COMMITTEE PRINT

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

115TH CONGRESS
1ST SESSION

H. R. 2430

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

IN THE HOUSE OF REPRESENTATIVES

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

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A BILL

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

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:

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TITLE I—FEES RELATING TO DRUGS

SEC. 101. SHORT TITLE; FINDING.

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

(b) FINDING.—The Congress finds that the fees authorized by the amendments made in this title will be dedicated toward expediting the drug development process and the process for the review of human drug applications, including postmarket drug safety activities, as set forth in the goals identified for purposes of part 2 of subchapter

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

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

(a) TYPES OF FEES.—

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

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

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

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

(D) in paragraph (1)(A)—

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

(ii) in clause (ii), by striking ''A fee established'' and all that follows through

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

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

(F) in paragraph (1)(F)—

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

(ii) by striking the second sentence;

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

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

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

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

applicant in a human drug application, and who, after September 1, 1992, had pending before the Secretary a human drug application or supplement, shall pay the annual prescription drug program fee established for a fiscal year under subsection (c)(5) for each prescription drug product that is identified in such a human drug application approved as of October 1 of such fiscal year.'';

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

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

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

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

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

than 5 prescription drug program fees for a fiscal year for prescription drug products identified in such approved human drug application.''.

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

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

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

''(b) FEE REVENUE AMOUNTS.—

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

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

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

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

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

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

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

''(i) $20,077,793 for fiscal year 2018;

''(ii) $21,317,472 for fiscal year 2019;

''(iii) $16,953,329 for fiscal year 2020;

''(iv) $5,426,896 for fiscal year 2021; and

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

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

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

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

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

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

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

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

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

''(1) INFLATION ADJUSTMENT.—

''(A) IN GENERAL.—For purposes of subsection (b)(1)(B), the dollar amount of the inflation adjustment to the annual base revenue

for each fiscal year shall be equal to the product of—

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

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

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

''(i) the average annual percent change in the cost, per full-time equivalent position of the Food and Drug Administration, of all personnel compensation and benefits paid with respect to such positions for the first 3 years of the preceding 4 fiscal years, multiplied by the proportion of personnel compensation and benefits costs to total costs of the process for the review of human drug applications (as defined in section 735(6)) for the first 3 years of the preceding 4 fiscal years; and

''(ii) the average annual percent change that occurred in the Consumer Price Index for urban consumers (Wash-

ington-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 meet-

ings, 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 estab-

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

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

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

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

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

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

"(3) OPERATING RESERVE ADJUSTMENT.—

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

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

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

''(4) ADDITIONAL DIRECT COST ADJUSTMENT.—

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

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

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

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

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

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

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

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

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

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

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

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

(1) in paragraph (1)—

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

(B) by striking subparagraph (C); and

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

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

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

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

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

(B) in subparagraph (B)—

(i) by striking clause (ii);

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

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

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

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

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

(1) in paragraph (3)—

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

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

(2) by striking paragraph (4).

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

SEC. 103. REAUTHORIZATION; REPORTING REQUIREMENTS.

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

(1) in subsection (a)(1)—

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

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

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

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

SEC. 104. SUNSET DATES.

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

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

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

SEC. 105. EFFECTIVE DATE.

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

SEC. 106. SAVINGS CLAUSE.

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

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

TITLE II—FEES RELATING TO DEVICES

SEC. 201. SHORT TITLE; FINDINGS.

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

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

SEC. 202. DEFINITIONS.

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

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

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

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

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

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

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

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

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

(2) in paragraph (2)—

(A) in subparagraph (A)—

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

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

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

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

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

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

''(b) FEE AMOUNTS.—

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

''(2) BASE FEE AMOUNTS SPECIFIED.—For purposes of paragraph (1), the base fee amounts specified in this paragraph are as follows:

"Fee Type	Fiscal Year 2018	Fiscal Year 2019	Fiscal Year 2020	Fiscal Year 2021	Fiscal Year 2022
Premarket Application	$294,000	$300,000	$310,000	$328,000	$329,000
Establishment Registration	$4,375	$4,548	$4,760	$4,975	$4,978

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

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

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

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

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

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

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

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

(2) in paragraph (2)—

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

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

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

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

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

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

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

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

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

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

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

(3) in paragraph (3)—

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

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

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

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

(2) in paragraph (2)(C)—

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

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

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

(f) FEE WAIVER OR REDUCTION.—

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

(2) CONFORMING CHANGES.—

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

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

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

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

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

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

(1) by striking ''or periodic reporting concerning a class III device'' and inserting ''periodic reporting concerning a class III device, or de novo classification request''; and

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

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

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

(1) in paragraph (3)—

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

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

(2) by striking paragraph (4).

SEC. 204. REAUTHORIZATION; REPORTING REQUIREMENTS.

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

(1) in paragraph (1)—

(A) in subparagraph (A)—

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

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

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

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

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

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

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

SEC. 205. CONFORMITY ASSESSMENT PILOT PROGRAM.

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

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

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

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

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

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

''(A) review determinations by testing laboratories accredited pursuant to this subsection, including by conducting periodic audits of such determinations or processes of accredited bodies or testing laboratories and, following such re-

view, taking additional measures under this Act, such as suspension or withdrawal of accreditation of such testing laboratory under paragraph (1)(A) or requesting additional information with respect to such device, as the Secretary determines appropriate; and

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

''(3) IMPLEMENTATION AND REPORTING.—

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

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

''(i) not later than September 30, 2019, issue draft guidance regarding the goals and implementation of the pilot program under this subsection; and

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

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

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

''(4) SUNSET.—As of October 1, 2022—

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

''(B) the Secretary—

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

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

''(C) except for purposes of accepting a determination described in subparagraph (B)(ii), the Secretary shall not continue to recognize the accreditation of testing laboratories accredited under paragraph (1)(A); and

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

SEC. 206. REAUTHORIZATION OF REVIEW.

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

(1) in subsection (a)(3)—

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

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

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

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

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

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

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

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

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

''(iii) beginning on the date such guidance is finalized, designate and post on the

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

(C) by adding at the end the following:

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

(2) in subsection (b)—

(A) in paragraph (2)—

(i) by striking subparagraph (D); and

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

(B) in paragraph (3)—

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

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

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

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

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

SEC. 207. ELECTRONIC FORMAT FOR SUBMISSIONS.

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

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

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

and submissions for devices described in paragraph (1) (and any appeals of action taken by the Secretary with respect to such presubmissions or submissions) shall be submitted solely in such electronic format as specified by the Secretary in such guidance.

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

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

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

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

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

SEC. 208. SAVINGS CLAUSE.

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

SEC. 209. EFFECTIVE DATE.

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

SEC. 210. SUNSET CLAUSE.

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

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

(c) PREVIOUS SUNSET PROVISION.—

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

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

TITLE III—FEES RELATING TO GENERIC DRUGS

SEC. 301. SHORT TITLE; FINDING.

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

(b) FINDING.—The Congress finds that the fees authorized by the amendments made in this title will be dedicated to human generic drug activities, as set forth in the goals identified for purposes of part 7 of subchapter C of chapter VII of the Federal Food, Drug, and Cosmetic Act, in the letters from the Secretary of Health and

Human Services to the Chairman of the Committee on Health, Education, Labor, and Pensions of the Senate and the Chairman of the Committee on Energy and Commerce of the House of Representatives, as set forth in the Congressional Record.

SEC. 302. DEFINITIONS.

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

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

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

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

(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'';

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

''(i) APPLICATIONS NOT CONSIDERED TO HAVE BEEN RECEIVED AND APPLICATIONS WITHDRAWN PRIOR TO BEING RECEIVED.—The Secretary shall refund 75 percent of the fee paid under subparagraph (A) for any abbreviated new drug application that the Secretary considers not to

have been received within the meaning of section 505(j)(5)(A) for a cause other than failure to pay fees, or that has been withdrawn prior to being received within the meaning of section 505(j)(5)(A).

''(ii) APPLICATIONS NO LONGER RECEIVED.—The Secretary shall refund 100 percent of the fee paid under subparagraph (A) for any abbreviated new drug application if the Secretary initially receives the application under section 505(j)(5)(A) and subsequently determines that an exclusivity period for a listed drug should have prevented the Secretary from receiving such application, such that the abbreviated new drug application is no longer received within the meaning of section 505(j)(5)(A).'';

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

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

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

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

(5) in paragraph (4)—

(A) in subparagraph (A)—

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

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

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

(iv) in clause (iii), by striking ‘‘to fees under both such clauses’’ and inserting

''only to the fee attributable to the manufacture of the finished dosage forms''; and

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

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

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

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

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

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

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

''(5) GENERIC DRUG APPLICANT PROGRAM FEE.—

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

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

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

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

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

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

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

(1) in paragraph (1)—

(A) in subparagraph (A)—

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

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

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

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

(B) in subparagraph (B)—

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

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

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

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

(2) in paragraph (2)—

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

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

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

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

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

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

''(C) Twenty percent shall be derived from fees under subsection (a)(4)(A)(i) (relating to generic drug facilities). The amount of the fee for a contract manufacturing organization facility shall be equal to one-third the amount of the fee for a facility that is not a contract manufacturing organization facility. The amount of the fee for a facility located outside the United

States and its territories and possessions shall be $15,000 higher than the amount of the fee for a facility located in the United States and its territories and possessions.'';

(D) in subparagraph (D)—

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

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

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

(E) by adding at the end the following:

''(E)(i) Thirty-five percent shall be derived from fees under subsection (a)(5) (relating to generic drug applicant program fees). For purposes of this subparagraph, if a person has affiliates, a single program fee shall be assessed with respect to that person, including its affiliates, and may be paid by that person or any one of its affiliates. The Secretary shall determine the fees as follows:

''(I) If a person (including its affiliates) owns at least one but not more than

5 approved abbreviated new drug applications on the due date for the fee under this subsection, the person (including its affiliates) shall be assessed a small business generic drug applicant program fee equal to one-tenth of the large size operation generic drug applicant program fee.

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

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

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

deemed not to be approved if the applicant has submitted a written request for withdrawal of approval of such abbreviated new drug application by April 1 of the previous fiscal year.''.

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

(1) in paragraph (1)—

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

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

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

(2) in paragraph (2)—

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

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

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

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

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

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

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

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

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

(1) by striking paragraph (1);

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

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

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

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

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

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

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

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

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

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

(F) by adding at the end the following:

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

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

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

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

(3) by adding at the end the following:

''(5) GENERIC DRUG APPLICANT PROGRAM FEE.—

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

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

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

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

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

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

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

(1) in paragraph (2)—

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

(B) in subparagraph (D)—

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

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

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

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

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

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

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

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

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

drug applications and all approved abbreviated new drug applications owned by any such affiliate.

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

SEC. 304. REAUTHORIZATION; REPORTING REQUIREMENTS.

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

(1) in subsection (a)—

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

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

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

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

SEC. 305. SUNSET DATES.

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

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

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

SEC. 306. EFFECTIVE DATE.

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

SEC. 307. SAVINGS CLAUSE.

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

355(j)(5)(A)), prior approval supplements that were submitted, and drug master files for Type II active pharmaceutical ingredients that were first referenced with respect to assessing and collecting any fee required by such part for a fiscal year prior to fiscal year 2018.

TITLE IV—FEES RELATING TO BIOSIMILAR BIOLOGICAL PRODUCTS

SEC. 401. SHORT TITLE; FINDING.

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

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

SEC. 402. DEFINITIONS.

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

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

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

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

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

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

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

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

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

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

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

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

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

ation for a refund under this clause, a person shall submit to the Secretary a written request for such refund not later than 180 days after the marketing application is accepted for filing.'';

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

(9) in paragraph (1)(D)—

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

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

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

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

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

MENT PROGRAM FEES'' and inserting ''BIOSIMILAR BIOLOGICAL PRODUCT DEVELOPMENT FEES'';

(12) in paragraph (1)(F)—

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

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

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

(13) in paragraph (2)—

(A) in the heading of paragraph (2), by striking ''AND SUPPLEMENT'';

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

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

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

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

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

''(i) be subject to any biosimilar biological product application fees that may be assessed at the time when such bio-

similar biological product application is submitted; and

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

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

(D) in subparagraphs (C) through (F)—

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

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

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

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

''(A) IN GENERAL.—Each person who is named as the applicant in a biosimilar biological product application shall pay the annual biosimilar biological product program fee established for a fiscal year under subsection (c)(5) for each biosimilar biological product that—

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

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

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

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

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

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

''(D) LIMITATION.—A person who is named as the applicant in a biosimilar biological product application shall not be assessed more than 5 biosimilar biological product program fees for a fiscal year for biosimilar bio-

logical products identified in such biosimilar biological product application.''.

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

''(b) FEE REVENUE AMOUNTS.—

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

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

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

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

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

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

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

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

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

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

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

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

''(iii) Biosimilar biological product program fees under subsection (a)(3).

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

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

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

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

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

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

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

(2) in subsections (a)(2)(F) and (g), by striking ''subsection (c)'' and inserting ''subsection (d)'';

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

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

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

''(1) INFLATION ADJUSTMENT.—

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

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

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

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

''(i) the average annual percent change in the cost, per full-time equivalent position of the Food and Drug Administration, of all personnel compensation and benefits paid with respect to such positions for the first 3 years of the preceding 4 fiscal years, multiplied by the proportion of personnel compensation and benefits costs to total costs of the process for the review of biosimilar biological product applications (as defined in section 744G(13)) for the first 3 years of the preceding 4 fiscal years; and

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

first 3 years of the preceding 4 fiscal years.

''(2) CAPACITY PLANNING ADJUSTMENT.—

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

''(B) CAPACITY PLANNING METHODOLOGY.—

''(i) DEVELOPMENT; EVALUATION AND REPORT.—The Secretary shall obtain, through a contract with an independent accounting or consulting firm, a report evaluating options and recommendations for a new methodology to accurately assess changes in the resource and capacity needs of the process for the review of biosimilar biological product applications. The capacity planning methodological options and recommendations presented in such report

shall utilize and be informed by personnel time reporting data as an input. The report shall be published for public comment not later than September 30, 2020.

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

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

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

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

amount of the inflation adjustment for the fiscal year).

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

''(3) OPERATING RESERVE ADJUSTMENT.—

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

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

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

mines appropriate for long-term financial planning purposes; or

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

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

''(4) FISCAL YEAR 2018 ADJUSTMENT.—

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

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

the methodology used to calculate the fiscal year 2018 adjustment under this paragraph in the Federal Register notice establishing fee revenue and fees for fiscal year 2018.

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

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

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

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

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

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

(1) by striking subparagraph (B);

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

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

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

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

(1) in paragraph (2)—

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

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

(B) in subparagraph (D)—

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

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

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

SEC. 404. REAUTHORIZATION; REPORTING REQUIREMENTS.

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

(1) in subsection (a)—

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

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

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

(3) by striking subsection (d);

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

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

SEC. 405. SUNSET DATES.

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

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

(c) PREVIOUS SUNSET PROVISION.—

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

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

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

SEC. 406. EFFECTIVE DATE.

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

SEC. 407. SAVINGS CLAUSE.

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

TITLE V—REAUTHORIZATIONS AND IMPROVEMENTS RELATED TO DRUGS

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

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

SEC. 502. REAUTHORIZATION OF ORPHAN GRANTS PROGRAM.

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

SEC. 503. REAUTHORIZATION OF PEDIATRIC STUDY OF DRUGS.

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

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

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

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

(2) by adding at the end the following:

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

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

''(8) Notwithstanding subsection (a), any person who violates section 301(i)(3) by knowingly 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.''.

TITLE VI—DEVICE INSPECTION AND REGULATORY IMPROVEMENTS

Subtitle A—Improving the Process for Inspections of Device Establishments

SEC. 601. RISK-BASED INSPECTIONS FOR DEVICES.

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

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

''(A) IN GENERAL.—The Secretary, acting through one or more officers or employees duly designated by the Secretary, shall inspect 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 which the United States recognizes for purposes of inspecting device establishments.''; and

SEC. 602. RECOGNITION OF FOREIGN GOVERNMENT INSPECTIONS.

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

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

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

''(h)(1) In the case of inspections other than for-cause inspections, the Secretary shall review processes and standards applicable to inspections of domestic and foreign device establishments in effect as of the date of the

enactment of this subsection, and update such processes and standards through the adoption of uniform processes and standards applicable to such inspections. Such processes and standards shall provide for—

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

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

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

''(D) regular communications during the inspection with the owner, operator, or agent in charge of the establishment regarding inspection status, which

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

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

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

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

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

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

(b) GUIDANCE.—

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

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

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

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

(C) establishes, with respect to inspections of both domestic and foreign device establishments (as referred to in section 510(h)(2) of the Federal Food, Drug, and Cosmetic Act, as amended by section 1), a standard timeframe for such inspections that—

(i) occurs over consecutive days;

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

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

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

SEC. 604. CERTIFICATES TO FOREIGN GOVERNMENTS FOR DEVICES.

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

(1) by adding at the end the following:

''(E)(i) If the Secretary denies a request made under subparagraph (A)(ii) for certification with respect to a device, the Secretary shall provide, in writing, to the person seeking such certification the basis for such denial, and specifically identify the finding upon which such denial is based.

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

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

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

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

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

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

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

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

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

conditions and requirements as a fee charged under subparagraph (B) for a certification issued under such subparagraph. ''; and

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

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

SEC. 605. FACILITATING INTERNATIONAL HARMONIZATION.

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

''(15) Notwithstanding any other provision of this subsection, for purposes of conducting inspections of establishments that manufacture, prepare, propagate, compound, or process devices except types of devices licensed under section 351 of the Public Health Service Act, which inspections are required under section 510(h) or are inspections of such establishments required to register pursuant to

section 510(i), the Secretary may recognize auditing organizations that are recognized by organizations established by governments to facilitate international harmonization. Nothing in this paragraph affects the authority of the Secretary to inspect any device establishment pursuant to this Act. Nothing in this paragraph affects the authority of the Secretary to determine the official classification of an inspection. ''.

SEC. 606. REAUTHORIZATION OF INSPECTION PROGRAM.

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

Subtitle B—Other Provisions

SEC. 611. REAUTHORIZATION OF PEDIATRIC HUMANITARIAN DEVICE EXCEPTIONS.

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

SEC. 612. REAUTHORIZATION OF PEDIATRIC DEVICE CONSORTIA.

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

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

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

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

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

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

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

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

"(D) that may—

"(i) use wireless technology; or

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

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

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

(b) REGULATIONS TO ESTABLISH CATEGORY.—

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

posed regulations closes, shall issue such final regulations.

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

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

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

(C) include requirements for appropriate labeling of the over-the-counter hearing aid, including how consumers may report adverse events, any conditions or contraindications, and any advisements to consult promptly with a licensed physician; and

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

(3) PREMARKET NOTIFICATION.—The Secretary shall make findings under section 510(m) of the Federal Food, Drug, and Cosmetic Act (21

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

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

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

section (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.

TITLE VII—GENERIC DRUG ACCESS AND COMPETITION

SEC. 701. COMPETITIVE GENERIC THERAPIES.

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

''SEC. 506H. COMPETITIVE GENERIC THERAPIES.

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

''(b) DESIGNATION PROCESS.—

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

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

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

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

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

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

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

''(1) Hold meetings with the sponsor and the review team throughout the development of the drug

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

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

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

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

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

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

''(d) DEFINITIONS.—In this section:

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

''(2) The term 'inadequate generic competition' means there is not more than one approved drug

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

''(A) the reference listed drug; or

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

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

(b) GUIDANCE; AMENDED REGULATIONS.—

(1) IN GENERAL.—

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

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

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

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

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

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

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

(2) AMENDED REGULATIONS.—

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

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

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

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

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

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

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

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

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

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

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

SEC. 703. INCENTIVIZING COMPETITIVE GENERIC THERAPY DEVELOPMENT.

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

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

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

''(I) EFFECTIVENESS OF APPLICATION.—If the application is for a competitive generic therapy, 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.

''(II) DEFINITION.—In this clause and subparagraph (D)(iv), 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 blocking patents or exclusivities on the list of products described in section 505(j)(7)(A).''; 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 the holder of the approved abbreviated application for the competitive generic therapy involved if the holder fails to market the competitive generic therapy within 75 days after the date on which the approval of the application is made effective.''.

SEC. 704. TROPICAL DISEASE PRODUCT APPLICATION.

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

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

(2) in clause (ii), by inserting ''and'' after the semicolon at the end; and

(3) by adding at the end the following:

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

''(I) are essential to the approval of the application and conducted or sponsored by the applicant; and

"(II) were not relied upon for marketing authority by a foreign national regulatory authority prior to September 27, 2007.".

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

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

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

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

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

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

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

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

(E) the processes and practices for communication between the Food and Drug 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) CONSULTATION.—The Comptroller General shall conduct the study under subsection (a) in consultation with—

(1) the Secretary of Health and Human Services, acting through the Commissioner of Food and Drugs; and

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

(c) INITIATION AND COMPLETION DATES.—Not later than 90 days after the date of enactment of this Act, the Comptroller General shall initiate the study under subsection (a). 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 Rep-

resentatives, and the Committee on Health, Education, Labor, and Pensions of the Senate.

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

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

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

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

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

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

(B) For purposes of this paragraph, the term ''complete response letter'' means a written communication to the sponsor of a generic drug application

or holder of a drug master file (DMF) from the Food and Drug Administration describing all of the deficiencies that the Administration has identified in the generic drug application (including pending amendments) or drug master file that must be satisfactorily addressed before the generic drug application can be approved.

TITLE VIII—ADDITIONAL PROVISIONS

SEC. 801. TECHNICAL CORRECTIONS.

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

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

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

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

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

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

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

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

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

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

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

SEC. 802. 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''.