”; and

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

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

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

14 **SEC. 305. SUNSET DATES.**

15 (a) AUTHORIZATION.—Sections 744A and 744B of
16 the Federal Food, Drug, and Cosmetic Act (21 U.S.C.
17 379j-41; 379j-42) shall cease to be effective October 1,
18 2022.

19 (b) REPORTING REQUIREMENTS.—Section 744C of
20 the Federal Food, Drug, and Cosmetic Act (21 U.S.C.
21 379j-43) 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 304 of the
24 Food and Drug Administration Safety and Innovation Act
25 (Public Law 112-144) are repealed.

1 **SEC. 306. 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 7 of
5 subchapter C of chapter VII of the Federal Food, Drug,
6 and Cosmetic Act shall be assessed for all abbreviated new
7 drug applications received on or after October 1, 2017,
8 regardless of the date of the enactment of this Act.

9 **SEC. 307. SAVINGS CLAUSE.**

10 Notwithstanding the amendments made by this title,
11 part 7 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 abbreviated new drug applica-
15 tions (as defined in such part as of such day) that on or
16 after October 1, 2012, but before October 1, 2017, were
17 received by the Food and Drug Administration within the
18 meaning of 505(j)(5)(A) of such Act (21 U.S.C.
19 355(j)(5)(A)), prior approval supplements that were sub-
20 mitted, and drug master files for Type II active pharma-
21 ceutical ingredients that were first referenced with respect
22 to assessing and collecting any fee required by such part
23 for a fiscal year prior to fiscal 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 au-
8 thorized by the amendments made in this title will be dedi-
9 cated to expediting the process for the review of biosimilar
10 biological product applications, including postmarket safe-
11 ty activities, as set forth in the goals identified for pur-
12 poses of part 8 of subchapter C of chapter VII of the Fed-
13 eral Food, Drug, and Cosmetic Act, in the letters from
14 the Secretary of Health and Human Services to the Chair-
15 man of the Committee on Health, Education, Labor, and
16 Pensions of the Senate and the Chairman of the Com-
17 mittee on Energy and Commerce of the House of Rep-
18 resentatives, as set forth 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
24 a fiscal year is the Consumer Price Index for urban
25 consumers (Washington-Baltimore, DC–MD–VA–

1 WV; Not Seasonally Adjusted; All items; Annual
2 Index) for October of the preceding fiscal year di-
3 vided by such Index for October 2011.”.

4 (b) BIOSIMILAR BIOLOGICAL PRODUCT.—Section
5 744G(3) of the Federal Food, Drug, and Cosmetic Act
6 (21 U.S.C. 379j–51(3)) is amended by striking “means
7 a product” and inserting “means a specific strength of
8 a biological product in final dosage form”.

9 **SEC. 403. AUTHORITY TO ASSESS AND USE BIOSIMILAR**
10 **FEEES.**

11 (a) TYPES OF FEES.—Section 744H(a) of the Fed-
12 eral Food, Drug, and Cosmetic Act (21 U.S.C. 379j–
13 52(a)) is amended—

14 (1) in the matter preceding paragraph (1), by
15 striking “fiscal year 2013” and inserting “fiscal year
16 2018”;

17 (2) in the heading of paragraph (1), by striking
18 “BIOSIMILAR” and inserting “BIOSIMILAR BIOLOGI-
19 CAL PRODUCT”;

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

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

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

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

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

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

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

5 (9) in paragraph (1)(D)—

6 (A) in clause (i) in the matter preceding
7 subclause (I), by inserting “, if the person seeks
8 to resume participation in such program,” be-
9 fore “pay a fee”;

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

13 (C) in clause (i)(II), by inserting after
14 “discontinued)” the following: “by such per-
15 son”;

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

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

22 (12) in paragraph (1)(F)—

23 (A) in the heading of subparagraph (F), by
24 striking “BIOSIMILAR DEVELOPMENT PRO-
25 GRAM” before “FEES”; and

1 (B) by amending clause (i) to read as fol-
2 lows:

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

10 (13) in paragraph (2)—

11 (A) in the heading of paragraph (2), by
12 striking “AND SUPPLEMENT”;

13 (B) by amending subparagraphs (A) and
14 (B) to read as follows:

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

19 “(i) A fee established under sub-
20 section (c)(5) for a biosimilar biological
21 product application for which clinical data
22 (other than comparative bioavailability
23 studies) with respect to safety or effective-
24 ness are required for approval.

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

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

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

21 “(ii) be entitled to no reduction of
22 such application fees based on the amount
23 of fees paid for that product before Octo-
24 ber 1, 2017 under such subparagraphs
25 (A), (B), or (D).”;

1 (C) in the heading of subparagraph (D),
2 by striking “OR SUPPLEMENT”; and

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

4 (i) by striking “or supplement” each
5 place it appears; and

6 (ii) in subparagraph (D), by striking
7 “or a supplement”;

8 (14) by amending paragraph (3) to read as fol-
9 lows:

10 “(3) BIOSIMILAR BIOLOGICAL PRODUCT PRO-
11 GRAM FEE.—

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

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

21 “(ii) as of October 1 of such fiscal
22 year, does not appear on a list, developed
23 and maintained by the Secretary, of dis-
24 continued biosimilar biological products.

1 “(B) DUE DATE.—The biosimilar biological
2 product program fee for a fiscal year shall
3 be due on the later of—

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

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

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

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

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

24 “(b) FEE REVENUE AMOUNTS.—

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

4 “(A) \$45,000,000; and

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

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

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

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

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

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

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

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

7 “(i) initial and annual biosimilar 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 sub-
18 section (a) for a fiscal year after fiscal year
19 2018 shall not exceed 125 percent of the
20 amount of such fee for fiscal year 2018.

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

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

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

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

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

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

20 (2) in subsections (a)(2)(F) and (g), by striking
21 “subsection (c)” and inserting “subsection (d)”;

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

24 and

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

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

4 “(1) INFLATION ADJUSTMENT.—

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

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

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

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

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

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

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

20 “(2) CAPACITY PLANNING ADJUSTMENT.—

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

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

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

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

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

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

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

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

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

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

24 “(3) OPERATING RESERVE ADJUSTMENT.—

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

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

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

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

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

9 “(4) FISCAL YEAR 2018 ADJUSTMENT.—

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

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

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

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

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

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

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

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

1 (1) by striking subparagraph (B);

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

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

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

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

16 (1) in paragraph (2)—

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

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

1 (B) in subparagraph (D)—

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

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

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

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

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

11 (1) in subsection (a)—

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

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

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

19 (3) by striking subsection (d);

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

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

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

2 (a) AUTHORIZATION.—Sections 744G and 744H of
3 the Federal Food, Drug, and Cosmetic Act, as amended
4 by section 403 of this Act, shall cease to be effective Octo-
5 ber 1, 2022.

6 (b) REPORTING REQUIREMENTS.—Section 744I of
7 the Federal Food, Drug, and Cosmetic Act, as amended
8 by section 404 of this Act, shall cease to be effective Janu-
9 ary 31, 2023.

10 (c) PREVIOUS SUNSET PROVISION.—

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

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

20 **SEC. 406. EFFECTIVE DATE.**

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

1 1, 2017, regardless of the date of the enactment of this
2 Act.

3 **SEC. 407. SAVINGS CLAUSE.**

4 Notwithstanding the amendments made by this title,
5 part 8 of subchapter C of chapter VII of the Federal Food,
6 Drug, and Cosmetic Act, as in effect on the day before
7 the date of the enactment of this title, shall continue to
8 be in effect with respect to biosimilar biological product
9 applications and supplements (as defined in such part as
10 of such day) that were accepted by the Food and Drug
11 Administration for filing on or after October 1, 2012, but
12 before October 1, 2017, 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 **TITLE V—REAUTHORIZATION OF**
16 **OTHER PROGRAMS**

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

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

1 **SEC. 502. REAUTHORIZATION OF PEDIATRIC HUMANI-**
2 **TARIAN DEVICE EXCEPTIONS.**

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

6 **SEC. 503. REAUTHORIZATION OF THE CRITICAL PATH PUB-**
7 **LIC-PRIVATE PARTNERSHIPS.**

8 Section 566(f) of the Federal Food, Drug, and Cos-
9 metic Act (21 U.S.C. 360bbb–5(f)) is amended by striking
10 “2013 through 2017” and inserting “2018 through
11 2022”.

12 **SEC. 504. REAUTHORIZATION OF PEDIATRIC DEVICE CON-**
13 **SORTIA.**

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

18 **SEC. 505. REAUTHORIZATION OF ORPHAN GRANTS PRO-**
19 **GRAM.**

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

23 **SEC. 506. REAUTHORIZATION OF INSPECTION PROGRAM.**

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

1 **SEC. 507. REAUTHORIZATION OF PEDIATRIC STUDY OF**
2 **DRUGS.**

3 Section 409I(e)(1) of the Public Health Service Act
4 (42 U.S.C. 284m(e)(1)) is amended by striking “2013
5 through 2017” and inserting “2018 through 2022”.

6 **TITLE VI—ADDITIONAL**
7 **PROVISIONS**

8 **SEC. 601. TECHNICAL CORRECTIONS.**

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

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

14 (2) in paragraph (2), by striking “section
15 2074(1)(C)” and inserting “section 3102(1)(C)”.

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

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

22 (d) Section 505F(d) of the Federal Food, Drug, and
23 Cosmetic Act (21 U.S.C. 355g(d)) is amended by striking
24 “2” and inserting “3”.

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

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

4 (2) section 515C of the Federal Food, Drug,
5 and Cosmetic Act (21 U.S.C. 360e–3), as inserted
6 by such section 3051(a), is redesignated as section
7 515B.

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

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