Calendar No. 76

115TH CONGRESS
1ST SESSION

S. 934

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

IN THE SENATE OF THE UNITED STATES

APRIL 25, 2017

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

MAY 11, 2017

Reported by Mr. ALEXANDER, with an amendment

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

A BILL

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

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; and

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

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

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 ac-

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

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

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

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

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

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 Register 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 in-

serting ''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 ''Medical Device User Fee Amendments of 2017''; and

(B) in subparagraph (B), by striking ''the Medical Device User Fee Amendments of

2012'' and inserting ''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 October 1, 2021 (or such later date as may be specified by the Secretary under subparagraph (B)), 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 guidance issued under subparagraph (C).

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

tronic format referred to in such paragraph, extend such date until such later date as the Secretary may specify, but in no event later than April 1, 2023.

''(C) GUIDANCE.—The Secretary shall, not later than January 1, 2021, or such later date as may be specified by the Secretary under subparagraph (B), issue 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) set forth criteria for waivers of and exemptions from the requirements of this subsection.''.

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

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

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

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

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

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

22 (c) PREVIOUS SUNSET PROVISION.—

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

Amendments of 2012 (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 207.

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 prevented 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 ge-

neric 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 under this section 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 purposes 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''; and

(B) by striking ''2018'' and inserting ''2023''.

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

(1) in subsection (c)(2), by striking ''Such fees may only be used in fiscal year 2018.''; and

(2) in subsection (d)—

(A) 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).'';

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

(C) 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 H 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 HELD 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 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 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 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 all urban consumers (all items; United States city average) 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 in-

serting ''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 the heading of subparagraph (F) of paragraph (1), by striking ''BIOSIMILAR DEVELOPMENT PROGRAM FEES'' and inserting ''BIOSIMILAR BIOLOGICAL PRODUCT DEVELOPMENT FEES'';

(12) in paragraph (1)(F)—

(A) in the heading of subparagraph (F), 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).'';

(13) in paragraph (2)—

(A) in the heading of paragraph (2), 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 subparagraph (A), (B), or (D).";

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

(D) in subparagraphs (C) through (F)—

(i) by striking "or supplement" each place it appears; and

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

(14) 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 established 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 pro-

viding 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 develop-

ment 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 (g), 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 appro-

priate 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) estab-

lishing 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 devel-

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

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

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

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

(1) by striking subparagraph (B);

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

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

(c) EFFECT OF FAILURE TO PAY FEES.—Subsection (c) 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—REAUTHORIZATION OF OTHER PROGRAMS

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 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. 503. 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''.~~

~~SEC. 504. REAUTHORIZATION OF PEDIATRIC DEVICE CONSORTIA.~~

~~Section 305(e) of 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. 505. 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''.~~

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; and

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

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

"(2) CAPACITY PLANNING ADJUSTMENT.—

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

"(B) INTERIM METHODOLOGY.—

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

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

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

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

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

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

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

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

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 Register 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 "Medical Device User Fee Amendments of 2017"; and

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

"(iii) a device that is intended to be life sustaining or life supporting, unless otherwise determined by the Secretary in accordance with subparagraph (B)(i)(II) and listed as eligible for review under subparagraph (B)(iii); or

"(iv) 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, and whether there is a detailed public health justification for permitting the review by an accredited person of a specific life sustaining or life supporting device;

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

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

issued under subparagraph (B), issue final guidance.".

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 collecting 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.—

(1) IN GENERAL.—Effective October 1, 2017, section 207(a) of the Medical Device User Fee Amendments of 2012 (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 207.

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 manu-

facturing 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 prevented 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.".

(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 purposes 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"; and

(B) by striking "2018" and inserting "2023".

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

(1) in subsection (c)(2), by striking "Such fees may only be used in fiscal year 2018."; and

(2) in subsection (d)—

(A) 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).";

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

(C) 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 ap-

plicant 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 HELD 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 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 application 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 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 all urban consumers (all items; United States city average)

(Washington-Baltimore, DC-MD, VA-WV; Not Seasonally Adjusted; All items) for October of the preceding fiscal year divided by such Index for October 2011 divided by such index for September 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 develop-

ment" 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 the heading of subparagraph (F) of paragraph (1), by striking "BIOSIMILAR DEVELOPMENT PROGRAM FEES" and inserting "BIOSIMILAR BIOLOGICAL PRODUCT DEVELOPMENT FEES";

(12) in paragraph (1)(F)—

(A) in the heading of subparagraph (F), 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).";

(13) in paragraph (2)—

(A) in the heading of paragraph (2), 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 subparagraph (A), (B), or (D).";

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

(D) in subparagraphs (C) through (F)—

(i) by striking "or supplement" each place it appears; and

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

(14) 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 established 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 develop-

ment 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 (g), 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 devel-

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

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

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

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

(1) by striking subparagraph (B);

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

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

(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—PEDIATRIC DRUGS AND DEVICES

SEC. 501. PEDIATRIC DEVICES.

(a) PEDIATRIC USE OF DEVICES.—Section 515A of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360e–1) is amended—

(1) in subsection (a)(3)—

(A) by redesignating subparagraphs (B) through (D) as subparagraphs (D) through (F), respectively;

(B) by inserting after subparagraph (A) the following:

"(B) an assessment of pediatric device labeling needs based on a review of real world evidence collected on the off-label use of medical de-

vices in children, using data available to the Secretary;

"(C) the number of devices that receive a humanitarian use exemption under section 520(m);";

(C) in subparagraph (E), as so redesignated, by striking "; and" and inserting ";";

(D) in subparagraph (F) (as so redesignated), by striking "(B), and (C)." and inserting "(C), (D), and (E); and"; and

(E) by adding at the end the following:

"(G) the number of devices for which extrapolation was used to support the approval of pediatric labeling of such devices.

For the items described in this paragraph, such report shall disaggregate the number of devices by pediatric subpopulation.";

(2) by redesignating subsection (c) as subsection (d); and

(3) by inserting after subsection (b), the following:

"(c) PEDIATRIC DEVICE INNOVATION.—

"(1) IN GENERAL.—The Secretary shall, not later than 1 year after the date of enactment of the FDA Reauthorization Act of 2017, establish within

the Center for Devices and Radiological Health a structure to—

"(A) provide assistance to device manufacturers that would result in the development, approval, and labeling of medical devices for children;

"(B) oversee an internal pediatrics team that—

"(i) is comprised of employees of the Food and Drug Administration with expertise in pediatrics and appropriate expertise pertaining to the relevant devices under review; and

"(ii) provides expertise and consultation, to all applicable divisions within the Center for Devices and Radiological Health, on—

"(I) the application of subsection (b), section 520(m), section 510(k), and section 522 of this Act and section 402 of the Public Health Service Act to pediatric devices; and

"(II) pediatrics, as it pertains to reviewing devices;

"(C) coordinate pediatric activities within the Center for Devices and Radiological Health; and

"(D) collaborate with other programs, offices, and centers of the Food and Drug Administration, including the consortia program authorized under section 305 of the Pediatric Medical Device Safety and Improvement Act of 2007.

"(2) STAFF.—Such structure shall include a chief pediatric medical officer and other appropriate individuals, as the Secretary determines necessary.".

(b) HUMANITARIAN DEVICE EXEMPTION.—Section 520(m) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360j(m)) is amended—

(1) in paragraph (4)—

(A) in subparagraph (B), by inserting "or an appropriate local committee" after "review committee" each place such term appears; and

(B) in the matter following subparagraph (B), by inserting "or an appropriate local committee" after "review committee" each place such term appears; and

(2) in paragraph (6)(A)(iv), by striking "2017" and inserting "2022".

(c) DEMONSTRATION GRANTS FOR IMPROVING PEDIATRIC AVAILABILITY.—Section 305 of the Pediatric Medical Device Safety and Improvement Act of 2007 (Public Law 110–85; 42 U.S.C. 282 note) is amended—

(1) in subsection (c)—

(A) in paragraph (4), by striking "and" at the end;

(B) in paragraph (5), by striking the period and inserting "; and"; and

(C) by adding at the end the following:

"(6) providing regulatory consultation to device sponsors in support of the submission of an application for a pediatric device, where appropriate."; and

(2) in subsection (e), by striking "2017" and inserting "2022".

(d) MEETING ON PEDIATRIC DEVICE DEVELOPMENT.—

(1) IN GENERAL.—Not later than 1 year after the date of enactment of this Act, the Secretary of Health and Human Services shall convene a public meeting regarding opportunities and barriers to the development, approval, and labeling of pediatric medical devices. Such meeting shall include representatives from the medical device industry, academia, recipients of funding under section 305 of the Pediatric

Medical Device Safety and Improvement Act of 2007 (Public Law 110–85; 42 U.S.C. 282 note), medical provider organizations, and organizations representing patients and consumers.

(2) TOPICS.—The meeting described in paragraph (1) shall include consideration of ways to—

(A) improve research infrastructure and research networks to facilitate the conduct of clinical studies of devices for children that would result in the approval and labeling of medical devices for children;

(B) appropriately use extrapolation under section 515A(b) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360e–1(b));

(C) enhance the appropriate use of postmarket registries and data to increase pediatric medical device labeling;

(D) increase Food and Drug Administration assistance to medical device manufactures in developing devices for children that are approved and labeled for their use; and

(E) identify current barriers to pediatric device development and incentives to address such barriers.

(3) REPORT.—Not later than 6 months after the meeting described in paragraph (1), the Secretary of Health and Human Services 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, and publish, including on the Internet website of the Food and Drug Administration, a report that summarizes and responds to the recommendations raised in such meeting.

SEC. 502. PEDIATRIC DRUG DEVELOPMENT.

(a) EARLY MEETING ON PEDIATRIC STUDY PLAN.—

(1) IN GENERAL.—Clause (i) of section 505B(e)(2)(C) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355c(e)(2)(C)) is amended to read as follows:

"(i) shall meet with the applicant—

"(I) if requested by the applicant with respect to a drug that is intended to treat a serious or life-threatening disease or condition, to discuss preparation of the initial pediatric study plan, not later than the end-of-Phase 1 meeting (as such term is used in section 312.82(b) of title 21, Code of Fed-

eral Regulations, or successor regulations) or within 30 calendar days of receipt of such request, whichever is later;

"(II) to discuss the initial pediatric study plan as soon as practicable, but not later than 90 calendar days after the receipt of such plan under subparagraph (A); and

"(III) to discuss any scientific or operational challenges that may be the basis of a deferral under subsection (a)(3) or a full or partial waiver under subsection (a)(4);".

(2) CONFORMING CHANGES.—Section 505B(e) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355c(e)) is amended—

(A) in the heading of paragraph (2), by striking "MEETING" and inserting "MEETINGS";

(B) in the heading of paragraph (2)(C), by striking "MEETING" and inserting "MEETINGS";

(C) in clauses (ii) and (iii) of paragraph (2)(C), by striking "no meeting" each place it appears and inserting "no meeting under clause (i)(II)"; and

(D) in paragraph (3) by striking "meeting under paragraph (2)(C)(i)" and inserting "meeting under paragraph (2)(C)(i)(II)".

(b) INFORMING INTERNAL REVIEW COMMITTEE.—Section 505A(f) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355a(f)) is amended by adding at the end the following:

"(7) INFORMING INTERNAL REVIEW COMMITTEE.—The Secretary shall provide to the committee referred to in paragraph (1) any response issued to an applicant or holder with respect to a proposed pediatric study request.".

(c) ACTION ON SUBMISSIONS.—

(1) IN GENERAL.—Section 505A(d) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355a(d)) is amended—

(A) by redesignating paragraphs (3) through (5) as paragraphs (4) through (6), respectively; and

(B) by inserting after paragraph (2) the following:

"(3) ACTION ON SUBMISSIONS.—The Secretary shall review and act upon a submission of a proposed pediatric study request or a sponsor's proposed

amendment to a written request for pediatric studies within 120 calendar days of the submission.".

(2) CONFORMING AMENDMENTS.—

(A) FFDCA.—Section 505A of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355a), as amended by paragraph (1), is further amended by striking subsection "(d)(3)" each place it appears and inserting "(d)(4)".

(B) PHSA.—Paragraphs (2), (3), and (4) of section 351(m) of the Public Health Service Act (42 U.S.C. 262(m)) are amended by striking "section 505A(d)(3)" each place it appears and inserting "section 505A(d)(4)".

(d) STUDY.—The Secretary of Health and Human Services, acting through the internal review committee established under section 505C of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355d) shall, not later than one year after the date of enactment of this Act, develop and implement a plan to achieve, when appropriate, earlier submission of pediatric studies under section 505A of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355a) or section 351(m) of the Public Health Service Act (42 U.S.C. 262(m)). Such plan shall include recommendations to achieve—

(1) earlier discussion of proposed pediatric study requests and written requests with sponsors, and if appropriate, at the meeting required under section 505B(e)(2)(C) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355c(e)(2)(C)), as amended by subsection (a);

(2) earlier issuance of written requests for a pediatric study under such section 505A, including for investigational new drugs prior to the submission of an application under section 505(b)(1) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(b)(1)); and

(3) shorter timelines, when appropriate, for the completion of studies pursuant to a written request under such section 505A or such section 351(m).

(e) NEONATOLOGY EXPERTISE.—

(1) IN GENERAL.—Section 6(d) of the Best Pharmaceuticals for Children Act (21 U.S.C. 393a(d)) is amended by striking "For the 5-year period beginning on the date of enactment of this subsection, at" and inserting "At".

(2) DRAFT GUIDANCE.—Not later than 2 years after the date of enactment of this Act, the Secretary shall issue draft guidance on clinical pharmacology

considerations for neonatal studies for drugs and biological products.

(f) SUBMISSION OF ASSESSMENTS.—Section 505B(d)(1) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355c(d)(1)) is amended by adding at the end the following: "The Secretary shall inform the Pediatric Advisory Committee of all letters and responses to such letters issued under this paragraph.".

(g) INTERNAL COMMITTEE.—Section 505C of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355d) is amended by inserting "or pediatric rare diseases" after "psychiatry".

SEC. 503. GUIDANCE ON MOLECULAR TARGETS IN PEDIATRIC ONCOLOGY.

(a) IN GENERAL.—The Secretary of Health and Human Services (referred to in this section as the "Secretary"), acting through the Commissioner of Food and Drugs, shall issue guidance on the development of oncology drugs or biological products directed at molecular targets, including for pediatric populations.

(b) COLLABORATION; PUBLIC MEETING.—In developing the guidance under subsection (a), the Secretary, acting through the Commissioner of Food and Drugs and in collaboration with the Director of the National Cancer Institute, shall convene a public meeting not later than 180

days after the date of enactment of this Act to solicit feedback from physicians and researchers (including pediatric oncologists), patients, and other stakeholders to provide input on development of the guidance. The Secretary shall seek input at such meeting on—

(1) the scientific data necessary to determine when an oncology drug or biological product directed at a molecular target is sufficient to support pediatric clinical development given the ethical, practical, and other barriers to clinical investigations in the pediatric population;

(2) how to determine relevancy of a molecular target to the growth or progression of a pediatric cancer, including the clinical data necessary to make such a determination;

(3) how to overcome the challenges related to pediatric oncology drug development, including issues related to conducting clinical trials in pediatric rare cancers with small patient populations;

(4) the advantages and disadvantages of innovative clinical trial designs in addressing the development of oncology drugs or biological products directed at molecular targets in pediatric cancer patients; and

(5) the ways in which the Secretary can improve the current process outlined under sections 505A and

505B of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355a, 355c) to encourage additional research and development of pediatric cancer treatments.

SEC. 504. BEST PHARMACEUTICALS FOR CHILDREN.

Section 409I of the Public Health Service Act (42 U.S.C. 284m) is amended—

(1) in subsection (a)(2)(A)(ii), by inserting "and identification of biomarkers for such diseases, disorders, or conditions," after "biologics,";

(2) in subsection (c)—

(A) in paragraph (6)(B)—

(i) by striking "shall be assigned a docket number by the Commissioner of Food and Drugs" and inserting ", not later than 90 days after submission, shall be posted on the Internet website of the Food and Drug Administration in an accessible manner"; and

(ii) by striking "become part of the docket file with respect to each of the drugs" and inserting "be posted on the Internet website of the Food and Drug Administration"; and

(B) in paragraph (7)—

(i) in the matter preceding subparagraph (A), by striking "submitted" and inserting "posted"; and

(ii) in subparagraph (C), by striking "(i) place" and all that follows through the period at the end and inserting "publish through posting on the Internet website of the Food and Drug Administration a summary of the report and a copy of any requested labeling changes.";

(3) by striking subsection (d);

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

(5) in paragraph (1) of subsection (d), as so redesignated, by striking "2013 through 2017" and inserting "2018 through 2022".

TITLE VI—REAUTHORIZATIONS AND IMPROVEMENTS RELATED TO DRUGS

SEC. 601. 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. 602. 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".

SEC. 603. 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. 604. GUIDANCE REGARDING BIOEQUIVALENCE.

(a) IN GENERAL.—In accordance with subsection (b), the Secretary of Health and Human Services, acting through the Commissioner of Food and Drugs, shall issue product-specific guidance that—

(1) applies to complex non-biologic drugs; and

(2) outlines how to demonstrate bioequivalence to the reference drug, in order to facilitate generic development for such drugs.

(b) DEADLINE FOR ISSUING GUIDANCE.—After the date of enactment of this Act, the Secretary of Health and Human Services, acting through the Commissioner of Food and Drugs, shall publish a guidance, for each complex non-biologic drug that is approved under section 505(b) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(b)), not less than 2 years prior to the earliest date on which

an abbreviated new drug application may be submitted pursuant to section 505(j) of the Federal, Food, Drug, and Cosmetic Act (21 U.S.C. 355(c)) that references such drug.

(c) APPLICABILITY.—This section applies to guidances for abbreviated new drug applications that reference new drug applications first approved on or after October 1, 2017.

SEC. 605. PATIENT EXPERIENCE DATA.

Section 569C(c)(2)(A) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360bbb–8c(c)(2)(A)) is amended by striking "impact of such disease or condition, or a related therapy," and inserting "physical and psychosocial impacts of such disease or condition, related therapy, or clinical investigation".

SEC. 606. COMMUNICATIONS PLANS.

Section 505–1(e)(3) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355–1(e)(3)) is amended—

(1) in subparagraph (B), by striking "; or";

(2) in subparagraph (C), by striking the period and inserting "; or"; and

(3) by adding at the end the following:

"(D) disseminating information to health care providers about the meaning of terms related to drug formulations or properties that are described in the drug labeling, including infor-

mation about the limitations or patient care implications of such formulations or properties, and how such formulations or properties may be related to serious adverse drug events associated with use of the drug.".

SEC. 607. 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 under section 506E or in the case of importation pursuant to section 804(j), no drug that is subject to section 503(b)(1) may be imported into the United States for commercial use if such drug is manufactured outside the United States, the manufacturer has not authorized the drug to be marketed in the United States, and the manufacturer has not caused the drug to be labeled to be marketed in the United States.".

(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 selling or dispensing, or holding for sale or dispensing, a drug that is a counterfeit drug shall be fined under title 18, United States Code, imprisoned for not more than 10 years, or both, unless the person acted in good faith and had no reason to believe the drug was a counterfeit drug.".

SEC. 608. TECHNICAL CORRECTIONS.

Section 527 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360cc) is amended—

(1) in subsection (a), in the matter following paragraph (2), by striking "such drug for such disease or condition" and inserting "the same drug for the same disease or condition";

(2) in subsection (b)—

(A) in the matter preceding paragraph (1), by striking "If an application" and all that follows through "such license if" and inserting "During the 7-year period described in subsection (a) for an approved application under section 505 or license under section 351 of the Public Health Service Act, the Secretary may approve an application or issue a license for a drug that is otherwise the same, as determined

by the Secretary, as the already approved drug for the same rare disease or condition if";

(B) in paragraph (1), by striking "notice" and all that follows through "assure" and inserting "of exclusive approval or licensure notice and opportunity for the submission of views, that during such period the holder of the exclusive approval or licensure cannot ensure"; and

(C) in paragraph (2), by striking "such holder provides" and inserting "the holder provides"; and

(3) by adding at the end the following:

"(c) CONDITION OF CLINICAL SUPERIORITY.—

"(1) IN GENERAL.—If a sponsor of a drug that is designated under section 526 and is otherwise the same, as determined by the Secretary, as an already approved or licensed drug is seeking exclusive approval or exclusive licensure described in subsection (a) for the same rare disease or condition as the already approved drug, the Secretary shall require such sponsor, as a condition of such exclusive approval or licensure, to demonstrate that such drug is clinically superior to any already approved or licensed drug that is the same drug.

"(2) DEFINITION.—For purposes of paragraph (1), the term 'clinically superior' with respect to a drug means that the drug provides a significant therapeutic advantage over and above an already approved or licensed drug in terms of greater efficacy, greater safety, or by providing a major contribution to patient care.

"(d) REGULATIONS.—The Secretary may promulgate regulations for the implementation of subsection (c). Until such time as the Secretary promulgates regulations in accordance with this subsection, any definitions set forth in regulations implementing this section that were promulgated prior to the date of enactment of the FDA Reauthorization Act of 2017 shall continue to apply.".

TITLE VII—DEVICE INSPECTION AND REGULATORY IMPROVEMENTS

SEC. 701. RISK-BASED INSPECTIONS FOR DEVICES.

(a) IN GENERAL.—Section 510(h) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360(h)) is amended—

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

"(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 establishments 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 the United States recognizes."; and

(2) in paragraph (4)—

(A) in the matter preceding subparagraph (A), by striking "paragraph (3)" and inserting "paragraph (2) or (3)"; and

(B) in subparagraph (C), by inserting "or device" after "drug".

(b) FOREIGN INSPECTIONS.—Section 809(a)(1) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 384e(a)(1)) is amended by striking "section 510(h)(3)" and inserting "paragraph (2) or (3) of section 510(h)".

SEC. 702. IMPROVEMENTS TO INSPECTIONS PROCESS.

(a) INSPECTION PROCEDURE.—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 that are not for-cause inspections, the Secretary shall review existing processes and standards for inspections of domestic and foreign device establishments, and update such processes and standards to ensure uniform processes and standards, with exceptions as appropriate. Such processes and standards shall include—

"(A) announcing the inspection to the establishment within a reasonable time before such inspection, which shall include notification to the owner, operator, or agent in charge of the establishment regarding the type and nature of the inspection;

"(B) providing a reasonable estimate of the timeframe for the duration of the inspection, an opportunity for advancing 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 records that will be requested in order to expedite the inspection; and

"(C) providing for requirements with respect to the frequency and conditions of 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) Nothing in this subsection affects the authority of the Secretary to conduct inspections otherwise permitted under this Act in order to ensure compliance.".

(b) REPORT RESPONSES.—Section 704(b) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 374(b)) is amended—

(1) by striking "Upon completion" and inserting "(1) Upon completion"; and

(2) by adding at the end the following:

"(2) In the case of establishments registered under section 510 that have received a report pursuant to paragraph (1), and for which the owner, operator, or agent in charge of such establishment submits a timely response to such report that includes a request for feedback to the actions proposed in such response, and which involves a public health priority, the Secretary shall provide nonbinding feedback

regarding such proposed actions within 45 days of receipt of such request.".

(c) GUIDANCE.—

(1) DRAFT GUIDANCE.—Not later than 1 year after the date of enactment of this Act, 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 subsection (h) of section 704 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 374), as amended by this section, and the requirements described in subsection (b)(2) of such section;

(B) provides standard methods for communications described in such subsections;

(C) establishes standard timeframes over consecutive days applicable to both domestic and foreign inspections, to which each inspector shall adhere unless an investigator can identify to the establishment a reason that more time is needed; and

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

(2) FINAL GUIDANCE.—Not later than 18 months after the close of the comment period on the draft guidance under paragraph (1), the Secretary shall issue final guidance consistent with such paragraph.

SEC. 703. 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".

SEC. 704. CERTIFICATES TO FOREIGN GOVERNMENTS FOR DEVICES.

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)(I) If the Secretary denies a request for certification under subparagraph (A)(ii) with respect to a device manufactured in an establishment (foreign or domestic) registered under section 510, 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 subclause (I) is based on 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, the Secretary shall provide a substantive summary of the specific grounds for noncompliance identified.

"(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 with respect to a device pursuant to subparagraph (A)(ii) if the Secretary and the owner, operator, or agent in charge of such establishment have agreed to a plan of correction in response to such report.

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

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

"(III) Not later than 1 year after date of enactment of the FDA Reauthorization Act of 2017, the Secretary shall

issue guidance providing for a process to carry out this subparagraph. Not later than 1 year after the close of the comment period for such guidance, the Secretary shall issue final guidance."; and

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

SEC. 705. FACILITATING INTERNATIONAL HARMONIZATION.

Section 704(g) of the Federal Food, Drug and Cosmetic Act (21 U.S.C. 374) 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 au-

thority of the Secretary to determine the official classification of an inspection.".

SEC. 706. NOTIFICATION OF GUIDANCE RELATED TO LAB-DEVELOPED TESTS.

Section 1143 of the Food and Drug Administration Safety and Innovation Act (Public Law 112–144) is amended—

(1) in subsection (a), by striking "60" and inserting "90"; and

(2) in subsection (b), by striking "5" and inserting "10".

SEC. 707. DIAGNOSTIC IMAGING DEVICES INTENDED FOR USE WITH CONTRAST AGENTS.

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)(1) The Secretary may approve an application or supplement to an application under section 515 for an applicable medical imaging device, may make a substantial equivalence determination as to an applicable medical imaging device for which a report or a supplement to a report has been submitted under section 510(k), or may grant a request under section 513(f)(2) for an applicable medical imaging device if the requirements of this subsection and other applicable premarket requirements are met, and the

indications and conditions of use proposed in such application or notification 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 such contrast agent, unless the Secretary determines, based on information contained in the application or report, that the difference does not adversely affect the safety or 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, unless the Secretary determines, based on information contained in the device application, request, or report, that any difference does not affect the safety or effectiveness of the contrast agent when used with the device;

"(C) in a patient population different from the patient population in the approved labeling for such contrast agent, unless the Secretary determines, based on information contained in the application or report, that the difference does not adversely affect the safety or effectiveness of the contrast agent when used with the device; or

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

"(2) An applicable medical imaging device that is eligible for approval under section 515, clearance under section 510(k), or classification under section 513(f)(2), or approval, clearance, or classification as described in paragraph (1) shall be subject only to such requirements of this Act that are applicable to devices.

"(3) An application under section 515, report under section 510(k), or classification under section 513(f)(2) for an applicable medical imaging device intended for use in conjunction with a contrast agent to which clause (ii) or (iii) of section 505(c)(3)(E) applies shall refer to such contrast agent in such application, report, or request by trade or brand name, rather than to the international nonproprietary name.

"(4) In conducting a review of an application or report submitted for an applicable medical imaging device, the agency center charged with the premarket review of devices center may consult with the agency center charged with the premarket review of drugs and biological products.

"(5) For purposes of this subsection—

"(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 a use that is not described in the indications and usage section of the approved labeling of such contrast agent or the approved labeling of any contrast agent in such class, as applicable; 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 sections 315.2 and 601.30 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. 708. DIAGNOSTIC CLARITY.

Not later than 18 months after the date of enactment of this Act, the Secretary of Health and Human Services (referred to in this section as the "Secretary") shall update

guidance with respect to the circumstances under which reagents, new instruments, or new combinations of instruments may be added to groups of instruments that have been cleared under section 510(k) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360(k)). The updated guidance shall provide standard definitions and describe procedures for sponsors seeking to add a new instrument, reagent, or combination of instruments to a cleared group of instruments to submit information to the Secretary demonstrating that the new reagent, new instrument, or new combination of instruments does not alter the assay's performance, as applicable. The Secretary shall consult with affected entities and other stakeholders in updating the guidance.

SEC. 709. APPROPRIATE CLASSIFICATION OF DEVICE ACCESSORIES.

Section 513(b)(9) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360c(b)(9)) is amended—

(1) by striking "(9) The Secretary" and inserting "(9)(A) The Secretary"; and

(2) by adding at the end the following:

"(B) The classification of any accessory classified prior to December 13, 2016, based on the intended use or uses of such accessory, shall continue to apply, unless otherwise determined by the Secretary under section 515(e)(1).

"(C)(i) If an accessory has been cleared or approved based on the classification of another device with which such accessory is intended to be used and the Secretary has established a classification for such accessory based on the intended use or uses of the accessory, in accordance with subparagraph (A), the manufacturer of such accessory may identify the classification so established for such accessory in a written notification to the Secretary.

"(ii) Unless the Secretary notifies a manufacturer within 30 calendar days of receipt of a written notification described in clause (i) that the Secretary does not agree that the classification identified in such written notification is appropriate for the accessory, the accessory shall be automatically reclassified in accordance with the classification identified in such written notification.

"(iii) A written notification that the Secretary disagrees with the classification identified in a written notification described in clause (ii) shall include a detailed description and justification for the determination to disagree.

"(D)(i) A manufacturer of an accessory that has not been classified by the Secretary based on the intended use or uses of the accessory as described in subparagraph (A), and for which the Secretary has not established a classification for the accessory type as a stand-alone device, may sub-

mit to the Secretary a written recommendation for the appropriate classification of such accessory based on its intended use or uses. Such submission shall include such information to support the recommendation as the Secretary may require.

"(ii) The Secretary shall respond to a submission under clause (i) within 60 calendar days of receiving the submission by approving or denying the recommended classification of the accessory. If the Secretary does not agree with the recommendation for classification submitted by the sponsor, the response shall include a detailed description and justification for such determination to disagree. The Secretary shall provide an opportunity for a manufacturer to meet with appropriate personnel to discuss appropriate classification of such accessory prior to submitting a written recommendation.

"(E)(i) At the time a sponsor submits an application for premarket approval pursuant to section 515(c) or a report pursuant to 510(k), the sponsor of such application or report may include a recommendation and supporting information for the proper classification of an accessory pursuant to subparagraph (A), if applicable. If such accessory type has not been classified by the Secretary based on its intended use or uses as a stand-alone device as described in subparagraph (A), the Secretary shall—

"(I) approve or deny such application pursuant to section 515(d), or find such report substantially equivalent or not substantially equivalent pursuant to section 510(k); and

"(II) approve or deny the classification of the accessory proposed in such application or report.

"(F) A manufacturer may at any time use the classification process described in section 513(f)(2) to obtain classification of an accessory.".

SEC. 710. DEVICE PILOT PROJECTS.

(a) POSTMARKET PILOT.—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.—

"(1) IN GENERAL.—In order to provide timely and reliable information on the safety and effectiveness of cleared or approved devices, including responses to adverse events and malfunctions, and to advance the objectives of part 803 of title 21, Code of Federal Regulations (or successor regulations), and advance the objectives of, and evaluate innovative new methods of compliance with, this section and section 522, the Secretary shall, within one year of the date of enactment of the FDA Reauthorization Act of 2017, initiate one or more pilot projects for voluntary par-

ticipation by a manufacturer or manufacturers of device or device type, or continue existing projects, in accordance with paragraph (3), that meet all of the following requirements:

"(A) Are 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) Inform the development of methods, systems, data criteria, and programs that could be used to support safety and active surveillance activities for devices not included in such project.

"(C) Are designed and conducted in coordination with a comprehensive system for evaluating medical device technology that operates under a governing board with appropriate representation of stakeholders, including consumer groups and device manufacturers.

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

"(E) Prioritize 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 has received public recommendations in accordance with paragraph (2)(B) and has determined to meet one of the criteria under clauses (i) through (iii) and is appropriate for a project under this subsection.

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

"(A) authorizing voluntary participation of a manufacturer of a device in the pilot project described in paragraph (1); and

"(B) facilitating public recommendations for devices to be prioritized under the pilot project described in paragraph (1), including re-

quirements for the data necessary to support such recommendation.

"(3) IMPLEMENTATION.—The Secretary may satisfy the requirements of paragraphs (1) and (2) by continuing or expanding existing projects, or by beginning new projects, that meet the criteria of subparagraphs (A) through (E) of paragraph (1) or 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 additional conditions:

"(A) If such public or private entities are a component of another organization, the entities have established appropriate security measures to maintain the confidentiality and privacy of the data described in paragraph (1)(D) and the entity shall not make an unauthorized disclosure of such data to the other components of the organization in breach of such confidentiality and privacy requirements.

"(B) In the case of the termination or nonrenewal of such contracts, cooperative agreements, grants, or other appropriate agreements,

the entities shall comply with each of the following:

"(i) Continue to comply with the confidentiality and privacy requirements under this subsection with respect to all data disclosed to the entity.

"(ii) Return any data disclosed to such entity under this subsection to which it would not otherwise have access or, if returning the data is not practicable, destroy the data.

"(C) Have at least one of the following qualifications:

"(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-identified data consistent with the requirements of this subsection.

"(ii) An information technology infrastructure in place to support electronic data and operational standards to provide security for such data, as appropriate.

"(iii) Experience with, and expertise on, the development of device safety and effectiveness research and surveillance using electronic health data.

"(iv) Other expertise which the Secretary determines necessary to fulfill the activities under this subsection.

"(4) REVIEW OF CONTRACT IN THE EVENT OF A MERGER OR ACQUISITION.—The Secretary shall review a contract with a qualified entity under this subsection in the event of a merger or acquisition of the entity in order to ensure that the requirements under this subsection will continue to be met.

"(5) REPORT TO CONGRESS.—Not later than 18 months after the date of enactment of the FDA Reauthorization Act of 2017, and annually thereafter, the Secretary shall submit to the Committee on Health, Education, Labor, and Pensions of the Senate and the Committee on Energy and Commerce of the House of Representatives a report containing a description of the pilot projects being conducted pursuant to this subsection, including for each pilot project—

"(A) how the project is being implemented in accordance with paragraph (3) and the contractor or grantee as applicable;

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

"(C) the data sources used;

"(D) the devices or device categories involved; and

"(E) the number of patients involved.

"(6) COMPLIANCE WITH REQUIREMENTS FOR RECORDS OR REPORTS ON DEVICES.—The participation of a manufacturer in a pilot project under this subsection shall not affect the eligibility of such manufacturer to participate in any quarterly reporting program implemented under this Act. The Secretary may determine that, for the specified time period to be determined by the Secretary, a manufacturer's participation in a pilot project under this subsection may meet certain other requirements of this section or section 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 the pilot public, to the extent possible, if collected pursuant to this section or section 522.

"(7) PRIVACY REQUIREMENTS.—With respect to the pilot projects conducted pursuant to this subsection—

"(A) individual identifiable health information shall not be disclosed when presenting any information from such project; and

"(B) such projects shall comply with 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.

"(8) OTHER COMPLIANCE.—Any pilot program undertaken in coordination with the comprehensive system described in paragraph (1)(C), including pilot projects under this subsection, that relates to the use of real world evidence for devices shall comply with paragraph (1)(B), the conditions listed in subparagraphs (A) and (B) of paragraph (3), and paragraphs (4), (5), (6), and (7).

"(9) SUNSET.—This subsection shall cease to have force or effect on 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, shall 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 amended by subsection (a), for informing premarket and postmarket decisionmaking for multiple device types, and to determine whether the methods, systems, and programs in such pilot projects efficiently generate reliable and timely evidence about the effectiveness or safety surveillance of devices.

SEC. 711. 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), as amended by section 707, is further amended by adding at the end the following:

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

"(1) DEFINITION.—In this subsection, the term 'over-the-counter hearing aid' means a device that—

"(A) 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 regula-

tion) or wireless air conduction hearing aids (as defined in section 874.3305 of title 21, Code of Federal Regulations) (or any successor regulation);

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

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

"(D) may—

"(i) use wireless technology; or

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

"(E) is available over-the-counter, without the supervision, prescription, or other order, involvement, or intervention of a licensed person, to consumers through in-person transactions, by mail, or online.

"(2) REGULATION.—An over-the-counter hearing aid shall be subject to the regulations promulgated in accordance with section 711(b) of the FDA Reauthorization Act of 2017 and shall be exempt from sections 801.420 and 801.421 of title 21, Code of Federal Regulations (or any successor regulations).".

(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 (q) 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 how consumers may report adverse events, any conditions or contraindications, and

any 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(q) 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, or order specifically applicable 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(q) 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.

(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) STUDY.—Not later than 3 years after the date of enactment of this Act, the Comptroller General of the United States shall submit to Congress a report evaluating consumer experience with hearing health care, hearing screen-

ing in the primary care setting, and consumer adoption, usage, and outcomes related to hearing technology. The Comptroller General shall update such report not later than 2 years after the final regulations described in subsection (b) are issued, and shall evaluate how implementation of such regulations has impacted hearing health care, including recommendations for improving consumer access to appropriate hearing health care.

TITLE VIII—ADDITIONAL PROVISIONS

SEC. 801. GAO REPORT.

(a) IN GENERAL.—Not later than September 30, 2018, the Comptroller General of the United States shall issue a report, after consultation with patients and drug and medical device manufacturers, regarding the implementation of sections 569A and 569B of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360bbb–8a, 360bbb–8b). Such report shall assess the progress the Food and Drug Administration has made on—

(1) working with other regulatory authorities of similar standing to foster and encourage uniform, scientifically driven clinical trial standards with respect to medical products around the world;

(2) providing consistent parallel scientific advice to manufacturers seeking simultaneous global develop-

ment and approval of new medical products, in coordination with regulatory authorities of similar standing; and

(3) facilitating the use of foreign clinical trial data to minimize duplicative clinical trials.

(b) ADDITIONAL REQUIREMENTS.—The report under subsection (a) shall include specific examples, if possible and available, and a list of activities at the Food and Drug Administration regarding the harmonization of premarket medical product requirements.

SEC. 802. STREAMLINING AND IMPROVING CONSISTENCY IN PERFORMANCE REPORTING.

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

(1) in paragraph (1)(B)—

(A) in clause (vi), by inserting "and the number of designations and denials issued by the agency for such applications" before the semicolon;

(B) in clause (vii), by striking "; and" and inserting "and the number of designations and denials issued by the agency for such applications; and"; and

(C) in clause (viii) by striking the period and inserting "and the number of designations and denials issued by the agency for such applications."; and

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

"(3) REAL TIME REPORTING.—

"(A) IN GENERAL.—Beginning with fiscal year 2018, every 30 calendar days, the Secretary shall post the data described in subparagraph (B) on the Internet website of the Food and Drug Administration and remove duplicative data from the annual performance report.

"(B) DATA.—The following data is required to be posted in accordance with subparagraph (A):

"(i) The number and titles of draft and final guidance issued by the Center for Drug Evaluation and Research or the Center for Biologics Evaluation and Research, and the justification for the issuance and finalization of each such guidance.

"(ii) The number and titles of public meetings held by the Center for Drug Evaluation and Research and the Center for

Biologics Evaluation and Research each fiscal year.

"(iii) The list of standard new drug applications and biologics license applications, by fiscal year of receipt.

"(iv) The number of filed applications by each review division.

"(4) CAPACITY PLANNING AND IMPROVED TIME REPORTING.—Beginning with fiscal year 2020, the Secretary shall include in the annual report under paragraph (1)—

"(A) the number of full-time equivalents agreed upon in the letters described in section 101(b) of the Prescription Drug User Fee Amendments of 2017 and the number of appropriated full time equivalents at the Food and Drug Administration by each division within the Center for Drug Evaluation and Research, the Center for Biologics Evaluation and Research, the Office of Regulatory Affairs, and the Office of the Commissioner;

"(B) identification by name of all time reporting categories that Food and Drug Administration uses for capacity planning and time reporting with respect to the Center for Drug Eval-

uation and Research, the Center for Biologics Evaluation and Research, the Office of Regulatory Affairs, and the Office of the Commissioner, pursuant to the 'resource capacity planning and modernized time reporting implementation plan' in the letters described in section 101(b) of the Prescription Drug User Fee Amendments of 2017;

"(C) the processes by which the Center for Drug Evaluation and Research, the Center for Biologics Evaluation and Research, the Office of Regulatory Affairs, and the Office of the Commissioner require reporting on the amount of an employee's time that is dedicated to the review of human drug applications, as required by the letters described in section 101(b) of the Prescription Drug User Fee Amendments of 2017, including information regarding employees dedicated to such activities on a full-time basis, and employees dedicated to such activities on a part-time basis; and

"(D) for each of the Center for Drug Evaluation and Research, the Center for Biologics Evaluation and Research, the Office of Regulatory Affairs, and the Office of the Commis-

sioner, the number of employees described in subparagraph (C) (both full-time equivalents and employees dedicated to such activities on a part-time basis) for whom time reporting is required as described in subparagraph (C), and the number of such employees required to estimate time dedicated to the review of human drug applications.''.

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

(1) by striking ''Beginning with'' and inserting the following:

''(i) GENERAL REQUIREMENTS.—Beginning with''; and

(2) by adding at the end the following:

''(ii) ADDITIONAL INFORMATION.—Beginning with fiscal year 2018, the annual report under this subparagraph shall include the progress of the Center for Devices and Radiological Health in achieving the goals, and future plans for meeting the goals, including, for each review division—

''(I) the number of premarket applications filed under section 515 per

fiscal year for each review division, and the number of approvable letters, major deficiency letters, not approvable letters, and denials for such applications;

"(II) the number of reports filed under section 510(k) per fiscal year for each review division and the number of devices cleared or not substantially equivalent for such reports; and

"(III) the number of expedited access pathway designations for a fiscal year for each review division and the number of cleared or approved devices or denials for such applications.

"(iii) REAL TIME REPORTING.—

"(I) IN GENERAL.—Beginning with fiscal year 2018, the Secretary shall, every 30 calendar days, post the data described in subclause (II) on the Internet website of the Food and Drug Administration and remove duplicative data from the annual report under this subparagraph.

"(II) DATA.—The following data is required to be posted in accordance with subclause (I):

"(aa) The number and titles of draft and final guidance issued by the Center for Devices and Radiological Health and the justification for the issuance and finalization of such guidance.

"(bb) The number and titles of public meetings held by the Center for Devices and Radiological Health each fiscal year.".

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

(1) by striking "Beginning with" and inserting the following:

"(1) GENERAL REQUIREMENTS.—Beginning with"; and

(2) by adding at the end the following:

"(2) ADDITIONAL INFORMATION.—Beginning with fiscal year 2018, the report under this subsection shall include the progress of the Office of Generic

Drugs in achieving the goals, and future plans for meeting the goals, including—

"(A) the number of original abbreviated new drug applications filed per fiscal year;

"(B) the number of amendments to abbreviated new drug applications filed per fiscal year; and

"(C) the number of actions taken delineated by the type of action, including final approvals, tentative approvals, complete response letters, and the number of 'refuse to receive' letters issued by the Food and Drug Administration per fiscal year.

"(3) REAL TIME REPORTING.—

"(A) IN GENERAL.—Beginning with fiscal year 2018, the Secretary shall, every 30 calendar days, post the data described in subparagraph (B) on the Internet website of the Food and Drug Administration and remove duplicative data from the annual report under this subsection.

"(B) DATA.—The following data is required to be posted in accordance with subparagraph (A):

"(i) The number and titles of draft and final guidance issued by the Office of Ge-

neric Drugs and the justification for the issuance and finalization of such guidance.

"(ii) The number and titles of public meetings held by the Office of Generic Drugs each fiscal year.".

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

(1) by striking "Beginning with" and inserting the following:

"(1) GENERAL REQUIREMENTS.—Beginning with"; and

(2) by adding at the end the following:

"(2) ADDITIONAL INFORMATION.—Beginning with fiscal year 2018, the report under this subsection shall include the progress of the Center for Biologics Evaluation and Research in achieving the goals, and future plans for meeting the goals, including—

"(A) information on all previous cohorts for which the Secretary has not given a complete response on all biosimilar biological product applications and supplements in the cohort;

"(B) the number of original biosimilar biological product applications filed per fiscal year, and the number of approvals or complete re-

sponse letters issued by the agency for such applications; and

"(C) the number of resubmitted original biosimilar biological product applications filed per fiscal year and the number of approvals or complete response letters issued by the agency for such applications.

"(3) REAL TIME REPORTING.—

"(A) IN GENERAL.—Beginning with fiscal year 2018, the Secretary shall, every 30 calendar days, post the data described in subparagraph (B) on the Internet website of the Food and Drug Administration and remove duplicative data from the annual report under this subsection.

"(B) DATA.—The following data is required to be posted in accordance with subparagraph (A):

"(i) The number and titles of draft and final guidance issued by the Center for Drug Evaluation and Research and the Center for Biologics Evaluation and Research and the justification for the issuance and finalization of such guidance.

"(ii) The number and titles of public meetings held by the Center for Drug Eval-

uation and Research and the Center for Biologic Evaluation and Research each fiscal year.".

"(4) CAPACITY PLANNING AND TIME REPORTING.—Beginning with fiscal year 2020, the Secretary shall include in the annual report under paragraph (1)—

"(A) the number of full-time equivalents agreed upon in the letters described in section 401(b) of the Biosimilar User Fee Amendments of 2017 and the number of appropriated full time equivalents at the Food and Drug Administration by each division within the Center for Drug Evaluation and Research, the Center for Biologics Evaluation and Research, the Office of Regulatory Affairs, and the Office of the Commissioner;

"(B) identification by name of all time reporting categories that the Food and Drug Administration uses for capacity planning and time reporting under the 'resource capacity planning and modernized time reporting implementation plan' in the letters described in section 401(b) of the Biosimilar User Fee Amendments of 2017 for the Center for Drug Evaluation and

Research, the Center for Biologics Evaluation and Research, the Office of Regulatory Affairs and the Office of the Commissioner;

"(C) the process by which the Center for Drug Evaluation and Research, the Center for Biologics Evaluation and Research, the Office of Regulatory Affairs, and the Office of the Commissioner require reporting on the amount of an employee's time that is dedicated to the review of biosimilar biological product applications, required pursuant to the letters described in section 401(b) of the Biosimilar User Fee Amendments of 2017, including information regarding both employees dedicated to such activities on a full-time basis, and employees dedicated to such activities on a part-time basis; and

"(D) for each of the Center for Drug Evaluation and Research, the Center for Biologics Evaluation and Research, the Office of Regulatory Affairs, and the Office of the Commissioner, the actual number of employees described in subparagraph (C) (both full-time equivalents and employees dedicated to such activities on a part-time basis) for whom time reporting is required as described in subparagraph (C), and the

number of such employees required to estimate time dedicated to the review of biosimilar biological product applications.".

SEC. 803. ANALYSIS OF USE OF FUNDS.

(a) PDUFA REPORTS.—

(1) ANALYSIS IN PDUFA PERFORMANCE REPORTS.—Section 736B(a) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 379h–2(a)), as amended by section 802(a), is further amended by adding at the end the following:

"(5) ANALYSIS.—For each fiscal year, the Secretary shall include in the report under paragraph (1) an analysis of the following:

"(A) The difference between the number of human drug applications filed and the number of approvals or complete response letters issued by the agency, accounting for—

"(i) such applications filed during one fiscal year for which a decision is not scheduled to be made until the following fiscal year;

"(ii) such applications pending with the Center for Drug Evaluation and Research and the Center for Biologics Evaluation and Research that did not meet the

goals identified in the letters described in section 101(b) of the Prescription Drug User Fee Amendments of 2017 for the corresponding fiscal year and the future plans of the Food and Drug Administration to meet these goals; and

"(iii) the most common causes within the agency for missing such goals.

"(B) Relevant data to determine whether the Center for Drug Evaluation and Research and the Center for Biologics Evaluation and Research have met performance enhancement goals identified in the letters described in section 101(b) of the Prescription Drug User Fee Amendments of 2017 for the corresponding fiscal year.

"(C) External or other circumstances impacting the Center for Drug Evaluation and Research, the Center for Biologics Evaluation and Research, or the Food and Drug Administration, that impacted the ability of the agency to meet the review time and performance enhancement goals identified in the letters described in section 101(b) of the Prescription Drug User Fee Amendments of 2017.".

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

(A) by redesignating subsections (c) and (d) as subsections (e) and (f), respectively; and

(B) inserting after subsection (b) the following:

"(c) CORRECTIVE ACTION REPORT.—Beginning with fiscal year 2018, and for each fiscal year for which fees are collected under this part, the Secretary shall prepare and submit a corrective action report to the Committee on Energy and Commerce and the Committee on Appropriations of the House of Representatives and the Committee on Health, Education, Labor, and Pensions and the Committee on Appropriations of the Senate upon submission of the performance report in subsection (a) for the corresponding fiscal year. The report shall include the following information, as applicable:

"(1) GOALS MET.—For each fiscal year, if the Secretary determines, based on the analysis under subsection (a)(5), that each of the goals identified in the letters described in section 101(b) of the Prescription Drug User Fee Amendments of 2017 for the corresponding fiscal year have been met, the corrective action report shall include a summary of goals met,

and recommendations on ways in which the Secretary can improve and streamline the human drug application review process.

"(2) GOALS MISSED.—For each of the goals identified in the letters described in section 101(b) of the Prescription Drug User Fee Amendments of 2017 for the corresponding fiscal year that the Secretary determines to not have been met, the corrective action report shall include a detailed justification for such determination and—

"(A) a detailed description of the circumstances under which each drug application that missed the review goal time was approved during the first cycle review, as applicable;

"(B) aggregate data on the circumstances for all unapproved drug applications for which the review goal time was missed; and

"(C) the performance enhancement goals that were not achieved during the previous fiscal year and a detailed description of efforts the agency has put in place for the current fiscal year to improve the ability of the agency to meet each such goal, while maintaining standards of approval, for the current fiscal year.

"(d) ENHANCED COMMUNICATION.—

"(1) COMMUNICATIONS WITH CONGRESS.—Each fiscal year, as applicable, representatives from the Center for Drug Evaluation and Research and the Center for Biologics Evaluation and Research shall meet with representatives from the Committee on Health, Education, Labor, and Pensions of the Senate and the Committee on Energy and Commerce of the House of Representatives to report on the contents described in the reports under this section.

"(2) PARTICIPATION IN CONGRESSIONAL HEARING.—Each fiscal year, as applicable, representatives from the Center for Drug Evaluation and Research and the Center for Biologics Evaluation and Research shall participate in a public hearing before the Committee on Health, Education, Labor, and Pensions of the Senate and the Committee on Energy and Commerce of the House of Representatives, to report on the contents described in the reports under this section. Such hearing shall occur not later than 120 days after the end of each fiscal year for which fees are collected under this part.

"(3) PUBLICLY AVAILABLE UPDATES.—The Secretary shall provide an update on progress made for the corrective action report during the following fiscal year on the publically available Internet website of

the Food and Drug Administration every 30 business days.".

(b) MDUFA REPORTS.—

(1) ANALYSIS IN MDUFA PERFORMANCE REPORTS.—Section 738A(a)(1)(A) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 379j–1(a)(1)(A)), as amended by section 802(b), is further amended by adding at the end the following:

"(iv) ANALYSIS.—For each fiscal year, the Secretary shall include in the report under clause (i) an analysis of the following:

"(I) The difference between the number of premarket applications filed under section 515 and applications filed under section 510(k) and the number of major deficiency letters, not approvable letters, and denials for such applications issued by the agency, accounting for—

"(aa) such applications filed during one fiscal year for which a decision is not scheduled to be made until the following fiscal year;

"(bb) such applications pending with the Center for Devices and Radiological Health that did not meet the goals as identified by the letters described in section 201(b) of the Medical Device User Fee Amendments of 2017 for the corresponding fiscal year and the future plans of the Food and Drug Administration to meet these goals; and

"(cc) the most common causes within the agency for missing such goals.

"(II) Relevant data to determine whether the Center Devices and Radiological Health have met performance enhancement goals identified by the letters described in section 201(b) of the Medical Device User Fee Amendments of 2017 for the corresponding fiscal year.

"(III) External or other circumstances impacting the Center Devices and Radiological Health or the

Food and Drug Administration that impacted the ability of the agency to meet review time and performance enhancement goals identified by the letters described in section 201(b) of the Medical Device User Fee Amendments of 2017.".

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

(A) by redesignating paragraphs (2) and (3) as paragraphs (4) and (5), respectively; and

(B) by inserting after paragraph (1) the following:

"(2) CORRECTIVE ACTION REPORT.—Beginning with fiscal year 2018, and for each fiscal year for which fees are collected under this part, the Secretary shall prepare and submit a corrective action report to the Committee on Energy and Commerce and the Committee on Appropriations of the House of Representatives and the Committee on Health, Education, Labor, and Pensions and the Committee on Appropriations of the Senate upon submission of the performance report in paragraph (1)(A) for the cor-

responding fiscal year. The report shall include the following information, as applicable:

"(A) GOALS MET.—For each fiscal year, if the Secretary determines, based on the analysis under paragraph (1)(A)(iv), that each of the goals identified by the letters described in section 201(b) of the Medical Device User Fee Amendments of 2017 for the corresponding fiscal year have been met, the corrective action report shall include a summary of goals met, and recommendations on ways in which the Secretary can improve and streamline the medical device application review process.

"(B) GOALS MISSED.—For each of the goals identified by the letters described in section 201(b) of the Medical Device User Fee Amendments of 2017 for the corresponding fiscal year that the Secretary determines to not have been met, the corrective action report shall include a detailed justification for such determination and—

"(i) a detailed description of the circumstances under which each application or report submitted under section 515 or section 510(k) missed the review goal time but

was approved during the first cycle review, as applicable;

"(ii) aggregate data on the circumstances for all unapproved medical device applications for which the review goal time was missed; and

"(iii) the performance enhancement goals that were not achieved during the previous fiscal year and a detailed description of efforts the agency has put in place for the current fiscal year to improve the ability of the agency to meet each such goal, while maintaining standards of approval, for the current fiscal year.

"(3) ENHANCED COMMUNICATION.—

"(A) COMMUNICATIONS WITH CONGRESS.—Each fiscal year, as applicable, representatives from the Center for Devices and Radiological Health shall meet with representatives from the Committee on Health, Education, Labor, and Pensions of the Senate and the Committee on Energy and Commerce of the House of Representatives to report on the contents described in the reports under this section.

"(B) PARTICIPATION IN CONGRESSIONAL HEARING.—Each fiscal year, as applicable, representatives from the Center for Devices and Radiological Health shall participate in a public hearing before the Committee on Health, Education, Labor, and Pensions of the Senate and the Committee on Energy and Commerce of the House of Representatives, to report on the contents described in the reports under this section. Such hearing shall occur not later than 120 days after the end of each fiscal year for which fees are collected under this part.

"(C) PUBLICLY AVAILABLE UPDATES.—The Secretary shall provide an update on progress made for the corrective action report during the following fiscal year on the publically available Internet website of the Food and Drug Administration every 30 business days.".

(c) GDUFA REPORTS.—

(1) ANALYSIS IN GDUFA PERFORMANCE REPORTS.—Section 744C(a) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 379j–43(a)), as amended by section 802(c) is further amended by adding at the end the following:

"(4) ANALYSIS.—For each fiscal year, the Secretary shall include in the report an analysis of the following:

"(A) The difference between the number of abbreviated new drug applications filed and the number of approvals or complete response letters issued by the agency, accounting for —

"(i) such applications filed during one fiscal year for which a decision is not scheduled to be made until the following fiscal year;

"(ii) such applications pending with the Office of Generic Drugs that did not meet the goals identified by the letters described in section 301(b) of the Generic Drug User Fee Amendments of 2017 for the corresponding fiscal year and the future plans of the Food and Drug Administration to meet these goals; and

"(iii) the most common causes within the agency for missing such goals.

"(B) Relevant data to determine whether the Office of Generic Drugs has met the performance enhancement goals identified by the letters described in section 301(b) of the Generic Drug

User Fee Amendments of 2017 for the corresponding fiscal year.

"(C) External or other circumstances impacting the Office of Generic Drugs or the Food and Drug Administration that impacted the ability of the agency to meet review time and performance enhancement goals identified by the letters described in section 301(b) of the Generic Drug User Fee Amendments of 2017.".

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

(A) by redesignating subsections (c) and (d) as subsections (e) and (f), respectively; and

(B) inserting after subsection (b) the following:

"(c) CORRECTIVE ACTION REPORT.—Beginning with fiscal year 2018, and for each fiscal year for which fees are collected under this part, the Secretary shall prepare and submit a corrective action report to the Committee on Energy and Commerce and the Committee on Appropriations of the House of Representatives and the Committee on Health, Education, Labor, and Pensions and the Committee on Appropriations of the Senate upon submission of the performance report in subsection (a) for the corresponding

fiscal year. The report shall include the following information, as applicable:

"(1) GOALS MET.—For each fiscal year, if the Secretary determines, based on the analysis under subsection (a)(4), that each of the goals identified by the letters described in section 301(b) of the Generic Drug User Fee Amendments of 2017 for the corresponding fiscal year have been met, the corrective action report shall include a summary of goals met, and recommendations on ways in which the Secretary can improve and streamline the abbreviated new drug application review process.

"(2) GOALS MISSED.—For each of the goals identified by the letters described in section 301(b) of the Generic Drug User Fee Amendments of 2017 for the corresponding fiscal year that the Secretary determines to not have been met, the corrective action report shall include a detailed justification for such determination and—

"(A) a detailed description of the circumstances under which each abbreviated new drug application missed the review goal time but was approved during the first cycle review, as applicable;

"(B) aggregate data on the circumstances for all unapproved abbreviated new drug applications for which the review goal time was missed; and

"(C) the performance enhancement goals that were not achieved during the previous fiscal year and a detailed description of efforts the agency has put in place for the current fiscal year to improve the ability of the agency to meet each such goal for the current fiscal year.

"(d) ENHANCED COMMUNICATION.—

"(1) COMMUNICATIONS WITH CONGRESS.—Each fiscal year, as applicable, representatives from the Office of Generic Drugs shall meet with representatives from the Committee on Health, Education, Labor, and Pensions of the Senate and the Committee on Energy and Commerce of the House of Representatives to report on the contents described in the reports under this section.

"(2) PARTICIPATION IN CONGRESSIONAL HEARING.—Each fiscal year, as applicable, representatives from the Center for Drug Evaluation and Research shall participate in a public hearing before the Committee on Health, Education, Labor, and Pensions of the Senate and the Committee on Energy and Com-

merce of the House of Representatives, to report on the contents described in the reports under this section. Such hearing shall occur not later than 120 days after the end of each fiscal year for which fees are collected under this part.

"(3) PUBLICLY AVAILABLE UPDATES.—The Secretary shall provide an update on progress made for the corrective action report during the following fiscal year on the publically available Internet website of the Food and Drug Administration every 30 business days.".

(d) BSUFA REPORTS.—

(1) ANALYSIS IN BSUFA PERFORMANCE REPORTS.—Section 744I(a) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 379j–53(a)) as amended by section 802(d) is further amended by adding at the end the following:

"(5) ANALYSIS.—For each fiscal year, the Secretary shall include in the report an analysis of the following:

"(A) The difference between the number of biosimilar biological product applications and supplements filed and the number of approvals or complete response letters issued by the agency, accounting for—

"(i) such applications filed during one fiscal year for which a decision is not scheduled to be made until the following fiscal year;

"(ii) such applications pending with the Center for Drug Evaluation and Research or the Center for Biologics Evaluation and Research that did not meet the goals identified by the letters described in section 401(b) of the Biosimilar User Fee Amendments of 2017 for the corresponding fiscal year and the future plans of the Food and Drug Administration to meet these goals; and

"(iii) the most common causes within the agency for missing such goals.

"(B) Relevant data to determine whether the Center for Drug Evaluation and Research and the Center for Biologics Evaluation and Research have met the performance enhancement goals identified by the letters described in section 401(b) of the Biosimilar User Fee Amendments of 2017 for the corresponding fiscal year.

"(C) External or other circumstances impacting the Center for Drug Evaluation and Re-

search, the Center for Biologics Evaluation and Research, and the Food and Drug Administration that impacted the ability of the agency to meet review time and performance enhancement goals identified by the letters described in section 401(b) of the Biosimilar User Fee Amendments of 2017.".

(2) ISSUANCE OF CORRECTIVE ACTION REPORTS.—Section 744I of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 379j–53), as amended by section 404, is further amended—

(A) by redesignating subsections (c) and (d) as subsections (e) and (f), respectively; and

(B) inserting after subsection (b) the following:

"(c) CORRECTIVE ACTION REPORT.—Beginning with fiscal year 2018, and for each fiscal year for which fees are collected under this part, the Secretary shall prepare and submit a corrective action report to the Committee on Energy and Commerce and Committee on Appropriations of the House of Representatives and the Committee on Health, Education, Labor, and Pensions and Committee on Appropriations of the Senate upon submission of the performance report in subsection (a) for the corresponding fiscal year.

The report shall include the following information, as applicable:

"(1) GOALS MET.—For each fiscal year, if the Secretary determines, based on the analysis under subsection (a)(5), that each of the goals identified by the letters described in section 401(b) of the Biosimilar User Fee Amendments of 2017 for the corresponding fiscal year have been met, the corrective action report shall include a summary of goals met, and recommendations on ways in which the Secretary can improve and streamline the biosimilar biological product application review process.

"(2) GOALS MISSED.—For each of the goals identified by the letters described in section 401(b) of the Biosimilar User Fee Amendments of 2017 for the corresponding fiscal year that the Secretary determines to not have been met, the corrective action report shall include a detailed justification for such determination and—

"(A) a detailed description of the circumstances under which each biosimilar biological product application missed the review goal time but was approved during the first cycle review, as applicable;

"(B) aggregate data on the circumstances for all biosimilar biological product applications for which the review goal time was missed; and

"(C) the performance enhancement goals that were not achieved during the previous fiscal year and a detailed description of efforts the agency has put in place for the current fiscal year to improve the ability of the agency to meet each such goal for the current fiscal year.

"(d) ENHANCED COMMUNICATION.—

"(1) COMMUNICATIONS WITH CONGRESS.—Each fiscal year, as applicable, representatives from the Center for Drug Evaluation and Research and the Center for Biologics Evaluation and Research shall meet with representatives from the Committee on Health, Education, Labor, and Pensions of the Senate and the Committee on Energy and Commerce of the House of Representatives to report on the contents described in the reports under this section.

"(2) PARTICIPATION IN CONGRESSIONAL HEARING.—Each fiscal year, as applicable, representatives from the Center for Drug Evaluation and Research and the Center for Biologics Evaluation and Research shall participate in a public hearing before the Committee on Health, Education, Labor, and Pensions of

the Senate and the Committee on Energy and Commerce of the House of Representatives, to report on the contents described in the reports under this section. Such hearing shall occur not later than 120 days after the end of each fiscal year for which fees are collected under this part.

"(3) PUBLICLY AVAILABLE UPDATES.—The Secretary shall provide an update on progress made for the corrective action report during the following fiscal year on the publically available Internet website of the Food and Drug Administration every 30 business days.".

SEC. 804. INFORMATION ON TECHNOLOGY CONTRACTING.

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

(1) by striking "report on the" and inserting "report on—

"(1) the";

(2) by striking the period at the end and inserting "; and";

(3) by adding at the end the following:

"(2) the amount of the fees collected that are invested in the information technology infrastructure of the Food and Drug Administration, the entities receiving contracts to develop such infrastructure, the

length of such contracts (including renewals), and the progress such entities have made toward meeting the goals described in such contracts.''.

SEC. 805. FACILITIES MANAGEMENT.

(a) EVALUATION.—

(1) STUDY.—The Comptroller General of the United States shall conduct a study on the expenses incurred by the Food and Drug Administration related to facility maintenance and renovation in fiscal years 2012 through 2019. The study shall include the following:

(A) A review of purchases and expenses differentiated by appropriated funds, and resources authorized by the Food and Drug Administration Safety and Innovation Act (Public Law 112–144) and this Act, as applicable, that contributed to—

(i) the maintenance of scientific equipment and any existing facility plan or plans to maintain previously purchased scientific equipment;

(ii) the renovation of facilities in the Center for Drug Evaluation and Research, the Center for Biologics Evaluation and Research, and the Center for Devices and Ra-

diological Health, and the purpose of such renovation including the need for the renovation;

(iii) the assets purchased or repaired under the "repair of facilities and acquisition" authority under parts 2, 3, 7, and 8 of subchapter C of chapter VII of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 379f et seq.);

(iv) the maintenance and repair of facilities and fixtures, including a description of any unanticipated repairs and maintenance as well as scheduled repairs maintenance, and the budget plan for the scheduled or anticipated maintenance;

(v) the acquisition of furniture, a description of the furniture purchased, and the purpose of the furniture including purchases for the Center for Drug Evaluation and Research, the Center for Biologics Evaluation and Research, and the Center for Devices and Radiological Health; and

(vi) the acquisition of other necessary materials and supplies by product category under the authority under parts 2, 3, 7,

and 8 of subchapter C of chapter VII of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 379f et seq.).

(B) An analysis of the Food and Drug Administration's ability to further its public health mission and review medical products by incurring the expenses listed in clauses (i) through (vi) of subparagraph (A). In conducting the analysis, the Comptroller General shall request information from and consult with appropriate employees, including staff and those responsible for the fiscal decisions regarding facility maintenance and renovation for the agency.

(C) RECOMMENDATIONS.—The Comptroller General may provide recommendations, as applicable, on methods through which the Food and Drug Administration may improve planning for—

(i) the maintenance, renovation, and repair of facilities;

(ii) the purchase of furniture or other acquisitions; and

(iii) ways the agency may allocate the expenses described in clauses (i) and (ii), as

informed by the analysis under subparagraph (B).

(2) REPORT.—The Comptroller General shall issue a report to the Committee on Health, Education, Labor, and Pensions of the Senate and the Committee on Energy and Commerce of the House of Representatives not later than September 30, 2020, containing the results of the study under paragraph (1).

(b) ADMINISTRATION.—

(1) PDUFA.—Section 736(f) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 379h(f)) is amended by adding at the end the following:

"(3) LIMITATION.—Beginning on October 1, 2023, the authorities under section 735(7)(C) shall only include expenditures for leasing and necessary scientific equipment.".

(2) MDUFA.—Section 738(h) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 379j(h)) is amended by adding at the end the following:

"(3) LIMITATION.—Beginning on October 1, 2023, the authorities under section 737(9)(C) shall only include leasing and necessary scientific equipment.".

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

(A) in the subsection heading, by striking "LIMIT" and inserting "LIMITATIONS";

(B) by striking "The total amount" and inserting the following:

"(1) IN GENERAL.—The total amount"; and

(C) by adding at the end the following:

"(2) LEASING AND NECESSARY EQUIPMENT.—Beginning on October 1, 2023, the authorities under section 744A(11)(C) shall only include leasing and necessary scientific equipment.".

(4) BSUFA.—Section 744H(e)(2)(B) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 379j–52(e)(2)(B)) is amended—

(A) in the subparagraph heading, by striking "LIMITATION" and inserting "LIMITATIONS";

(B) by striking "The fees authorized" and inserting the following:

"(i) IN GENERAL.—The fees authorized"; and

(C) by adding at the end the following:

"(ii) LEASING AND NECESSARY EQUIPMENT.—Beginning on October 1, 2023, the

authorities under section 744G(9)(C) shall only include leasing and necessary scientific equipment.''.

SEC. 806. EXPANDED ACCESS.

(a) PATIENT ACCESS TO EXPERIMENTAL TREATMENTS.—

(1) PUBLIC MEETING.—

(A) IN GENERAL.—The Secretary of Health and Human Services (referred to in this section as the ''Secretary''), acting through the Commissioner of Food and Drugs, in coordination with the Director of the National Institutes of Health, and in consultation with patients, health care providers, drug sponsors, bioethicists, and other stakeholders, shall, not later than 180 days after the date of enactment of this Act, convene a public meeting to discuss clinical trial inclusion and exclusion criteria to inform the guidance under paragraph (3). The Secretary shall inform the Comptroller General of the United States of the date when the public meeting will take place.

(B) TOPICS.—The Secretary shall provide a publicly available report on the topics discussed at the meeting described in subparagraph (A)

within 30 days of such meeting. Such topics shall include discussion of—

(i) the rationale for, and potential barriers for patients created by, clinical trial inclusion and exclusion criteria;

(ii) how patient populations most likely to be affected by a drug can benefit from the results of trials that employ alternative designs, as well as potential risks associated with alternative clinical trial designs;

(iii) barriers to participation in clinical trials, including—

(I) information regarding any potential risks and benefits of participation;

(II) regulatory, geographical, and socioeconomic barriers; and

(III) the impact of exclusion criteria on the enrollment in clinical trials of infants and children, pregnant and lactating women, seniors, individuals with advanced disease, and individuals with co-morbid conditions;

(iv) clinical trial designs and methods that increase enrollment of more diverse pa-

tient populations while facilitating the collection of data to support substantial evidence of safety and effectiveness; and

(v) how changes to clinical trial inclusion and exclusion criteria may impact the complexity of the clinical trial design and length of clinical trials, and potential approaches to mitigating those impacts to ensure that the ability to demonstrate safety and effectiveness is not hindered through potential changes in eligibility criteria.

(2) REPORT.—Not later than 1 year after the Secretary issues a report on the topics discussed at the public meeting under paragraph (1)(B), the Comptroller General of the United States shall report to the Committee on Health, Education, Labor, and Pensions of the Senate and the Committee on Energy and Commerce of the House of Representatives on individual access to investigational drugs through the expanded access program under section 561(b) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360bbb(b)). The report shall include—

(A) a description of actions taken by manufacturers under section 561A of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360bbb–0);

(B) consideration of whether Form FDA 3926 and the guidance document entitled "Expanded Access to Investigational Drugs for Treatment Use—Questions and Answers", issued by the Food and Drug Administration in June 2016, has reduced application burden with respect to individuals and physicians seeking access to investigational new drugs pursuant to section 561(b) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360bbb) and improved clarity for patients, physicians, and drug manufacturers about such process;

(C) consideration of whether the guidance or regulations released or updated under section 561 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360bbb) have improved access for individual patients who do not qualify for clinical trials of such investigational drugs, and what barriers to such access remain;

(D) an assessment of how patients and health care providers navigate different avenues to engage with the Food and Drug Administration or drug sponsors on expanded access; and

(E) an analysis of the Secretary's report under paragraph (1)(B).

(3) GUIDANCE.—

(A) IN GENERAL.—Not later than 180 days after the publication of the report under paragraph (1), the Secretary, acting through the Commissioner of Food and Drugs, shall issue one or more draft guidances regarding eligibility criteria for clinical trials. Not later than 18 months after the public comment period on each such draft guidance ends, the Secretary shall issue a revised draft guidance or final guidance.

(B) CONTENTS.—The guidance documents described in subparagraph (A) shall address methodological approaches that a manufacturer or sponsor of an investigation of a new drug may take to—

(i) broaden eligibility criteria for clinical trials, especially with respect to drugs for the treatment of serious and life-threatening conditions or diseases for which there is an unmet medical need; and

(ii) develop eligibility criteria for, and increase trial recruitment to, clinical trials so that enrollment in such trials more accurately reflects the patients most likely to receive the drug, as applicable and as appro-

priate, while supporting findings of substantial evidence of safety and effectiveness.

(b) IMPROVING INSTITUTIONAL REVIEW BOARD REVIEW OF SINGLE PATIENT EXPANDED ACCESS PROTOCOL.—Not later than 1 year after the date of enactment of this Act, the Secretary, acting through the Commissioner of Food and Drugs, shall issue guidance or regulations, or revise existing guidance or regulations, to streamline the institutional review board review for individual pediatric and adult patient expanded access protocol under 561(b) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360bbb(b)). Such guidance or regulation may include a description of the conditions under which an institutional review board chair (or designee) may review individual patient expanded access protocol submitted under section 505(i) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(i)) for a drug and how centralized institutional review boards may facilitate the use of expanded access protocols. The Secretary shall update any relevant forms associated with individual patient expanded access protocol as necessary.

(c) EXPANDED ACCESS POLICY TRANSPARENCY.—Section 561A(f) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360bbb–0(f)) is amended—

(1) in the matter preceding paragraph (1), by striking "later" and inserting "earlier";

(2) by striking paragraph (1);

(3) by redesignating paragraph (2) as paragraph (1);

(4) in paragraph (1) as so redesignated, by striking the period at the end and inserting "; or"; and

(5) by adding at the end the following:

"(2) as applicable, 15 days after the drug receives a designation as a breakthrough therapy, fast track product, or regenerative advanced therapy under subsection (a), (b), or (g), respectively, of section 506.".

SEC. 807. TECHNICAL CORRECTIONS.

(a) CROSS-REFERENCE.—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) 506G.—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".

TITLE IX—GENERIC DRUG ACCESS

Subtitle A—Removing Regulatory Barriers to Competition

SEC. 901. IMPROVING ACCESS TO GENERIC DRUGS.

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

"(11)(A) The Secretary shall prioritize the review of, and act within 240 calendar days of the date of the submission of, an original abbreviated new drug application submitted for review under this subsection, or on a supplement to such an application, that is for a drug—

"(i) for which there are not more than 3 approved drugs listed under paragraph (7), except that the review of an application submitted more than 30 months in advance of the last applicable expiration date for a patent for which a certification under paragraph (2)(A)(vii)(III) has been submitted, or of the expiration date for an applicable period of exclusivity under this Act, will not be expedited; or

"(ii) that has been included on the list under section 506E.

"(B) The Secretary shall require the applicant, not later than 60 days prior to the submission of an application

described in subparagraph (A), to provide complete, accurate information regarding facilities involved in manufacturing processes and testing, including facilities in corresponding Type II active pharmaceutical ingredients drug master files submitted with an application and sites or organizations involved in bioequivalence and clinical studies used to support the application, in order to make a determination regarding whether an inspection of an establishment is necessary.

"(C) The Secretary may expedite an inspection or reinspection under section 704 of an establishment that proposes to manufacture a drug described in subparagraph (A).

"(D) Nothing in this paragraph shall prevent the Secretary from prioritizing the review of other applications as the Secretary determines appropriate.

"(12) The Secretary shall provide review status updates to applicants regarding applications under this subsection, as appropriate, including when the application is awaiting final regulatory action by the office charged with review.

"(13) The Secretary shall publish on the Internet website of the Food and Drug Administration a list of all drugs approved under subsection (b) for which all patents and periods of exclusivity under this Act have expired. Such list shall be updated at least once every 180 days.".

SEC. 902. REPORTING ON PENDING GENERIC DRUG APPLICATIONS, PRIORITY REVIEW APPLICATIONS, AND INSPECTIONS.

(a) IN GENERAL.—Not later than 180 calendar days after the date of enactment of this Act, and quarterly thereafter until October 1, 2022, the Secretary of Health and Human Services (referred to in this section as the "Secretary") shall post on the Internet website of the Food and Drug Administration a report that provides—

(1) the number of applications filed under section 505(j) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(j)) awaiting action by the applicant, including such applications that were filed prior to October 1, 2014;

(2) the number of applications filed under section 505(j) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(j)) awaiting action by the Secretary, including such applications that were filed prior to October 1, 2014;

(3) the number of applications filed under section 505(j) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(j)) and prior approval supplements withdrawn in each month covered by the report;

(4) the mean and median approval and tentative approval times for applications covered by the report;

(5) the number of applications described in paragraphs (1), (2), and (3) that are subject to priority review; and

(6) the number of such applications on which the Secretary has taken action pursuant to section 506H(b) of the Federal Food, Drug, and Cosmetic Act, as added by section 911.

(b) ANNUAL REPORT ON PRIORITY REVIEW APPLICATIONS.—

(1) IN GENERAL.—The Secretary shall submit to the Committee on Health, Education, Labor, and Pensions and the Special Committee on Aging of the Senate and the Committee on Energy and Commerce of the House of Representatives an annual report, not later than March 31 of each year, on the following:

(A) The number of applications filed under section 505(j) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(j)) that are subject to priority review during the most recent calendar year and are awaiting action by the applicant.

(B) The number of applications filed under section 505(j) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(j)) that are subject to priority review during the most recent cal-

endar year and are awaiting action by the Secretary.

(C) The number of applications filed under section 505(j) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(j)) that are subject to priority review during the most recent calendar year and have been approved by the Secretary.

(D) For each of subparagraphs (A) through (C), the number of such applications—

(i) for which there are not more than 3 approved drugs listed under section 505(j)(7) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(j)(7)); and

(ii) the number of such applications that are for a drug on the drug shortage list under section 506E of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 356e).

(c) ANNUAL REPORT ON INSPECTIONS.—Not later than March 1 of each year, the Secretary shall post on the Internet website of the Food and Drug Administration—

(1) the average and median amount of time, following a request by staff of the Food and Drug Administration reviewing an application or report submitted under an applicable section described in sub-

paragraph (A), (B), or (C), to schedule and complete inspections of facilities necessary for—

(A) approval of a drug under section 505 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355);

(B) approval of a device under section 515 of such Act (21 U.S.C. 360e); and

(C) clearance of a device under section 510(k) of such Act (21 U.S.C. 360(k)); and

(2) the average and median amount of time to schedule and complete for-cause inspections of facilities of drugs and devices.

Subtitle B—Incentivizing Competition

SEC. 911. EXPEDITING GENERIC COMPETITION.

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

"SEC. 506H. EXPEDITING GENERIC DRUG DEVELOPMENT.

"(a) IN GENERAL.—The Secretary shall, at the request of an applicant, expedite the development and review of an application under subsection (j) of section 505 for a drug—

"(1) for which there are not more than 3 approved drug products listed under section 505(j)(7); or

"(2) that is included on the list under section 506E.

"(b) REQUEST FROM SPONSORS.—A request to expedite the development and review of an application under subsection (a) shall be submitted by the applicant prior to the submission of such application.

"(c) OTHER APPLICATIONS.—Nothing in this section shall prevent the Secretary from expediting the development and review of other applications as the Secretary determines appropriate.

"(d) ADDITIONAL COMMUNICATION.—The Secretary shall take such actions as are appropriate to expedite the development and review of the application for approval of a drug described in subsection (a), including, as appropriate—

"(1) holding meetings with the sponsor and the review team throughout the development of the drug prior to submission of the application;

"(2) providing timely advice to, and interactive communication with, the sponsor regarding the development of the application to ensure that the collection of nonclinical and clinical data necessary for approval is as efficient as practicable;

"(3) in the case of a complex product, assigning a cross-disciplinary project lead for the review team

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

"(4) in the case of a complex product, including drug-device combinations, involving senior managers and experienced review staff, as appropriate, in a collaborative, cross- disciplinary review.

"(e) REPORTING REQUIREMENT.—A sponsor of a drug expedited under this section shall report to the Secretary, one year following approval of an application under section 505(j), on whether the approved drug has been marketed in interstate commerce since approval.".

SEC. 912. LIST OF GENERIC DRUGS WITH LIMITED COMPETITION.

Chapter V of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 351 et seq.) is amended by inserting after section 506H, as added by section 911, the following:

"SEC. 506I. DRUG LISTING.

"(a) REMOVAL, WITHDRAWAL, OR TRANSFER.—The holder of an application approved under subsection (b) or (j) of section 505 shall notify the Secretary within 180 days of removing the drug that is the subject of such application from interstate commerce, withdrawing such approved application, or transferring such approved application, and a reason for such removal, withdrawal, or transfer. If com-

pliance with this subsection within such 180-day period is not practicable, then the holder shall comply as soon as practicable. The Secretary shall cross-reference information listed pursuant to section 506C where applicable to avoid duplicative reporting.

"(b) DRUGS WITH LIMITED COMPETITION.—

"(1) INFORMATION.—The Secretary shall—

"(A) maintain information with respect to applications approved under section 505(j); and

"(B) publish on the Internet website of the Food and Drug Administration such information under subparagraph (A) with respect to drugs for which there are 3 or fewer application holders; and

"(C) update the information published pursuant to subparagraph (B) every 180 days.

"(2) CONTENTS.—The public information maintained and published under paragraph (1)(B) shall include—

"(A) the name of the drug, name of the holder of the approved application, and the marketing status for each drug; and

"(B) an indication of whether the Secretary considers the drug to be for the treatment or prevention of a serious disease or medical condition,

for which there is no alternative drug that is judged by medical professionals to be an adequate substitute available in adequate supply.

"(c) PUBLIC HEALTH EXCEPTION.—The Secretary may choose not to make information collected under this section publicly available if the Secretary determines that disclosure of such information would adversely affect the public health.

"(d) NOTIFICATION.—When the Secretary first publishes the information under subsection (b), the Secretary shall notify relevant Federal agencies, including the Centers for Medicare & Medicaid Services and the Federal Trade Commission, that the information has been published and will be updated regularly.".

SEC. 913. SUITABILITY PETITIONS.

(a) IN GENERAL.—It is the sense of the Senate that the Food and Drug Administration shall meet the requirement under section 505(j)(2)(C) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(j)(2)(C)) and section 314.93(e) of title 21, Code of Federal Regulations, of responding to suitability petitions within 90 days of submission.

(b) REPORT.—The Secretary of Health and Human Services shall include in the annual reports under section 902(b)—

(1) the number of pending petitions under section 505(j)(2)(C) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(j)(2)(C)); and

(2) the number of such petitions pending a substantive response for more than 180 days from the date of receipt.

SEC. 914. INSPECTIONS.

Section 505(j) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(j)), as amended by section 901, is further amended by adding at the end the following:

"(14) If the Secretary issues feedback pursuant to section 704(b)(2) with respect to information submitted in response to a report under section 704(b)(1), and a report that was issued under section 704(b)(1) is the only obstacle to approval of an application under this subsection or the Secretary determines that the public health benefit of approving an application under this subsection outweighs any risk to public health, the Secretary shall, within 45 days of notification by the applicant that necessary changes have been made to the establishment to address any findings or deficiencies identified previously by the Secretary—

"(A) re-inspect the establishment with respect to which the report was issued; or

"(B) make a determination regarding the response to such report and review of such application.".

Calendar No. 76

115TH CONGRESS
1ST SESSION

S. 934

A BILL

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

MAY 11, 2017

Reported with an amendment