

## COMMITTEE PRINT

[SHOWING THE TEXT OF H.R. 2430 AS FORWARDED BY THE SUBCOMMITTEE  
ON HEALTH ON MAY 18, 2017]

115TH CONGRESS  
1ST SESSION

# H. R. 2430

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

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### IN THE HOUSE OF REPRESENTATIVES

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

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## 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

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- Sec. 301. Short title; finding.
- Sec. 302. Definitions.
- Sec. 303. Authority to assess and use human generic drug fees.
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- Sec. 306. Effective date.
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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.
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TITLE V—REAUTHORIZATIONS AND IMPROVEMENTS RELATED TO DRUGS

- Sec. 501. Reauthorization of provision relating to exclusivity of certain drugs containing single enantiomers.
- Sec. 502. Reauthorization of orphan grants program.
- Sec. 503. Reauthorization of pediatric study of drugs.

Sec. 504. Protecting and strengthening the drug supply chain.

TITLE VI—DEVICE INSPECTION AND REGULATORY IMPROVEMENTS

Subtitle A—Improving the Process for Inspections of Device Establishments

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

Subtitle B—Other Provisions

- Sec. 611. Reauthorization of pediatric humanitarian device exceptions.
Sec. 612. Reauthorization of pediatric device consortia.
Sec. 613. Regulation of over-the-counter hearing aids.

TITLE VII—GENERIC DRUG ACCESS AND COMPETITION

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

TITLE VIII—ADDITIONAL PROVISIONS

- Sec. 801. Technical corrections.
Sec. 802. Reauthorization of the critical path public-private partnerships.

1 TITLE I—FEES RELATING TO
2 DRUGS

3 SEC. 101. SHORT TITLE; FINDING.

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

6 (b) FINDING.—The Congress finds that the fees au-
7 thorized by the amendments made in this title will be dedi-
8 cated toward expediting the drug development process and
9 the process for the review of human drug applications, in-
10 cluding postmarket drug safety activities, as set forth in
11 the goals identified for purposes of part 2 of subchapter

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

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

9 (a) TYPES OF FEES.—

10 (1) IN GENERAL.—Section 736(a) of the Fed-  
11 eral Food, Drug, and Cosmetic Act (21 U.S.C.  
12 379h(a)) is amended—

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

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

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

21 (D) in paragraph (1)(A)—

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

24 (ii) in clause (ii), by striking “A fee  
25 established” and all that follows through

1 “are required.” and inserting the following:

2 “A fee established under subsection (e)(5)  
3 for a human drug application for which  
4 clinical data (other than bioavailability or  
5 bioequivalence studies) with respect to  
6 safety or effectiveness are not required for  
7 approval.”;

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

10 (F) in paragraph (1)(F)—

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

13 (ii) by striking the second sentence;

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

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

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

22 (J) in subparagraph (A) of such paragraph  
23 (2), by amending the first sentence to read as  
24 follows: “Except as provided in subparagraphs  
25 (B) and (C), each person who is named as the

1 applicant in a human drug application, and  
2 who, after September 1, 1992, had pending be-  
3 fore the Secretary a human drug application or  
4 supplement, shall pay the annual prescription  
5 drug program fee established for a fiscal year  
6 under subsection (c)(5) for each prescription  
7 drug product that is identified in such a human  
8 drug application approved as of October 1 of  
9 such fiscal year.”;

10 (K) in subparagraph (B) of such para-  
11 graph (2)—

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

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

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

23 “(C) LIMITATION.—A person who is  
24 named as the applicant in an approved human  
25 drug application shall not be assessed more

1           than 5 prescription drug program fees for a fis-  
2           cal year for prescription drug products identi-  
3           fied in such approved human drug applica-  
4           tion.”.

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

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

12           (b) FEE REVENUE AMOUNTS.—Subsection (b) of sec-  
13           tion 736 of the Federal Food, Drug, and Cosmetic Act  
14           (21 U.S.C. 379h) is amended to read as follows:

15           “(b) FEE REVENUE AMOUNTS.—

16                   “(1) IN GENERAL.—For each of the fiscal years  
17           2018 through 2022, fees under subsection (a) shall,  
18           except as provided in subsections (c), (d), (f), and  
19           (g), be established to generate a total revenue  
20           amount under such subsection that is equal to the  
21           sum of—

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

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

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

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

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

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

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

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

18                  “(iii) \$16,953,329 for fiscal year  
19                  2020;

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

21                  and

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

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



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

4           “(B) 80 percent shall be derived from pre-  
5           scription drug program fees under subsection  
6           (a)(2).

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

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

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

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

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

22           “(1) INFLATION ADJUSTMENT.—

23           “(A) IN GENERAL.—For purposes of sub-  
24           section (b)(1)(B), the dollar amount of the in-  
25           flation adjustment to the annual base revenue

1 for each fiscal year shall be equal to the prod-  
2 uct of—

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

5 “(ii) the inflation adjustment percent-  
6 age under subparagraph (B).

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

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

23 “(ii) the average annual percent  
24 change that occurred in the Consumer  
25 Price Index for urban consumers (Wash-

1                   ington-Baltimore, DC–MD–VA–WV; Not  
2                   Seasonally Adjusted; All items; Annual  
3                   Index) for the first 3 years of the pre-  
4                   ceding 4 years of available data multiplied  
5                   by the proportion of all costs other than  
6                   personnel compensation and benefits costs  
7                   to total costs of the process for the review  
8                   of human drug applications (as defined in  
9                   section 735(6)) for the first 3 years of the  
10                  preceding 4 fiscal years.

11                  “(2) CAPACITY PLANNING ADJUSTMENT.—

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

21                   “(B) INTERIM METHODOLOGY.—

22                   “(i) IN GENERAL.—Until the capacity  
23                   planning methodology described in sub-  
24                   paragraph (C) is effective, the adjustment

1 under this paragraph for a fiscal year shall  
2 be based on the product of—

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

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

8 “(ii) ADJUSTMENT PERCENTAGE.—  
9 The adjustment percentage under this  
10 clause for a fiscal year is the weighted  
11 change in the 3-year average ending in the  
12 most recent year for which data are avail-  
13 able, over the 3-year average ending in the  
14 previous year, for—

15 “(I) the total number of human  
16 drug applications, efficacy supple-  
17 ments, and manufacturing supple-  
18 ments submitted to the Secretary;

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

22 “(III) the total number of formal  
23 meetings scheduled by the Secretary,  
24 and written responses issued by the  
25 Secretary in lieu of such formal meet-

1                   ings, as identified in section I.H of  
2                   the letters described in section 101(b)  
3                   of the Prescription Drug User Fee  
4                   Amendments of 2017.

5                   “(C)   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 human  
15                  drug applications. The capacity planning  
16                  methodological options and recommenda-  
17                  tions presented in such report shall utilize  
18                  and be informed by personnel time report-  
19                  ing data as an input. The report shall be  
20                  published for public comment no later than  
21                  the end of fiscal year 2020.

22                  “(ii)   ESTABLISHMENT   AND   IMPLE-  
23                  MENTATION.—After review of the report  
24                  described in clause (i) and any public com-  
25                  ments thereon, the Secretary shall estab-

1           lish a capacity planning methodology for  
2           purposes of this paragraph, which shall—

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

5                   “(II) incorporate such ap-  
6                   proaches and attributes as the Sec-  
7                   retary determines 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 cir-  
13                 cumstances shall an adjustment under this  
14                 paragraph result in fee revenue for a fiscal year  
15                 that is less than the sum of the amounts under  
16                 subsections (b)(1)(A) (the annual base revenue  
17                 for the fiscal year) and (b)(1)(B) (the dollar  
18                 amount of the inflation adjustment for the fis-  
19                 cal year).

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

25                 “(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  
5           fees if such an adjustment is necessary to pro-  
6           vide for not more than 14 weeks of operating  
7           reserves of carryover user fees for the process  
8           for the review of human drug applications.

9           “(B) DECREASE.—If the Secretary has  
10          carryover balances for such process in excess of  
11          14 weeks of such operating reserves, the Sec-  
12          retary shall decrease such fee revenue and fees  
13          to provide for not more than 14 weeks of such  
14          operating reserves.

15          “(C) NOTICE OF RATIONALE.—If an ad-  
16          justment under subparagraph (A) or (B) is  
17          made, the rationale for the amount of the in-  
18          crease or decrease (as applicable) in fee revenue  
19          and fees shall be contained in the annual Fed-  
20          eral Register notice under paragraph (5) estab-  
21          lishing fee revenue and fees for the fiscal year  
22          involved.

23          “(4) ADDITIONAL DIRECT COST ADJUST-  
24          MENT.—

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

5                   “(i) for fiscal year 2018, by  
6                   \$8,730,000; and

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

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

12                   “(i) \$8,730,000, multiplied by

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

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

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



1 section (b) and the adjustments provided under  
2 this subsection; and

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

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

10 (d) FEE WAIVER OR REDUCTION.—Section 736(d) of  
11 the Federal Food, Drug, and Cosmetic Act (21 U.S.C.  
12 379h(d)) is amended—

13 (1) in paragraph (1)—

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

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

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

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

21 (3) by redesignating paragraph (4) as para-  
22 graph (3); and

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

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

4 (B) in subparagraph (B)—

5 (i) by striking clause (ii);

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

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

11 (e) EFFECT OF FAILURE TO PAY FEES.—Section  
12 736(e) of the Federal Food, Drug, and Cosmetic Act (21  
13 U.S.C. 379h(e)) is amended by striking “all fees” and in-  
14 serting “all such fees”.

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

20 (g) CREDITING AND AVAILABILITY OF FEES.—Sec-  
21 tion 736(g) of the Federal Food, Drug, and Cosmetic Act  
22 (21 U.S.C. 379h(g)) is amended—

23 (1) in paragraph (3)—

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

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

3 (2) by striking paragraph (4).

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

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

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

12 (1) in subsection (a)(1)—

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

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

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

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

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

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

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

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

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

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

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

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

1 on or after October 1, 2012, but before October 1, 2017,  
2 were accepted by the Food and Drug Administration for  
3 filing with respect to assessing and collecting any fee re-  
4 quired by such part for a fiscal year prior to fiscal year  
5 2018.

## 6 **TITLE II—FEES RELATING TO** 7 **DEVICES**

### 8 **SEC. 201. SHORT TITLE; FINDINGS.**

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

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

### 23 **SEC. 202. DEFINITIONS.**

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

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

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

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

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

12 (4) in paragraph (11) (as redesignated by para-  
13 graph (1)), by striking “2011” and inserting  
14 “2016”.

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

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

19 (1) in paragraph (1), by striking “fiscal year  
20 2013” and inserting “fiscal year 2018”; and

21 (2) in paragraph (2)—

22 (A) in subparagraph (A)—

23 (i) in the matter preceding clause (i),  
24 by striking “October 1, 2012” and insert-  
25 ing “October 1, 2017”;

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

3 (iii) by adding at the end the fol-  
4 lowing new clause:

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

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

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

15 “(b) FEE AMOUNTS.—

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

22 “(2) BASE FEE AMOUNTS SPECIFIED.—For  
23 purposes of paragraph (1), the base fee amounts  
24 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

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  
13           inserting “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  
22                           year is the product of—



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

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

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

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

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

16 “(i) adjust the base fee amounts spec-  
17 ified in subsection (b)(2) for such fiscal  
18 year by multiplying such amounts by the  
19 applicable inflation adjustment under sub-  
20 paragraph (B) for such year; and

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

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

3 (3) in paragraph (3)—

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

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

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

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

16 (2) in paragraph (2)(C)—

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

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

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

1 (f) FEE WAIVER OR REDUCTION.—

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

5 (2) CONFORMING CHANGES.—

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

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

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

16 (ii) in subsection (a)(2)(A), by strik-  
17 ing “(d), (e), and (f)” and inserting “(d)  
18 and (e)”; and

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

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

1 (1) by striking “or periodic reporting con-  
2 cerning a class III device” and inserting “periodic  
3 reporting concerning a class III device, or de novo  
4 classification request”; and

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

7 (h) CONDITIONS.—Subsection (g)(1)(A), as redesi-  
8 gnated, of section 738 of the Federal Food, Drug, and Cos-  
9 metic Act (21 U.S.C. 379j) is amended by striking  
10 “\$280,587,000” and inserting “\$320,825,000”.

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

15 (1) in paragraph (3)—

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

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

21 (2) by striking paragraph (4).

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

23 (a) PERFORMANCE REPORTS.—Section 738A(a) of  
24 the Federal Food, Drug, and Cosmetic Act (21 U.S.C.  
25 379j-1(a)) is amended—

1 (1) in paragraph (1)—

2 (A) in subparagraph (A)—

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

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

9 (B) in subparagraph (B), by striking “the  
10 Medical Device User Fee Amendments of  
11 2012” and inserting “Medical Device User Fee  
12 Amendments of 2017”; and

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

15 (b) REAUTHORIZATION.—Section 738A(b) of the  
16 Federal Food, Drug, and Cosmetic Act (21 U.S.C. 379j-  
17 1(b)) is amended—

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

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

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

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

1       “(d) PILOT ACCREDITATION SCHEME FOR CON-  
2 FORMITY ASSESSMENT.—

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

5                       “(A) testing laboratories may be accred-  
6 ited, by accreditation bodies meeting criteria  
7 specified by the Secretary, to assess the con-  
8 formance of a device with certain standards rec-  
9 ognized under this section; and

10                      “(B) subject to paragraph (2), determina-  
11 tions by testing laboratories so accredited that  
12 a device conforms with such standard or stand-  
13 ards shall be accepted by the Secretary for pur-  
14 poses of demonstrating such conformity under  
15 this section unless the Secretary finds that a  
16 particular such determination shall not be so  
17 accepted.

18               “(2) SECRETARIAL REVIEW OF ACCREDITED  
19 LABORATORY DETERMINATIONS.—The Secretary  
20 may—

21                      “(A) review determinations by testing lab-  
22 oratories accredited pursuant to this subsection,  
23 including by conducting periodic audits of such  
24 determinations or processes of accredited bodies  
25 or testing laboratories and, following such re-

1 view, taking additional measures under this  
2 Act, such as suspension or withdrawal of ac-  
3 creditation of such testing laboratory under  
4 paragraph (1)(A) or requesting additional infor-  
5 mation with respect to such device, as the Sec-  
6 retary determines appropriate; and

7 “(B) if the Secretary becomes aware of in-  
8 formation materially bearing on safety or effec-  
9 tiveness of a device assessed for conformity by  
10 a testing laboratory so accredited, take such ad-  
11 ditional measures under this Act as the Sec-  
12 retary determines appropriate, such as suspen-  
13 sion or withdrawal of accreditation of such test-  
14 ing laboratory under paragraph (1)(A), or re-  
15 questing additional information with regard to  
16 such device.

17 “(3) IMPLEMENTATION AND REPORTING.—

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

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

3                   “(i) not later than September 30,  
4                   2019, issue draft guidance regarding the  
5                   goals and implementation of the pilot pro-  
6                   gram under this subsection; and

7                   “(ii) not later than September 30,  
8                   2021, issue final guidance with respect to  
9                   the implementation of such program.

10                  “(C) PILOT PROGRAM INITIATION.—Not  
11                  later than September 30, 2020, the Secretary  
12                  shall initiate the pilot program under this sub-  
13                  section.

14                  “(D) REPORT.—The Secretary shall make  
15                  available on the website of the Food and Drug  
16                  Administration an annual report on the  
17                  progress of the pilot program under this sub-  
18                  section.

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

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

24                  “(B) the Secretary—



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

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

6           “(C) except for purposes of accepting a de-  
7           termination described in subparagraph (B)(ii),  
8           the Secretary shall not continue to recognize  
9           the accreditation of testing laboratories accred-  
10          ited under paragraph (1)(A); and

11          “(D) the Secretary may take actions in ac-  
12          cordance with paragraph (2) with respect to the  
13          determinations made prior to such date and  
14          recognition of the accreditation of testing lab-  
15          oratories pursuant to determinations made  
16          prior to such date.”.

17 **SEC. 206. REAUTHORIZATION OF REVIEW.**

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

20                 (1) in subsection (a)(3)—

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

23                                 “(ii) a device classified under section  
24                                 513(f)(2) or designated under section  
25                                 515C(d); or

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

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

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

8 “(i) issue draft guidance on the fac-  
9 tors 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  
12 review by an accredited person, includ-  
13 ing—

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

16 “(II) whether the device type, or  
17 subset of such device type, is perma-  
18 nently implantable, life sustaining, or  
19 life supporting;

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

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

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

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

17 (2) in subsection (b)—

18 (A) in paragraph (2)—

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

20 (ii) by redesignating subparagraph

21 (E) as subparagraph (D); and

22 (B) in paragraph (3)—

23 (i) by redesignating subparagraph (E)

24 as subparagraph (F);

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

22 **SEC. 210. SUNSET CLAUSE.**

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

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

5 (c) PREVIOUS SUNSET PROVISION.—

6 (1) IN GENERAL.—Effective October 1, 2017,  
7 section 207(a) of the Medical Device User Fee  
8 Amendments of 2012 (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  
13 contents in section 2 by striking the item relating to  
14 section 207.

## 15 **TITLE III—FEES RELATING TO** 16 **GENERIC DRUGS**

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

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

20 (b) FINDING.—The Congress finds that the fees au-  
21 thorized by the amendments made in this title will be dedi-  
22 cated to human generic drug activities, as set forth in the  
23 goals identified for purposes of part 7 of subchapter C  
24 of chapter VII of the Federal Food, Drug, and Cosmetic  
25 Act, in the letters from the Secretary of Health and

1 Human Services to the Chairman of the Committee on  
2 Health, Education, Labor, and Pensions of the Senate and  
3 the Chairman of the Committee on Energy and Commerce  
4 of the House of Representatives, as set forth in the Con-  
5 gressional Record.

6 **SEC. 302. DEFINITIONS.**

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

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

12 “(i) for a positron emission tomog-  
13 raphy drug; or

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

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

20 (3) by inserting after paragraph (4) the fol-  
21 lowing:

22 “(5) The term ‘contract manufacturing organi-  
23 zation facility’ means a manufacturing facility of a  
24 finished dosage form of a drug approved pursuant to  
25 an abbreviated new drug application, where such



1 manufacturing facility is not identified in an ap-  
2 proved abbreviated new drug application held by the  
3 owner of such facility or an affiliate of such owner  
4 or facility.”.

5 **SEC. 303. AUTHORITY TO ASSESS AND USE HUMAN GE-**  
6 **NERIC DRUG FEES.**

7 (a) TYPES OF FEES.—Section 744B(a) of the Fed-  
8 eral Food, Drug, and Cosmetic Act (21 U.S.C. 379j–  
9 42(a)) is 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  
22 through 2022, the Secretary shall publish in the  
23 Federal Register the amount of the drug mas-  
24 ter file fee established by this paragraph for  
25 such fiscal 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  
8 inserting “; or”; and

9 (III) by adding at the end the  
10 following:

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  
20 PRIOR 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  
3 through 2022, the Secretary shall publish in the  
4 Federal Register the amount of the fees under  
5 subparagraph (A) for such fiscal year.

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

11           (D) in subparagraph (D)—

12           (i) in the heading, by inserting “, IS  
13 WITHDRAWN PRIOR TO BEING RECEIVED,  
14 OR IS NO LONGER RECEIVED” after “RE-  
15 CEIVED”;

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

1           have been received within the meaning of  
2           section 505(j)(5)(A) for a cause other than  
3           failure to pay fees, or that has been with-  
4           drawn prior to being received within the  
5           meaning 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)”  
25                  and 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 manu-  
2 facture 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 spec-  
6 ified in subsection (d)(1), the Secretary shall  
7 publish in the Federal Register the amount of  
8 the 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 sub-  
12 paragraph (A) for such fiscal year shall be due  
13 on the 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  
17 enactment of an appropriations Act pro-  
18 viding for the collection and obligation of  
19 fees for such year under this section for  
20 such year.”;

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

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

1           “(5) GENERIC DRUG APPLICANT PROGRAM  
2 FEE.—

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

6           “(B) AMOUNT.—The amount of fees estab-  
7 lished under subparagraph (A) shall be estab-  
8 lished under subsection (d).

9           “(C) NOTICE.—Within the timeframe spec-  
10 ified in subsection (d)(1), the Secretary shall  
11 publish in the Federal Register the amount of  
12 the fees under subparagraph (A) for such fiscal  
13 year.

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

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

20           “(ii) the first business day after the  
21 date of enactment of an appropriations Act  
22 providing for the collection and obligation  
23 of fees for such fiscal year under this sec-  
24 tion for such fiscal year.”.

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

4 (1) in paragraph (1)—

5 (A) in subparagraph (A)—

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

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

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

12 (iv) by striking “Of that amount” and  
13 all that follows through the end of clause  
14 (ii); and

15 (B) in subparagraph (B)—

16 (i) in the heading, by striking “2014  
17 THROUGH 2017” and inserting “2019  
18 THROUGH 2022”;

19 (ii) by striking “2014 through 2017”  
20 and inserting “2019 through 2022”;

21 (iii) by striking “paragraphs (2)  
22 through (4)” and inserting “paragraphs  
23 (2) through (5)”;

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



1 (2) in paragraph (2)—

2 (A) in the matter preceding subparagraph

3 (A)—

4 (i) by striking “paragraph (1)(A)(ii)

5 for fiscal year 2013 and paragraph (1)(B)

6 for each of fiscal years 2014 through

7 2017” and inserting “such paragraph for a

8 fiscal year”; and

9 (ii) by striking “through (4)” and in-

10 sserting “through (5)”;

11 (B) in subparagraph (A), by striking “Six

12 percent” and inserting “Five percent”;

13 (C) by amending subparagraphs (B) and

14 (C) to read as follows:

15 “(B) Thirty-three percent shall be derived

16 from fees under subsection (a)(3) (relating to

17 abbreviated new drug applications).

18 “(C) Twenty percent shall be derived from

19 fees under subsection (a)(4)(A)(i) (relating to

20 generic drug facilities). The amount of the fee

21 for a contract manufacturing organization facil-

22 ity shall be equal to one-third the amount of the

23 fee for a facility that is not a contract manufac-

24 turing organization facility. The amount of the

25 fee for a facility located outside the United

1 States and its territories and possessions shall  
2 be \$15,000 higher than the amount of the fee  
3 for a facility located in the United States and  
4 its territories and possessions.”;

5 (D) in subparagraph (D)—

6 (i) by striking “Fourteen percent”  
7 and inserting “Seven percent”;

8 (ii) by striking “not less than \$15,000  
9 and not more than \$30,000” and inserting  
10 “\$15,000”; and

11 (iii) by striking “, as determined” and  
12 all that follows through the period at the  
13 end and inserting a period; and

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

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

24 “(I) If a person (including its affili-  
25 ates) owns at least one but not more than

1                   5 approved abbreviated new drug applica-  
2                   tions on the due date for the fee under this  
3                   subsection, the person (including its affili-  
4                   ates) shall be assessed a small business ge-  
5                   neric drug applicant program fee equal to  
6                   one-tenth of the large size operation ge-  
7                   neric drug applicant program fee.

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

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

24                  “(ii) For purposes of this subparagraph,  
25                  an abbreviated new drug application shall be

1           deemed not to be approved if the applicant has  
2           submitted a written request for withdrawal of  
3           approval of such abbreviated new drug applica-  
4           tion by April 1 of the previous fiscal year.”.

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

8           (1) in paragraph (1)—

9                (A) by striking “2014” and inserting  
10              “2019”;

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

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

17           (2) in paragraph (2)—

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

20              (B) by striking “the first 3 months of fis-  
21              cal year 2018” and inserting “the first 3  
22              months of fiscal year 2023”; and

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

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

4 (1) by striking paragraphs (1) and (2) and in-  
5 serting the following:

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

13 (2) by redesignating paragraph (3) as para-  
14 graph (2); and

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

19 (e) IDENTIFICATION OF FACILITIES.—Section  
20 744B(f) of the Federal Food, Drug, and Cosmetic Act (21  
21 U.S.C. 379j–42(f)) is amended—

22 (1) by striking paragraph (1);

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

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

1 (A) by striking “paragraph (4)” and in-  
2 serting “paragraph (3)”; and

3 (B) by striking “Such information shall”  
4 and all that follows through the end of subpara-  
5 graph (B) and inserting “Such information  
6 shall, for each fiscal year, be submitted, up-  
7 dated, or reconfirmed on or before June 1 of  
8 the previous fiscal year.”; and

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

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

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

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

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

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

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

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

1 (f) EFFECT OF FAILURE TO PAY FEES.—Section  
2 744B(g) of the Federal Food, Drug, and Cosmetic Act  
3 (21 U.S.C. 379–42(g)) is amended—

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

7 (2) in paragraph (2)(C)(ii), by striking “of  
8 505(j)(5)(A)” and inserting “of section  
9 505(j)(5)(A)”; and

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

11 “(5) GENERIC DRUG APPLICANT PROGRAM  
12 FEE.—

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

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

20 “(ii) Any abbreviated new drug appli-  
21 cation submitted by the generic drug appli-  
22 cant or an affiliate of such applicant shall  
23 not be received, within the meaning of sec-  
24 tion 505(j)(5)(A).

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

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

10                  (g) LIMITATIONS.—Section 744B(h)(2) of the Fed-  
11                  eral Food, Drug, and Cosmetic Act (21 U.S.C. 379–  
12                  42(h)(2)) is amended by striking “for Type II active phar-  
13                  maceutical ingredient drug master files, abbreviated new  
14                  drug applications and prior approval supplements, and ge-  
15                  neric drug facilities and active pharmaceutical ingredient  
16                  facilities”.

17                  (h) CREDITING AND AVAILABILITY OF FEES.—Sec-  
18                  tion 744B(i) of the Federal Food, Drug, and Cosmetic Act  
19                  (21 U.S.C. 379–42(i)) is amended—

20                         (1) in paragraph (2)—

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

23                                 (B) in subparagraph (D)—

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



1 (ii) by striking “(after fiscal year  
2 2013)”; and

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

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

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

13 “(o) INFORMATION ON ABBREVIATED NEW DRUG  
14 APPLICATIONS OWNED BY APPLICANTS AND THEIR AF-  
15 FILIATES.—

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

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

23 “(B) if any affiliate of such person also  
24 owns an abbreviated new drug application, all  
25 affiliates that own any such abbreviated new

1 drug applications and all approved abbreviated  
2 new drug applications owned by any such affil-  
3 iate.

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

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

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

10 (1) in subsection (a)—

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

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

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

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

20 **SEC. 305. SUNSET DATES.**

21 (a) **AUTHORIZATION.**—Sections 744A and 744B of  
22 the Federal Food, Drug, and Cosmetic Act (21 U.S.C.  
23 379j–41; 379j–42) shall cease to be effective October 1,  
24 2022.

1 (b) REPORTING REQUIREMENTS.—Section 744C of  
2 the Federal Food, Drug, and Cosmetic Act (21 U.S.C.  
3 379j–43) shall cease to be effective January 31, 2023.

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

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

16 **SEC. 307. SAVINGS CLAUSE.**

17 Notwithstanding the amendments made by this title,  
18 part 7 of subchapter C of chapter VII of the Federal Food,  
19 Drug, and Cosmetic Act, as in effect on the day before  
20 the date of the enactment of this title, shall continue to  
21 be in effect with respect to abbreviated new drug applica-  
22 tions (as defined in such part as of such day) that on or  
23 after October 1, 2012, but before October 1, 2017, were  
24 received by the Food and Drug Administration within the  
25 meaning of 505(j)(5)(A) of such Act (21 U.S.C.

1 355(j)(5)(A)), prior approval supplements that were sub-  
2 mitted, and drug master files for Type II active pharma-  
3 ceutical ingredients that were first referenced with respect  
4 to assessing and collecting any fee required by such part  
5 for a fiscal year prior to fiscal year 2018.

6 **TITLE IV—FEES RELATING TO**  
7 **BIOSIMILAR BIOLOGICAL**  
8 **PRODUCTS**

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

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

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

1 **SEC. 402. DEFINITIONS.**

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

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

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

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

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

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

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

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

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

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

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

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

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

1           ation for a refund under this clause, a per-  
2           son shall submit to the Secretary a written  
3           request for such refund not later than 180  
4           days after the marketing application is ac-  
5           cepted for filing.”;

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

10          (9) in paragraph (1)(D)—

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

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

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

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

23          (11) in the heading of subparagraph (F) of  
24          paragraph (1), by striking “BIOSIMILAR DEVELOP-

1           MENT PROGRAM FEES” and inserting “BIOSIMILAR  
2           BIOLOGICAL PRODUCT DEVELOPMENT FEES”;

3           (12) in paragraph (1)(F)—

4                 (A) in the heading of subparagraph (F), by  
5           striking “BIOSIMILAR DEVELOPMENT PRO-  
6           GRAM” before “FEES”; and

7                 (B) by amending clause (i) to read as fol-  
8           lows:

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

16           (13) in paragraph (2)—

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

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

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



1           “(i) 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 required for approval.

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

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

22                 “(i) be subject to any biosimilar bio-  
23                 logical product application fees that may  
24                 be assessed at the time when such bio-

1 similar biological product application is  
2 submitted; and

3 “(ii) be entitled to no reduction of  
4 such application fees based on the amount  
5 of fees paid for that product before Octo-  
6 ber 1, 2017 under such subparagraphs  
7 (A), (B), or (D).”;

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

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

11 (i) by striking “or supplement” each  
12 place it appears; and

13 (ii) in subparagraph (D), by striking  
14 “or a supplement”;

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

17 “(3) BIOSIMILAR BIOLOGICAL PRODUCT PRO-  
18 GRAM FEE.—

19 “(A) IN GENERAL.—Each person who is  
20 named as the applicant in a biosimilar biologi-  
21 cal product application shall pay the annual bio-  
22 similar biological product program fee estab-  
23 lished for a fiscal year under subsection (e)(5)  
24 for each biosimilar biological product that—

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

4           “(ii) as of October 1 of such fiscal  
5           year, does not appear on a list, developed  
6           and maintained by the Secretary, of dis-  
7           continued biosimilar biological products.

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

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

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

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

21          “(D) LIMITATION.—A person who is  
22          named as the applicant in a biosimilar biologi-  
23          cal product application shall not be assessed  
24          more than 5 biosimilar biological product pro-  
25          gram fees for a fiscal year for biosimilar bio-

1           logical products identified in such biosimilar bi-  
2           ological product application.”.

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

6           “(b) FEE REVENUE AMOUNTS.—

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

10                   “(A) \$45,000,000; and

11                   “(B) the dollar amount equal to the fiscal  
12           year 2018 adjustment (as determined under  
13           subsection (c)(4)).

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

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

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

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

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

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

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

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

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

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

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

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

3           “(C) BIOSIMILAR BIOLOGICAL PRODUCT  
4           DEVELOPMENT FEES.—The initial biosimilar bi-  
5           ological product development fee under sub-  
6           section (a)(1)(A) for a fiscal year shall be equal  
7           to the annual biosimilar biological product de-  
8           velopment fee under subsection (a)(1)(B) for  
9           that fiscal year.

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

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

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

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

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

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

7 and

8 (4) by inserting after subsection (b) the fol-  
9 lowing:

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

11 “(1) INFLATION ADJUSTMENT.—

12 “(A) IN GENERAL.—For purposes of sub-  
13 section (b)(2)(B), the dollar amount of the in-  
14 flation adjustment to the annual base revenue  
15 for each fiscal year shall be equal to the prod-  
16 uct of—

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

19 “(ii) the inflation adjustment percent-  
20 age under subparagraph (B).

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

1           “(i) the average annual percent  
2 change in the cost, per full-time equivalent  
3 position of the Food and Drug Administra-  
4 tion, of all personnel compensation and  
5 benefits paid with respect to such positions  
6 for the first 3 years of the preceding 4 fis-  
7 cal years, multiplied by the proportion of  
8 personnel compensation and benefits costs  
9 to total costs of the process for the review  
10 of biosimilar biological product applications  
11 (as defined in section 744G(13)) for the  
12 first 3 years of the preceding 4 fiscal  
13 years; and

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



1 first 3 years of the preceding 4 fiscal  
2 years.

3 “(2) CAPACITY PLANNING ADJUSTMENT.—

4 “(A) IN GENERAL.—Beginning with the  
5 fiscal year described in subparagraph  
6 (B)(ii)(II), the Secretary shall, in addition to  
7 the adjustment under paragraph (1), further in-  
8 crease the fee revenue and fees under this sec-  
9 tion for a fiscal year to reflect changes in the  
10 resource capacity needs of the Secretary for the  
11 process for the review of biosimilar biological  
12 product applications.

13 “(B) CAPACITY PLANNING METHOD-  
14 OLOGY.—

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

1 shall utilize and be informed by personnel  
2 time reporting data as an input. The re-  
3 port shall be published for public comment  
4 not later than September 30, 2020.

5 “(ii) ESTABLISHMENT AND IMPLE-  
6 MENTATION.—After review of the report  
7 described in clause (i) and receipt and re-  
8 view of public comments thereon, the Sec-  
9 retary shall establish a capacity planning  
10 methodology for purposes of this para-  
11 graph, which shall—

12 “(I) incorporate such approaches  
13 and attributes as the Secretary deter-  
14 mines appropriate; and

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

19 “(C) LIMITATION.—Under no cir-  
20 cumstances shall an adjustment under this  
21 paragraph result in fee revenue for a fiscal year  
22 that is less than the sum of the amounts under  
23 subsections (b)(2)(A) (the annual base revenue  
24 for the fiscal year) and (b)(2)(B) (the dollar

1 amount of the inflation adjustment for the fis-  
2 cal year).

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

8 “(3) OPERATING RESERVE ADJUSTMENT.—

9 “(A) INTERIM APPLICATION; FEE REDUC-  
10 TION.—Until the first fiscal year for which the  
11 capacity planning adjustment under paragraph  
12 (2) is effective, the Secretary may, in addition  
13 to the adjustment under paragraph (1), reduce  
14 the fee revenue and fees under this section for  
15 a fiscal year as the Secretary determines appro-  
16 priate for long-term financial planning pur-  
17 poses.

18 “(B) GENERAL APPLICATION AND METH-  
19 ODOLOGY.—Beginning with the first fiscal year  
20 for which the capacity planning adjustment  
21 under paragraph (2) is effective, the Secretary  
22 may, in addition to the adjustments under  
23 paragraphs (1) and (2)—

24 “(i) reduce the fee revenue and fees  
25 under this section as the Secretary deter-

1 mines appropriate for long-term financial  
2 planning purposes; or

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

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

17 “(4) FISCAL YEAR 2018 ADJUSTMENT.—

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

24 “(B) METHODOLOGY.—The Secretary shall  
25 publish under paragraph (5) a description of

1 the methodology used to calculate the fiscal  
2 year 2018 adjustment under this paragraph in  
3 the Federal Register notice establishing fee rev-  
4 enue and fees for fiscal year 2018.

5 “(C) LIMITATION.—No adjustment under  
6 this paragraph shall result in an increase in fee  
7 revenue and fees under this section in excess of  
8 \$9,000,000.

9 “(5) ANNUAL FEE SETTING.—For fiscal year  
10 2018 and each subsequent fiscal year, the Secretary  
11 shall, not later than 60 days before the start of each  
12 such fiscal year—

13 “(A) establish, for the fiscal year, initial  
14 and annual biosimilar biological product devel-  
15 opment fees and reactivation fees under sub-  
16 section (a)(1), biosimilar biological product ap-  
17 plication fees under subsection (a)(2), and bio-  
18 similar biological product program fees under  
19 subsection (a)(3), based on the revenue  
20 amounts established under subsection (b) and  
21 the adjustments provided under this subsection;  
22 and

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

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

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

10           (1) by striking subparagraph (B);

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

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

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

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

25           (1) in paragraph (2)—

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

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

10 (B) in subparagraph (D)—

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

13 (ii) by striking “(after fiscal year  
14 2013)”; and

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

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

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

20 (1) in subsection (a)—

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

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

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

3 (3) by striking subsection (d);

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

6 (5) in subsection (d), as so redesignated, by  
7 striking “2017” each place it appears and inserting  
8 “2022”.

9 **SEC. 405. SUNSET DATES.**

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

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

18 (c) PREVIOUS SUNSET PROVISION.—

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

23 (2) CONFORMING AMENDMENT.—The Food and  
24 Drug Administration Safety and Innovation Act  
25 (Public Law 112–144) is amended in the table of



1 contents in section 2 by striking the item relating to  
2 section 404.

3 **SEC. 406. 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 8 of  
7 subchapter C of chapter VII of the Federal Food, Drug,  
8 and Cosmetic Act shall be assessed for all biosimilar bio-  
9 logical product applications received on or after October  
10 1, 2017, regardless of the date of the enactment of this  
11 Act.

12 **SEC. 407. SAVINGS CLAUSE.**

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

1 **TITLE VI—DEVICE INSPECTION**  
2 **AND REGULATORY IMPROVE-**  
3 **MENTS**

4 **Subtitle A—Improving the Process**  
5 **for Inspections of Device Estab-**  
6 **lishments**

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

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

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

12 “(A) IN GENERAL.—The Secretary, acting  
13 through one or more officers or employees duly  
14 designated by the Secretary, shall inspect estab-  
15 lishments described in paragraph (1) that are  
16 engaged in the manufacture, propagation,  
17 compounding, or processing of a device or de-  
18 vices (referred to in this subsection as ‘device  
19 establishments’) in accordance with a risk-based  
20 schedule established by the Secretary.

21 “(B) FACTORS AND CONSIDERATIONS.—In  
22 establishing the risk-based schedule under sub-  
23 paragraph (A), the Secretary shall—

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

4 “(ii) consider the participation of the  
5 device establishment, as applicable, in  
6 international device audit programs in  
7 which the United States participates or  
8 which the United States recognizes for  
9 purposes of inspecting device establish-  
10 ments.”; and

11 **SEC. 602. RECOGNITION OF FOREIGN GOVERNMENT IN-**  
12 **SPECTIONS.**

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

17 **SEC. 603. IMPROVEMENTS TO INSPECTIONS PROCESS FOR**  
18 **DEVICE ESTABLISHMENTS.**

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

22 “(h)(1) In the case of inspections other than for-  
23 cause inspections, the Secretary shall review processes and  
24 standards applicable to inspections of domestic and for-  
25 eign device establishments in effect as of the date of the

1 enactment of this subsection, and update such processes  
2 and standards through the adoption of uniform processes  
3 and standards applicable to such inspections. Such proc-  
4 esses and standards shall provide for—

5           “(A) exceptions to such processes and stand-  
6           ards, as appropriate;

7           “(B) announcing the inspection of the establish-  
8           ment within a reasonable time before such inspection  
9           occurs, including by providing to the owner, oper-  
10          ator, or agent in charge of the establishment a noti-  
11          fication regarding the type and nature of the inspec-  
12          tion;

13          “(C) a reasonable estimate of the timeframe for  
14          the inspection, an opportunity for advance commu-  
15          nications between the officers or employees carrying  
16          out the inspection under subsection (a)(1) and the  
17          owner, operator, or agent in charge of the establish-  
18          ment concerning appropriate working hours during  
19          the inspection, and, to the extent feasible, advance  
20          notice of some records that will be requested in  
21          order to expedite the inspection; and

22          “(D) regular communications during the inspec-  
23          tion with the owner, operator, or agent in charge of  
24          the establishment regarding inspection status, which

1           may be recorded by either party with advance notice  
2           and mutual consent.

3           “(2)(A) The Secretary shall, with respect to a request  
4 described in subparagraph (B), provide nonbinding feed-  
5 back with respect to such request not later than 45 days  
6 after the Secretary receives such request.

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

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

12                   “(ii) with respect to actions proposed to be  
13 taken by a device establishment in a response to a  
14 report received by such establishment pursuant to  
15 subsection (b) that involve a public health priority,  
16 that implicate systemic or major actions, or relate to  
17 emerging safety issues (as determined by the Sec-  
18 retary).

19           “(3) Nothing in this subsection limits the authority  
20 of the Secretary to conduct inspections otherwise per-  
21 mitted under this Act in order to ensure compliance with  
22 this Act.”.

23           (b) GUIDANCE.—

24                   (1) DRAFT GUIDANCE.—Not later than 18  
25 months after the date of enactment of this section,

1 the Secretary of Health and Human Services shall  
2 issue draft guidance that—

3 (A) specifies how the Food and Drug Ad-  
4 ministration will implement the process de-  
5 scribed in paragraph (1) of subsection (h) of  
6 section 704 of the Federal Food, Drug, and  
7 Cosmetic Act (21 U.S.C. 374), as added by  
8 subsection (a), and the requirements described  
9 in paragraph (2) of such subsection;

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

12 (C) establishes, with respect to inspections  
13 of both domestic and foreign device establish-  
14 ments (as referred to in section 510(h)(2) of  
15 the Federal Food, Drug, and Cosmetic Act, as  
16 amended by section 1), a standard timeframe  
17 for such inspections that—

18 (i) occurs over consecutive days;

19 (ii) to which each investigator con-  
20 ducting such an inspection shall adhere un-  
21 less the investigator identifies to the estab-  
22 lishment involved a reason that more time  
23 is needed to conduct such investigation;  
24 and



1 (D) identifies practices for investigators  
2 and device establishments to facilitate the con-  
3 tinuity of inspections of such establishments.

4 (2) FINAL GUIDANCE.—Not later than 1 year  
5 after providing notice and opportunity for public  
6 comment on the draft guidance issued under para-  
7 graph (1), the Secretary of Health and Human  
8 Services shall issue final guidance to implement sub-  
9 section (h) of section 704 of the Federal Food,  
10 Drug, and Cosmetic Act (21 U.S.C. 374), as added  
11 by subsection (a).

12 **SEC. 604. CERTIFICATES TO FOREIGN GOVERNMENTS FOR**  
13 **DEVICES.**

14 (a) IN GENERAL.—Subsection (e)(4) of section 801  
15 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C.  
16 381(e)(4)) is amended—

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

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

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

3                   “(I) grounds other than an injunction  
4                   proceeding pursuant to section 302, seizure  
5                   action pursuant to section 304, or a recall  
6                   designated Class I or Class II pursuant to  
7                   part 7, title 21, Code of Federal Regula-  
8                   tions, and

9                   “(II) an establishment being consid-  
10                  ered out of compliance with part 820, title  
11                  21, Code of Federal Regulations,

12           the Secretary shall provide a substantive sum-  
13           mary of the specific grounds for noncompliance  
14           so identified, if such grounds have not been pre-  
15           viously communicated to the manufacturer.

16                  “(iii) With respect to a device manufac-  
17                  tured in an establishment that has received a  
18                  report under section 704(b), the Secretary shall  
19                  not deny a request for certification under sub-  
20                  paragraph (A)(ii) based exclusively on the  
21                  issuance of that report if the owner, operator,  
22                  or agent in charge of such establishment has  
23                  agreed to a plan of correction in response to  
24                  such report.

1           “(F)(i) The Secretary shall provide a proc-  
2           ess for a person who is denied a certification as  
3           described in subparagraph (E)(i) to request a  
4           review that conforms to the standards of section  
5           517A(b).

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

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

23          “(ii) The Secretary may charge a fee for  
24          the issuance of a certification described in  
25          clause (i), and such fee is subject to the same

1 conditions and requirements as a fee charged  
2 under subparagraph (B) for a certification  
3 issued under such subparagraph. ”; and

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

6 (b) GUIDANCE.—Not later than 1 year after date of  
7 the enactment of this section, the Secretary of Health and  
8 Human Services shall issue guidance providing for a proce-  
9 ss to carry out subparagraph (F) of section 801(e)(4) of  
10 the Federal Food, Drug, and Cosmetic Act (21 U.S.C.  
11 381(e)(4)), as added by subsection (a). Not later than 12  
12 months after the comment period closes for the draft guid-  
13 ance, the Secretary shall issue final guidance.

14 **SEC. 605. FACILITATING INTERNATIONAL HARMONIZATION.**

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

18 “(15) Notwithstanding any other provision of  
19 this subsection, for purposes of conducting inspec-  
20 tions of establishments that manufacture, prepare,  
21 propagate, compound, or process devices except  
22 types of devices licensed under section 351 of the  
23 Public Health Service Act, which inspections are re-  
24 quired under section 510(h) or are inspections of  
25 such establishments required to register pursuant to

1 section 510(i), the Secretary may recognize auditing  
2 organizations that are recognized by organizations  
3 established by governments to facilitate international  
4 harmonization. Nothing in this paragraph affects the  
5 authority of the Secretary to inspect any device es-  
6 tablishment pursuant to this Act. Nothing in this  
7 paragraph affects the authority of the Secretary to  
8 determine the official classification of an inspection.  
9 ”.

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

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

14 **Subtitle B—Other Provisions**

15 **SEC. 611. REAUTHORIZATION OF PEDIATRIC HUMANI-  
16 TARIAN DEVICE EXCEPTIONS.**

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

20 **SEC. 612. REAUTHORIZATION OF PEDIATRIC DEVICE CON-  
21 SORTIA.**

22 Section 305(e) of Pediatric Medical Device Safety  
23 and Improvement Act of 2007 (Public Law 110–85; 42  
24 U.S.C. 282 note)) is amended by striking “2013 through  
25 2017” and inserting “2018 through 2022”.

1 **SEC. 613. REGULATION OF OVER-THE-COUNTER HEARING**  
2 **AIDS.**

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

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

8 “(1) DEFINITION.—In this subsection, the term  
9 ‘over-the-counter hearing aid’ means a device—

10 “(A) that uses the same fundamental sci-  
11 entific technology as air conduction hearing  
12 aids (as defined in section 874.3300 of title 21,  
13 Code of Federal Regulations) (or any successor  
14 regulation) or wireless air conduction hearing  
15 aids (as defined in section 874.3305 of title 21,  
16 Code of Federal Regulations) (or any successor  
17 regulation);

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

21 “(C) that, through tools, tests, or software,  
22 allows the user to control the over-the-counter  
23 hearing aid and customize it to the user’s hear-  
24 ing needs;

25 “(D) that may—

26 “(i) use wireless technology; or

1                   “(ii) include tests for self-assessment  
2                   of hearing loss; and

3                   “(E) that is available over-the-counter,  
4                   without the supervision, prescription, or other  
5                   order, involvement, or intervention of a licensed  
6                   person, to consumers through in-person trans-  
7                   actions, by mail, or online.

8                   “(2) REGULATION.—An over-the-counter hear-  
9                   ing aid shall be subject to the regulations promul-  
10                  gated in accordance with section 613(b) of the FDA  
11                  Reauthorization Act of 2017 and shall be exempt  
12                  from sections 801.420 and 801.421 of title 21, Code  
13                  of Federal Regulations (or any successor regula-  
14                  tions).”.

15                  (b) REGULATIONS TO ESTABLISH CATEGORY.—

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

1       posed regulations closes, shall issue such final regu-  
2       lations.

3               (2) REQUIREMENTS.—In promulgating the reg-  
4       ulations under paragraph (1), the Secretary shall—

5                       (A) include requirements that provide rea-  
6       asonable assurances of the safety and efficacy of  
7       over-the-counter hearing aids;

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

11                      (C) include requirements for appropriate  
12      labeling of the over-the-counter hearing aid, in-  
13      cluding how consumers may report adverse  
14      events, any conditions or contraindications, and  
15      any advisements to consult promptly with a li-  
16      censed physician; and

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

23               (3) PREMARKET NOTIFICATION.—The Sec-  
24      retary shall make findings under section 510(m) of  
25      the Federal Food, Drug, and Cosmetic Act (21



1 U.S.C. 360(m)) to determine whether over-the-  
2 counter hearing aids (as defined in section 520(p) of  
3 the Federal Food, Drug, and Cosmetic Act (21  
4 U.S.C. 360j), as amended by subsection (a)) require  
5 a report under section 510(k) to provide reasonable  
6 assurance of safety and effectiveness.

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

24 (c) NEW GUIDANCE ISSUED.—Not later than the  
25 date on which final regulations are issued under sub-

1 section (b), the Secretary shall update and finalize the  
2 draft guidance of the Department of Health and Human  
3 Services entitled, “Regulatory Requirements for Hearing  
4 Aid Devices and Personal Sound Amplification Products”,  
5 issued on November 7, 2013. Such updated and finalized  
6 guidance shall clarify which products, on the basis of  
7 claims or other marketing, advertising, or labeling mate-  
8 rial, meet the definition of a device in section 201 of the  
9 Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321)  
10 and which products meet the definition of a personal  
11 sound amplification product, as set forth in such guidance.

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

14 **SEC. 701. COMPETITIVE GENERIC THERAPIES.**

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

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

19 “(a) IN GENERAL.—The Secretary shall, at the re-  
20 quest of the sponsor of a drug that is designated as a  
21 competitive generic therapy pursuant to subsection (b), ex-  
22 pedite the development and review of such drug pursuant  
23 to section 505(j).

24 “(b) DESIGNATION PROCESS.—

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

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

8           “(3) CRITERIA.—A drug is eligible for designa-  
9           tion as a competitive generic therapy if the Sec-  
10          retary determines that there is inadequate generic  
11          competition.

12          “(4) DESIGNATION.—Not later than 60 cal-  
13          endar days after the receipt of a request under para-  
14          graph (1), the Secretary shall—

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

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

21          “(c) ACTIONS.—In expediting the development and  
22          review of a drug under subsection (a), the Secretary shall,  
23          as appropriate, take actions including the following:

24                 “(1) Hold meetings with the sponsor and the  
25                 review team throughout the development of the drug

1 prior to submission of the application for such drug  
2 under section 505(j).

3 “(2) Provide timely advice to, and interactive  
4 communication with, the sponsor regarding the de-  
5 velopment of the drug to ensure that the develop-  
6 ment program to gather the nonclinical and clinical  
7 data necessary for approval is as efficient as prac-  
8 ticable.

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

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

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

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

21 “(d) DEFINITIONS.—In this section:

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

24 “(2) The term ‘inadequate generic competition’  
25 means there is not more than one approved drug

1 product on the list of products described in section  
2 505(j)(7)(A) (not including products on the discon-  
3 tinued section of such list) that is—

4 “(A) the reference listed drug; or

5 “(B) a generic drug with the same ref-  
6 erence listed drug as the drug for which des-  
7 ignation as a competitive generic therapy is  
8 sought.

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

12 (b) GUIDANCE; AMENDED REGULATIONS.—

13 (1) IN GENERAL.—

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

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

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

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

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

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

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

14 (2) AMENDED REGULATIONS.—

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

9 “(I) EFFECTIVENESS OF APPLICATION.—If  
10 the application is for a competitive generic ther-  
11 apy, the application shall be made effective on  
12 the date that is 180 days after the date of the  
13 first commercial marketing of the competitive  
14 generic therapy.

15 “(II) DEFINITION.—In this clause and  
16 subparagraph (D)(iv), the term ‘competitive ge-  
17 neric therapy’ means a drug—

18 “(aa) that is designated as a competi-  
19 tive generic therapy under section 506H;  
20 and

21 “(bb) for which there are no blocking  
22 patents or exclusivities on the list of prod-  
23 ucts described in section 505(j)(7)(A).”;  
24 and

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



1                   “(iv) SPECIAL FORFEITURE RULE FOR  
2                   COMPETITIVE GENERIC THERAPY.—The  
3                   180-day exclusivity period described in  
4                   subparagraph (B)(v) shall be forfeited by  
5                   the holder of the approved abbreviated ap-  
6                   plication for the competitive generic ther-  
7                   apy involved if the holder fails to market  
8                   the competitive generic therapy within 75  
9                   days after the date on which the approval  
10                  of the application is made effective.”.

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

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

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

16                  (2) in clause (ii), by inserting “and” after the  
17 semicolon at the end; and

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

19                                 “(iii) that contains reports of one or  
20                                 more new clinical investigations (other  
21                                 than bio-availability studies) that—

22   “(I) are essential to the approval  
23   of the application and conducted or  
24   sponsored by the applicant; and

1                   “(II) were not relied upon for  
2                   marketing authority by a foreign na-  
3                   tional regulatory authority prior to  
4                   September 27, 2007.”.

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

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

10           (1) The rate of first cycle approvals and ten-  
11           tative approvals for generic drug applications sub-  
12           mitted during the period beginning on October 1,  
13           2012, and ending on September 30, 2017. The rate  
14           of first cycle approvals and tentative approvals shall  
15           be determined and reported per each GDUFA cohort  
16           year during this period.

17           (2) If the rate determined pursuant to para-  
18           graph (1) for any GDUFA cohort year is lower than  
19           20 percent, the reasons contributing to the relatively  
20           low rate of first cycle approvals and tentative ap-  
21           provals for generic drug applications shall be  
22           itemized, assessed, and reported. In making the as-  
23           sessment required by this paragraph, the Comp-  
24           troller General shall consider, among other things,  
25           the role played by—

1 (A) the Food and Drug Administration's  
2 implementation of approval standards for ge-  
3 neric drug applications;

4 (B) the extent to which those approval  
5 standards are communicated clearly to industry  
6 and applied consistently during the review pro-  
7 cess;

8 (C) the procedures for reviewing generic  
9 drug applications, including timelines for review  
10 activities by the Food and Drug Administra-  
11 tion;

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

15 (E) the processes and practices for com-  
16 munication between the Food and Drug Admin-  
17 istration and sponsors of generic drug applica-  
18 tions; and

19 (F) the completeness and quality of origi-  
20 nal generic drug applications submitted to the  
21 Food and Drug Administration.

22 (3) Taking into account the determinations  
23 made pursuant to paragraphs (1) and (2) and any  
24 review process improvements implemented pursuant  
25 to this Act, whether there are ways the review pro-

1       ess for generic drugs could be improved to increase  
2       the rate of first cycle approvals and tentative ap-  
3       provals for generic drug applications. In making this  
4       determination, the Comptroller General shall con-  
5       sider, among other things, options for increasing re-  
6       view efficiency and communication effectiveness.

7       (b) CONSULTATION.—The Comptroller General shall  
8       conduct the study under subsection (a) in consultation  
9       with—

10           (1) the Secretary of Health and Human Serv-  
11           ices, acting through the Commissioner of Food and  
12           Drugs; and

13           (2) sponsors of generic drug applications and  
14           organizations representing sponsors of generic drug  
15           applications.

16       (c) INITIATION AND COMPLETION DATES.—Not later  
17       than 90 days after the date of enactment of this Act, the  
18       Comptroller General shall initiate the study under sub-  
19       section (a). Not later than the expiration of the 2-year  
20       period beginning on the date of enactment of this Act, the  
21       Comptroller General shall complete the study under sub-  
22       section (a) and submit a report describing the findings  
23       and conclusions of the study to the Secretary, the Com-  
24       mittee on Energy and Commerce of the House of Rep-

1 representatives, and the Committee on Health, Education,  
2 Labor, and Pensions of the Senate.

3 (d) DEFINITIONS.—For purposes of this section:

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

6 (2) The term “generic drug” means a drug that  
7 is approved or is seeking approval under section  
8 505(j) of the Federal Food, Drug, and Cosmetic Act  
9 (21 U.S.C. 355(j)).

10 (3) The term “generic drug application” means  
11 an abbreviated new drug application for the approval  
12 of a generic drug under section 505(j) of the Fed-  
13 eral Food, Drug, and Cosmetic Act (21 U.S.C.  
14 355(j)).

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

17 (5)(A) The term “first cycle approvals and ten-  
18 tative approvals” means the approval or tentative  
19 approval of a generic drug application after the  
20 Food and Drug Administration’s complete review of  
21 the application and without issuance of one or more  
22 complete response letters.

23 (B) For purposes of this paragraph, the term  
24 “complete response letter” means a written commu-  
25 nication to the sponsor of a generic drug application

1 or holder of a drug master file (DMF) from the  
2 Food and Drug Administration describing all of the  
3 deficiencies that the Administration has identified in  
4 the generic drug application (including pending  
5 amendments) or drug master file that must be satis-  
6 factorily addressed before the generic drug applica-  
7 tion can be approved.

## 8 **TITLE VIII—ADDITIONAL** 9 **PROVISIONS**

### 10 **SEC. 801. TECHNICAL CORRECTIONS.**

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

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

16 (2) in paragraph (2), by striking “section  
17 2074(1)(C)” and inserting “section 3102(1)(C)”.

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

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

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

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

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

9 (2) section 515C of the Federal Food, Drug,  
10 and Cosmetic Act (21 U.S.C. 360e–3), as inserted  
11 by such section 3051(a), is redesignated as section  
12 515B.

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

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

1 **SEC. 802. 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”.