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IN THE SENATE OF THE UNITED STATES

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AN ACT

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

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

SECTION 1. SHORT TITLE.

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

SEC. 2. TABLE OF CONTENTS.

The table of contents for this Act is as follows:

TITLE I—FEES RELATING TO DRUGS

SEC. 101. SHORT TITLE; FINDING.

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

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

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

(a) TYPES OF FEES.—

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

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

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

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

(D) in paragraph (1)(A)—

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

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

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

(F) in paragraph (1)(F)—

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

(ii) by striking the second sentence;

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

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

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

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

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

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

(ii) by striking ''A prescription drug product shall not be assessed a fee'' and

inserting ''A prescription drug program fee shall not be assessed for a prescription drug product''; and

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

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

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

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

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

''(b) FEE REVENUE AMOUNTS.—

''(1) IN GENERAL.—For each of the fiscal years 2018 through 2022, fees under subsection (a) shall,

except as provided in subsections (c), (d), (f), and (g), be established to generate a total revenue amount under such subsection that is equal to the sum of—

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

''(c) ADJUSTMENTS; ANNUAL FEE SETTING.—

''(1) INFLATION ADJUSTMENT.—

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

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

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

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

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

eral Register notice under paragraph (5) of 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) estab-

lishing 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 each such 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; FINDING.

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

(b) FINDING.—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.

(a) IN GENERAL.—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''.

(b) CONFORMING AMENDMENT.—Section 714(b)(1) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 379d–3(b)(1)) is amended by striking ''737(8)'' and inserting ''737(9)''.

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 AMENDMENTS.—

(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 so 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 so 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 so redesignated, of section 738 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 379j) is amended—

(1) in paragraph (3)—

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

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

(2) by striking paragraph (4).

SEC. 204. REAUTHORIZATION; REPORTING REQUIREMENTS.

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

(1) in paragraph (1)—

(A) in subparagraph (A)—

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

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

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

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

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

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

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

SEC. 205. CONFORMITY ASSESSMENT PILOT PROGRAM.

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

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

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

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

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

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

''(A) review determinations by testing laboratories accredited pursuant to this subsection,

including by conducting periodic audits of such determinations or processes of accredited bodies or testing laboratories and, following such review, taking additional measures under this Act, such as suspension or withdrawal of accreditation of such testing laboratory under paragraph (1)(A) or requesting additional information with respect to such device, as the Secretary determines appropriate; and

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

''(3) IMPLEMENTATION AND REPORTING.—

''(A) PUBLIC MEETING.—The Secretary shall publish in the Federal Register a notice of a public meeting to be held no later than September 30, 2018, to discuss and obtain input and recommendations from stakeholders regard-

ing 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 internet 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 permanently implantable, 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 such device type or subset;

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

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

(C) by adding at the end the following:

"(C) INTERIM RULE.—Until the date on which the updated list is designated and posted

in accordance with subparagraph (B)(iii), the list in effect on the date of enactment the Medical Device User Fee Amendments of 2017 shall be in effect.'';

(2) in subsection (b)—

(A) in paragraph (2)—

(i) by striking subparagraph (D); and

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

(B) in paragraph (3)—

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

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

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

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

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

SEC. 207. ELECTRONIC FORMAT FOR SUBMISSIONS.

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

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

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

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

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

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

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

''(C) FINAL GUIDANCE.—The Secretary shall, not later than 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 DATES.

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

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

(c) PREVIOUS SUNSET PROVISION.—Effective October 1, 2017, section 207(a) of the Food and Drug Administration Safety and Innovation Act (Public Law 112–144) is repealed.

TITLE III—FEES RELATING TO GENERIC DRUGS

SEC. 301. SHORT TITLE; FINDING.

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

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

SEC. 302. DEFINITIONS.

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

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

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

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

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

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

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

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

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

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

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

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

(3) in paragraph (2)—

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

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

(B) in subparagraph (E)—

(i) in clause (i)—

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

''(I) the date'';

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

(III) by adding at the end the following:

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

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

(4) in paragraph (3)—

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

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

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

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

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

(D) in subparagraph (D)—

(i) in the heading, by inserting ", IS WITHDRAWN PRIOR TO BEING RECEIVED, OR IS NO LONGER RECEIVED" after "RECEIVED"; and

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

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

"(ii) APPLICATIONS NO LONGER RECEIVED.—The Secretary shall refund 100 percent of the fee paid under subparagraph (A) for any abbreviated new drug application if the Secretary initially receives the

application under section 505(j)(5)(A) and subsequently determines that an exclusivity period for a listed drug should have 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 ge-

neric 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 sub-

paragraph (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 applica-

tions on the due date for the fee under this subsection, the person (including its affiliates) shall be assessed a medium size operation generic drug applicant program fee equal to two-fifths of the large size operation generic drug applicant program fee.

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

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

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

(1) in paragraph (1)—

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

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

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

(2) in paragraph (2)—

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

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

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

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

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

''(1) FISCAL YEARS 2018 THROUGH 2022.—Not more than 60 days before the first day of each of fiscal years 2018 through 2022, the Secretary shall establish the fees described in paragraphs (2) through (5) of subsection (a), based on the revenue

amounts established under subsection (b) and the adjustments provided under subsection (c).'';

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

(3) in paragraph (2) (as so redesignated), in the matter preceding subparagraph (A), by striking ''fees under paragraphs (1) and (2)'' and inserting ''fee under paragraph (1)''.

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

(1) by striking paragraph (1);

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

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

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

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

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

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

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

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

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

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

(F) by adding at the end the following:

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

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

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. 379j–42(i)) is amended—

(1) in paragraph (2)—

(A) in subparagraph (A), by striking ''subparagraphs (C) and (D)'' and inserting ''subparagraph (C)'';

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

(C) in subparagraph (D)—

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

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

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

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

(i) INFORMATION ON ABBREVIATED NEW DRUG APPLICATIONS OWNED BY APPLICANTS AND THEIR AFFILIATES.—Section 744B of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 379j–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 a designated affiliate of such person, shall submit, on behalf of the person and the affiliates of such person, 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.—

(1) IN GENERAL.—Effective October 1, 2017, section 304 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 304.

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 were received by the Food and Drug Administration within the meaning of section 505(j)(5)(A) of such Act (21 U.S.C. 355(j)(5)(A)), prior approval supplements that were submitted, and drug master files for Type II active pharmaceutical ingredients that were first referenced 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 IV—FEES RELATING TO BIOSIMILAR BIOLOGICAL PRODUCTS

SEC. 401. SHORT TITLE; FINDING.

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

(b) FINDING.—The Congress finds that the fees authorized by the amendments made in this title will be dedicated to expediting the process for the review of biosimilar biological product applications, including postmarket safety activities, as set forth in the goals identified for purposes of part 8 of subchapter C of chapter VII of the Federal Food, Drug, and Cosmetic Act, in the letters from the Secretary of Health and Human Services to the Chairman of the Committee on Health, Education, Labor, and Pensions of the Senate and the Chairman of the Committee on Energy and Commerce of the House of Representatives, as set forth in the Congressional Record.

SEC. 402. DEFINITIONS.

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

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

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

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

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

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

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

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

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

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

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

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

''(iv) REFUND.—If a person submits a marketing application for a biosimilar biological product before October 1 of a fiscal year and such application is accepted for filing on or after October 1 of such fiscal year, the person may request a refund equal to the annual biosimilar biological product development fee paid by the person for the product for such fiscal year. To qualify for consideration for a refund under this clause, a person shall submit to

the Secretary a written request for such refund not later than 180 days after the marketing application is accepted for filing.'';

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

(9) in paragraph (1)(D)—

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

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

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

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

(11) in paragraph (1)(F)—

(A) in the subparagraph heading, by striking ''BIOSIMILAR DEVELOPMENT PROGRAM''; and

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

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

(12) in paragraph (2)—

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

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

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

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

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

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

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

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

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

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

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

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

''(3) BIOSIMILAR BIOLOGICAL PRODUCT PROGRAM FEE.—

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

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

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

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

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

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

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

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

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

''(c) ADJUSTMENTS; ANNUAL FEE SETTING.—

''(1) INFLATION ADJUSTMENT.—

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

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

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

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

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

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

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

''(2) CAPACITY PLANNING ADJUSTMENT.—

''(A) IN GENERAL.—Beginning with the fiscal year described in subparagraph (B)(ii)(II), the Secretary shall, in addition to the adjustment under paragraph (1), further increase the fee revenue and fees under this sec-

tion 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 Sec-

retary 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)(B) 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)(B) a description of the methodology used to calculate the fiscal year 2018 adjustment under this paragraph in the Federal Register notice establishing fee revenue and fees for fiscal year 2018.

''(C) LIMITATION.—No adjustment under this paragraph shall result in an increase in fee revenue and fees under this section in excess of $9,000,000.

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

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

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

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

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

(1) by striking subparagraph (B);

(2) by striking ''; and'' at the end of subparagraph (A) and inserting a period; and

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

(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 shall cease to be effective October 1, 2022.

(b) REPORTING REQUIREMENTS.—Section 744I of the Federal Food, Drug, and Cosmetic 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. 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)—

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

''(B) AVAILABILITY OF REPORTS.—

"(i) IN GENERAL.—Each report submitted under subparagraph (A) shall be considered to be in the public domain (subject to section 505A(d)(4) of the Federal Food, Drug, and Cosmetic Act) and not later than 90 days after submission of such report, shall be—

"(I) posted on the internet website of the National Institutes of Health in a manner that is accessible and consistent with all applicable Federal laws and regulations, including such laws and regulations for the protection of—

"(aa) human research participants, including with respect to privacy, security, informed consent, and protected health information; and

"(bb) proprietary interests, confidential commercial information, and intellectual property rights; and

"(II) assigned a docket number by the Commissioner of Food and

Drugs and made available for the submission of public comments.

''(ii) SUBMISSION OF COMMENTS.—An interested person may submit written comments concerning such pediatric studies to the Commissioner of Food and Drugs, and the submitted comments shall become part of the docket file with respect to each of the drugs.''; and

(ii) in subparagraph (C), by striking ''appropriate action'' and all that follows through the period and inserting ''action in a timely and appropriate manner in response to the reports submitted under subparagraph (A), and shall begin such action upon receipt of the report under subparagraph (A), in accordance with paragraph (7).''; and

(B) in paragraph (7)—

(i) in the matter preceding subparagraph (A), by striking ''During'' and inserting ''Within'';

(ii) in subparagraph (C)(i), by striking ''place'' and all that follows through ''and of'' and inserting ''include in the

public docket file a reference to the location of the report on the internet website of the National Institutes of Health and a copy of''; and

(iii) in clause (ii), by striking ''in the Federal Register and'';

(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''.

SEC. 502. PEDIATRIC DEVICES.

(a) PEDIATRIC USE OF DEVICES.—Section 515A(a)(3) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360e–1(a)(3)) is amended—

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

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

''(B) any information, based on a review of data available to the Secretary, regarding devices used in pediatric patients but not labeled for such use for which the Secretary determines

that approved pediatric labeling could confer a benefit to pediatric patients;

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

(3) in subparagraph (E), as so redesignated, by striking ''; and'' and inserting '';'';

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

(5) by adding at the end the following:

''(G) the number of devices for which the Secretary relied on data with respect to adults to support a determination of a reasonable assurance of safety and effectiveness in pediatric patients; and

''(H) the number of devices for which the Secretary relied on data from one pediatric subpopulation to support a determination of a reasonable assurance of safety and effectiveness in another pediatric subpopulation.

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

(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 ''2013 through 2017'' and inserting ''2018 through 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 on the development, approval or clearance, and labeling of pediatric medical devices. The Secretary shall invite to such meeting 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 pediatric populations that would result in the approval or

clearance, and labeling, of medical devices for such populations;

(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 manufacturers in developing devices for pediatric populations that are approved or cleared, and labeled, for their use; and

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

(3) REPORT.—The report submitted under section 515A(a)(3) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360e–1(a)(3)) with respect to the calendar year in which the meeting described in paragraph (1) is held shall include a summary of, and responses to, recommendations raised in such meeting.

SEC. 503. EARLY MEETING ON PEDIATRIC STUDY PLAN.

(a) 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 or biological product 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 Federal 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 the bases for the deferral under subsection (a)(4) or a

full or partial waiver under subsection (a)(5);''.

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

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

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

(3) 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

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

SEC. 504. DEVELOPMENT OF DRUGS AND BIOLOGICAL PRODUCTS FOR PEDIATRIC CANCERS.

(a) MOLECULAR TARGETS REGARDING CANCER DRUGS AND BIOLOGICAL PRODUCTS.—Section 505B of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355c) is amended—

(1) in subsection (a)—

(A) in paragraph (1)—

(i) by redesignating subparagraphs (A) and (B) as clauses (i) and (ii), respec-

tively, and adjusting the margins accordingly;

(ii) by striking ''A person'' and inserting the following:

''(A) GENERAL REQUIREMENTS.—Except with respect to an application for which subparagraph (B) applies, a person'';

(iii) in clause (i), as so redesignated, by striking '', or'' at the end and inserting ''; or''; and

(iv) by adding after subparagraph (A), as so designated by clause (ii), the following:

''(B) CERTAIN MOLECULARLY TARGETED CANCER INDICATIONS.—A person that submits, on or after the date that is 3 years after the date of enactment of the FDA Reauthorization Act of 2017, an original application for a new active ingredient under section 505 of this Act or section 351 of the Public Health Service Act, shall submit with the application reports on the investigation described in paragraph (3) if the drug or biological product that is the subject of the application is—

''(i) intended for the treatment of an adult cancer; and

''(ii) directed at a molecular target that the Secretary determines to be substantially relevant to the growth or progression of a pediatric cancer.'';

(B) in paragraph (2)(A), by striking ''paragraph (1)'' and inserting ''paragraph (1)(A)'';

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

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

''(3) MOLECULARLY TARGETED PEDIATRIC CANCER INVESTIGATION.—

''(A) IN GENERAL.—With respect to a drug or biological product described in paragraph (1)(B), the investigation described in this paragraph is a molecularly targeted pediatric cancer investigation, which shall be designed to yield clinically meaningful pediatric study data, gathered using appropriate formulations for each age group for which the study is required, regarding dosing, safety, and preliminary efficacy to inform potential pediatric labeling.

''(B) EXTRAPOLATION OF DATA.—Paragraph (2)(B) shall apply to investigations described in this paragraph to the same extent and in the same manner as paragraph (2)(B) applies with respect to the assessments required under paragraph (1)(A).

''(C) DEFERRALS AND WAIVERS.—Deferrals and waivers under paragraphs (4) and (5) shall apply to investigations described in this paragraph to the same extent and in the same manner as such deferrals and waivers apply with respect to the assessments under paragraph (2)(B).'';

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

(i) by striking ''assessments required under paragraph (1)'' each place it appears and inserting ''assessments required under paragraph (1)(A) or reports on the investigation required under paragraph (1)(B)'';

(ii) in subparagraph (A)(ii)(I), by inserting ''or reports on the investigation'' after ''assessments'';

(iii) in subparagraph (B)(ii), by striking ''assessment under paragraph (1)'' and

inserting ''assessment under paragraph (1)(A) or reports on the investigation under paragraph (1)(B)''; and

(iv) in subparagraph (C)(ii)(II), by inserting ''or investigation'' after ''assessment''; and

(F) in paragraph (5), as so redesignated, by inserting ''or reports on the investigation'' after ''assessments'' each place it appears;

(2) in subsection (d)—

(A) by striking ''subsection (a)(3)'' each place it appears and inserting ''subsection (a)(4)'';

(B) by inserting ''AND REPORTS ON THE INVESTIGATION'' after ''SUBMISSION OF ASSESSMENTS'' in the heading; and

(C) by inserting ''or the investigation described in subsection (a)(3)'' after ''assessment described in subsection (a)(2)'' each place it appears;

(3) in subsection (e)—

(A) in paragraph (1), by inserting ''or the investigation described in subsection (a)(3)'' after ''under subsection (a)(2)''; and

(B) in paragraph (2)(A)(i), by inserting ''or the investigation described in subsection (a)(3)'' after ''under subsection (a)(2)''; and

(4) by adding at the end the following:

''(m) LIST OF PRIMARY MOLECULAR TARGETS.—

''(1) IN GENERAL.—Within one year of the date of enactment of the FDA Reauthorization Act of 2017, the Secretary shall establish and update regularly, and shall publish on the internet website of the Food and Drug Administration—

''(A) a list of molecular targets considered, on the basis of data the Secretary determines to be adequate, to be substantially relevant to the growth and progression of a pediatric cancer, and that may trigger the requirements under this section; and

''(B) a list of molecular targets of new cancer drugs and biological products in development for which pediatric cancer study requirements under this section will be automatically waived.

''(2) CONSULTATION.—In establishing the lists described in paragraph (1), the Secretary shall consult the National Cancer Institute, members of the internal committee under section 505C, and the Pe-

diatric Oncology Subcommittee of the Oncologic Drugs Advisory Committee, and shall take into account comments from the meeting under subsection (c).

''(3) RULE OF CONSTRUCTION.—Nothing in paragraph (1) shall be construed—

''(A) to require the inclusion of a molecular target on the list published under such paragraph as a condition for triggering the requirements under subsection (a)(1)(B) with respect to a drug or biological product directed at such molecular target; or

''(B) to authorize the disclosure of confidential commercial information, as prohibited under section 301(j) of this Act or section 1905 of title 18, United States Code.''.

(b) ORPHAN DRUGS.—Section 505B(k) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355c(k)) is amended to read as follows:

''(k) RELATION TO ORPHAN DRUGS.—

''(1) IN GENERAL; EXEMPTION FOR ORPHAN INDICATIONS.—Unless the Secretary requires otherwise by regulation and except as provided in paragraph (2), this section does not apply to any drug or biological product for an indication for which or-

phan designation has been granted under section 526.

''(2) APPLICABILITY DESPITE ORPHAN DESIGNATION OF CERTAIN INDICATIONS.—This section shall apply with respect to a drug or biological product for which an indication has been granted orphan designation under 526 if the investigation described in subsection (a)(3) applies to the drug or biological product as described in subsection (a)(1)(B).''.

(c) MEETING, CONSULTATION, AND GUIDANCE.—

(1) MEETING.—The Secretary of Health and Human Services (referred to in this subsection as 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 1 year after the date of enactment of this Act to solicit feedback from physicians and researchers (including pediatric oncologists and rare disease specialists), patients, and other stakeholders to provide input on development of the guidance under paragraph (2) and the list under subsection (m) of section 505B of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355c), as added by subsection (a). The Secretary shall seek input at such meeting on—

(A) the data necessary to determine that there is scientific evidence that a drug or biological product is directed at a molecular target that is considered to be substantially relevant to the growth or progression of a pediatric cancer;

(B) the data necessary to determine that there is scientific evidence that a molecular target is considered to be substantially relevant to the growth or progression of a pediatric cancer;

(C) the data needed to meet the requirement of conducting an investigation described in section 505B(a)(3) of the Federal Food, Drug, and Cosmetic Act, as amended by subsection (a);

(D) considerations when developing the list under section 505B(m) of the Federal Food, Drug, and Cosmetic Act that contains molecular targets shared between different tumor types;

(E) the process the Secretary shall utilize to update regularly a list of molecular targets that may trigger a pediatric study under section 505B of the Federal Food, Drug, and Cosmetic Act, as so amended, and how often such updates shall occur;

(F) how to overcome the challenges related to pediatric cancer drug and biological product development, including issues related to the ethical, practical, and other barriers to conducting clinical trials in pediatric cancer with small patient populations;

(G) scientific or operational challenges associated with performing an investigation described in section 505B(a)(1)(B) of the Federal Food, Drug, and Cosmetic Act, including the effect on pediatric studies currently underway in a pediatric patient population, treatment of a pediatric patient population, and the ability to complete adult clinical trials;

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

(I) 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;

(J) the ways in which the Secretary might streamline and improve the written request process, including when studies contained in a request under such section 505A are not feasible due to the ethical, practical, or other barriers to conducting clinical trials in pediatric cancer populations;

(K) how the Secretary will facilitate collaboration among pediatric networks, academic centers and experts in pediatric cancer to conduct an investigation described in such section 505B(a)(3);

(L) how the Secretary may facilitate collaboration among sponsors of same-in-class drugs and biological products that would be subject to the requirements for an investigation under such section 505B based on shared molecular targets; and

(M) the ways in which the Secretary will help to mitigate the risks, if any, of discouraging the research and development of orphan drugs when implementing such section 505B as amended.

(2) GUIDANCE.—Not later than 2 years after the date of enactment of this Act, the Secretary, act-

ing through the Commissioner of Food and Drugs, shall issue final guidance on implementation of the amendments to section 505B of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355c) regarding molecularly targeted cancer drugs made by this section, including—

(A) the scientific criteria, types of data, and regulatory considerations for determining whether a molecular target is substantially relevant to the growth or progression of a pediatric cancer and would trigger an investigation under section 505B of the Federal Food, Drug, and Cosmetic Act, as amended;

(B) the process by which the Secretary will engage with sponsors to discuss determinations, investigation requirements, deferrals, waivers, and any other issues that need to be resolved to ensure that any required investigation based on a molecular target can be reasonably conducted;

(C) the scientific or operational challenges for which the Secretary may issue deferrals or waivers for an investigation described in subsection (a)(3) of such section 505B, including adverse impacts on current pediatric studies un-

derway in a pediatric patient population, studies involving drugs designated as orphan drugs, treatment of a pediatric patient population, or the ability to complete adult clinical trials;

(D) how the Secretary and sponsors will facilitate collaboration among pediatric networks, academic centers, and experts in pediatric cancer to conduct an investigation described in subsection (a)(3) of such section 505B;

(E) scientific and regulatory considerations for study designs, including the applicability of innovative clinical trial designs for pediatric cancer drug and biological product developments under sections 505A and 505B of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355a, 355c);

(F) approaches to streamline and improve the amendment process, including when studies contained in a request under such section 505A are not feasible due to the ethical, practical, or other barriers to conducting clinical trials in pediatric cancer populations;

(G) the process for submission of an initial pediatric study plan for the investigation de-

scribed in section 505B(a)(3) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355c(a)(3)), including the process for a sponsor to meet and reach agreement with the Secretary on the initial pediatric study plan; and

(H) considerations for implementation of such section 505B, as so amended, and waivers of the requirements of such section 505B with regard to molecular targets for which several drugs or biological products may be under investigation.

(d) REPORT TO CONGRESS.—Section 508(b) of the Food and Drug Administration Safety and Innovation Act (21 U.S.C. 355c–1(b)) is amended—

(1) in paragraph (10), by striking ''; and'' and inserting '';''; and

(2) by striking paragraph (11) and inserting the following:

''(11) an assessment of the impact of the amendments to such section 505B made by the FDA Reauthorization Act of 2017 on pediatric research and labeling of drugs and biological products and pediatric labeling of molecularly targeted drugs and biological products for the treatment of cancer;

''(12) an assessment of the efforts of the Secretary to implement the plan developed under section 505C–1 of the Federal Food, Drug, and Cosmetic Act, regarding earlier submission of pediatric studies under sections 505A and 505B of such Act and section 351(m) of the Public Health Service Act, including—

''(A) the average length of time after the approval of an application under section 505(b)(1) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(b)(1)) or section 351(a) of the Public Health Service Act (42 U.S.C. 262(a)) before studies conducted pursuant to such section 505A, 505B, or section 351(m) are completed, submitted, and incorporated into labeling;

''(B) the average length of time after the receipt of a proposed pediatric study request before the Secretary responds to such request;

''(C) the average length of time after the submission of a proposed pediatric study request before the Secretary issues a written request for such studies;

''(D) the number of written requests issued for each investigational new drug or biological

product prior to the submission of an application under section 505(b)(1) of the Federal Food, Drug, and Cosmetic Act or section 351(a) of the Public Health Service Act; and

''(E) the average number, and range of numbers, of amendments to written requests issued, and the time the Secretary requires to review and act on proposed amendments to written requests;

''(13) a list of sponsors of applications or holders of approved applications who received exclusivity under such section 505A or such section 351(m) after receiving a letter issued under such section 505B(d)(1) for any drug or biological product before the studies referred to in such letter were completed and submitted;

''(14) a list of assessments and investigations required under such section 505B;

''(15) how many requests under such section 505A for molecular targeted cancer drugs, as defined by subsection (a)(1)(B) of such section 505B, approved prior to 3 years after the date of enactment of the FDA Reauthorization Act of 2017, have been issued by the Food and Drug Administration,

and how many such requests have been completed; and

''(16) the Secretary's assessment of the overall impact of the amendments made by section 504 of the FDA Reauthorization Act of 2017 on the conduct and effectiveness of pediatric cancer research and the orphan drug program, as well any subsequent recommendations.''.

(e) RULE OF CONSTRUCTION.—Nothing in this section, including the amendments made by this section, shall limit the authority of the Secretary of Health and Human Services to issue written requests 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)), or to negotiate or implement amendments to such requests proposed by the an applicant.

(f) GAO REPORT.—

(1) IN GENERAL.—Beginning on the date that is 5 years after the date of enactment of this Act, the Comptroller General of the United States shall conduct a study of the effectiveness of requiring assessments and investigations described in section 505B of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355c), as amended by this section, in the development of drugs and biological products for pe-

diatric cancer indications. The Comptroller General shall examine—

(A) the indications and associated molecular targets studied in assessments and investigations required for drugs or biological products intended for the treatment of an adult cancer;

(B) the indication for which the study was requested as compared to the indication requested under the new drug application filed by the sponsor;

(C) the number of pediatric cancer indications for which assessments and investigations have been required under such section 505B;

(D) the number of requests for deferral and waiver of pediatric assessments and investigations required under such section and the number of such deferral and waiver requests granted and denied;

(E) the number of orphan-designated indications for drugs and biological products for which assessments and investigations were required under such section;

(F) the number of drugs and biological products approved for the treatment of cancer

in the pediatric population for which the supportive studies were required to be conducted under such section;

(G) the number of written requests made under section 505A of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355a) relating to investigations required under subsection (a)(1)(B) of such section 505B; and

(H) any additional considerations by the Secretary regarding the effectiveness of requiring pediatric assessments described in such section 505B in the development of drugs and biological products for pediatric cancer indications.

(2) REVIEW.—The study under paragraph (1) shall include a review of the Food and Drug Administration's use of the authority under section 505B of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355c), as amended by this section, including the amendments to the deferral and waiver criteria under such section and how such criteria have been applied.

(3) CONSULTATION.—In conducting the study under paragraph (1), the Comptroller General of the United States shall consult with appropriate stakeholders that may be required to conduct the trials

under section 505B of the Federal Food, Drug, and Cosmetic Act, and the ability of such stakeholders to adhere to the requests issued by the Food and Drug Administration.

(4) REPORT.—Not later than the date that is 6 years after the date of enactment of this Act, the Comptroller General of the United States shall submit a report containing the results of the study under paragraph (1) to the Secretary of Health and Human Services, the Committee on Health, Education, Labor, and Pensions of the Senate, and the Committee on Energy and Commerce of the House of Representatives.

SEC. 505. ADDITIONAL PROVISIONS ON DEVELOPMENT OF DRUGS AND BIOLOGICAL PRODUCTS FOR PEDIATRIC USE.

(a) 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.''.

(b) 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 by a sponsor or holder of a proposed pediatric study request or a proposed amendment to a written request for pediatric studies within 120 calendar days of the submission.''.

(2) CONFORMING AMENDMENTS.—

(A) FEDERAL FOOD, DRUG, AND COSMETIC ACT.—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) PUBLIC HEALTH SERVICE ACT.—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)''.

(c) PLAN.—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, discussion of such requests 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 section 503(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 such 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).

(d) 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.

(e) 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 letters issued under this paragraph and responses to such letters.''.

(f) 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''.

(g) REPORT ON LABELING OF ORPHAN DRUGS.—

(1) IN GENERAL.—Not later than 2 years after the date of the enactment of this Act, the Secretary of Health and Human Services 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, and make publicly available, including through posting on the internet website of the Food and Drug Administration, a report on the lack of information in the labeling of drugs for indications that have received an orphan designation under section 526 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360bbb) with respect to the use of such drugs pediatric populations.

(2) CONTENTS.—The report described in paragraph (1) shall include—

(A) a list of drugs for which—

(i) an indication was granted an orphan designation under section 526 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360bbb);

(ii) an application described under section 505B(a)(1) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355c(a)(1)) for such indication was sub-

mitted to the Secretary of Health and Human Services on or after April 1, 1999; and

(iii) the labeling for such indication lacks important pediatric information, including information related to safety, dosing, and effectiveness;

(B) a description of the lack of information referred to in subparagraph (A)(iii) for each drug for an indication on such list; and

(C) Federal policy recommendations to improve the labeling of drugs for indications that have received an orphan designation under such section 526 with respect to the use of such drugs pediatric populations.''

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. 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, 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, unless the manufacturer has authorized the drug

to be marketed in the United States and has 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 knowingly making, selling or dispensing, or holding for sale or dispensing, a counterfeit drug shall be imprisoned for not more than 10 years or fined in accordance with title 18, United States Code, or both.''.

SEC. 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 ''impact (including physical and psychosocial impacts) of such disease or condition, or a related therapy or clinical investigation''.

SEC. 606. COMMUNICATION 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 drug formulations or properties, including information 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. ORPHAN DRUGS.

(a) IN GENERAL.—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). Beginning on the date of enactment of the FDA Reauthorization Act of 2017, until such time as the Secretary promulgates regulations in accordance with this subsection, the Secretary may apply any definitions set forth in regulations that were promulgated prior to such date of enactment, to the extent such definitions are not inconsistent with the terms of this section, as amended by such Act.

''(e) DEMONSTRATION OF CLINICAL SUPERIORITY STANDARD.—To assist sponsors in demonstrating clinical superiority as described in subsection (c), the Secretary—

''(1) upon the designation of any drug under section 526, shall notify the sponsor of such drug in writing of the basis for the designation, including, as applicable, any plausible hypothesis offered by the

sponsor and relied upon by the Secretary that the drug is clinically superior to a previously approved drug; and

''(2) upon granting exclusive approval or licensure under subsection (a) on the basis of a demonstration of clinical superiority as described in subsection (c), shall publish a summary of the clinical superiority findings.''.

(b) RULE OF CONSTRUCTION.—Nothing in the amendments made by subsection (a) shall affect any determination under sections 526 and 527 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360bb, 360cc) made prior to the date of enactment of the FDA Reauthorization Act of 2017.

SEC. 608. PEDIATRIC INFORMATION ADDED TO LABELING.

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

(1) in the subsection heading, by striking ''**UNDER SECTION 505(j)**'';

(2) in paragraph (1)—

(A) by striking ''under section 505(j)'' and inserting ''under subsection (b)(2) or (j) of section 505''; and

(B) by striking ''or by exclusivity under clause (iii) or (iv) of section 505(j)(5)(F)'' and

inserting ‘‘, or by exclusivity under clause (iii) or (iv) of section 505(j)(5)(F), clause (iii) or (iv) of section 505(c)(3)(E), or section 527(a), or by an extension of such exclusivity under this section or section 505E’’;

(3) in paragraph (2), in the matter preceding subparagraph (A)—

(A) by inserting ‘‘clauses (iii) and (iv) of section 505(c)(3)(E), or section 527,’’ after ‘‘section 505(j)(5)(F),’’; and

(B) by striking ‘‘drug approved under section 505(j)’’ and inserting ‘‘drug approved pursuant to an application submitted under subsection (b)(2) or (j) of section 505’’; and

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

‘‘(3) PRESERVATION OF PEDIATRIC EXCLUSIVITY AND EXTENSIONS.—This subsection does not affect—

‘‘(A) the availability or scope of exclusivity under—

‘‘(i) this section;

‘‘(ii) section 505 for pediatric formulations; or

‘‘(iii) section 527;

"(B) the availability or scope of an extension to any such exclusivity, including an extension under this section or section 505E;

"(C) the question of the eligibility for approval under section 505 of any application described in subsection (b)(2) or (j) of such section that omits any other aspect of labeling protected by exclusivity under—

"(i) clause (iii) or (iv) of section 505(j)(5)(F);

"(ii) clause (iii) or (iv) of section 505(c)(3)(E); or

"(iii) section 527(a); or

"(D) except as expressly provided in paragraphs (1) and (2), the operation of section 505 or section 527.".

SEC. 609. SENSE OF CONGRESS ON LOWERING THE COST OF PRESCRIPTION DRUGS.

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

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

(2) in lowering such cost, will—

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

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

SEC. 610. EXPANDED ACCESS.

(a) PATIENT ACCESS TO INVESTIGATIONAL DRUGS.—

(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 270 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 make available on the internet website of the Food and Drug Administration a report on the topics discussed at the meeting described in subparagraph (A) within 90 days of such meeting. Such topics shall include discussion of—

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

(ii) how appropriate patient populations can benefit from the results of trials that employ alternative 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 particular populations, including infants and children, pregnant and lactating women, seniors, individuals with advanced disease, and individuals with co-morbid conditions;

(iv) clinical trial designs and methods, including expanded access trials, that increase enrollment of more diverse patient populations, when appropriate, while facilitating the collection of data to establish safe use and support substantial evidence of effectiveness, including data obtained from expanded access trials; and

(v) how changes to clinical trial inclusion and exclusion criteria may impact the complexity and length of clinical trials, the data necessary to demonstrate safety and effectiveness, and potential approaches to mitigating those impacts.

(2) REPORT.—Not later than 1 year after the Secretary issues the report 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 and distributors 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 documents titled ''Expanded Access to Investigational Drugs for Treatment Use—Questions and Answers'' and ''Individual Patient Expanded Access Applications: Form FDA 3926'', issued by the Food and Drug Administration in June 2016, have 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 issued to implement section 561 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360bbb) have improved access for individual patients to investigational drugs who do not qualify for clinical trials of such investigational drugs, and what barriers to such access remain;

(D) an assessment of methods patients and health care providers use 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 1 year after the publication of the report under paragraph (1)(B), 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 1 year 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 and expanded access 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;

(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 appropriate, while establishing safe use and supporting findings of substantial evidence of effectiveness; and

(iii) use the criteria described in clauses (i) and (ii) in a manner that is appropriate for drugs intended for the treatment of rare diseases or conditions.

(b) IMPROVING INSTITUTIONAL REVIEW BOARD REVIEW OF SINGLE PATIENT EXPANDED ACCESS PRO-

TOCOL.—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 of individual patient expanded access protocols submitted under 561(b) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360bbb(b)). To facilitate the use of expanded access protocols, any guidance or regulations so issued or revised may include a description of the process for any person acting through a physician licensed in accordance with State law to request that an institutional review board chair (or designated member of the institutional review board) review a single patient expanded access protocol submitted under such section 561(b) for a drug. The Secretary shall update any relevant forms associated with individual patient expanded access requests under such section 561(b) 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. 611. TROPICAL DISEASE PRODUCT APPLICATION.

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

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

(2) by adding at the end the following:

''(iii) that contains reports of one or more new clinical investigations (other than bioavailability studies) that are essential to the approval of the application and conducted or sponsored by the sponsor of such application; and

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

(b) EFFECTIVE DATE.—The amendments made by subsection (a) shall apply to human drug applications submitted after September 30, 2017.

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 for purposes of inspecting device establishments.''; 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 FOR DEVICE ESTABLISHMENTS.

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

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

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

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

''(C) a reasonable estimate of the timeframe for the inspection, an opportunity for advance communications between the officers or employees carrying out the inspection under subsection (a)(1) and the owner, operator, or agent in charge of the establishment concerning appropriate working hours during the inspection, and, to the extent feasible, advance notice of some records that will be requested; and

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

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

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

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

''(ii) with respect to actions proposed to be taken by a device establishment in a response to a report received by such establishment pursuant to

subsection (b) that involve a public health priority, that implicate systemic or major actions, or relate to emerging safety issues (as determined by the Secretary).

''(3) Nothing in this subsection affects the authority of the Secretary to conduct inspections otherwise permitted under this Act in order to ensure compliance with this Act.''.

(b) GUIDANCE.—

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

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

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

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

(i) that occurs over consecutive days; and

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

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

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

(c) ADULTERATED DEVICES.—Subsection (j) of section 501 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 351) is amended by inserting ''or device'' after ''drug''.

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, and is based on the facility being out of compliance with part 820 of title 21, Code of Federal Regulations, the Secretary shall provide a substantive summary of the specific grounds for noncompliance identified by the Secretary.

''(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 as described in subclause (I) with respect to a device based solely on the issuance of that report if the owner, operator, or agent in charge of such establishment has agreed to a plan of correction in response to such report.

''(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 the 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.

''(iii)(I) Subject to subclause (II), this subparagraph applies to requests for certification on behalf of any device establishment registered under section 510, whether the establishment is located inside or outside of the United States, and regardless of whether such devices are to be exported from the United States.

''(II) If an establishment described in subclause (I) is not located within the United States and does not demonstrate that the devices manufactured, prepared, propagated, compounded, or processed at such establishment are to be exported from the United States, this subparagraph shall apply only if—

''(aa) the establishment has been inspected by the Secretary within 3 years of the date of the request; or

''(bb) the establishment participates in an audit program in which the United States participates or

the United States recognizes, an audit under such program has been conducted, and the findings of such audit are provided to the Secretary within 3 years of the date of the request.''; 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)(A) Notwithstanding any other provision of this subsection, the Secretary may recognize auditing organizations that are recognized by organizations established by governments to facilitate international harmonization for purposes of conducting inspections of—

''(i) establishments that manufacture, prepare, propagate, compound, or process devices (other than types of devices licensed under section 351 of the Public Health Service Act), as required under section 510(h); or

''(ii) establishments required to register pursuant to section 510(i).

''(B) Nothing in this paragraph affects—

''(i) the authority of the Secretary to inspect any device establishment pursuant to this Act; or

''(ii) the authority of the Secretary to determine the official classification of an inspection.''.

SEC. 706. FOSTERING INNOVATION IN MEDICAL IMAGING.

(a) APPROVAL OF APPLICATIONS FOR CERTAIN DIAGNOSTIC MEDICAL IMAGING DEVICES.—Section 520 of the Federal Food, Drug, and Cosmetic Act (42 U.S.C. 360j) is amended by adding at the end the following:

''(p) DIAGNOSTIC IMAGING DEVICES INTENDED FOR USE WITH CONTRAST AGENTS.—

''(1) IN GENERAL.—The Secretary may, subject to the succeeding provisions of this subsection, approve an application (or a supplement to such an application) submitted under section 515 with respect to an applicable medical imaging device, or, in the case of an applicable medical imaging device for which a notification is submitted under section 510(k), may make a substantial equivalence determination with respect to an applicable medical imaging device, or may grant a request submitted under section 513(f)(2) for an applicable medical imaging device, if such application, notification, or request involves 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 la-

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

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

''(C) in a patient population that is different from those described in the approved labeling of the contrast agent, except that the Secretary may approve such application, make such substantial equivalence determination, or grant such request if the Secretary determines

such differences in patient population exist but do not adversely affect the safety and effectiveness of the contrast agent when used with the device; or

''(D) in an imaging modality that is different from those described in the approved labeling of the contrast agent.

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

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

''(B) review information and data provided to the Secretary by the sponsor of a contrast agent in an application submitted under section 505 of this Act or section 351 of the Public Health Service Act, so long as the sponsor of such contrast agent has provided to the sponsor of the applicable medical imaging device that is the subject of such review a right of reference

and the application is submitted in accordance with this subsection.

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

''(4) DEFINITIONS.—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 an imaging use that is not described in the approved labeling of such contrast agent (or the approved labeling of any contrast agent in the same class as such contrast agent); and

''(B) the term 'contrast agent' means a drug that is approved under section 505 or licensed under section 351 of the Public Health Service Act, is intended for use in conjunction

with an applicable medical imaging device, and—

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

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

(b) APPLICATIONS FOR APPROVAL OF CONTRAST AGENTS INTENDED FOR USE WITH CERTAIN DIAGNOSTIC MEDICAL IMAGING DEVICES.—Section 505 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355) is amended by adding at the end the following:

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

"(1) IN GENERAL.—The sponsor of a contrast agent for which an application has been approved under this section may submit a supplement to the application seeking approval for a new use following the authorization of a premarket submission for an applicable medical imaging device for that use with the contrast agent pursuant to section 520(p)(1).

''(2) REVIEW OF SUPPLEMENT.—In reviewing a supplement submitted under this subsection, the agency center charged with the premarket review of drugs may—

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

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

''(3) DEFINITIONS.—For purposes of this subsection—

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

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

SEC. 707. RISK-BASED CLASSIFICATION OF ACCESSORIES.

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

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

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

''(C)(i) In the case of a device intended to be used with an accessory, where the accessory has been included in an application for premarket approval of such device under section 515 or a report under section 510(k) for

clearance of such device and the Secretary has not classified such accessory distinctly from another device in accordance with subparagraph (A), the person filing the application or report (as applicable) at the time such application or report is filed—

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

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

''(III) shall, if the request under subclause (I) is requesting classification of the accessory in class II, include in the application an initial draft proposal for special controls, if special controls would be required pursuant to subsection (a)(1)(B).

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

''(iii) The Secretary's evaluation of an accessory under clause (i) shall constitute an order establishing a

new classification for such accessory for the specified intended use or uses of such accessory and for any accessory with the same intended use or uses as such accessory.

''(D) For accessories that have been granted marketing authorization as part of a submission for another device with which the accessory involved is intended to be used, through an application for such other device under section 515(c), a report under section 510(k), or a request for classification under paragraph (2) of this subsection, the following shall apply:

''(i) Not later than the date that is one year after the date of enactment of the FDA Reauthorization Act of 2017 and at least once every 5 years thereafter, and as the Secretary otherwise determines appropriate, pursuant to this paragraph, the Secretary shall publish in the Federal Register a notice proposing a list of such accessories that the Secretary determines may be suitable for a distinct classification in class I and the proposed regulations for such classifications. In developing such list, the Secretary shall consider recommendations from sponsors of device submissions and other stakeholders for accessories to be included on such list. The notices shall provide for a period of not less than 60 calendar days for public comment. Within 180 days

after the end of the comment period, the Secretary shall publish in the Federal Register a final action classifying such suitable accessories into class I.

''(ii) A manufacturer or importer of an accessory that has been granted such marketing authorization may submit to the Secretary a written request for the appropriate classification of the accessory based on the risks and appropriate level of regulatory controls as described in subparagraph (A), and shall, if the request is requesting classification of the accessory in class II, include in the submission an initial draft proposal for special controls, if special controls would be required pursuant to subsection (a)(1)(B). Such request shall include such information as may be necessary for the Secretary to evaluate, based on the least burdensome approach, the appropriate class for the accessory under subsection (a). The Secretary shall provide an opportunity for a manufacturer or importer to meet with appropriate personnel of the Food and Drug Administration to discuss the appropriate classification of such accessory prior to submitting a written request under this clause for classification of the accessory.

''(iii) The Secretary shall respond to a request made under clause (ii) not later than 85 calendar

days after receiving such request by issuing a written order classifying the accessory or denying the request. If the Secretary does not agree with the recommendation for classification submitted by the manufacturer or importer, the response shall include a detailed description and justification for such determination. Within 30 calendar days after granting such a request, the Secretary shall publish a notice in the Federal Register announcing such response.

''(E) Nothing in this paragraph may be construed as precluding a manufacturer of an accessory of a new type from using the classification process described in subsection (f)(2) to obtain classification of such accessory in accordance with the criteria and requirements set forth in that subsection.''.

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

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

SEC. 708. 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) POSTMARKET PILOT.—

''(1) IN GENERAL.—In order to provide timely and reliable information on the safety and effectiveness of devices approved under section 515, cleared under section 510(k), or classified under section 513(f)(2), 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 participation by a manufacturer or manufacturers of a device or device type, or continue existing projects, in accordance with paragraph (3), that—

''(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 included or not included in such project;

"(C) may be 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 patient groups and device manufacturers;

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

"(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—

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

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

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

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

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

"(3) CONTINUATION OF ONGOING PROJECTS.—The Secretary may continue or expand projects, with respect to providing timely and reliable information

on the safety and effectiveness of devices approved under section 515, cleared under section 510(k), or classified under section 513(f)(2), that are being carried out as of the date of the enactment of the FDA Reauthorization Act of 2017. The Secretary shall, beginning on such date of enactment, take such steps as may be necessary—

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

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

''(4) IMPLEMENTATION.—

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

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

''(ii) In the case of the termination or nonrenewal of such a contract, cooperative agreement, grant, or other appropriate agreement, the entity or entities involved shall comply with each of the following:

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

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

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

''(I) research, statistical, epidemiologic, or clinical capability and expertise to conduct and complete the activities under this subsection, including the capability and expertise to provide the Secretary access to de-identified data consistent with the requirements of this subsection;

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

''(III) experience with, and expertise on, the development of research on, and surveillance of, device safety

and effectiveness using electronic health data; or

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

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

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

ticipation in a pilot project under this subsection or a project continued or expanded under paragraph (3) may meet the applicable 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 such project public, to the extent possible.

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

''(A) individually identifiable health information so collected shall not be disclosed when presenting any information from such project; and

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

''(7) LIMITATIONS.—No pilot project under this subsection, or in coordination with the comprehensive system described in paragraph (1)(C), may allow for an entity participating in such project, other than the Secretary, to make determinations of safety or effectiveness, or substantial equivalence, for purposes of this Act.

''(8) OTHER PROJECTS REQUIRED TO COMPLY.—Paragraphs (1)(B), (4)(A)(i), (4)(A)(ii), (5), (6), and (7) shall apply with respect to any pilot project undertaken in coordination with the comprehensive system described in paragraph (1)(C) that relates to the use of real world evidence for devices in the same manner and to the same extent as such paragraphs apply with respect to pilot projects conducted under this subsection.

''(9) REPORT TO CONGRESS.—Not later than 18 months after the date of enactment of this Act, and annually thereafter, the Secretary shall submit to the Committee on Energy and Commerce of the House of Representatives and the Committee on Health, Education, Labor and Pensions of the Senate a report containing a description of the pilot projects being conducted under this subsection and

projects continued or expanded pursuant to paragraph (3), including for each such project—

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

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

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

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

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

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

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

(b) REPORT.—Not later than January 31, 2021, the Secretary of Health and Human Services, acting through the Commissioner of Food and Drugs, 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 decision-making 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. 709. 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 708, is further amended by adding at the end the following:

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

''(1) DEFINITION.—

''(A) IN GENERAL.—In this subsection, the term 'over-the-counter hearing aid' means a device that—

''(i) uses the same fundamental scientific technology as air conduction hear-

ing aids (as defined in section 874.3300 of title 21, Code of Federal Regulations) (or any successor regulation) or wireless air conduction hearing aids (as defined in section 874.3305 of title 21, Code of Federal Regulations) (or any successor regulation);

''(ii) is intended to be used by adults age 18 and older to compensate for perceived mild to moderate hearing impairment;

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

''(iv) may—

''(I) use wireless technology; or

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

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

''(B) EXCEPTION.—Such term does not include a personal sound amplification product in-

tended to amplify sound for nonhearing impaired consumers in situations including hunting and bird-watching.

''(2) REGULATION.—An over-the-counter hearing aid shall be subject to the regulations promulgated in accordance with section 709(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 effectiveness 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 over-the-counter hearing aids, including requirements that such labeling include a conspicuous statement that the device is only intended for adults age 18 and older, information on how consumers may report adverse events, information on any contraindications, conditions, or symptoms of medically treatable causes of hearing loss, and advisements to consult promptly with a licensed health care practitioner; 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, order, or other requirement specifically related to hearing products that would restrict or interfere with the servicing, marketing, sale, dispensing, use, customer support, or distribution of over-the-counter hearing aids (as defined in section 520(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.

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

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

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

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

SEC. 710. REPORT ON SERVICING OF DEVICES.

(a) IN GENERAL.—Not later than 270 days after the date of enactment of this Act, the Secretary of Health and Human Services, acting through the Commissioner of Food and Drugs, shall post on the internet website of the Food and Drug Administration a report on the continued quality, safety, and effectiveness of devices (as defined in section 201(h) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321(h))) with respect to servicing (as defined in subsection (c)).

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

(1) the status of, and findings to date, with respect to, the proposed rule entitled ''Refurbishing, Reconditioning, Rebuilding, Remarketing, Remanufacturing, and Servicing of Medical Devices Performed by Third-Party Entities and Original Equipment Manufacturers; Request for Comments'' published in the Federal Register by the Food and Drug Administration on March 4, 2016 (81 Fed. Reg. 11477);

(2) information presented during the October 2016 public workshop entitled ''Refurbishing, Recon-

ditioning, Rebuilding, Remarketing, Remanufacturing, and Servicing of Medical Devices Performed by Third-Party Entities and Original Equipment Manufacturers'';

(3) a description of the statutory and regulatory authority of the Food and Drug Administration with respect to the servicing of devices conducted by any entity, including original equipment manufacturers and third party entities;

(4) details regarding how the Food and Drug Administration currently regulates devices with respect to servicing to ensure safety and effectiveness, how the agency could improve such regulation using the authority described in paragraph (3), and whether additional authority is recommended;

(5) information on actions the Food and Drug Administration could take under the authority described in paragraphs (3) and (4) to assess the servicing of devices, including the size, scope, location, and composition of third party entities;

(6) information on actions the Food and Drug Administration could take to track adverse events caused by servicing errors performed by any entity, including original equipment manufacturers and third party entities;

(7) information regarding the regulation by States, the Joint Commission, or other regulatory bodies of device servicing performed by any entity, including original equipment manufacturers and third party entities; and

(8) any additional information determined by the Secretary (acting through the Commissioner) to be relevant to ensuring the quality, safety, and effectiveness of devices with respect to servicing.

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

TITLE VIII—IMPROVING GENERIC DRUG ACCESS

SEC. 801. PRIORITY REVIEW OF 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) Subject to subparagraph (B), the Secretary shall prioritize the review of, and act within 8 months of the date of the submission of, an original abbreviated new drug application submitted for review under this subsection that is for a drug—

''(i) for which there are not more than 3 approved drug products listed under paragraph (7) and for which there are no blocking patents and exclusivities; or

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

''(B) To qualify for priority review under this paragraph, not later than 60 days prior to the submission of an application described in subparagraph (A) or that the Secretary may prioritize pursuant to subparagraph (D), the applicant shall provide complete, accurate information regarding facilities involved in manufacturing processes and testing of the drug that is the subject of the application, including facilities in corresponding Type II active pharmaceutical ingredients drug master files referenced in an application and sites or organizations involved in bioequivalence and clinical studies used to support the application, to enable the Secretary to make a determination regarding whether an inspection of a facility is necessary. Such information shall include the relevant (as determined by the Secretary) sections of such application, which shall be unchanged relative to the date of the submission of such application, except to the extent that a change is made to such information to exclude a facility that was not used to generate data to meet any application require-

ments for such submission and that is not the only facility intended to conduct one or more unit operations in commercial production. Information provided by an applicant under this subparagraph shall not be considered the submission of an application under this subsection.

''(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 publish on the internet website of the Food and Drug Administration, and update at least once every 6 months, a list of all drugs approved under subsection (c) for which all patents and periods of exclusivity under this Act have expired and for which no application has been approved under this subsection.''.

SEC. 802. ENHANCING REGULATORY TRANSPARENCY TO ENHANCE GENERIC COMPETITION.

Section 505(j) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355), as amended by section 801, is further amended by adding at the end the following:

''(13) Upon the request of an applicant regarding one or more specified pending applications under this sub-

section, the Secretary shall, as appropriate, provide review status updates indicating the categorical status of the applications by each relevant review discipline.''.

SEC. 803. COMPETITIVE GENERIC THERAPIES.

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

''SEC. 506H. COMPETITIVE GENERIC THERAPIES.

''(a) IN GENERAL.—The Secretary may, at the request of an applicant of a drug that is designated as a competitive generic therapy pursuant to subsection (b), expedite the development and review of an abbreviated new drug application under section 505(j) for such drug.

''(b) DESIGNATION PROCESS.—

''(1) REQUEST.—The applicant may request the Secretary to designate the drug as a competitive generic therapy.

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

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

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

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

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

''(c) ACTIONS.—In expediting the development and review of an application under subsection (a), the Secretary may, as requested by the applicant, take actions including the following:

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

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

''(3) Involve senior managers and experienced review staff, as appropriate, in a collaborative, coordinated review of such application, including with

respect to drug-device combination products and other complex products.

''(4) Assign a cross-disciplinary project lead—

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

''(B) to serve as a scientific liaison between the review team and the applicant.

''(d) REPORTING REQUIREMENT.—Not later than one year after the date of the approval of an application under section 505(j) with respect to a drug for which the development and review is expedited under this section, the sponsor of such drug shall report to the Secretary on whether the drug has been marketed in interstate commerce since the date of such approval.

''(e) DEFINITIONS.—In this section:

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

''(2) The term 'inadequate generic competition' means, with respect to a drug, there is not more than one approved drugs on the list of drugs described in section 505(j)(7)(A) (not including drugs on the discontinued section of such list) that is—

''(A) the reference listed drug; or

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

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

(b) GUIDANCE; AMENDED REGULATIONS.—

(1) IN GENERAL.—

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

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

(ii) not later than 1 year after the close of the comment period for the draft guidance, issue final guidance on such section 506H.

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

(i) specify the process and criteria by which the Secretary makes a designation under section 506H of the Federal Food,

Drug, and Cosmetic Act, as added by subsection (a);

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

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

(2) AMENDED REGULATIONS.—The Secretary of Health and Human Services shall issue or revise any regulations as may be necessary to carry out this section not later than 2 years after the date of enactment of this Act.

SEC. 804. ACCURATE INFORMATION ABOUT 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 803, the following:

"SEC. 506I. PROMPT REPORTS OF MARKETING STATUS.

''(a) NOTIFICATION OF WITHDRAWAL.—The holder of an application approved under subsection (c) or (j) of section 505 shall notify the Secretary in writing 180 days prior to withdrawing the approved drug from sale, or if 180 days is not practicable as soon as practicable but not

later than the date of withdrawal. The holder shall include with such notice the—

''(1) National Drug Code;

''(2) identity of the drug by established name and by proprietary name, if any;

''(3) new drug application number or abbreviated application number;

''(4) strength of the drug;

''(5) date on which the drug is expected to no longer be available for sale; and

''(6) reason for withdrawal of the drug.

''(b) NOTIFICATION OF DRUG NOT AVAILABLE FOR SALE.—The holder of an application approved under subsection (c) or (j) shall notify the Secretary in writing within 180 calendar days of the date of approval of the drug if the drug will not be available for sale within 180 calendar days of such date of approval. The holder shall include with such notice the—

''(1) identity of the drug by established name and by proprietary name, if any;

''(2) new drug application number or abbreviated application number;

''(3) strength of the drug;

''(4) date on which the drug will be available for sale, if known; and

''(5) reason for not marketing the drug after approval.

''(c) ADDITIONAL ONE-TIME REPORT.—Within 180 days of the date of enactment of this section, all holders of applications approved under subsection (c) or (j) of section 505 shall review the information in the list published under subsection 505(j)(7)(A) and shall notify the Secretary in writing that—

''(1) all of the application holder's drugs in the active section of the list published under subsection 505(j)(7)(A) are available for sale; or

''(2) one or more of the application holder's drugs in the active section of the list published under subsection 505(j)(7)(A) have been withdrawn from sale or have never been available for sale, and include with such notice the information required pursuant to subsection (a) or (b), as applicable.

''(d) FAILURE TO MEET REQUIREMENTS.—If a holder of an approved application fails to submit the information required under subsection (a), (b), or (c), the Secretary may move the application holder's drugs from the active section of the list published under subsection 505(j)(7)(A) to the discontinued section of the list, except that the Secretary shall remove from the list in accordance with subsection 505(j)(7)(C) drugs the Secretary deter-

mines have been withdrawn from sale for reasons of safety of effectiveness.

''(e) UPDATES.—The Secretary shall update the list published under subsection 505(j)(7)(A) based on the information provided under subsections (a), (b), and (c) by moving drugs that are not available for sale from the active section to the discontinued section of the list, except that drugs the Secretary determines have been withdrawn from sale for reasons of safety or effectiveness shall be removed from the list in accordance with subsection 505(j)(7)(C). The Secretary shall make monthly updates to the list based on the information provided pursuant to subsections (a) and (b), and shall update the list based on the information provided under subsection (c) as soon as practicable.

''(f) LIMITATION ON USE OF NOTICES.—Any notice submitted under this section shall not be made public by the Secretary and shall be used solely for the purpose of the updates described in subsection (e).''.

SEC. 805. SUITABILITY PETITIONS.

(a) IN GENERAL.—It is the sense of Congress 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 807—

(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. 806. INSPECTIONS.

Within 6 months of the date of enactment of this Act, the Secretary of Health and Human Services shall develop and implement a protocol for expediting review of timely responses to reports of observations from an inspection under section 704 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 374). Such protocol shall—

(1) apply to responses to such reports pertaining to applications submitted under section 505 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355)—

(A) for which the approval is dependent upon remediation of conditions identified in the report;

(B) for which concerns related to observations from an inspection under such section 704 are the only barrier to approval; and

(C) where the drug that is the subject of the application is a drug—

(i) for which there are not more than 3 other approved applications under section 505(j) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(j)) that reference the same listed drug and for which there are less than 6 abbreviated new drug applications tentatively approved; or

(ii) that is included on the list under section 506E of such Act (21 U.S.C. 356e);

(2) address expedited re-inspection of facilities, as appropriate; and

(3) establish a 6-month timeline for completion of review of such responses to such reports.

SEC. 807. REPORTING ON PENDING GENERIC DRUG APPLICATIONS AND PRIORITY REVIEW APPLICATIONS.

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

shall post on the internet website of the Food and Drug Administration a report that provides, with respect to the months covered by the report—

(1) with respect to applications filed under section 505(j) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(j)) that, during the most recent calendar year, were subject to priority review under paragraph (11) of such section 505(j) (as added by section 801) or expedited development and review under section 506H of the Federal Food, Drug, and Cosmetic Act (as added by section 803), the numbers of such applications (with denotation of such applications that were filed prior to October 1, 2014) that are—

(A) awaiting action by the applicant;

(B) awaiting action by the Secretary; and

(C) approved by the Secretary;

(2) 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;

(3) the mean and median approval and tentative approval times and the number of review cycles for such applications;

(4) the number and type of meetings requested and held under such section 506H (as added by section 803); and

(5) the number of such applications on which the Secretary has taken action pursuant to subsection (c) of such section 506H (as added by section 803) and any effect such section 506H may have on the length of time for approval of applications under such section 505(j) and the number of review cycles for such approvals.

SEC. 808. INCENTIVIZING COMPETITIVE GENERIC DRUG DEVELOPMENT.

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

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

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

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

of the first commercial marketing of the competitive generic therapy (including the commercial marketing of the listed drug) by any first approved applicant.

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

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

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

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

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

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

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

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

"(CC) is not for a drug for which all drug versions have forfeited eligibility for a 180-day exclusivity period under clause (iv) pursuant to subparagraph (D).''; and

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

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

applicant's application for the competitive generic therapy is made effective.''.

SEC. 809. GAO STUDY OF ISSUES REGARDING FIRST CYCLE APPROVALS OF GENERIC MEDICINES.

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

(1) The rate of first cycle approvals and tentative approvals for applications submitted under section 505(j) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(j)) during the period beginning on October 1, 2012, and ending on September 30, 2017. The rate of first cycle approvals and tentative approvals shall be determined and reported per each GDUFA cohort year during this period.

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

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

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

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

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

(E) the processes and practices for communication between the Food and Drug Administration and sponsors of generic drug applications; and

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

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

ess for generic drugs could be improved to increase the rate of first cycle approvals and tentative approvals for generic drug applications. In making this determination, the Comptroller General shall consider, among other things, options for increasing review efficiency and communication effectiveness.

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

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

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

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

(3) The term ''generic drug application'' means an abbreviated new drug application for the approval of a generic drug under section 505(j) of the Fed-

eral Food, Drug, and Cosmetic Act (21 U.S.C. 355(j)).

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

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

(B) For purposes of this paragraph, the term ''complete response letter'' means a written communication to the sponsor of a generic drug application or holder of a drug master file from the Food and Drug Administration describing all of the deficiencies that the Administration has identified in the generic drug application (including pending amendments) or drug master file that must be satisfactorily addressed before the generic drug application can be approved.

TITLE IX—ADDITIONAL PROVISIONS

SEC. 901. TECHNICAL CORRECTIONS.

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

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

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

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

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

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

(e) Section 510(h)(6) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360(h)(6)) is amended by striking ''February 1'' and replacing with ''May 1''.

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

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

(2) section 515C of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360e–3), as inserted

by such section 3051(a), is redesignated as section 515B.

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

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

SEC. 902. ANNUAL REPORT ON INSPECTIONS.

Not later than March 1 of each year, the Secretary of Health and Human Services shall post on the internet website of the Food and Drug Administration information related to inspections of facilities necessary for approval of a drug under section 505 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355), approval of a device under section 515 of such Act (21 U.S.C. 360e), or clearance of a device under section 510(k) of such Act (21 U.S.C. 360(k)) that were conducted during the previous calendar year. Such information shall include the following:

(1) The median time following a request from staff of the Food and Drug Administration reviewing an application or report to the beginning of the inspection, and the median time from the beginning of an inspection to the issuance of a report pursuant to section 704(b) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 374(b)).

(2) The median time from the issuance of a report pursuant to such section 704(b) to the sending of a warning letter, issuance of an import alert, or holding of a regulatory meeting for inspections for which the Secretary concluded that regulatory or enforcement action was indicated.

(3) The median time from the sending of a warning letter, issuance of an import alert, or holding of a regulatory meeting to resolution of the regulatory or enforcement action indicated for inspections for which the Secretary concluded that such action was indicated.

(4) The number of times that a facility was issued a report pursuant to such section 704(b) and approval of an application was delayed due to the issuance of a withhold recommendation.

SEC. 903. 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)), as amended by section 103, is further amended by inserting after paragraph (2) the following:

''(3) REAL TIME REPORTING.—

''(A) IN GENERAL.—Not later than 30 calendar days after the end of the second quarter of fiscal year 2018, and not later than 30 calendar days after the end of each quarter of each fiscal year thereafter, the Secretary shall post the data described in subparagraph (B) on the internet website of the Food and Drug Administration for such quarter and on a cumulative basis for such fiscal year, and may remove duplicative data from the annual performance report under this subsection.

''(B) DATA.—The Secretary shall post the following data in accordance with subparagraph (A):

''(i) The number and titles of draft and final guidance on topics related to the process for the review of human drug applications, and whether such guidances were issued as required by statute or pur-

suant to a commitment under the letters described in section 101(b) of the Prescription Drug User Fee Amendments of 2017.

''(ii) The number and titles of public meetings held on topics related to the process for the review of human drug applications, and whether such meetings were required by statute or pursuant to a commitment under the letters described in section 101(b) of the Prescription Drug User Fee Amendments of 2017.

''(iii) The number of new drug applications and biological licensing applications approved.

''(iv) The number of new drug applications and biological licensing applications filed.

''(4) RATIONALE FOR PDUFA PROGRAM CHANGES.—Beginning with fiscal year 2020, the Secretary shall include in the annual report under paragraph (1)—

''(A) data, analysis, and discussion of the changes in the number of full-time equivalents hired as agreed upon in the letters described in section 101(b) of the Prescription Drug User

Fee Amendments of 2017 and the number of full time equivalents funded by budget authority 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) data, analysis, and discussion of the changes in the fee revenue amounts and costs for the process for the review of human drugs, including identifying drivers of such changes; and

''(C) 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 number of employees for whom time reporting is required and the number of employees for whom time reporting is not required.''.

(b) MDUFA.—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 204, is further 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—

''(I) the number of premarket applications filed under section 515 per fiscal year for each review division;

''(II) the number of reports submitted under section 510(k) per fiscal year for each review division; and

''(III) the number of expedited development and priority review designations under section 515C per fiscal year.

''(iii) REAL TIME REPORTING.—

''(I) IN GENERAL.—Not later than 30 calendar days after the end of

the second quarter of fiscal year 2018, and not later than 30 calendar days after the end of each quarter of each fiscal year thereafter, the Secretary shall post the data described in subclause (II) on the internet website of the Food and Drug Administration for such quarter and on a cumulative basis for such fiscal year, and may remove duplicative data from the annual report under this subparagraph.

''(II) DATA.—The Secretary shall post the following data in accordance with subclause (I):

''(aa) The number and titles of draft and final guidance on topics related to the process for the review of devices, and whether such guidances were issued as required by statute or pursuant to the letters described in section 201(b) of the Medical Device User Fee Amendments of 2017; and

''(bb) The number and titles of public meetings held on topics related to the process for the review of devices, and if such meetings were required by statute or pursuant to a commitment under the letters described in section 201(b) of the Medical Device User Fee Amendments of 2017.

''(iv) RATIONALE FOR MDUFA PROGRAM CHANGES.—Beginning with fiscal year 2020, the Secretary shall include in the annual report under paragraph (1)—

''(I) data, analysis, and discussion of the changes in the number of full-time equivalents hired as agreed upon in the letters described in section 201(b) of the Medical Device User Fee Amendments of 2017 and the number of full time equivalents funded by budget authority at the Food and Drug Administration by each division within the Center for Devices and Radiological Health, the Center for Biologics Evaluation and

Research, the Office of Regulatory Affairs, and the Office of the Commissioner;

''(II) data, analysis, and discussion of the changes in the fee revenue amounts and costs for the process for the review of devices, including identifying drivers of such changes; and

''(III) for each of the Center for Devices and Radiological Health, the Center for Biologics Evaluation and Research, the Office of Regulatory Affairs, and the Office of the Commissioner, the number of employees for whom time reporting is required and the number of employees for whom time reporting is not required.''.

(c) GDUFA.—Section 744C(a) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 379j–43(a)), as amended by section 304, is further 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) REAL TIME REPORTING.—

''(A) IN GENERAL.—Not later than 30 calendar days after the end of the second quarter of fiscal year 2018, and not later than 30 calendar days after the end of each quarter of each fiscal year thereafter, the Secretary shall post the data described in subparagraph (B) on the internet website of the Food and Drug Administration, and may remove duplicative data from the annual report under this subsection.

''(B) DATA.—The Secretary shall post the following data in accordance with subparagraph (A):

''(i) The number and titles of draft and final guidance on topics related to human generic drug activities and whether such guidances were issued as required by statute or pursuant to a commitment under the letters described in section 301(b) of the Generic Drug User Fee Amendments of 2017.

''(ii) The number and titles of public meetings held on topics related to human generic drug activities and whether such meetings were required by statute or pur-

suant to a commitment under the letters described in section 301(b) of the Generic Drug User Fee Amendments of 2017.

''(3) RATIONALE FOR GDUFA PROGRAM CHANGES.—Beginning with fiscal year 2020, the Secretary shall include in the annual report under paragraph (1)—

''(A) data, analysis, and discussion of the changes in the number of full-time equivalents hired as agreed upon in the letters described in section 301(b) of the Generic Drug User Fee Amendments of 2017 and the number of full time equivalents funded by budget authority 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) data, analysis, and discussion of the changes in the fee revenue amounts and costs for human generic drug activities, including identifying drivers of such changes; and

''(C) for each of the Center for Drug Evaluation and Research, the Center for Biologics Evaluation and Research, the Office of Regu-

latory Affairs, and the Office of the Commissioner, the number of employees for whom time reporting is required and the number of employees for whom time reporting is not required.''.

(d) BSUFA.—Section 744I(a) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 379j–53(a)), as amended by section 404, is further 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 Food and Drug Administration 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 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 letters issued by the agency for such applications.

''(3) REAL TIME REPORTING.—

''(A) IN GENERAL.—Not later than 30 calendar days after the end of the second quarter of fiscal year 2018, and not later than 30 calendar days after the end of each quarter of each fiscal year thereafter, the Secretary shall post the data described in subparagraph (B) for such quarter and on a cumulative basis for the fiscal year on the internet website of the Food and Drug Administration, and may remove duplicative data from the annual report under this subsection.

''(B) DATA.—The Secretary shall post the following data in accordance with subparagraph (A):

''(i) The number and titles of draft and final guidance on topics related to the process for the review of biosimilars, and whether such guidances were required by

statute or pursuant to a commitment under the letters described in section 401(b) of the Biosimilar User Fee Amendments of 2017.

''(ii) The number and titles of public meetings held on topics related to the process for the review of biosimilars, and whether such meetings were required by statute or pursuant to a commitment under the letters described in section 401(b) of the Biosimilar User Fee Amendments of 2017.

''(4) RATIONALE FOR BSUFA PROGRAM CHANGES.—Beginning with fiscal year 2020, the Secretary shall include in the annual report under paragraph (1)—

''(A) data, analysis, and discussion of the changes in the number of full-time equivalents hired as agreed upon in the letters described in section 401(b) of the Biosimilar User Fee Amendments of 2017 and the number of full time equivalents funded by budget authority at the Food and Drug Administration by each division within the Center for Drug Evaluation and Research, the Center for Biologics Evalua-

tion and Research, the Office of Regulatory Affairs, and the Office of the Commissioner;

''(B) data, analysis, and discussion of the changes in the fee revenue amounts and costs for the process for the review of biosimilar biological product applications, including identifying drivers of such changes; and

''(C) 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 number of employees for whom time reporting is required and the number of employees for whom time reporting is not required.''.

SEC. 904. 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 903(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 aggregate number of human drug applications filed and the aggregate number of approvals, 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) the aggregate number of applications for each fiscal year 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 applicable fiscal year.

''(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 applicable fiscal year.

''(C) The most common causes and trends of external or other circumstances affecting the ability of the Center for Drug Evaluation and

Research, the Center for Biologics Evaluation and Research, Office of Regulatory Affairs, and the Food and Drug Administration 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) by inserting after subsection (b) the following:

''(c) CORRECTIVE ACTION REPORT.—Beginning with fiscal year 2018, 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. 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 applicable fiscal year have been met, the corrective action report shall include recommendations on ways in which the Secretary can improve and streamline the human drug application review process.

''(2) GOALS MISSED.—For any of the goals identified in the letters described in section 101(b) of the Prescription Drug User Fee Amendments of 2017 for the applicable fiscal year that the Secretary determines to not have been met, the corrective action report shall include—

''(A) a detailed justification for such determination and a description, as applicable, of the types of circumstances and trends under which human drug applications that missed the review goal time were approved during the first cycle review, or application review goals were missed; and

''(B) with respect to performance enhancement goals that were not achieved, a description of efforts the Food and Drug Administration has put in place for the fiscal year in which the

report is submitted to improve the ability of such agency to meet each such goal for the such fiscal year.

''(d) ENHANCED COMMUNICATION.—

''(1) COMMUNICATIONS WITH CONGRESS.—Each fiscal year, as applicable and requested, representatives from the Centers with expertise in the review of human 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 and requested, representatives from the Food and Drug Administration 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.''.

(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 903(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 aggregate number of premarket applications filed under section 515 and aggregate reports submitted under section 510(k) and the aggregate number of major deficiency letters, not approvable letters, and denials for such applications issued by the agency, accounting for—

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

''(bb) the aggregate number of applications for each fiscal year 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 applicable fiscal year.

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

''(III) The most common causes and trends for external or other circumstances affecting the ability of the Center for Devices and Radiological Health, the Office of Regulatory Affairs, or the Food and Drug Administration 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, 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. 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 applicable fiscal year have been met, the corrective action report shall include 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 applicable fiscal year that the Secretary determines to not have been met, the corrective action report shall include—

''(i) a justification for such determination;

''(ii) a description of the types of circumstances, in the aggregate, under which applications or reports submitted under section 515 or notifications submitted under section 510(k) missed the review goal times but were approved during the first cycle review, as applicable;

''(iii) a summary and any trends with regard to the circumstances for which a review goal was missed; and

"(iv) the performance enhancement goals that were not achieved during the previous fiscal year and a description of efforts the Food and Drug Administration has put in place for the fiscal year in which the report is submitted to improve the ability of such agency to meet each such goal for the such fiscal year.

"(3) ENHANCED COMMUNICATION.—

"(A) COMMUNICATIONS WITH CONGRESS.—Each fiscal year, as applicable and requested, representatives from the Centers with expertise in the review of devices 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 and requested, representatives from the Food and Drug Administration 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) 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 903(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 aggregate number of abbreviated new drug applications filed and the aggregate number of approvals or aggregate number of 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; and

''(ii) the aggregate number of applications for each fiscal year 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 applicable fiscal year.

''(B) Relevant data to determine whether the Food and Drug Administration 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 applicable fiscal year.

''(C) The most common causes and trends for external or other circumstances that affected the ability of the Secretary 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) by inserting after subsection (b) the following:

''(c) CORRECTIVE ACTION REPORT.—Beginning with fiscal year 2018, 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. 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 applicable fiscal year have been met, the corrective action report shall include 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 applicable fiscal year that the Secretary de-

termines to not have been met, the corrective action report shall include—

''(A) a detailed justification for such determination and a description, as applicable, of the types of circumstances and trends under which abbreviated new drug applications missed the review goal times but were approved during the first cycle review, or review goals were missed; and

''(B) with respect to performance enhancement goals that were not achieved, a detailed description of efforts the Food and Drug Administration has put in place for the fiscal year in which the report is submitted to improve the ability of such agency to meet each such goal for the such fiscal year.

''(d) ENHANCED COMMUNICATION.—

''(1) COMMUNICATIONS WITH CONGRESS.—Each fiscal year, as applicable and requested, representatives from the Centers with expertise in the review of human 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 and requested, representatives from the Food and Drug Administration 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.''.

(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 903(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 aggregate number of biosimilar biological product applications and supplements filed and the aggregate

number of approvals 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; and

"(ii) the aggregate number of applications for each fiscal year 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 applicable fiscal year.

"(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 applicable fiscal year.

"(C) The most common causes and trends for external or other circumstances affecting the ability of the Secretary 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) by 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. 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 applicable fiscal year have been met, the corrective action

report shall include 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 applicable fiscal year that the Secretary determines to not have been met, the corrective action report shall include—

''(A) a justification for such determination and a description of the types of circumstances and trends, as applicable, under which biosimilar biological product applications missed the review goal times but were approved during the first cycle review, or review goals were missed; and

''(B) with respect to performance enhancement goals that were not achieved, a description of efforts the Food and Drug Administration has put in place for the fiscal year in which the report is submitted to improve the ability of such agency to meet each such goal for the such fiscal year.

''(d) ENHANCED COMMUNICATION.—

''(1) COMMUNICATIONS WITH CONGRESS.—Each fiscal year, as applicable and requested, representatives from the Centers with expertise in the review of human 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 and requested, representatives from the Food and Drug Administration 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.''.

SEC. 905. 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 re-

lated to facility maintenance and renovation in fiscal years 2012 through 2019. The study under this paragraph 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 Radiological 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 Fed-

eral 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.

(2) REPORT.—

(A) IN GENERAL.—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 July 30, 2020, containing the results of the study under paragraph (1).

(B) RECOMMENDATIONS.—As part of the report under this paragraph, 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 Food and Drug Administration may allocate the expenses described in clauses (i) and (ii) of paragraph (1)(A), as informed by the analysis under paragraph (1)(B).

(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 include only 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 include only 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 include only 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 include only leasing and necessary scientific equipment.''.

Passed the House of Representatives July 12, 2017.

Attest: KAREN L. HAAS,

Clerk.

Calendar No. 174

115TH CONGRESS
1ST SESSION

H. R. 2430

AN ACT

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

JULY 17, 2017

Read the second time and placed on the calendar