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H. R. 2430

[Report No. 115–201]

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

IN THE HOUSE OF REPRESENTATIVES

MAY 16, 2017

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

JULY 11, 2017

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

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

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

A BILL

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

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,

SECTION 1. SHORT TITLE.

This Act may be cited as the "FDA Reauthorization Act of 2017".

SEC. 2. TABLE OF CONTENTS.

The table of contents for this Act is as follows:

TITLE I—FEES RELATING TO DRUGS

SEC. 101. SHORT TITLE; FINDING.

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

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

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

(a) TYPES OF FEES.—

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

(A) in the matter preceding paragraph (1), by striking "fiscal year 2013" and inserting "fiscal year 2018";

(B) in the heading of paragraph (1), by striking "AND SUPPLEMENT";

(C) in paragraph (1), by striking "or a supplement" and "or supplement" each place either appears;

(D) in paragraph (1)(A)—

(i) in clause (i), by striking "(c)(4)" and inserting "(c)(5)"; and

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

(E) in the heading of paragraph (1)(C), by striking "OR SUPPLEMENT";

(F) in paragraph (1)(F)—

(i) in the heading, by striking "OR INDICATION"; and

(ii) by striking the second sentence;

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

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

(I) in the heading of paragraph (2), as so redesignated, by striking "PRESCRIPTION DRUG PRODUCT FEE" and inserting "PRESCRIPTION DRUG PROGRAM FEE";

(J) in subparagraph (A) of such paragraph (2), by amending the first sentence to read as follows: "Except as provided in subparagraphs (B) and (C), each person who is named as the applicant in a human drug application, and who, after September 1, 1992, had pending before the Secretary a human drug application or supplement, shall pay the annual prescription drug program fee established for a fiscal year under subsection (c)(5) for each prescription drug product that is identified in such a human drug application approved as of October 1 of such fiscal year.";

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

(i) in the heading of subparagraph (B), by inserting after "EXCEPTION" the following: "FOR CERTAIN PRESCRIPTION DRUG PRODUCTS"; and

(ii) by striking "A prescription drug product shall not be assessed a fee" and inserting "A prescription drug program fee shall not be assessed for a prescription drug product"; and

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

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

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

"(C) LIMITATION.—An establishment shall be assessed only one fee per fiscal year under this section.".

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

"(b) FEE REVENUE AMOUNTS.—

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

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

"(B) the dollar amount equal to the inflation adjustment for the fiscal year (as determined under subsection (c)(1));

"(C) the dollar amount equal to the capacity planning adjustment for the fiscal year (as determined under subsection (c)(2));

"(D) the dollar amount equal to the operating reserve adjustment for the fiscal year, if applicable (as determined under subsection (c)(3));

"(E) the dollar amount equal to the additional direct cost adjustment for the fiscal year (as determined under subsection (c)(4)); and

"(F) additional dollar amounts for each fiscal year as follows:

"(i) $20,077,793 for fiscal year 2018.

"(ii) $21,317,472 for fiscal year 2019.

"(iii) $16,953,329 for fiscal year 2020.

"(iv) $5,426,896 for fiscal year 2021.

"(v) $2,769,609 for fiscal year 2022.

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

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

"(B) 80 percent shall be derived from prescription drug program fees under subsection (a)(2).

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

"(A) for fiscal year 2018, $878,590,000; and

"(B) for fiscal years 2019 through 2022, the dollar amount of the total revenue amount established under paragraph (1) for the previous fiscal year, not including any adjustments made under subsection (c)(3) or (c)(4).".

(c) ADJUSTMENTS; ANNUAL FEE SETTING.—Subsection (c) of section 736 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 379h) is amended to read as follows:

"(c) ADJUSTMENTS; ANNUAL FEE SETTING.—

"(1) INFLATION ADJUSTMENT.—

"(A) IN GENERAL.—For purposes of subsection (b)(1)(B), the dollar amount of the inflation adjustment to the annual base revenue for each fiscal year shall be equal to the product of—

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

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

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

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

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

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

"(2) CAPACITY PLANNING ADJUSTMENT.—

"(A) IN GENERAL.—For each fiscal year, after the annual base revenue established in subsection (b)(1)(A) is adjusted for inflation in accordance with paragraph (1), such revenue shall be adjusted further for such fiscal year, in accordance with this paragraph, to reflect changes

in the resource capacity needs of the Secretary for the process for the review of human drug applications.

"(B) INTERIM METHODOLOGY.—

"(i) IN GENERAL.—Until the capacity planning methodology described in subparagraph (C) is effective, the adjustment under this paragraph for a fiscal year shall be based on the product of—

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

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

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

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

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

"(III) the total number of formal meetings scheduled by the Secretary, and written responses issued by the Secretary in lieu of such formal meetings, as identified in section I.H of the letters described in section 101(b) of the Prescription Drug User Fee Amendments of 2017.

"(C) CAPACITY PLANNING METHODOLOGY.—

"(i) DEVELOPMENT; EVALUATION AND REPORT.—The Secretary shall obtain, through a contract with an independent accounting or consulting firm, a report evaluating options and recommendations for a new methodology to accurately assess changes in the resource and capacity needs of the process for the review of human drug applications. The capacity planning methodological options and recommendations presented in such report shall utilize and be informed by personnel time reporting data as an input. The report shall be published

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

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

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

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

"(III) be effective beginning with the first fiscal year for which fees are set after such capacity planning methodology is established.

"(D) LIMITATION.—Under no circumstances shall an adjustment under this paragraph result in fee revenue for a fiscal year that is less than the sum of the amounts under subsections (b)(1)(A) (the annual base revenue for the fiscal year) and (b)(1)(B) (the dollar amount of the inflation adjustment for the fiscal year).

"(E) PUBLICATION IN FEDERAL REGISTER.—The Secretary shall publish in the Federal Register notice under paragraph (5) the fee revenue and fees resulting from the adjustment and the methodologies under this paragraph.

"(3) OPERATING RESERVE ADJUSTMENT.—

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

"(B) DECREASE.—If the Secretary has carryover balances for such process in excess of 14 weeks of such operating reserves, the Secretary shall decrease such fee revenue and fees to provide for not more than 14 weeks of such operating reserves.

"(C) NOTICE OF RATIONALE.—If an adjustment under subparagraph (A) or (B) is made, the rationale for the amount of the increase or decrease (as applicable) in fee revenue and fees shall be contained in the annual Federal Reg-

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

"(4) ADDITIONAL DIRECT COST ADJUSTMENT.—

"(A) IN GENERAL.—The Secretary shall, in addition to adjustments under paragraphs (1), (2), and (3), further increase the fee revenue and fees—

"(i) for fiscal year 2018, by $8,730,000; and

"(ii) for fiscal year 2019 and subsequent fiscal years, by the amount determined under subparagraph (B).

"(B) AMOUNT.—The amount determined under this subparagraph is—

"(i) $8,730,000, multiplied by

"(ii) the Consumer Price Index for urban consumers (Washington-Baltimore, DC–MD–VA–WV; Not Seasonally Adjusted; All Items; Annual Index) for the most recent year of available data, divided by such Index for 2016.

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

"(A) establish, for the next fiscal year, human drug application fees and prescription drug program fees under subsection (a), based on the revenue amounts established under subsection (b) and the adjustments provided under this subsection; and

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

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

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

(1) in paragraph (1)—

(A) by inserting "or" at the end of subparagraph (B);

(B) by striking subparagraph (C); and

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

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

(3) by redesignating paragraph (4) as paragraph (3); and

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

(A) in subparagraphs (A) and (B), by striking "paragraph (1)(D)" and inserting "paragraph (1)(C)"; and

(B) in subparagraph (B)—

(i) by striking clause (ii);

(ii) by striking "shall pay" through "(i) application fees" and inserting "shall pay application fees"; and

(iii) by striking "; and" at the end and inserting a period.

(e) EFFECT OF FAILURE TO PAY FEES.—Section 736(e) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 379h(e)) is amended by striking "all fees" and inserting "all such fees".

(f) LIMITATIONS.—Section 736(f)(2) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 379h(f)(2)) is amended by striking "supplements, prescription drug establishments, and prescription drug products" and inserting "prescription drug program fees".

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

(1) in paragraph (3)—

(A) by striking "2013 through 2017" and inserting "2018 through 2022"; and

(B) by striking "and paragraph (4) of this subsection"; and

(2) by striking paragraph (4).

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

SEC. 103. REAUTHORIZATION; REPORTING REQUIREMENTS.

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

(1) in subsection (a)(1)—

(A) in the matter before subparagraph (A), by striking "2013" and inserting "2018"; and

(B) in subparagraph (A), by striking "Prescription Drug User Fee Amendments of 2012" and inserting "Prescription Drug User Fee Amendments of 2017";

(2) in subsection (b), by striking "2013" and inserting "2018"; and

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

SEC. 104. SUNSET DATES.

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

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

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

SEC. 105. EFFECTIVE DATE.

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

SEC. 106. SAVINGS CLAUSE.

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

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

TITLE II—FEES RELATING TO DEVICES

SEC. 201. SHORT TITLE; FINDINGS.

(a) SHORT TITLE.—This title may be cited as the "Medical Device User Fee Amendments of 2017".

(b) FINDINGS.—The Congress finds that the fees authorized under the amendments made by this title will be dedicated toward expediting the process for the review of device applications and for assuring the safety and effectiveness of devices, as set forth in the goals identified for purposes of part 3 of subchapter C of chapter VII of the Federal Food, Drug, and Cosmetic Act in the letters from the Secretary of Health and Human Services to the Chairman of the Committee on Health, Education, Labor, and Pensions of the Senate and the Chairman of the Committee on Energy and Commerce of the House of Representatives, as set forth in the Congressional Record.

SEC. 202. DEFINITIONS.

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

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

(2) by inserting after paragraph (7) the following new paragraph:

"(8) The term 'de novo classification request' means a request made under section 513(f)(2)(A) with respect to the classification of a device.";

(3) in subparagraph (D) of paragraph (10) (as redesignated by paragraph (1)), by striking "and submissions" and inserting "submissions, and de novo classification requests"; and

(4) in paragraph (11) (as redesignated by paragraph (1)), by striking "2011" and inserting "2016".

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

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

(1) in paragraph (1), by striking "fiscal year 2013" and inserting "fiscal year 2018"; and

(2) in paragraph (2)—

(A) in subparagraph (A)—

(i) in the matter preceding clause (i), by striking "October 1, 2012" and inserting "October 1, 2017";

(ii) in clause (viii), by striking "2" and inserting "3.4"; and

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

"(xi) For a de novo classification request, a fee equal to 30 percent of the fee that applies under clause (i).."; and

(B) in subparagraph (B)(v)(I), by striking "or premarket notification submission" and inserting "premarket notification submission, or de novo classification request".

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

"(b) FEE AMOUNTS.—

"(1) IN GENERAL.—Subject to subsections (c), (d), (e), and (h), for each of fiscal years 2018 through 2022, fees under subsection (a) shall be derived from the base fee amounts specified in paragraph (2), to generate the total revenue amounts specified in paragraph (3).

"(2) BASE FEE AMOUNTS SPECIFIED.—For purposes of paragraph (1), the base fee amounts 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*

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

"(A) $183,280,756 for fiscal year 2018.

"(B) $190,654,875 for fiscal year 2019.

"(C) $200,132,014 for fiscal year 2020.

"(D) $211,748,789 for fiscal year 2021.

"(E) $213,687,660 for fiscal year 2022.".

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

(1) in paragraph (1), by striking "2012" and inserting "2017";

(2) in paragraph (2)—

(A) in subparagraph (A), by striking "2014" and inserting "2018";

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

"(B) APPLICABLE INFLATION ADJUSTMENT.—The applicable inflation adjustment for fiscal year 2018 and each subsequent fiscal year is the product of—

"(i) the base inflation adjustment under subparagraph (C) for such fiscal year; and

"(ii) the product of the base inflation adjustment under subparagraph (C) for each of the fiscal years preceding such fiscal year, beginning with fiscal year 2016.";

(C) in subparagraph (C), in the heading, by striking "TO TOTAL REVENUE AMOUNTS"; and

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

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

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

"(ii) if the Secretary determines necessary, increase (in addition to the adjustment under clause (i)) such base fee amounts, on a uniform proportionate basis, to generate the total revenue amounts under

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

(3) in paragraph (3)—

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

(B) by striking ''further adjusted'' and inserting ''increased''.

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

(1) in paragraph (1), by striking ''specified in clauses (i) through (v) and clauses (vii), (ix), and (x)'' and inserting ''specified in clauses (i) through (vii) and clauses (ix), (x), and (xi)''; and

(2) in paragraph (2)(C)—

(A) by striking ''supplement, or'' and inserting ''supplement,''; and

(B) by inserting '', or a de novo classification request'' after ''class III device''.

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

(f) FEE WAIVER OR REDUCTION.—

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

(2) CONFORMING CHANGES.—

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

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

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

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

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

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

(1) by striking "or periodic reporting concerning a class III device" and inserting "periodic reporting

concerning a class III device, or de novo classification request"; and

(2) by striking "all fees" and inserting "all such fees".

(h) CONDITIONS.—Subsection (g)(1)(A), as redesignated, of section 738 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 379j) is amended by striking "$280,587,000" and inserting "$320,825,000".

(i) CREDITING AND AVAILABILITY OF FEES.—Subsection (h), as redesignated, of section 738 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 379j) is amended—

(1) in paragraph (3)—

(A) by striking "2013 through 2017" and inserting "2018 through 2022"; and

(B) by striking "subsection (c)" and all that follows through the period at the end and inserting "subsection (c)."; and

(2) by striking paragraph (4).

SEC. 204. REAUTHORIZATION; REPORTING REQUIREMENTS.

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

(1) in paragraph (1)—

(A) in subparagraph (A)—

(i) by striking "2013" and inserting "2018"; and

(ii) by striking "the Medical Device User Fee Amendments of 2012" and inserting "the Medical Device User Fee Amendments of 2017"; and

(B) in subparagraph (B), by striking "the Medical Device User Fee Amendments Act of 2012" and inserting "the Medical Device User Fee Amendments of 2017"; and

(2) in paragraph (2), by striking "2013 through 2017" and inserting "2018 through 2022".

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

(1) in paragraph (1), by striking "2017" and inserting "2022"; and

(2) in paragraph (5), by striking "2017" and inserting "2022".

SEC. 205. CONFORMITY ASSESSMENT PILOT PROGRAM.

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

"(d) PILOT ACCREDITATION SCHEME FOR CONFORMITY ASSESSMENT.—

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

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

"(B) subject to paragraph (2), determinations by testing laboratories so accredited that a device conforms with such standard or standards shall be accepted by the Secretary for purposes of demonstrating such conformity under this section unless the Secretary finds that a particular such determination shall not be so accepted.

"(2) SECRETARIAL REVIEW OF ACCREDITED LABORATORY DETERMINATIONS.—The Secretary may—

"(A) review determinations by testing laboratories accredited pursuant to this subsection, including by conducting periodic audits of such determinations or processes of accredited bodies or testing laboratories and, following such review, taking additional measures under this Act, such as suspension or withdrawal of accreditation of such testing laboratory under paragraph (1)(A) or requesting additional information with

respect to such device, as the Secretary determines appropriate; and

"(B) if the Secretary becomes aware of information materially bearing on safety or effectiveness of a device assessed for conformity by a testing laboratory so accredited, take such additional measures under this Act as the Secretary determines appropriate, such as suspension or withdrawal of accreditation of such testing laboratory under paragraph (1)(A), or requesting additional information with regard to such device.

"(3) IMPLEMENTATION AND REPORTING.—

"(A) PUBLIC MEETING.—The Secretary shall publish in the Federal Register a notice of a public meeting to be held no later than September 30, 2018, to discuss and obtain input and recommendations from stakeholders regarding the goals and scope of, and a suitable framework and procedures and requirements for, the pilot program under this subsection.

"(B) PILOT PROGRAM GUIDANCE.—The Secretary shall—

"(i) not later than September 30, 2019, issue draft guidance regarding the goals

and implementation of the pilot program under this subsection; and

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

"(C) PILOT PROGRAM INITIATION.—Not later than September 30, 2020, the Secretary shall initiate the pilot program under this subsection.

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

"(4) SUNSET.—As of October 1, 2022—

"(A) the authority for accreditation bodies to accredit testing laboratories pursuant to paragraph (1)(A) shall cease to have force or effect;

"(B) the Secretary—

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

"(ii) may accept such a determination made prior to such date;

"(C) except for purposes of accepting a determination described in subparagraph (B)(ii),

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

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

SEC. 206. REAUTHORIZATION OF REVIEW.

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

(1) in subsection (a)(3)—

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

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

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

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

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

"(i) issue draft guidance on the factors the Secretary will use in determining whether a class I or class II device type, or subset of such device types, is eligible for review by an accredited person, including—

"(I) the risk of the device type, or subset of such device type; and

"(II) whether the device type, or subset of such device type, is permanently implantable, life sustaining, or life supporting;

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

"(iii) beginning on the date such guidance is finalized, designate and post on the internet website of the Food and Drug Administration, an updated list of class I and class II device types, or subsets of such device types, and the Secretary's determination with respect to whether each such device type, or subset of a device type, is eligible or not eligible for review by an accredited person under this section based on the factors described in clause (i).''; and

(C) by adding at the end the following:

"(C) INTERIM RULE.—Until the date on which the updated list is designated and posted in accordance with subparagraph (B)(iii), the list in effect on the date of enactment the Medical Device User Fee Amendments of 2017 shall be in effect.";

(2) in subsection (b)—

(A) in paragraph (2)—

(i) by striking subparagraph (D); and

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

(B) in paragraph (3)—

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

(ii) in subparagraph (F) (as so redesignated), by striking "The operations of" and all that follows through "it will—" and inserting "Such person shall agree, at a minimum, to include in its request for accreditation a commitment to, at the time of accreditation, and at any time it is performing any review pursuant to this section—"; and

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

"(E) The operations of such person shall be in accordance with generally accepted professional and ethical business practices."; and

(3) in subsection (c), by striking "2017" and inserting "2022".

SEC. 207. ELECTRONIC FORMAT FOR SUBMISSIONS.

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

"(3) PRESUBMISSIONS AND SUBMISSIONS SOLELY IN ELECTRONIC FORMAT.—

"(A) IN GENERAL.—Beginning on such date as the Secretary specifies in final guidance issued under subparagraph (C), presubmissions and submissions for devices described in paragraph (1) (and any appeals of action taken by the Secretary with respect to such presubmissions or submissions) shall be submitted solely in such electronic format as specified by the Secretary in such guidance.

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

"(i) any further standards for the submission by electronic format required under subparagraph (A);

"(ii) a timetable for the establishment by the Secretary of such further standards; and

"(iii) criteria for waivers of and exemptions from the requirements of this subsection.

"(C) FINAL GUIDANCE.—The Secretary shall, not later than 12 months after the close of the public comment period on the draft guidance issued under subparagraph (B), issue final guidance described in clauses (i) through (iii) of such subparagraph.".

SEC. 208. SAVINGS CLAUSE.

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

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

SEC. 209. EFFECTIVE DATE.

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

SEC. 210. SUNSET CLAUSE.

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

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

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

TITLE III—FEES RELATING TO GENERIC DRUGS

SEC. 301. SHORT TITLE; FINDING.

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

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

SEC. 302. DEFINITIONS.

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

(1) in paragraph (1)(B), by striking "application for a positron emission tomography drug." and inserting "application—

"(i) for a positron emission tomography drug; or

"(ii) submitted by a State or Federal governmental entity for a drug that is not distributed commercially.";

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

(3) by inserting after paragraph (4) the following:

"(5) The term 'contract manufacturing organization facility' means a manufacturing facility of a finished dosage form of a drug approved pursuant to an abbreviated new drug application, where such manufacturing facility is not identified in an approved abbreviated new drug application held by the owner of such facility or an affiliate of such owner or facility.".

SEC. 303. AUTHORITY TO ASSESS AND USE HUMAN GENERIC DRUG FEES.

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

(1) in the matter preceding paragraph (1), by striking "fiscal year 2013" and inserting "fiscal year 2018";

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

"(E) SUNSET.—This paragraph shall cease to be effective October 1, 2022.";

(3) in paragraph (2)—

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

"(C) NOTICE.—Not later than 60 days before the start of each of fiscal years 2018 through 2022, the Secretary shall publish in the Federal Register the amount of the drug master file fee established by this paragraph for such fiscal year."; and

(B) in subparagraph (E)—

(i) in clause (i)—

(I) by striking "no later than the date" and inserting "on the earlier of—

"(I) the date";

(II) by striking the period and inserting "; or"; and

(III) by adding at the end the following:

"(II) the date on which the drug master file holder requests the initial completeness assessment."; and

(ii) in clause (ii), by striking "notice provided for in clause (i) or (ii) of subparagraph (C), as applicable" and inserting "notice provided for in subparagraph (C)";

(4) in paragraph (3)—

(A) in the heading, by striking "AND PRIOR APPROVAL SUPPLEMENT";

(B) in subparagraph (A), by striking "or a prior approval supplement to an abbreviated new drug application";

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

"(B) NOTICE.—Not later than 60 days before the start of each of fiscal years 2018 through 2022, the Secretary shall publish in the Federal Register the amount of the fees under subparagraph (A) for such fiscal year.

"(C) FEE DUE DATE.—The fees required by subparagraphs (A) and (F) shall be due no later than the date of submission of the abbreviated new drug application or prior approval supplement for which such fee applies.";

(D) in subparagraph (D)—

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

IS NO LONGER RECEIVED" after "RECEIVED"; and

(ii) by striking "The Secretary shall" and all that follows through the period and inserting the following:

"(i) APPLICATIONS NOT CONSIDERED TO HAVE BEEN RECEIVED AND APPLICATIONS WITHDRAWN PRIOR TO BEING RECEIVED.—The Secretary shall refund 75 percent of the fee paid under subparagraph (A) for any abbreviated new drug application that the Secretary considers not to have been received within the meaning of section 505(j)(5)(A) for a cause other than failure to pay fees, or that has been withdrawn prior to being received within the meaning of section 505(j)(5)(A).

"(ii) APPLICATIONS NO LONGER RECEIVED.—The Secretary shall refund 100 percent of the fee paid under subparagraph (A) for any abbreviated new drug application if the Secretary initially receives the application under section 505(j)(5)(A) and subsequently determines that an exclusivity period for a listed drug should have pre-

vented the Secretary from receiving such application, such that the abbreviated new drug application is no longer received within the meaning of section 505(j)(5)(A).";

(E) in subparagraph (E), by striking "or prior approval supplement"; and

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

(i) by striking "2012" and inserting "2017"; and

(ii) by striking "subsection (d)(3)" and inserting "subsection (d)(2)";

(5) in paragraph (4)—

(A) in subparagraph (A)—

(i) in the matter preceding clause (i) and in clause (iii), by striking ", or intended to be identified, in at least one generic drug submission that is pending or" and inserting "in at least one generic drug submission that is";

(ii) in clause (i), by striking "or intended to be identified in at least one generic drug submission that is pending or" and inserting "in at least one generic drug submission that is";

(iii) in clause (ii), by striking "produces," and all that follows through "such a" and inserting "is identified in at least one generic drug submission in which the facility is approved to produce one or more active pharmaceutical ingredients or in a Type II active pharmaceutical ingredient drug master file referenced in at least one such"; and

(iv) in clause (iii), by striking "to fees under both such clauses" and inserting "only to the fee attributable to the manufacture of the finished dosage forms"; and

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

"(C) NOTICE.—Within the timeframe specified in subsection (d)(1), the Secretary shall publish in the Federal Register the amount of the fees under subparagraph (A) for such fiscal year.

"(D) FEE DUE DATE.—For each of fiscal years 2018 through 2022, the fees under subparagraph (A) for such fiscal year shall be due on the later of—

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

"(ii) the first business day after the enactment of an appropriations Act providing for the collection and obligation of fees for such year under this section for such year.";

(6) by redesignating paragraph (5) as paragraph (6); and

(7) by inserting after paragraph (4) the following:

"(5) GENERIC DRUG APPLICANT PROGRAM FEE.—

"(A) IN GENERAL.—A generic drug applicant program fee shall be assessed annually as described in subsection (b)(2)(E).

"(B) AMOUNT.—The amount of fees established under subparagraph (A) shall be established under subsection (d).

"(C) NOTICE.—Within the timeframe specified in subsection (d)(1), the Secretary shall publish in the Federal Register the amount of the fees under subparagraph (A) for such fiscal year.

"(D) FEE DUE DATE.—For each of fiscal years 2018 through 2022, the fees under subparagraph (A) for such fiscal year shall be due on the later of—

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

"(ii) the first business day after the date of enactment of an appropriations Act providing for the collection and obligation of fees for such fiscal year for such fiscal year.".

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

(1) in paragraph (1)—

(A) in subparagraph (A)—

(i) in the heading, by striking "2013" and inserting "2018";

(ii) by striking "2013" and inserting "2018";

(iii) by striking "$299,000,000" and inserting "$493,600,000"; and

(iv) by striking "Of that amount" and all that follows through the end of clause (ii); and

(B) in subparagraph (B)—

(i) in the heading, by striking "2014 THROUGH 2017" and inserting "2019 THROUGH 2022";

(ii) by striking "2014 through 2017" and inserting "2019 through 2022";

(iii) by striking "paragraphs (2) through (4)" and inserting "paragraphs (2) through (5)"; and

(iv) by striking "$299,000,000" and inserting "$493,600,000"; and

(2) in paragraph (2)—

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

(i) by striking "paragraph (1)(A)(ii) for fiscal year 2013 and paragraph (1)(B) for each of fiscal years 2014 through 2017" and inserting "such paragraph for a fiscal year"; and

(ii) by striking "through (4)" and inserting "through (5)";

(B) in subparagraph (A), by striking "Six percent" and inserting "Five percent";

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

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

"(C) Twenty percent shall be derived from fees under subsection (a)(4)(A)(i) (relating to generic drug facilities). The amount of the fee for a contract manufacturing organization facility shall be equal to one-third the amount of the fee for a facility that is not a contract manufacturing organization facility. The amount of the fee for a facility located outside the United States and its territories and possessions shall be $15,000 higher than the amount of the fee for a facility located in the United States and its territories and possessions.";

(D) in subparagraph (D)—

(i) by striking "Fourteen percent" and inserting "Seven percent";

(ii) by striking "not less than $15,000 and not more than $30,000" and inserting "$15,000"; and

(iii) by striking ", as determined" and all that follows through the period at the end and inserting a period; and

(E) by adding at the end the following:

"(E)(i) Thirty-five percent shall be derived from fees under subsection (a)(5) (relating to generic drug applicant program fees). For pur-

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

"(I) If a person (including its affiliates) owns at least one but not more than 5 approved abbreviated new drug applications on the due date for the fee under this subsection, the person (including its affiliates) shall be assessed a small business generic drug applicant program fee equal to one-tenth of the large size operation generic drug applicant program fee.

"(II) If a person (including its affiliates) owns at least 6 but not more than 19 approved abbreviated new drug applications on the due date for the fee under this subsection, the person (including its affiliates) shall be assessed a medium size operation generic drug applicant program fee equal to two-fifths of the large size operation generic drug applicant program fee.

"(III) If a person (including its affiliates) owns 20 or more approved abbreviated new drug applications on the due date for the fee under this subsection, the person (including its affiliates) shall be assessed a large size operation generic drug applicant program fee.

"(ii) For purposes of this subparagraph, an abbreviated new drug application shall be deemed not to be approved if the applicant has submitted a written request for withdrawal of approval of such abbreviated new drug application by April 1 of the previous fiscal year.".

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

(1) in paragraph (1)—

(A) by striking "2014" and inserting "2019";

(B) by inserting "to equal the product of the total revenues established in such notice for the prior fiscal year multiplied" after "a fiscal year,"; and

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

(2) in paragraph (2)—

(A) by striking "2017" each place it appears and inserting "2022";

(B) by striking "the first 3 months of fiscal year 2018" and inserting "the first 3 months of fiscal year 2023"; and

(C) by striking "Such fees may only be used in fiscal year 2018.".

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

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

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

(2) by redesignating paragraph (3) as paragraph (2); and

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

under paragraphs (1) and (2)" and inserting "fee under paragraph (1)".

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

(1) by striking paragraph (1);

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

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

(A) by striking "paragraph (4)" and inserting "paragraph (3)"; and

(B) by striking "Such information shall" and all that follows through the end of subparagraph (B) and inserting "Such information shall, for each fiscal year, be submitted, updated, or reconfirmed on or before June 1 of the previous fiscal year."; and

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

(A) in the heading, by striking "CONTENTS OF NOTICE" and inserting "INFORMATION REQUIRED TO BE SUBMITTED";

(B) in the matter preceding subparagraph (A), by striking "paragraph (2)" and inserting "paragraph (1)";

(C) in subparagraph (A), by striking "or intended to be identified";

(D) in subparagraph (D), by striking "and" at the end;

(E) in subparagraph (E), by striking the period and inserting "; and"; and

(F) by adding at the end the following:

"(F) whether the facility is a contract manufacturing organization facility.".

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

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

(2) in paragraph (2)(C)(ii), by striking "of 505(j)(5)(A)" and inserting "of section 505(j)(5)(A)"; and

(3) by adding at the end the following:

"(5) GENERIC DRUG APPLICANT PROGRAM FEE.—

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

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

"(i) The Secretary shall place the person on a publicly available arrears list.

"(ii) Any abbreviated new drug application submitted by the generic drug applicant or an affiliate of such applicant shall not be received, within the meaning of section 505(j)(5)(A).

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

"(B) APPLICATION OF PENALTIES.—The penalties under subparagraph (A) shall apply until the fee required under subsection (a)(5) is paid.".

(g) LIMITATIONS.—Section 744B(h)(2) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 379–42(h)(2)) is amended by striking "for Type II active pharmaceutical ingredient drug master files, abbreviated new drug applications and prior approval supplements, and generic drug facilities and active pharmaceutical ingredient facilities".

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

(1) in paragraph (2)—

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

(B) in subparagraph (D)—

(i) in the heading, by striking "IN SUBSEQUENT YEARS"; and

(ii) by striking "(after fiscal year 2013)"; and

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

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

(i) INFORMATION ON ABBREVIATED NEW DRUG APPLICATIONS OWNED BY APPLICANTS AND THEIR AFFILIATES.—Section 744B of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 379–42) is amended by adding at the end the following:

"(o) INFORMATION ON ABBREVIATED NEW DRUG APPLICATIONS OWNED BY APPLICANTS AND THEIR AFFILIATES.—

"(1) IN GENERAL.—By April 1 of each year, each person that owns an abbreviated new drug application, or any affiliate of such person, shall submit, on behalf of the person and its affiliates, to the Secretary a list of—

"(A) all approved abbreviated new drug applications owned by such person; and

"(B) if any affiliate of such person also owns an abbreviated new drug application, all affiliates that own any such abbreviated new drug applications and all approved abbreviated new drug applications owned by any such affiliate.

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

SEC. 304. REAUTHORIZATION; REPORTING REQUIREMENTS.

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

(1) in subsection (a)—

(A) by striking "2013" and inserting "2018"; and

(B) by striking "Generic Drug User Fee Amendments of 2012" and inserting "Generic Drug User Fee Amendments of 2017";

(2) in subsection (b), by striking "2013" and inserting "2018"; and

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

SEC. 305. SUNSET DATES.

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

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

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

SEC. 306. EFFECTIVE DATE.

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

SEC. 307. SAVINGS CLAUSE.

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

TITLE IV—FEES RELATING TO BIOSIMILAR BIOLOGICAL PRODUCTS

SEC. 401. SHORT TITLE; FINDING.

(a) SHORT TITLE.—This title may be cited as the "Biosimilar User Fee Amendments of 2017".

(b) FINDING.—The Congress finds that the fees authorized by the amendments made in this title will be dedicated to expediting the process for the review of biosimilar biological product applications, including postmarket safety activities, as set forth in the goals identified for purposes of

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

SEC. 402. DEFINITIONS.

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

"(1) The term 'adjustment factor' applicable to a fiscal year is the Consumer Price Index for urban consumers (Washington-Baltimore, DC–MD–VA–WV; Not Seasonally Adjusted; All items; Annual Index) for October of the preceding fiscal year divided by such Index for October 2011.".

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

SEC. 403. AUTHORITY TO ASSESS AND USE BIOSIMILAR FEES.

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

(1) in the matter preceding paragraph (1), by striking "fiscal year 2013" and inserting "fiscal year 2018";

(2) in the heading of paragraph (1), by striking "BIOSIMILAR" and inserting "BIOSIMILAR BIOLOGICAL PRODUCT";

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

(4) in paragraph (1)(B)(i), by striking "(b)(1)(B) for biosimilar biological product development" and inserting "(c)(5) for the biosimilar biological product development program";

(5) in paragraph (1)(B)(ii), by striking "annual biosimilar biological product development program fee" and inserting "annual biosimilar biological product development fee";

(6) in paragraph (1)(B)(iii), by striking "annual biosimilar development program fee" and inserting "annual biosimilar biological product development fee";

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

"(iv) REFUND.—If a person submits a marketing application for a biosimilar biological product before October 1 of a fiscal year and such application is accepted for filing on or after October 1 of such fiscal year, the person may request a refund equal to the annual biosimilar development fee paid by the person for the product for such fiscal year. To qualify for consideration for a refund under this clause, a person shall submit to the Secretary a written request for such refund not later than 180 days after the marketing application is accepted for filing.";

(8) in paragraph (1)(C), by striking "for a product effective October 1 of a fiscal year by," and inserting "for a product, effective October 1 of a fiscal year, by,";

(9) in paragraph (1)(D)—

(A) in clause (i) in the matter preceding subclause (I), by inserting ", if the person seeks to resume participation in such program," before "pay a fee";

(B) in clause (i)(I), by inserting after "grants a request" the following: "by such person"; and

(C) in clause (i)(II), by inserting after "discontinued)" the following: "by such person";

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

(11) in paragraph (1)(F)—

(A) in the subparagraph heading, by striking "BIOSIMILAR DEVELOPMENT PROGRAM" before "FEES"; and

(B) by amending clause (i) to read as follows:

"(i) REFUNDS.—Except as provided in subparagraph (B)(iv), the Secretary shall not refund any initial or annual biosimilar biological product development fee paid under subparagraph (A) or (B), or any reactivation fee paid under subparagraph (D).";

(12) in paragraph (2)—

(A) in the paragraph heading, by striking "AND SUPPLEMENT";

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

"(A) IN GENERAL.—Each person that submits, on or after October 1, 2017, a biosimilar biological product application shall be subject to the following fees:

"(i) A fee established under subsection (c)(5) for a biosimilar biological product application for which clinical data (other than comparative bioavailability studies) with respect to safety or effectiveness are required for approval.

"(ii) A fee established under subsection (c)(5) for a biosimilar biological product application for which clinical data (other than comparative bioavailability studies) with respect to safety or effectiveness are not required for approval. Such fee shall be equal to half of the amount of the fee described in clause (i).

"(B) RULE OF APPLICABILITY; TREATMENT OF CERTAIN PREVIOUSLY PAID FEES.—Any person who pays a fee under subparagraph (A), (B), or (D) of paragraph (1) for a product before October 1, 2017, but submits a biosimilar biological product application for that product after such date, shall—

"(i) be subject to any biosimilar biological product application fees that may be assessed at the time when such biosimilar biological product application is submitted; and

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

(C) in the heading of subparagraph (D), by striking "OR SUPPLEMENT";

(D) in subparagraphs (C) through (F), by striking "or supplement" each place it appears; and

(E) in subparagraph (D), by striking "or a supplement";

(13) by amending paragraph (3) to read as follows:

"(3) BIOSIMILAR BIOLOGICAL PRODUCT PROGRAM FEE.—

"(A) IN GENERAL.—Each person who is named as the applicant in a biosimilar biological product application shall pay the annual biosimilar biological product program fee estab-

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

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

"(ii) as of October 1 of such fiscal year, does not appear on a list, developed and maintained by the Secretary, of discontinued biosimilar biological products.

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

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

"(ii) the first business day after the enactment of an appropriations Act providing for the collection and obligation of fees for such year under this section.

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

"(D) LIMITATION.—A person who is named as the applicant in a biosimilar biological product application shall not be assessed more than

5 biosimilar biological product program fees for a fiscal year for biosimilar biological products identified in such biosimilar biological product application.".

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

"(b) FEE REVENUE AMOUNTS.—

"(1) FISCAL YEAR 2018.—For fiscal year 2018, fees under subsection (a) shall be established to generate a total revenue amount equal to the sum of—

"(A) $45,000,000; and

"(B) the dollar amount equal to the fiscal year 2018 adjustment (as determined under subsection (c)(4)).

"(2) SUBSEQUENT FISCAL YEARS.—For each of the fiscal years 2019 through 2022, fees under subsection (a) shall, except as provided in subsection (c), be established to generate a total revenue amount equal to the sum of—

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

"(B) the dollar amount equal to the inflation adjustment for the fiscal year (as determined under subsection (c)(1));

"(C) the dollar amount equal to the capacity planning adjustment for the fiscal year (as determined under subsection (c)(2)); and

"(D) the dollar amount equal to the operating reserve adjustment for the fiscal year, if applicable (as determined under subsection (c)(3)).

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

"(A) ALLOCATION.—The Secretary shall determine the percentage of the total revenue amount for a fiscal year to be derived from, respectively—

"(i) initial and annual biosimilar development fees and reactivation fees under subsection (a)(1);

"(ii) biosimilar biological product application fees under subsection (a)(2); and

"(iii) biosimilar biological product program fees under subsection (a)(3).

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

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

"(C) BIOSIMILAR BIOLOGICAL PRODUCT DEVELOPMENT FEES.—The initial biosimilar biological product development fee under subsection (a)(1)(A) for a fiscal year shall be equal to the annual biosimilar biological product development fee under subsection (a)(1)(B) for that fiscal year.

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

"(4) ANNUAL BASE REVENUE.—For purposes of paragraph (2), the dollar amount of the annual base revenue for a fiscal year shall be the dollar amount of the total revenue amount for the previous fiscal year, excluding any adjustments to such revenue amount under subsection (c)(3).".

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

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

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

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

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

"(c) ADJUSTMENTS; ANNUAL FEE SETTING.—

"(1) INFLATION ADJUSTMENT.—

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

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

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

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

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

of the Food and Drug Administration, of all personnel compensation and benefits paid with respect to such positions for the first 3 years of the preceding 4 fiscal years, multiplied by the proportion of personnel compensation and benefits costs to total costs of the process for the review of biosimilar biological product applications (as defined in section 744G(13)) for the first 3 years of the preceding 4 fiscal years; and

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

"(2) CAPACITY PLANNING ADJUSTMENT.—

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

"(B) CAPACITY PLANNING METHODOLOGY.—

"(i) DEVELOPMENT; EVALUATION AND REPORT.—The Secretary shall obtain, through a contract with an independent accounting or consulting firm, a report evaluating options and recommendations for a new methodology to accurately assess changes in the resource and capacity needs of the process for the review of biosimilar biological product applications. The capacity planning methodological options and recommendations presented in such report shall utilize and be informed by personnel time reporting data as an input. The report shall be published for public comment not later than September 30, 2020.

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

"(I) incorporate such approaches and attributes as the Secretary determines appropriate; and

"(II) be effective beginning with the first fiscal year for which fees are set after such capacity planning methodology is established.

"(C) LIMITATION.—Under no circumstances shall an adjustment under this paragraph result in fee revenue for a fiscal year that is less than the sum of the amounts under subsections (b)(2)(A) (the annual base revenue for the fiscal year) and (b)(2)(B) (the dollar amount of the inflation adjustment for the fiscal year).

"(D) PUBLICATION IN FEDERAL REGISTER.—The Secretary shall publish in the Federal Register notice under paragraph (5) the fee

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

"(3) OPERATING RESERVE ADJUSTMENT.—

"(A) INTERIM APPLICATION; FEE REDUCTION.—Until the first fiscal year for which the capacity planning adjustment under paragraph (2) is effective, the Secretary may, in addition to the adjustment under paragraph (1), reduce the fee revenue and fees under this section for a fiscal year as the Secretary determines appropriate for long-term financial planning purposes.

"(B) GENERAL APPLICATION AND METHODOLOGY.—Beginning with the first fiscal year for which the capacity planning adjustment under paragraph (2) is effective, the Secretary may, in addition to the adjustments under paragraphs (1) and (2)—

"(i) reduce the fee revenue and fees under this section as the Secretary determines appropriate for long-term financial planning purposes; or

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

fees for the process for the review of biosimilar biological product applications.

"(C) FEDERAL REGISTER NOTICE.—If an adjustment under subparagraph (A) or (B) is made, the rationale for the amount of the increase or decrease (as applicable) in fee revenue and fees shall be contained in the annual Federal Register notice under paragraph (5) establishing fee revenue and fees for the fiscal year involved.

"(4) FISCAL YEAR 2018 ADJUSTMENT.—

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

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

"(C) LIMITATION.—No adjustment under this paragraph shall result in an increase in fee

revenue and fees under this section in excess of $9,000,000.

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

"(A) establish, for the fiscal year, initial and annual biosimilar biological product development fees and reactivation fees under subsection (a)(1), biosimilar biological product application fees under subsection (a)(2), and biosimilar biological product program fees under subsection (a)(3), based on the revenue amounts established under subsection (b) and the adjustments provided under this subsection; and

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

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

(d) APPLICATION FEE WAIVER FOR SMALL BUSINESS.—Subsection (d)(1) of section 744H of the Federal

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

(1) by striking subparagraph (B);

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

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

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

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

(1) in paragraph (2)—

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

"(C) COMPLIANCE.—The Secretary shall be considered to have met the requirements of subparagraph (B) in any fiscal year if the costs described in such subparagraph are not more than

15 percent below the level specified in such subparagraph."; and

(B) in subparagraph (D)—

(i) in the heading, by striking "IN SUBSEQUENT YEARS"; and

(ii) by striking "(after fiscal year 2013)"; and

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

SEC. 404. REAUTHORIZATION; REPORTING REQUIREMENTS.

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

(1) in subsection (a)—

(A) by striking "2013" and inserting "2018"; and

(B) by striking "Biosimilar User Fee Act of 2012" and inserting "Biosimilar User Fee Amendments of 2017";

(2) in subsection (b), by striking "2013" and inserting "2018";

(3) by striking subsection (d);

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

(5) in subsection (d), as so redesignated, by striking "2017" each place it appears and inserting "2022".

SEC. 405. SUNSET DATES.

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

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

(c) PREVIOUS SUNSET PROVISION.—

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

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

SEC. 406. EFFECTIVE DATE.

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

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

SEC. 407. SAVINGS CLAUSE.

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

TITLE V—REAUTHORIZATIONS AND IMPROVEMENTS RELATED TO DRUGS

SEC. 501. REAUTHORIZATION OF PROVISION RELATING TO EXCLUSIVITY OF CERTAIN DRUGS CONTAINING SINGLE ENANTIOMERS.

Section 505(u)(4) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(u)(4)) is amended by striking "2017" and inserting "2022".

SEC. 502. REAUTHORIZATION OF ORPHAN GRANTS PROGRAM.

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

SEC. 503. REAUTHORIZATION OF PEDIATRIC STUDY OF DRUGS.

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

SEC. 504. PROTECTING AND STRENGTHENING THE DRUG SUPPLY CHAIN.

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

(1) by striking "(d)(1) Except as" and inserting "(d)(1)(A) Except as"; and

(2) by adding at the end the following:

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

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

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

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

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

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

(2) in lowering such cost, will—

(A) balance the need to encourage innovation with the need to improve affordability; and

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

TITLE VI—DEVICE INSPECTION AND REGULATORY IMPROVEMENTS

Subtitle A—Improving the Process for Inspections of Device Establishments

SEC. 601. RISK-BASED INSPECTIONS FOR DEVICES.

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

"(2) RISK-BASED SCHEDULE FOR DEVICES.—

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

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

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

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

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

SEC. 602. RECOGNITION OF FOREIGN GOVERNMENT INSPECTIONS.

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

SEC. 603. IMPROVEMENTS TO INSPECTIONS PROCESS FOR DEVICE ESTABLISHMENTS.

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

"(h)(1) In the case of inspections other than for-cause inspections, the Secretary shall review processes and standards applicable to inspections of domestic and foreign device establishments in effect as of the date of the enactment of this subsection, and update such processes and standards through the adoption of uniform processes and standards applicable to such inspections. Such processes and standards shall provide for—

"(A) exceptions to such processes and standards, as appropriate;

"(B) announcing the inspection of the establishment within a reasonable time before such inspection occurs, including by providing to the owner, operator, or agent in charge of the establishment a notification regarding the type and nature of the inspection;

"(C) a reasonable estimate of the timeframe for the inspection, an opportunity for advance communications between the officers or employees carrying out the inspection under subsection (a)(1) and the owner, operator, or agent in charge of the establishment concerning appropriate working hours during

the inspection, and, to the extent feasible, advance notice of some records that will be requested in order to expedite the inspection; and

"(D) regular communications during the inspection with the owner, operator, or agent in charge of the establishment regarding inspection status, which may be recorded by either party with advance notice and mutual consent.

"(2)(A) The Secretary shall, with respect to a request described in subparagraph (B), provide nonbinding feedback with respect to such request not later than 45 days after the Secretary receives such request.

"(B) A request described in this subparagraph is a request for feedback—

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

"(ii) with respect to actions proposed to be taken by a device establishment in a response to a report received by such establishment pursuant to subsection (b) that involve a public health priority, that implicate systemic or major actions, or relate to emerging safety issues (as determined by the Secretary).

"(3) Nothing in this subsection limits the authority of the Secretary to conduct inspections otherwise permitted

under this Act in order to ensure compliance with this Act.".

(b) GUIDANCE.—

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

(A) specifies how the Food and Drug Administration will implement the process described in paragraph (1) of subsection (h) of section 704 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 374), as added by subsection (a), and the requirements described in paragraph (2) of such subsection;

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

(C) establishes, with respect to inspections of both domestic and foreign device establishments (as referred to in section 510(h)(2) of the Federal Food, Drug, and Cosmetic Act, as amended by subsection (a)), a standard timeframe for such inspections—

(i) that occurs over consecutive days; and

(ii) to which each investigator conducting such an inspection shall adhere unless the investigator identifies to the establishment involved a reason that more time is needed to conduct such investigation; and

(D) identifies practices for investigators and device establishments to facilitate the continuity of inspections of such establishments.

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

SEC. 604. CERTIFICATES TO FOREIGN GOVERNMENTS FOR DEVICES.

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

(1) by adding at the end the following:

"(E)(i) If the Secretary denies a request made under subparagraph (A)(ii) for certification with respect to a device, the Secretary shall provide, in writing, to the person

seeking such certification the basis for such denial, and specifically identify the finding upon which such denial is based.

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

"(I) grounds other than an injunction proceeding pursuant to section 302, seizure action pursuant to section 304, or a recall designated Class I or Class II pursuant to part 7, title 21, Code of Federal Regulations, and

"(II) an establishment being considered out of compliance with part 820, title 21, Code of Federal Regulations,

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

"(iii) With respect to a device manufactured in an establishment that has received a report under section 704(b), the Secretary shall not deny a request for certification under subparagraph (A)(ii) based exclusively on the issuance of that report if the owner, operator, or agent in charge of such establishment has agreed to a plan of correction in response to such report.

"(F)(i) The Secretary shall provide a process for a person who is denied a certification as described in subparagraph (E)(i) to request a review that conforms to the standards of section 517A(b).

"(ii) Notwithstanding any previous review conducted pursuant to clause (i), a person who has been denied a certification for a device as described in subparagraph (E)(i) may, at any time, request a review of that denial in order to present new information relating to actions taken by such person to address the reasons identified by the Secretary for such denial, including evidence that corrective actions are being or have been implemented to address the grounds for noncompliance identified by the Secretary under subparagraph (E)(ii).

"(G)(i) This paragraph applies to requests for certification on behalf of any device establishment registered under section 510, whether the establishment is located in the United States or another country.

"(ii) The Secretary may charge a fee for the issuance of a certification described in clause (i), and such fee is subject to the same conditions and requirements as a fee charged under subparagraph (B) for a certification issued under such subparagraph."; and

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

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

SEC. 605. FACILITATING INTERNATIONAL HARMONIZATION.

Section 704(g) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 374(g)) is amended by adding at the end the following:

"(15) Notwithstanding any other provision of this subsection, for purposes of conducting inspections of establishments that manufacture, prepare, propagate, compound, or process devices except types of devices licensed under section 351 of the Public Health Service Act, which inspections are required under section 510(h) or are inspections of such establishments required to register pursuant to section 510(i), the Secretary may recognize auditing organizations that are recognized by organizations established by governments to facilitate international harmonization. Nothing in this paragraph affects the authority of the Secretary to inspect any device establishment pursuant to this Act. Nothing in

this paragraph affects the authority of the Secretary to determine the official classification of an inspection.".

SEC. 606. REAUTHORIZATION OF INSPECTION PROGRAM.

Section 704(g)(11) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 374(g)(11)) is amended by striking "October 1, 2017" and inserting "October 1, 2022".

Subtitle B—Other Provisions

SEC. 611. REAUTHORIZATION OF PEDIATRIC HUMANITARIAN DEVICE EXCEPTIONS.

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

SEC. 612. REAUTHORIZATION OF PEDIATRIC DEVICE CONSORTIA.

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

SEC. 613. REGULATION OF OVER-THE-COUNTER HEARING AIDS.

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

"(p) REGULATION OF OVER-THE-COUNTER HEARING AIDS.—

"(1) DEFINITION.—

"(A) In this subsection, the term 'over-the-counter hearing aid' means a device—

"(i) that uses the same fundamental scientific technology as air conduction hearing aids (as defined in section 874.3300 of title 21, Code of Federal Regulations) (or any successor regulation) or wireless air conduction hearing aids (as defined in section 874.3305 of title 21, Code of Federal Regulations) (or any successor regulation);

"(ii) that is intended to be used by adults over the age of 18 to compensate for perceived mild to moderate hearing impairment;

"(iii) that, through tools, tests, or software, allows the user to control the over-the-counter hearing aid and customize it to the user's hearing needs;

"(iv) that may—

"(I) use wireless technology; or

"(II) include tests for self-assessment of hearing loss; and

"(v) that is available over-the-counter, without the supervision, prescription, or

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

"(B) Such term does not include a personal sound amplification product intended to amplify sound for nonhearing impaired consumers in situations including hunting and bird-watching.

"(2) REGULATION.—An over-the-counter hearing aid shall be subject to the regulations promulgated in accordance with section 613(b) of the FDA Reauthorization Act of 2017 and shall be exempt from sections 801.420 and 801.421 of title 21, Code of Federal Regulations (or any successor regulations).".

(b) REGULATIONS TO ESTABLISH CATEGORY.—

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

(2) REQUIREMENTS.—In promulgating the regulations under paragraph (1), the Secretary shall—

(A) include requirements that provide reasonable assurances of the safety and efficacy of over-the-counter hearing aids;

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

(C) include requirements for appropriate labeling of the over-the-counter hearing aid, including requirements that such labeling include a conspicuous statement that the device is only intended for adults over the age of 18, information on how consumers may report adverse events, information on any contraindications, conditions, or symptoms of medically treatable causes of hearing loss, and advisements to consult promptly with a licensed physician; and

(D) describe the requirements under which the sale of over-the-counter hearing aids is permitted, without the supervision, prescription, or other order, involvement, or intervention of a licensed person, to consumers through in-person transactions, by mail, or online.

(3) PREMARKET NOTIFICATION.—The Secretary shall make findings under section 510(m) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360(m)) to determine whether over-the-counter hearing aids (as defined in section 520(p) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360j), as amended by subsection (a)) require a report under section 510(k) to provide reasonable assurance of safety and effectiveness.

(4) EFFECT ON STATE LAW.—No State or local government shall establish or continue in effect any law, regulation, order, or other requirement specifically related to hearing products that would restrict or interfere with the servicing, marketing, sale, dispensing, use, customer support, or distribution of over-the-counter hearing aids (as defined in section 520(p) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360j), as amended by subsection (a)) through in-person transactions, by mail, or online, that is different from, in addition to, or otherwise not identical to, the regulations promulgated under this subsection, including any State or local requirement for the supervision, prescription, or other order, involvement, or intervention of a licensed person for consumers to access over-the-counter hearing aids.

(5) NO EFFECT ON PRIVATE REMEDIES.—Nothing in this section shall be construed to modify or otherwise affect the ability of any person to exercise a private right of action under any State or Federal product liability, tort, warranty, contract, or consumer protection law.

(c) NEW GUIDANCE ISSUED.—Not later than the date on which final regulations are issued under subsection (b), the Secretary shall update and finalize the draft guidance of the Department of Health and Human Services entitled "Regulatory Requirements for Hearing Aid Devices and Personal Sound Amplification Products", issued on November 7, 2013. Such updated and finalized guidance shall clarify which products, on the basis of claims or other marketing, advertising, or labeling material, meet the definition of a device in section 201 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321) and which products meet the definition of a personal sound amplification product, as set forth in such guidance.

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

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

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

(a) IN GENERAL.—Not later than 180 days after the date of enactment of this Act, the Secretary of Health and Human Services, acting through the Commissioner of Food and Drugs, shall submit to the Committee on Energy and Commerce of the House of Representatives and the Committee on Health, Education, Labor and Pensions of the Senate a report on how the Food and Drug Administration intends to ensure the quality, safety, and continued effectiveness of devices (as defined in section 201(h) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 301(h))) with respect to which servicing (as defined in subsection (c)) has been performed by any entity engaging in such servicing.

(b) CONTENTS.—The report submitted under subsection (a) shall contain—

(1) the status of, and findings to date with respect to, the notice entitled "Refurbishing, Reconditioning, Rebuilding, Remarketing, Remanufacturing, and Servicing of Medical Devices Performed by Third-Party Entities and Original Equipment Manufacturers; Request for Comments" published by the

Food and Drug Administration on April 25, 2016 (81 Fed. Reg. 24041 et seq.), including how the Food and Drug Administration intends to define the specific activities performed on a device by the manufacturer of the device or other entities;

(2) a description of the statutory or regulatory authority of the Food and Drug Administration used to oversee and regulate servicing conducted with respect to devices;

(3) details on how the Food and Drug Administration intends to protect the public health by ensuring consistent quality, safety, and continued effectiveness of devices with respect to which servicing has been performed by any entity engaging in such servicing;

(4) information on how the Food and Drug Administration can better understand the device servicing industry, including the size, scope, location, and composition of entities performing such servicing and the rate of adverse events related to such servicing;

(5) information regarding the current regulation by States, the Joint Commission, or other regulatory bodies of servicing conducted with respect to devices by all entities, including original equipment manufacturers, third-party entities, and hospitals; and

(6) any additional information determined by the Secretary (acting through the Commissioner) to be relevant to ensuring the quality, safety, and continued effectiveness of devices with respect to which servicing has been performed, including whether additional Federal statutory authority is necessary to ensure such quality, safety, and continued effectiveness.

(c) SERVICING DEFINED.—In this section, the term "servicing" includes, with respect to a device, refurbishing, reconditioning, rebuilding, remarketing, remanufacturing, repairing, or other servicing of the device by a person other than the manufacturer of the device.

SEC. 615. DEVICE PILOT PROJECTS TO GENERATE RELIABLE AND TIMELY SAFETY AND ACTIVE SURVEILLANCE DATA.

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

"(i) PILOT PROJECTS TO GENERATE RELIABLE AND TIMELY SAFETY AND ACTIVE SURVEILLANCE DATA.—

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

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

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

"(B) The project informs, to the extent applicable, the development of methods, systems, data criteria, and programs that could be used to support safety and active surveillance activities for any device.

"(C) The project shall be designed and conducted in coordination with a comprehensive system for evaluating device technology that operates under a governing board with appropriate representation of stakeholders, including patient groups and device manufacturers.

"(D) The project uses electronic health data including, as appropriate, claims data, patient survey data, and any other data, as the Secretary determines appropriate.

"(E) The project prioritizes devices and device types that meet one or more of the following criteria:

"(i) Devices and device types for which the collection and analysis of real world evidence regarding a device's safety and effectiveness is likely to advance public health.

"(ii) Devices and device types that are widely used.

"(iii) Devices and device types, the failure of which has significant health consequences.

"(iv) Devices and device types for which the Secretary—

"(I) has received public recommendations in accordance with paragraph (2)(B); and

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

"(2) PARTICIPATION.—The Secretary shall establish the conditions and processes—

"(A) under which a manufacturer of a device may voluntarily participate in a pilot project described in paragraph (1); and

"(B) for facilitating public recommendations for devices to be prioritized under such a pilot project, including requirements for the data necessary to support such a recommendation.

"(3) CONTINUATION OF ONGOING PROJECTS.—The Secretary may continue or expand projects, with respect to providing timely and reliable information on the safety and effectiveness of devices approved under section 515, cleared under section 510(k), or classified under section 513(f)(2), that are being carried out as of the date of the enactment of the FDA Reauthorization Act of 2017. The Secretary shall, beginning on such date of enactment, take such steps as may be necessary—

"(A) to ensure such projects meet the requirements of subparagraphs (A) through (E) of paragraph (1); and

"(B) to increase the voluntary participation in such projects of manufacturers of devices and facilitate public recommendations for any devices prioritized under such a project.

"(4) IMPLEMENTATION.—

"(A) CONTRACTING AUTHORITY.—The Secretary may carry out a pilot project meeting the criteria specified in subparagraphs (A) through (E) of paragraph (1) or a project continued or expanded under paragraph (3) by entering into contracts, cooperative agreements, grants, or other appropriate agreements with public or private entities that have a significant presence in the United States and meet the following conditions:

"(i) If such an entity is a component of another organization, the entity and the organization have established an agreement under which appropriate security measures are implemented to maintain the confidentiality and privacy of the data described in paragraph (1)(D) and such agreement ensures that the entity will not make an unauthorized disclosure of such data to the other components of the organization in breach of requirements with respect to confidentiality and privacy of such data established under such security measures.

"(ii) In the case of the termination or nonrenewal of such a contract, cooperative

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

"(I) The entity or entities shall continue to comply with the requirements with respect to confidentiality and privacy referred to in clause (i) under this subparagraph with respect to all data disclosed to the entity under such an agreement.

"(II) The entity or entities shall return any data disclosed to such entity pursuant to this subsection and to which it would not otherwise have access or, if returning such data is not practicable, destroy the data.

"(iii) The entity or entities shall have one or more qualifications with respect to—

"(I) research, statistical, epidemiologic, or clinical capability and expertise to conduct and complete the activities under this subsection, including the capability and expertise to provide the Secretary access to de-identi-

fied data consistent with the requirements of this subsection;

"(II) an information technology infrastructure to support electronic data and operational standards to provide security for such data, as appropriate;

"(III) experience with, and expertise on, the development of research on, and surveillance of, device safety and effectiveness using electronic health data; or

"(IV) such other expertise which the Secretary determines necessary to carry out such a project.

"(B) REVIEW OF CONTRACT IN THE EVENT OF A MERGER OR ACQUISITION.—The Secretary shall review any contract, cooperative agreement, grant, or other appropriate agreement entered into under this paragraph with an entity meeting the conditions specified in subparagraph (A) in the event of a merger or acquisition of the entity in order to ensure that the requirements specified in this subsection will continue to be met.

"(5) COMPLIANCE WITH REQUIREMENTS FOR RECORDS OR REPORTS ON DEVICES.—The participation of a manufacturer in pilot projects under this subsection shall not affect the eligibility of such manufacturer to participate in any quarterly reporting program with respect to devices carried out under section 519 or 522. The Secretary may determine that, for a specified time period to be determined by the Secretary, a manufacturer's participation in a pilot project under this subsection or a project continued or expanded under paragraph (3) may meet the applicable requirements of section 519 or 522, if—

"(A) the project has demonstrated success in capturing relevant adverse event information; and

"(B) the Secretary has established procedures for making adverse event and safety information collected from such project public, to the extent possible.

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

"(A) individually identifiable health information so collected shall not be disclosed when

presenting any information from such project; and

"(B) any such disclosure shall be made in compliance with regulations issued pursuant to section 264(c) of the Health Insurance Portability and Accountability Act of 1996 (42 U.S.C. 1320d–2 note) and sections 552 and 552a of title 5, United States Code.

"(7) LIMITATIONS.—

"(A) IN GENERAL.—No pilot project under this subsection undertaken in coordination with the comprehensive system described in paragraph (1)(C), shall allow for an entity participating in such program, other than the Secretary or the Secretary's designee, to make determinations of safety or effectiveness, or substantial equivalence, for purposes of the Act.

"(B) NO USE OF FEES.—Pilot projects initiated under this subsection may not primarily utilize funds collected pursuant to the Medical Device User Fee Amendments of 2017.

"(8) OTHER PROJECTS REQUIRED TO COMPLY.—Paragraphs (1)(B), (4)(A)(i), (4)(A)(ii), (5), and (6) shall apply with respect to any pilot program undertaken in coordination with the comprehensive system

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

"(9) REPORT TO CONGRESS.—Not later than 18 months after the date of enactment of this Act, and annually thereafter, the Secretary shall submit to the Committee on Energy and Commerce of the House of Representatives and the Committee on Health, Education, Labor and Pensions of the Senate a report containing a description of the pilot projects being conducted under this subsection and projects continued or expanded pursuant to paragraph (3), including for each such project—

"(A) how the project is being implemented in accordance with paragraph (4), including how such project is being implemented through a contract, cooperative agreement, grant, or other appropriate agreement, if applicable;

"(B) the number of manufacturers that have agreed to participate in such project;

"(C) the data sources used to conduct such project;

"(D) the devices or device categories involved in such project;

"(E) the number of patients involved in such project; and

"(F) the findings of the project in relation to device safety, including adverse events, malfunctions, and other safety information.

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

(b) REPORT.—Not later than January 31, 2021, the Secretary of Health and Human Services, acting through the Commissioner of Food and Drugs, may conduct a review through an independent third party to evaluate the strengths, limitations, and appropriate use of evidence collected pursuant to real world evidence pilot projects described in the letters described in section 201(b) of the Medical Device User Fee Amendments of 2017 and subsection (i) of section 519 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360i), as added by subsection (a)—

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

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

efficiently generate reliable and timely evidence about the effectiveness of the surveillance of devices with respect to safety.

SEC. 616. RISK-BASED CLASSIFICATION OF ACCESSORIES.

(a) IN GENERAL.—Subsection (f) of section 513 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360c) is amended by adding at the end the following new paragraph:

"(6)(A) Subject to the succeeding subparagraphs of this paragraph, the Secretary shall, by written order, classify an accessory under this section based on the risks of the accessory when used as intended and the level of regulatory controls necessary to provide a reasonable assurance of safety and effectiveness of the accessory, notwithstanding the classification of any other device with which such accessory is intended to be used.

"(B) The classification of any accessory distinct from another device by regulation or written order issued prior to December 13, 2016, shall continue to apply unless and until the accessory is reclassified by the Secretary, notwithstanding the classification of any other device with which such accessory is intended to be used. Nothing in this section shall preclude the Secretary's ability to initiate the classification of an accessory through regulation or written order, as appropriate.

"(C)(i) In the case of an accessory that has been granted marketing authorization as part of a submission under section 515(c), 510(k), or paragraph (2) of this subsection with another device with which such accessory is intended to be used, and with respect to which the Secretary has issued a written order classifying such accessory type distinct from another device in accordance with subparagraph (A), the manufacturer or importer of such accessory may, in lieu of submitting a request for classification of such accessory, submit a written request to the Secretary identifying such classification. A request under this clause shall include such information to support the request as may be specified by the Secretary.

"(ii) A request under clause (i) shall include a recommendation for the proper classification of the accessory pursuant to subparagraph (A), and shall include such information as may be necessary for the Secretary to evaluate, based on the least burdensome approach, the appropriate class for the accessory under subsection (a).

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

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

"(v) A written notification that the Secretary disagrees with the classification recommended in a request pursuant to clause (ii) shall include a detailed description and justification for the determination to disagree.

"(D)(i) In the case of a device intended to be used with an accessory, where the accessory has been included in an application for premarket approval of such device under section 515 or a report under section 510(k) for clearance of such device and the Secretary has not classified such accessory distinctly from another device in accordance with subparagraph (A), the person filing the application or report (as applicable) at the time such application or report is filed—

"(I) may include a written request for the proper classification of the accessory pursuant to subparagraph (A);

"(II) shall include in any such request such information as may be necessary for the Secretary to evaluate, based on the least burdensome approach, the appropriate class for the accessory under subsection (a); and

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

for special controls, if special controls would be required pursuant to subsection (a)(1)(B).

"(ii) The Secretary's response under section 515(d) or section 510(n) (as applicable) to an application or report described in clause (i) shall also contain the Secretary's granting or denial of the request for classification of the accessory involved.

"(iii) The Secretary's evaluation of an accessory under clause (i) shall constitute an order establishing a new classification for such accessory for the specified intended use or uses of such accessory and for any accessory with the same intended use or uses as such accessory.

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

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

ant to this paragraph, the Secretary shall publish in the Federal Register a notice proposing a list of such accessories that the Secretary believes may be suitable for a distinct classification in class I and the proposed regulations for such classifications. In developing such lists, the Secretary shall consider recommendations from sponsors of device submissions and other stakeholders for accessories to be included on such lists. The notices shall provide for a period of not less than 60 calendar days for public comment. Within 180 days after the end of the comment period, the Secretary shall publish in the Federal Register a final action classifying such suitable accessories into class I.

"(ii) A manufacturer or importer of an accessory that has been granted such marketing authorization may submit to the Secretary a written request for the appropriate classification of the accessory based on the risks and appropriate level of regulatory controls as described in subparagraph (A) or (C), and shall, if the request is requesting classification of the accessory in class II, include in the submission an initial draft proposal for special controls, if special controls would be required pursuant to subsection (a)(1)(B). Such request shall include such information as may

be necessary for the Secretary to evaluate, based on the least burdensome approach, the appropriate class for the accessory under subsection (a). The Secretary shall provide an opportunity for a manufacturer or importer to meet with appropriate personnel of the Food and Drug Administration to discuss the appropriate classification of such accessory prior to submitting a written request under this clause for classification of the accessory.

"(iii) The Secretary shall respond to a request made under clause (ii) not later than 90 calendar days after receiving such submission by granting or denying the request for classification of the accessory, and the Secretary shall by written order classify such accessory or deny the request. If the Secretary does not agree with the recommendation for classification submitted by the manufacturer or importer, the response shall include a detailed description and justification for such determination. Within 30 calendar days after granting such a request, the Secretary shall publish a notice in the Federal Register announcing such response.

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

(f)(2) to obtain classification of such accessory in accordance with the criteria and requirements set forth in that subsection.".

(b) CONFORMING CHANGE.—Section 513(b) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360c(b)) is amended by striking paragraph (9) (relating to classification of an accessory).

(c) EFFECTIVE DATE.—The amendments made by subsections (a) and (b) shall take effect on the date that is 60 days after the date of enactment of this Act.

TITLE VII—GENERIC DRUG ACCESS AND COMPETITION

SEC. 701. COMPETITIVE GENERIC THERAPIES.

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

"SEC. 506H. COMPETITIVE GENERIC THERAPIES.

"(a) IN GENERAL.—The Secretary shall, at the request of the sponsor of a drug that is designated as a competitive generic therapy pursuant to subsection (b), expedite the development and review of such drug pursuant to section 505(j).

"(b) DESIGNATION PROCESS.—

"(1) REQUEST.—The sponsor of a drug may request the Secretary to designate the drug as a competitive generic therapy.

"(2) TIMING.—A request under paragraph (1) may be made concurrently with, or at any time prior to, the submission of an abbreviated new drug application for the drug under section 505(j).

"(3) CRITERIA.—A drug is eligible for designation as a competitive generic therapy under this section if the Secretary determines that there is inadequate generic competition.

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

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

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

"(c) ACTIONS.—In expediting the development and review of a drug under subsection (a), the Secretary shall, as requested by the sponsor, take actions including the following:

"(1) Hold meetings with the sponsor and the review team throughout the development of the drug prior to submission of the application for such drug under section 505(j).

"(2) Provide timely advice to, and interactive communication with, the sponsor regarding the development of the drug to ensure that the development program to gather the data necessary for approval is as efficient as practicable.

"(3) Involve senior managers and experienced review staff, as appropriate, in a collaborative, coordinated review, including with respect to drug-device combination products and other complex products.

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

"(A) to facilitate an efficient review of the development program and application, including manufacturing inspections; and

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

"(d) DEFINITIONS.—In this section:

"(1) The term 'generic drug' means a drug that is approved pursuant to section 505(j).

"(2) The term 'inadequate generic competition' means, with respect to a product, there is not more

than one approved drug product on the list of products described in section 505(j)(7)(A) (not including products on the discontinued section of such list) that is—

"(A) the reference listed drug; or

"(B) a generic drug with the same reference listed drug as the drug for which designation as a competitive generic therapy is sought.

"(3) The term 'reference listed drug' means the listed drug (as such term is used in section 505(j)) for the drug involved.".

(b) GUIDANCE; AMENDED REGULATIONS.—

(1) IN GENERAL.—

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

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

(ii) not later than 1 year after the close of the comment period for the draft guidance, issue final guidance on such provisions.

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

(i) specify the process and criteria by which the Secretary makes a designation under section 506H of the Federal Food, Drug, and Cosmetic Act, as added by subsection (a);

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

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

(2) AMENDED REGULATIONS.—

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

(B) PROCEDURE.—In carrying out subparagraph (A), and in issuing any other regula-

tions to implement such section 506H, the Secretary shall—

(i) issue a notice of proposed rulemaking that includes the proposed regulation;

(ii) provide a period of not less than 60 days for comments on the proposed regulation; and

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

SEC. 702. ENHANCING REGULATORY TRANSPARENCY TO ENHANCE GENERIC COMPETITION.

Section 505(j) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355) is amended by adding at the end the following:

"(11) Upon the request of an applicant regarding one or more specified pending applications under this subsection, the Secretary shall—

"(A) by telephone or electronic mail, provide review status updates; and

"(B) indicate in such updates the categorical status of the applications by each relevant review discipline.".

SEC. 703. INCENTIVIZING COMPETITIVE GENERIC THERAPY DEVELOPMENT.

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

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

"(v) 180-DAY EXCLUSIVITY PERIOD FOR COMPETITIVE GENERIC THERAPIES.—

"(I) EFFECTIVENESS OF APPLICATION.—Subject to subparagraph (D)(iv), if the application is for a drug that is the same as a competitive generic therapy for which any first approved applicant has commenced commercial marketing, the application shall be made effective on the date that is 180 days after the date of the first commercial marketing of the competitive generic therapy (including the commercial marketing of the listed drug) by any first approved applicant.

"(II) LIMITATION.—The exclusivity period under subclause (I) shall not apply with respect to a competitive generic therapy that has previously received an exclusivity period under subclause (I).

"(III) DEFINITIONS.—In this clause and subparagraph (D)(iv):

"(aa) The term 'competitive generic therapy' means a drug—

"(AA) that is designated as a competitive generic therapy under section 506H; and

"(BB) for which there are no unexpired patents or blocking exclusivities on the list of products described in section 505(j)(7)(A) at the time of approval.

"(bb) The term 'first approved applicant' means any applicant that has submitted an application that—

"(AA) is for a competitive generic therapy that is approved on the first day on which any application for such competitive generic therapy is approved;

"(BB) is not eligible for a 180-day exclusivity period under clause (iv) for the drug that is the subject of the application for the competitive generic therapy; and

"(CC) is not for a drug for which all drug versions have forfeited eligi-

bility for a 180-day exclusivity period under clause (iv) pursuant to subparagraph (D).''; and

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

''(iv) SPECIAL FORFEITURE RULE FOR COMPETITIVE GENERIC THERAPY.—The 180-day exclusivity period described in subparagraph (B)(v) shall be forfeited by a first approved applicant if the applicant fails to market the competitive generic therapy within 75 days after the date on which the approval of the first approved applicant's application for the competitive generic therapy is made effective.''.

SEC. 704. TROPICAL DISEASE PRODUCT APPLICATION.

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

(1) in clause (i), by striking ''and'' at the end; and

(2) by adding at the end the following:

''(iii) that contains reports of one or more new clinical investigations (other than bioavailability studies) that are essential to

the approval of the application and conducted or sponsored by the sponsor of such application; and

"(iv) that contains an attestation from the sponsor of the application that such reports were not submitted as part of an application for marketing approval or licensure by a regulatory authority in India, Brazil, Thailand, or any country that is a member of the Pharmaceutical Inspection Convention or the Pharmaceutical Inspection Cooperation Scheme prior to September 27, 2007.".

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

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

(1) The rate of first cycle approvals and tentative approvals for generic drug applications submitted during the period beginning on October 1, 2012, and ending on September 30, 2017. The rate of first cycle approvals and tentative approvals shall be determined and reported per each GDUFA cohort year during this period.

(2) If the rate determined pursuant to paragraph (1) for any GDUFA cohort year is lower than 20 percent, the reasons contributing to the relatively low rate of first cycle approvals and tentative approvals for generic drug applications shall be itemized, assessed, and reported. In making the assessment required by this paragraph, the Comptroller General shall consider, among other things, the role played by—

(A) the Food and Drug Administration's implementation of approval standards for generic drug applications;

(B) the extent to which those approval standards are communicated clearly to industry and applied consistently during the review process;

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

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

(E) the processes and practices for communication between the Food and Drug Adminis-

tration and sponsors of generic drug applications; and

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

(3) Taking into account the determinations made pursuant to paragraphs (1) and (2) and any review process improvements implemented pursuant to this Act, whether there are ways the review process for generic drugs could be improved to increase the rate of first cycle approvals and tentative approvals for generic drug applications. In making this determination, the Comptroller General shall consider, among other things, options for increasing review efficiency and communication effectiveness.

(b) COMPLETION DATE.—Not later than the expiration of the 2-year period beginning on the date of enactment of this Act, the Comptroller General shall complete the study under subsection (a) and submit a report describing the findings and conclusions of the study to the Secretary, the Committee on Energy and Commerce of the House of Representatives, and the Committee on Health, Education, Labor, and Pensions of the Senate.

(c) DEFINITIONS.—For purposes of this section:

(1) The term "GDUFA cohort year" means a fiscal year.

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

(3) The term "generic drug application" means an abbreviated new drug application for the approval of a generic drug under section 505(j) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(j)).

(4) The term "Secretary" means the Secretary of Health and Human Services.

(5)(A) The term "first cycle approvals and tentative approvals" means the approval or tentative approval of a generic drug application after the Food and Drug Administration's complete review of the application and without issuance of one or more complete response letters.

(B) For purposes of this paragraph, the term "complete response letter" means a written communication to the sponsor of a generic drug application or holder of a drug master file (DMF) from the Food and Drug Administration describing all of the deficiencies that the Administration has identified in the generic drug application (including pending amend-

ments) or drug master file that must be satisfactorily addressed before the generic drug application can be approved.

TITLE VIII—FOSTERING INNOVATION IN MEDICAL IMAGING

SEC. 801. APPROVAL OF APPLICATIONS FOR CERTAIN DIAGNOSTIC MEDICAL IMAGING DEVICES.

Section 520 of the Federal Food, Drug, and Cosmetic Act (42 U.S.C. 360j), as amended by section 613, is further amended by adding at the end the following:

"(q) DIAGNOSTIC IMAGING DEVICES INTENDED FOR USE WITH CONTRAST AGENTS.—

"(1) The Secretary may, subject to the succeeding provisions of this subsection, approve an application (or a supplement to such an application) submitted under section 515 with respect to an applicable medical imaging device, or, in the case of an applicable medical imaging device for which a notification is submitted under section 510(k), may make a substantial equivalence determination with respect to an applicable medical imaging device, or may grant a request submitted under section 513(f)(2) for an applicable medical imaging device, if the indications and conditions of use proposed in such application, notifi-

cation, or request involve the use of a contrast agent that is not—

"(A) in a concentration, rate of administration, or route of administration that is different from those described in the approved labeling of the contrast agent, except that the Secretary may approve such application, make such substantial equivalence determination, or grant such request if the Secretary determines that such differences in concentration, rate of administration, or route of administration exist but do not adversely affect the safety and effectiveness of the contrast agent when used with the device;

"(B) in a region, organ, or system of the body that is different from those described in the approved labeling of the contrast agent, except that the Secretary may approve such application, make such substantial equivalence determination, or grant such request if the Secretary determines that such differences in region, organ, or system of the body exist but do not adversely affect the safety and effectiveness of the contrast agent when used with the device;

"(C) in a patient population that is different from those described in the approved label-

ing of the contrast agent, except that the Secretary may approve such application, make such substantial equivalence determination, or grant such request if the Secretary determines such differences in patient population exist but do not adversely affect the safety and effectiveness of the contrast agent when used with the device; or

"(D) in an imaging modality (such as an ultrasound, an x-ray, diagnostic radiopharmaceutical-based technologies, fluorescent imaging technology, or magnetic resonance) that is different from those described in the approved labeling of the contrast agent.

"(2) The agency center charged with premarket review of devices shall have primary jurisdiction with respect to the review of an application, notification, or request described in paragraph (1). In conducting such review, such agency center may—

"(A) consult with the agency center charged with the premarket review of drugs or biological products; and

"(B) review information and data provided to the Secretary by the sponsor of a contrast agent in an application submitted under section 505 of this Act or section 351 of the Public

Health Service Act, so long as the sponsor of such contrast agent has provided to the sponsor of the applicable medical imaging device that is the subject of such review a right of reference and the application is submitted in accordance with this subsection.

"(3) An application submitted under section 515, a notification submitted under section 510(k), or a request submitted under section 513(f)(2), as described in paragraph (1), with respect to an applicable medical imaging device shall be subject to the requirements of such respective section. Such application, notification, or request shall only be subject to the requirements of this Act applicable to devices.

"(4) For purposes of this subsection and section 505(y)—

"(A) the term 'applicable medical imaging device' means a device intended to be used in conjunction with a contrast agent (or class of contrast agents) for an imaging use that is not described in the approved labeling of such contrast agent (or the approved labeling of any contrast agent in the same class as such contrast agent); and

"(B) the term 'contrast agent' means a drug that is approved under section 505 or licensed under section 351 of the Public Health Service Act, is intended for use in conjunction with an applicable medical imaging device, and—

"(i) is a diagnostic radiopharmaceutical, as defined in section 315.2 and 601.31 of title 21, Code of Federal Regulations (or any successor regulations); or

"(ii) is a diagnostic agent that improves the visualization of structure or function within the body by increasing the relative difference in signal intensity within the target tissue, structure, or fluid.".

SEC. 802. APPLICATIONS FOR APPROVAL OF CONTRAST AGENTS INTENDED FOR USE WITH CERTAIN DIAGNOSTIC MEDICAL IMAGING DEVICES.

Section 505 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355) is amended by adding at the end the following:

"(y) CONTRAST AGENTS INTENDED FOR USE WITH APPLICABLE MEDICAL IMAGING DEVICES.—

"(1) The sponsor of a contrast agent for which an application has been approved under this section may submit a supplement to the application seeking

approval for the use of the contrast agent for a new indication and conditions of use following the authorization of a premarket submission for an applicable medical imaging device for that use with the contrast agent pursuant to section 520(q)(1).

"(2) In reviewing a supplement submitted under this subsection, the agency center charged with the premarket review of drugs may—

"(A) consult with the center charged with the premarket review of devices; and

"(B) review information and data submitted to the Secretary by the sponsor of an applicable medical imaging device pursuant to section 515, 510(k), or 513(f)(2) so long as the sponsor of such applicable medical imaging device has provided to the sponsor of the contrast agent a right of reference.

"(3) For purposes of this subsection—

"(A) the term 'new indication' means a use of a contrast agent that is described in the approved labeling of an applicable medical imaging device described in section 520(q), but that is not described in the approved labeling of the contrast agent; and

"(B) the term 'applicable medical imaging device' and 'contrast agent' have the meanings given such terms in section 520(q).".

TITLE IX—ADDITIONAL PROVISIONS

SEC. 901. TECHNICAL CORRECTIONS.

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

(1) in the matter preceding paragraph (1), by striking "as amended by section 2074" and inserting "as amended by section 3102"; and

(2) in paragraph (2), by striking "section 2074(1)(C)" and inserting "section 3102(1)(C)".

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

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

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

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

(1) section 3051(a) of such Act is amended by striking "by inserting after section 515B" and inserting "by inserting after section 515A"; and

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

(f) Section 515B(f)(2) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360e–3(f)(2)), as redesignated by subsection (e)(2) of this section, is amended by striking "a proposed guidance" and inserting "a draft version of that guidance".

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

SEC. 902. REAUTHORIZATION OF THE CRITICAL PATH PUBLIC-PRIVATE PARTNERSHIPS.

Section 566(f) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360bbb–5(f)) is amended by striking "2013 through 2017" and inserting "2018 through 2022".

Union Calendar No. 138

115TH CONGRESS
1ST SESSION

H. R. 2430

[Report No. 115–201]

A BILL

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

JULY 11, 2017

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