117TH CONGRESS
2d Session

HOUSE OF REPRESENTATIVES

REPORT
117–348

FOOD AND DRUG AMENDMENTS OF 2022

R E P O R T

OF THE

COMMITTEE ON ENERGY AND COMMERCE

TO ACCOMPANY

H.R. 7667

JUNE 7, 2022.—Committed to the Committee of the Whole House on the State of the Union and ordered to be printed

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Mr. PALLONE, from the Committee on Energy and Commerce, submitted the following

R E P O R T

[To accompany H.R. 7667]

The Committee on Energy and Commerce, to whom was referred the bill (H.R. 7667) 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, having considered the same, reports favorably thereon with an amendment and recommends that the bill as amended do pass.

CONTENTS

The amendment is as follows:

Strike all after the enacting clause and insert the following:

SECTION 1. SHORT TITLE.

This Act may be cited as the "Food and Drug Amendments of 2022".

SEC. 2. TABLE OF CONTENTS.

The table of contents of this Act is as follows:

TITLE VIII—TRANSPARENCY, PROGRAM INTEGRITY, AND REGULATORY IMPROVEMENTS

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 2022".

(b) FINDING.—The Congress finds that the fees authorized by the amendments made by 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 (21 U.S.C. 379g et seq.), 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. DEFINITIONS.

(a) HUMAN DRUG APPLICATION.—Section 735(1) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 379g(1)) is amended by striking "an allergenic extract product, or" and inserting "does not include an application with respect to an allergenic extract product licensed before October 1, 2022, does not include an application with respect to a standardized allergenic extract product submitted pursuant to a notification to the applicant from the Secretary regarding the existence of a potency test that measures the allergenic activity of an allergenic extract product licensed by the applicant before October 1, 2022, does not include an application with respect to".

(b) PRESCRIPTION DRUG PRODUCT.—Section 735(3) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 379g(3)) is amended—

(1) by redesignating subparagraphs (A), (B), and (C) as clauses (i), (ii), and (iii), respectively;

(2) by striking "(3) The term" and inserting "(3)(A) The term";

(3) by striking "Such term does not include whole blood" and inserting the following:

"(B) Such term does not include whole blood";

(4) by striking "an allergenic extract product," and inserting "an allergenic extract product licensed before October 1, 2022, a standardized allergenic extract product submitted pursuant to a notification to the applicant from the Secretary regarding the existence of a potency test that measures the allergenic activity of an allergenic extract product licensed by the applicant before October 1, 2022," ; and

(5) by adding at the end the following:

"(C)(i) If a written request to place a product in the discontinued section of either of the lists referenced in subparagraph (A)(iii) is submitted to the Secretary on behalf of an applicant, and the request identifies the date the product is withdrawn from sale, then for purposes of assessing the prescription drug program fee under section 736(a)(2), the Secretary shall consider such product to have been included in the discontinued section on the later of—

"(I) the date such request was received; or

"(II) if the product will be withdrawn from sale on a future date, such future date when the product is withdrawn from sale.

"(ii) For purposes of this subparagraph, a product shall be considered withdrawn from sale once the applicant has ceased its own distribution of the product, whether or not the applicant has ordered recall of all previously distributed lots of the product, except that a routine, temporary interruption in supply shall not render a product withdrawn from sale.".

(c) SKIN-TEST DIAGNOSTIC PRODUCT.—Section 735 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 379g) is amended by adding at the end the following:

"(12) The term 'skin-test diagnostic product'—

"(A) means a product—

"(i) for prick, scratch, intradermal, or subcutaneous administration;

"(ii) expected to produce a limited, local reaction at the site of administration (if positive), rather than a systemic effect;

"(iii) not intended to be a preventive or therapeutic intervention; and

"(iv) intended to detect an immediate- or delayed-type skin hypersensitivity reaction to aid in the diagnosis of—

"(I) an allergy to an antimicrobial agent;

"(II) an allergy that is not to an antimicrobial agent, if the diagnostic product was authorized for marketing prior to October 1, 2022; or

"(III) infection with fungal or mycobacterial pathogens; and

"(B) includes positive and negative controls required to interpret the results of a product described in subparagraph (A).".

SEC. 103. AUTHORITY TO ASSESS AND USE DRUG FEES.

(a) TYPES OF FEES.—

(1) HUMAN DRUG APPLICATION FEE.—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 2018" and inserting "fiscal year 2023";

(B) in paragraph (1)(A), by striking "(c)(5)" each place it appears and inserting "(c)(6)";

(C) in paragraph (1)(C), by inserting "prior to approval" after "or was withdrawn"; and

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

"(H) EXCEPTION FOR SKIN-TEST DIAGNOSTIC PRODUCTS.—A human drug application for a skin-test diagnostic product shall not be subject to a fee under subparagraph (A).".

(2) PRESCRIPTION DRUG PROGRAM FEE.—Section 736(a)(2) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 379h(a)(2)) is amended—

(A) in subparagraph (A)—

(i) by striking "Except as provided in subparagraphs (B) and (C)" and inserting the following:

"(i) FEE.—Except as provided in subparagraphs (B) and (C)";

(ii) by striking "subsection (c)(5)" and inserting "subsection (c)(6)"; and

(iii) by adding at the end the following:

"(ii) SPECIAL RULE.—If a drug product that is identified in a human drug application approved as of October 1 of a fiscal year is not a prescription drug product as of that date because the drug product is in the discontinued section of a list referenced in section 735(3)(A)(iii), and on any subsequent day during such fiscal year the drug product is a prescription drug product, then except as provided in subparagraphs (B) and (C), each person who is named as the applicant in a human drug application with respect to such product, and who, after September 1, 1992, had pending before the Secretary a human drug application or supplement with respect to such product, shall pay the annual prescription drug program fee established for a fiscal year under subsection (c)(6) for such prescription drug product. Such fee shall be due on the last business day of such fiscal year and shall be paid only once for each such product for a fiscal year in which the fee is payable."; and

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

"(B) EXCEPTION FOR CERTAIN PRESCRIPTION DRUG PRODUCTS.—A prescription drug program fee shall not be assessed for a prescription drug product under subparagraph (A) if such product is—

"(i) a large volume parenteral product (a sterile aqueous drug product packaged in a single-dose container with a volume greater than or equal to 100 mL, not including powders for reconstitution or pharmacy bulk packages) identified on the list compiled under section 505(j)(7);

"(ii) pharmaceutically equivalent (as defined in section 314.3 of title 21, Code of Federal Regulations (or any successor regulation)) to another product on the list of products compiled under section 505(j)(7) (not including the discontinued section of such list); or

"(iii) a skin-test diagnostic product.".

(b) FEE REVENUE AMOUNTS.—

(1) IN GENERAL.—Paragraph (1) of section 736(b) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 379h(b)) is amended to read as follows:

"(1) IN GENERAL.—For each of the fiscal years 2023 through 2027, 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 strategic hiring and retention adjustment for the fiscal year (as determined under subsection (c)(2));

"(D) the dollar amount equal to the capacity planning adjustment for the fiscal year (as determined under subsection (c)(3));

"(E) the dollar amount equal to the operating reserve adjustment for the fiscal year, if applicable (as determined under subsection (c)(4));

"(F) the dollar amount equal to the additional direct cost adjustment for the fiscal year (as determined under subsection (c)(5)); and

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

"(i) $65,773,693 for fiscal year 2023.

"(ii) $25,097,671 for fiscal year 2024.

"(iii) $14,154,169 for fiscal year 2025.

"(iv) $4,864,860 for fiscal year 2026.

"(v) $1,314,620 for fiscal year 2027.".

(2) ANNUAL BASE REVENUE.—Paragraph (3) of section 736(b) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 379h(b)) is amended to read as follows:

"(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 2023, $1,151,522,958; and

"(B) for fiscal years 2024 through 2027, 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)(4) or (c)(5).".

(c) ADJUSTMENTS; ANNUAL FEE SETTING.—

(1) INFLATION ADJUSTMENT.—Section 736(c)(1)(B)(ii) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 379h(c)(1)(B)(ii)) is amended by striking "Washington-Baltimore, DC–MD–VA–WV" and inserting "Washington-Arlington-Alexandria, DC–VA–MD–WV".

(2) STRATEGIC HIRING AND RETENTION ADJUSTMENT.—Section 736(c) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 379h(c)) is amended—

(A) by redesignating paragraphs (2) through (6) as paragraphs (3) through (7), respectively; and

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

"(2) STRATEGIC HIRING AND RETENTION ADJUSTMENT.—For each fiscal year, after the annual base revenue established in subsection (b)(1)(A) is adjusted for inflation in accordance with paragraph (1), the Secretary shall further increase the fee revenue and fees by the following amounts:

"(A) For fiscal year 2023, $9,000,000.

"(B) For each of fiscal years 2024 through 2027, $4,000,000.".

(3) CAPACITY PLANNING ADJUSTMENT.—Paragraph (3), as redesignated, of section 736(c) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 379h(c)) is amended to read as follows:

"(3) CAPACITY PLANNING ADJUSTMENT.—

"(A) IN GENERAL.—For each fiscal year, after the annual base revenue established in subsection (b)(1)(A) is adjusted in accordance with paragraphs (1) and (2), 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) METHODOLOGY.—For purposes of this paragraph, the Secretary shall employ the capacity planning methodology utilized by the Secretary in setting fees for fiscal year 2021, as described in the notice titled 'Prescription Drug User Fee Rates for Fiscal Year 2021' published in the Federal Register on August 3, 2020 (85 Fed. Reg. 46651). The workload categories used in applying such methodology in forecasting shall include only the activities described in that notice and, as feasible, additional activities that are also directly related to the direct review of applications and supplements, including additional formal meeting types, the direct review of postmarketing commitments and requirements, the direct review of risk evaluation and mitigation strategies, and the direct review of annual reports for approved

prescription drug products. Subject to the exceptions in the preceding sentence, the Secretary shall not include as workload categories in applying such methodology in forecasting any non-core review activities, including those activities that the Secretary referenced for potential future use in such notice but did not utilize in setting fees for fiscal year 2021.

"(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)(1)(A) (the annual base revenue for the fiscal year), (b)(1)(B) (the dollar amount of the inflation adjustment for the fiscal year), and (b)(1)(C) (the dollar amount of the strategic hiring and retention adjustment for the fiscal year).

"(D) PUBLICATION IN FEDERAL REGISTER.—The Secretary shall publish in the Federal Register notice under paragraph (6) of the fee revenue and fees resulting from the adjustment and the methodologies under this paragraph.".

(4) OPERATING RESERVE ADJUSTMENT.—Paragraph (4), as redesignated, of section 736(c) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 379h(c)) is amended—

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

"(A) INCREASE.—For fiscal year 2023 and subsequent fiscal years, the Secretary shall, in addition to adjustments under paragraphs (1), (2), and (3), further increase the fee revenue and fees if such an adjustment is necessary to provide for operating reserves of carryover user fees for the process for the review of human drug applications for each fiscal year in at least the following amounts:

"(i) For fiscal year 2023, at least 8 weeks of operating reserves.

"(ii) For fiscal year 2024, at least 9 weeks of operating reserves.

"(iii) For fiscal year 2025 and subsequent fiscal years, at least 10 weeks of operating reserves."; and

(B) in subparagraph (C), by striking "paragraph (5)" and inserting "paragraph (6)".

(5) ADDITIONAL DIRECT COST ADJUSTMENT.—Paragraph (5), as redesignated, of section 736(c) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 379h(c)) is amended to read as follows:

"(5) ADDITIONAL DIRECT COST ADJUSTMENT.—

"(A) INCREASE.—The Secretary shall, in addition to adjustments under paragraphs (1), (2), (3), and (4), further increase the fee revenue and fees—

"(i) for fiscal year 2023, by $44,386,150; and

"(ii) for each of fiscal years 2024 through 2027, by the amount set forth in clauses (i) through (iv) of subparagraph (B), as applicable, multiplied by the Consumer Price Index for urban consumers (Washington-Arlington-Alexandria, DC–VA–MD–WV; Not Seasonally Adjusted; All Items; Annual Index) for the most recent year of available data, divided by such Index for 2021.

"(B) APPLICABLE AMOUNTS.—The amounts referred to in subparagraph (A)(ii) are the following:

"(i) For fiscal year 2024, $60,967,993.

"(ii) For fiscal year 2025, $35,799,314.

"(iii) For fiscal year 2026, $35,799, 314.

"(iv) For fiscal year 2027, $35,799,314.".

(6) ANNUAL FEE SETTING.—Paragraph (6), as redesignated, of section 736(c) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 379h(c)) is amended by striking "September 30, 2017" and inserting "September 30, 2022".

(d) CREDITING AND AVAILABILITY OF FEES.—Section 736(g)(3) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 379h(g)(3)) is amended by striking "fiscal years 2018 through 2022" and inserting "fiscal years 2023 through 2027".

(e) WRITTEN REQUESTS FOR WAIVERS, REDUCTIONS, EXEMPTIONS, AND RETURNS; DISPUTES CONCERNING FEES.—Section 736(i) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 379h(i)) is amended to read as follows:

"(i) WRITTEN REQUESTS FOR WAIVERS, REDUCTIONS, EXEMPTIONS, AND RETURNS; DISPUTES CONCERNING FEES.—To qualify for consideration for a waiver or reduction under subsection (d), an exemption under subsection (k), or the return of any fee paid under this section, including if the fee is claimed to have been paid in error, a person shall—

"(1) not later than 180 days after such fee is due, submit to the Secretary a written request justifying such waiver, reduction, exemption, or return; and

"(2) include in the request any legal authorities under which the request is made.".

(f) ORPHAN DRUGS.—Section 736(k) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 379h(k)) is amended—

(1) in paragraph (1)(B), by striking "during the previous year" and inserting "as determined under paragraph (2)"; and

(2) by amending paragraph (2) to read as follows:

"(2) EVIDENCE OF QUALIFICATION.—An exemption under paragraph (1) applies with respect to a drug only if the applicant involved submits a certification that the applicant's gross annual revenues did not exceed $50,000,000 for the last calendar year ending prior to the fiscal year for which the exemption is requested. Such certification shall be supported by—

"(A) tax returns submitted to the United States Internal Revenue Service; or

"(B) as necessary, other appropriate financial information.".

SEC. 104. 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), by striking "Beginning with fiscal year 2018, not" and inserting "Not";

(2) by striking "Prescription Drug User Fee Amendments of 2017" each place it appears and inserting "Prescription Drug User Fee Amendments of 2022";

(3) in subsection (a)(3)(A), by striking "Not later than 30 calendar days after the end of the second quarter of fiscal year 2018, and not later than 30 calendar days after the end of each quarter of each fiscal year thereafter" and inserting "Not later than 30 calendar days after the end of each quarter of each fiscal year for which fees are collected under this part";

(4) in subsection (a)(3)(B), by adding at the end the following:

"(v) For fiscal years 2023 and 2024, of the meeting requests from sponsors for which the Secretary has determined that a face-to-face meeting is appropriate, the number of face-to-face meetings requested by sponsors to be conducted in person (in such manner as the Secretary shall prescribe on the internet website of the Food and Drug Administration), and the number of such in-person meetings granted by the Secretary.";

(5) in subsection (a)(4), by striking "Beginning with fiscal year 2020, the" and inserting "The";

(6) in subsection (b), by striking "Beginning with fiscal year 2018, not" and inserting "Not";

(7) in subsection (c), by striking "Beginning with fiscal year 2018, for" and inserting "For"; and

(8) in subsection (f)—

(A) in paragraph (1), in the matter preceding subparagraph (A), by striking "fiscal year 2022" and inserting "fiscal year 2027"; and

(B) in paragraph (5), by striking "January 15, 2022" and inserting "January 15, 2027".

SEC. 105. 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, 2027.

(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, 2028.

(c) PREVIOUS SUNSET PROVISION.—Effective October 1, 2022, subsections (a) and (b) of section 104 of the FDA Reauthorization Act of 2017 (Public Law 115–52) are repealed.

SEC. 106. EFFECTIVE DATE.

The amendments made by this title shall take effect on October 1, 2022, 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 (21 U.S.C. 379g et seq.) shall be assessed for all human drug applications received on or after October 1, 2022, regardless of the date of the enactment of this Act.

SEC. 107. 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 (21 U.S.C. 379g 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 human drug applications and supplements (as defined in such part as of such day) that on or after October 1, 2017, but before October 1, 2022, 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 2023.

TITLE II—FEES RELATING TO DEVICES

SEC. 201. SHORT TITLE; FINDING.

(a) SHORT TITLE.—This title may be cited as the "Medical Device User Fee Amendments of 2022".

(b) FINDING.—The Congress finds that the fees authorized under the amendments made by this title will be dedicated toward expediting the process for the review of device applications and for assuring the safety and effectiveness of devices, as set forth in the goals identified for purposes of part 3 of subchapter C of chapter VII of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 379i et seq.), 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) in paragraph (9)—

(A) in the matter preceding subparagraph (A), by striking "and premarket notification submissions" and inserting "premarket notification submissions, and de novo classification requests";

(B) in subparagraph (D), by striking "and submissions" and inserting "submissions, and requests";

(C) in subparagraph (F), by striking "and premarket notification submissions" and inserting "premarket notification submissions, and de novo classification requests";

(D) in each of subparagraphs (G) and (H), by striking "or submissions" and inserting "submissions, or requests"; and

(E) in subparagraph (K), by striking "or premarket notification submissions" and inserting "premarket notification submissions, or de novo classification requests"; and

(2) in paragraph (11), by striking "2016" and inserting "2021".

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 2018" and inserting "fiscal year 2023"; and

(2) in paragraph (2)—

(A) in subparagraph (A)—

(i) in the matter preceding clause (i), by striking "October 1, 2017" and inserting "October 1, 2022";

(ii) in clause (iii), by striking "75 percent" and inserting "80 percent"; and

(iii) in clause (viii), by striking "3.4 percent" and inserting "4.5 percent";

(B) in subparagraph (B)(iii), by striking "or premarket notification submission" and inserting "premarket notification submission, or de novo classification request"; and

(C) in subparagraph (C), by striking "or periodic reporting concerning a class III device" and inserting "periodic reporting concerning a class III device, 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—

(1) in paragraph (1), by striking "2018 through 2022" and inserting "2023 through 2027";

(2) by amending paragraph (2) to read as follows:

"(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 2023	Fiscal Year 2024	Fiscal Year 2025	Fiscal Year 2026	Fiscal Year 2027
Premarket Application	$425,000	$435,000	$445,000	$455,000	$470,000
Establishment Registration	$6,250	$6,875	$7,100	$7,575	$8,465''; and

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

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

"(A) $312,606,000 for fiscal year 2023.

"(B) $335,750,000 for fiscal year 2024.

"(C) $350,746,400 for fiscal year 2025.

"(D) $366,486,300 for fiscal year 2026.

"(E) $418,343,000 for fiscal year 2027.".

(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 "2017" and inserting "2022";

(2) in paragraph (2)—

(A) in subparagraph (A), by striking "2018" and inserting "2023";

(B) in subparagraph (B)—

(i) in the matter preceding clause (i), by striking "fiscal year 2018" and inserting "fiscal year 2023"; and

(ii) in clause (ii), by striking "fiscal year 2016" and inserting "fiscal year 2022";

(C) in subparagraph (C), by striking "Washington-Baltimore, DC–MD–VA–WV" and inserting "Washington-Arlington-Alexandria, DC–VA–MD–WV"; and

(D) in subparagraph (D), in the matter preceding clause (i), by striking "fiscal years 2018 through 2022" and inserting "fiscal years 2023 through 2027";

(3) in paragraph (3), by striking "2018 through 2022" and inserting "2023 through 2027";

(4) by redesignating paragraphs (4) and (5) as paragraphs (7) and (8), respectively; and

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

"(4) PERFORMANCE IMPROVEMENT ADJUSTMENT.—

"(A) IN GENERAL.—For each of fiscal years 2025 through 2027, after the adjustments under paragraphs (2) and (3), the base establishment registration fee amounts for such fiscal year shall be increased to reflect changes in the resource needs of the Secretary due to improved review performance goals for the process for the review of device applications identified in the letters described in section 201(b) of the Medical Device User Fee Amendments of 2022, as the Secretary determines necessary to achieve an increase in total fee collections for such fiscal year equal to the following amounts:

"(i) For fiscal year 2025, the product of—

"(I) the amount determined under subparagraph (B)(i)(I); and

"(II) the applicable inflation adjustment under paragraph (2)(B) for such fiscal year.

"(ii) For fiscal year 2026, the product of—

"(I) the sum of the amounts determined under subparagraphs (B)(i)(II), (B)(ii)(I), and (B)(iii)(I); and

"(II) the applicable inflation adjustment under paragraph (2)(B) for such fiscal year.

"(iii) For fiscal year 2027, the product of—

"(I) the sum of the amounts determined under subparagraphs (B)(i)(III), (B)(ii)(II), and (B)(iii)(II); and

"(II) the applicable inflation adjustment under paragraph (2)(B) for such fiscal year.

"(B) AMOUNTS.—

"(i) PRE-SUBMISSION AMOUNT.—For purposes of subparagraph (A), with respect to the pre-submission written feedback goal, the amounts determined under this subparagraph are as follows:

"(I) For fiscal year 2025, $15,396,600 if such goal for fiscal year 2023 is met.

"(II) For fiscal year 2026:

"(aa) $15,396,600 if such goal for fiscal year 2023 is met and such goal for fiscal year 2024 is not met.

"(bb) $36,792,200 if such goal for fiscal year 2024 is met.

"(III) For fiscal year 2027:

"(aa) $15,396,600 if such goal for fiscal year 2023 is met and such goal for each of fiscal years 2024 and 2025 is not met.

"(bb) $36,792,200 if such goal for fiscal year 2024 is met and such goal for fiscal year 2025 is not met.

"(cc) $40,572,600 if such goal for fiscal year 2025 is met.

"(ii) DE NOVO CLASSIFICATION AMOUNT.—For purposes of subparagraph (A), with respect to the de novo decision goal, the amounts determined under this subparagraph are as follows:

"(I) For fiscal year 2026, $6,323,500 if such goal for fiscal year 2023 is met.

"(II) For fiscal year 2027:

"(aa) $6,323,500 if such goal for fiscal year 2023 is met and such goal for fiscal year 2024 is not met.

"(bb) $11,765,400 if such goal for fiscal year 2024 is met.

"(iii) PREMARKET NOTIFICATION AND PREMARKET APPROVAL AMOUNT.—For purposes of subparagraph (A), with respect to the 510(k) decision goal, 510(k) shared outcome total time to decision goal, PMA decision goal, and PMA shared outcome total time to decision goal, the amounts determined under this subparagraph are as follows:

"(I) For fiscal year 2026, $1,020,000 if the four goals for fiscal year 2023 are met.

"(II) For fiscal year 2027:

"(aa) $1,020,000 if the four goals for fiscal year 2023 are met and one or more of the four goals for fiscal year 2024 are not met.

"(bb) $3,906,000 if the four goals for fiscal year 2024 are met.

"(C) PERFORMANCE CALCULATION.—For purposes of this paragraph, performance of the goals listed in subparagraph (D) shall be determined as specified in the letters described in section 201(b) of the Medical Device User Fee Amendments of 2022 and based on data available as of the following dates:

"(i) The performance of the pre-submission written feedback goal shall be based on data available as of—

"(I) for fiscal year 2023, March 31, 2024;

"(II) for fiscal year 2024, March 31, 2025; and

"(III) for fiscal year 2025, March 31, 2026.

"(ii) The performance of the de novo decision goal, 510(k) decision goal, 510(k) shared outcome total time to decision goal, PMA decision goal, and PMA shared outcome total time to decision goal shall be based on data available as of—

"(I) for fiscal year 2023, March 31, 2025; and

"(II) for fiscal year 2024, March 31, 2026.

"(D) GOALS DEFINED.—For purposes of this paragraph, the terms 'pre-submission written feedback goal', 'de novo decision goal', '510(k) decision goal', '510(k) shared outcome total time to decision goal', 'PMA decision goal', and 'PMA shared outcome total time to decision goal' refer to the goals identified by the same names in the letters described in section 201(b) of the Medical Device User Fee Amendments of 2022.

"(5) HIRING ADJUSTMENT.—

"(A) IN GENERAL.—For each of fiscal years 2025 through 2027, after the adjustments under paragraphs (2), (3), and (4), if applicable, if the number of hires to support the process for the review of device applications falls below the thresholds specified in subparagraph (B) for the applicable fiscal years, the base establishment registration fee amounts shall be decreased as the Secretary determines necessary to achieve a reduction in total fee collections equal to the hiring adjustment amount under subparagraph (C).

"(B) THRESHOLDS.—The thresholds specified in this subparagraph are as follows:

"(i) For fiscal year 2025, the threshold is 123 hires for fiscal year 2023.

"(ii) For fiscal year 2026, the threshold is 38 hires for fiscal year 2024.

"(iii) For fiscal year 2027, the threshold is—

"(I) 22 hires for fiscal year 2025 if the base establishment registration fees are not increased by the amount determined under paragraph (4)(A)(i); or

"(II) 75 hires for fiscal year 2025 if such fees are so increased.

"(C) HIRING ADJUSTMENT AMOUNT.—The hiring adjustment amount for fiscal year 2025 and each subsequent fiscal year is the product of—

"(i) the number of hires by which the hiring goal specified in subparagraph (D) for the fiscal year before the prior fiscal year was not met;

"(ii) $72,877; and

"(iii) the applicable inflation adjustment under paragraph (2)(B) for the fiscal year for which the hiring goal was not met.

"(D) HIRING GOALS.—The hiring goals for each of fiscal years 2023 through 2025 are as follows:

"(i) For fiscal year 2023, 144 hires.

"(ii) For fiscal year 2024, 42 hires.

"(iii) For fiscal year 2025:

"(I) 24 hires if the base establishment registration fees are not increased by the amount determined under paragraph (4)(A)(i).

"(II) 83 hires if the base establishment registration fees are increased by the amount determined under paragraph (4)(A)(i).

"(E) NUMBER OF HIRES.—For purposes of this paragraph, the number of hires shall be determined by the Secretary as set forth in the letters described in section 201(b) of the Medical Device User Fee Amendments of 2022.

"(6) OPERATING RESERVE ADJUSTMENT.—

"(A) IN GENERAL.—For each of fiscal years 2023 through 2027, after the adjustments under paragraphs (2), (3), (4), and (5), if applicable, if the Secretary has operating reserves of carryover user fees for the process for the review of device applications in excess of the designated amount in subparagraph (B), the Secretary shall decrease the base establishment registration fee amounts to provide for not more than such designated amount of operating reserves.

"(B) DESIGNATED AMOUNT.—Subject to subparagraph (C), for each fiscal year, the designated amount in this subparagraph is equal to the sum of—

"(i) 13 weeks of operating reserves of carryover user fees; and

"(ii) 1 month of operating reserves maintained pursuant to paragraph (8).

"(C) EXCLUDED AMOUNT.—For the period of fiscal years 2023 through 2026, a total amount equal to $118,000,000 shall not be considered part of the designated amount under subparagraph (B) and shall not be subject to the decrease under subparagraph (A).".

(d) SMALL BUSINESSES.—Section 738 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 379j) is amended in each of subsections (d)(2)(B)(iii) and (e)(2)(B)(iii) by inserting ", if extant," after "national taxing authority".

(e) CONDITIONS.—Section 738(g) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 379j(g)) is amended—

(1) in paragraph (1)(A), by striking "$320,825,000" and inserting "$398,566,000"; and

(2) in paragraph (2), by inserting "de novo classification requests," after "class III device,".

(f) CREDITING AND AVAILABILITY OF FEES.—Section 738(h)(3) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 379j(h)(3)) is amended to read as follows:

"(3) AUTHORIZATION OF APPROPRIATIONS.—

"(A) IN GENERAL.—For each of fiscal years 2023 through 2027, there is authorized to be appropriated for fees under this section an amount equal to the revenue amount determined under subparagraph (B), less the amount of reductions determined under subparagraph (C).

"(B) REVENUE AMOUNT.—For purposes of this paragraph, the revenue amount for each fiscal year is the sum of—

"(i) the total revenue amount under subsection (b)(3) for the fiscal year, as adjusted under paragraphs (2) and (3) of subsection (c); and

"(ii) the performance improvement adjustment amount for the fiscal year under subsection (c)(4), if applicable.

"(C) REDUCTIONS.—For purposes of this paragraph, the amount of reductions for each fiscal year is the sum of—

"(i) the hiring adjustment amount for the fiscal year under subsection (c)(5), if applicable; and

"(ii) the operating reserve adjustment amount for the fiscal year under subsection (c)(6), if applicable.".

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) by striking "fiscal year 2018" each place it appears and inserting "fiscal year 2023";

(2) by striking "Medical Device User Fee Amendments of 2017" each place it appears and inserting "Medical Device User Fee Amendments of 2022";

(3) in paragraph (1)—

(A) in subparagraph (A), by redesignating the second clause (iv) (relating to analysis) as clause (v); and

(B) in subparagraph (A)(iv), by striking "fiscal year 2020" and inserting "fiscal year 2023"; and

(4) in paragraph (4), by striking "2018 through 2022" and inserting "2023 through 2027".

(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 "2022" and inserting "2027"; and

(2) in paragraph (5), by striking "2022" and inserting "2027".

SEC. 205. CONFORMITY ASSESSMENT PILOT PROGRAM.

Section 514(d) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360d(d)) is amended to read as follows:

"(d) ACCREDITATION SCHEME FOR CONFORMITY ASSESSMENT.—

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

"(A) testing laboratories meeting criteria specified in guidance by the Secretary may be accredited by accreditation bodies meeting criteria specified in guidance by the Secretary, to conduct testing to support the assessment of the conformity of a device to certain standards recognized under this section; and

"(B) subject to paragraph (2), results from tests conducted to support the assessment of conformity of devices as described in subparagraph (A) conducted by testing laboratories accredited pursuant to this subsection shall be accepted by the Secretary for purposes of demonstrating such conformity unless the Secretary finds that certain results of such tests should not be so accepted.

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

"(A) review the results of tests conducted by testing laboratories accredited pursuant to this subsection, including by conducting periodic audits of such results or of the processes of accredited bodies or testing laboratories;

"(B) following such review, take additional measures under this Act, as the Secretary determines appropriate, such as—

"(i) suspension or withdrawal of accreditation of a testing laboratory or recognition of an accreditation body under paragraph (1)(A); or

"(ii) requesting additional information with respect to a device; and

"(C) if the Secretary becomes aware of information materially bearing on the safety or effectiveness of a device for which an assessment of conformity was supported by testing conducted by a testing laboratory accredited under this subsection, take such additional measures under this Act, as the Secretary determines appropriate, such as—

"(i) suspension or withdrawal of accreditation of a testing laboratory or recognition of an accreditation body under paragraph (1)(A); or

"(ii) requesting additional information with regard to such device.

"(3) IMPLEMENTATION AND REPORTING.—

"(A) PILOT PROGRAM TRANSITION.—After September 30, 2023, the pilot program previously initiated under this subsection, as in effect prior to the date of enactment of the Medical Device User Fee Amendments of 2022, shall be considered to be completed, and the Secretary may continue operating a program consistent with this subsection.

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

SEC. 206. REAUTHORIZATION OF THIRD-PARTY REVIEW PROGRAM.

Section 523(c) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360m(c)) is amended by striking "2022" and inserting "2027".

SEC. 207. SUNSET DATES.

(a) AUTHORIZATION.—Sections 737 and 738 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 379i; 379j) shall cease to be effective October 1, 2027.

(b) REPORTING REQUIREMENTS.—Section 738A (21 U.S.C. 379j– 1) of the Federal Food, Drug, and Cosmetic Act (regarding reauthorization and reporting requirements) shall cease to be effective January 31, 2028.

(c) PREVIOUS SUNSET PROVISIONS.—Effective October 1, 2022, subsections (a) and (b) of section 210 of the FDA Reauthorization Act of 2017 (Public Law 115–52) are repealed.

SEC. 208. EFFECTIVE DATE.

The amendments made by this title shall take effect on October 1, 2022, 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 (21

U.S.C. 379i et seq.) shall be assessed for all submissions listed in section 738(a)(2)(A) of such Act received on or after October 1, 2022, regardless of the date of the enactment of this Act.

SEC. 209. 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, 2017, but before October 1, 2022, were received by the Food and Drug Administration with respect to assessing and collecting any fee required by such part for a fiscal year prior to fiscal year 2023.

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 2022".

(b) FINDING.—The Congress finds that the fees authorized by the amendments made by 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 (21 U.S.C. 379j–41 et seq.), 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. 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 2018" and inserting "fiscal year 2023";

(2) in paragraph (2)(C), by striking "2018 through 2022" and inserting "2023 through 2027";

(3) in paragraph (3)(B), by striking "2018 through 2022" and inserting "2023 through 2027";

(4) in paragraph (4)(D), by striking "2018 through 2022" and inserting "2023 through 2027"; and

(5) in paragraph (5)(D), by striking "2018 through 2022" and inserting "2023 through 2027".

(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 "2018" and inserting "2023";

(ii) by striking "2018" and inserting "2023"; and

(iii) by striking "$493,600,000" and inserting "$582,500,000"; and

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

"(B) FISCAL YEARS 2024 THROUGH 2027.—

"(i) IN GENERAL.—For each of the fiscal years 2024 through 2027, fees under paragraphs (2) through (5) of subsection (a) shall be established to generate a total estimated revenue amount under such subsection that is equal to the base revenue amount for the fiscal year under clause (ii), as adjusted pursuant to subsection (c).

"(ii) BASE REVENUE AMOUNT.—The base revenue amount for a fiscal year referred to in clause (i) is equal to the total revenue amount established under this paragraph for the previous fiscal year, not including any adjustments made for such previous fiscal year under subsection (c)(3).."; and

(2) in paragraph (2)—

(A) in subparagraph (C), by striking "one-third the amount" and inserting "twenty-four percent";

(B) in subparagraph (D), by striking "Seven percent" and inserting "Six percent"; and

(C) in subparagraph (E)(i), by striking "Thirty-five percent" and inserting "Thirty-six percent".

(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) in the matter preceding subparagraph (A)—

(i) by striking "2019" and inserting "2024"; and

(ii) by striking "to equal the product of the total revenues established in such notice for the prior fiscal year multiplied" and inserting "to equal the base revenue amount for the fiscal year (as specified in subsection (b)(1)(B)) multiplied"; and

(B) in subparagraph (C), by striking "Washington-Baltimore, DC–MD–VA–WV" and inserting "Washington-Arlington-Alexandria, DC–VA–MD–WV"; and

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

"(2) CAPACITY PLANNING ADJUSTMENT.—

"(A) IN GENERAL.—Beginning with fiscal year 2024, 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, in accordance with this paragraph, to reflect changes in the resource capacity needs of the Secretary for human generic drug activities.

"(B) CAPACITY PLANNING METHODOLOGY.—The Secretary shall establish a capacity planning methodology for purposes of this paragraph, which shall—

"(i) be derived from the methodology and recommendations made in the report titled 'Independent Evaluation of the GDUFA Resource Capacity Planning Adjustment Methodology: Evaluation and Recommendations' announced in the Federal Register on August 3, 2020;

"(ii) incorporate approaches and attributes determined appropriate by the Secretary, including approaches and attributes made in such report, except that in incorporating such approaches and attributes the workload categories used in forecasting resources shall only be the workload categories specified in section VIII.B.2.e. of the letters described in section 301(b) of the Generic Drug User Fee Amendments of 2022; and

"(iii) be effective beginning with fiscal year 2024.

"(C) LIMITATIONS.—

"(i) IN GENERAL.—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 subsection (b)(1)(B)(ii) (the base revenue amount for the fiscal year) and paragraph (1) (the dollar amount of the inflation adjustment for the fiscal year).

"(ii) PERCENTAGE LIMITATION.—An adjustment under this paragraph shall not exceed three percent of the sum described in clause (i) for the fiscal year, except that such limitation shall be four percent if—

"(I) for purposes of a fiscal year 2024 adjustment, the Secretary determines that during the period from April 1, 2021, through March 31, 2023—

"(aa) the total number of abbreviated new drug applications submitted was greater than or equal to 2,000; or

"(bb) thirty-five percent or more of abbreviated new drug applications submitted related to complex products (as that term is defined in section XI of the letters described in section 301(b) of the Generic Drug User Fee Amendments of 2022);

"(II) for purposes of a fiscal year 2025 adjustment, the Secretary determines that during the period from April 1, 2022, through March 31, 2024—

"(aa) the total number of abbreviated new drug applications submitted was greater than or equal to 2,300; or

"(bb) thirty-five percent or more of abbreviated new drug applications submitted related to complex products (as so defined);

"(III) for purposes of a fiscal year 2026 adjustment, the Secretary determines that during the period from April 1, 2023, through March 31, 2025—

"(aa) the total number of abbreviated new drug applications submitted was greater than or equal to 2,300; or

"(bb) thirty-five percent or more of abbreviated new drug applications submitted related to complex products (as so defined); and

"(IV) for purposes of a fiscal year 2027 adjustment, the Secretary determines that during the period from April 1, 2024, through March 31, 2026—

"(aa) the total number of abbreviated new drug applications submitted was greater than or equal to 2,300; or

"(bb) thirty-five percent or more of abbreviated new drug applications submitted related to complex products (as so defined).

"(D) PUBLICATION IN FEDERAL REGISTER.—The Secretary shall publish in the Federal Register notice referred to in subsection (a) the fee revenue and fees resulting from the adjustment and the methodology under this paragraph.

"(3) OPERATING RESERVE ADJUSTMENT.—

"(A) IN GENERAL.—For fiscal year 2024 and each subsequent fiscal year, the Secretary may, in addition to adjustments under paragraphs (1) and (2), further increase the fee revenue and fees under this section for such fiscal year if such an adjustment is necessary to provide operating reserves of carryover user fees for human generic drug activities for not more than the number of weeks specified in subparagraph (B) with respect to that fiscal year.

"(B) NUMBER OF WEEKS.—The number of weeks specified in this subparagraph is—

"(i) 8 weeks for fiscal year 2024;

"(ii) 9 weeks for fiscal year 2025; and

"(iii) 10 weeks for each of fiscal year 2026 and 2027.

"(C) DECREASE.—If the Secretary has carryover balances for human generic drug activities in excess of 12 weeks of the operating reserves referred to in subparagraph (A), the Secretary shall decrease the fee revenue and fees referred to in such subparagraph to provide for not more than 12 weeks of such operating reserves.

"(D) RATIONALE FOR ADJUSTMENT.—If an adjustment under this paragraph 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 subsection (a) publishing the fee revenue and fees for the fiscal year involved.".

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

(1) in the paragraph heading, by striking "2018 THROUGH 2022" and inserting "2023 THROUGH 2027"; and

(2) by striking "more than 60 days before the first day of each of fiscal years 2018 through 2022" and inserting "later than 60 days before the first day of each of fiscal years 2023 through 2027".

(e) CREDITING AND AVAILABILITY OF FEES.—Section 744B(i)(3) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 379j–42(i)(3)) is amended by striking "fiscal years 2018 through 2022" and inserting "fiscal years 2023 through 2027".

(f) EFFECT OF FAILURE TO PAY FEES.—The heading of paragraph (3) of section 744B(g) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 379j–42(g)) is amended by striking "AND PRIOR APPROVAL SUPPLEMENT FEE".

SEC. 303. 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)(1), by striking "Beginning with fiscal year 2018, not" and inserting "Not";

(2) by striking "Generic Drug User Fee Amendments of 2017" each place it appears and inserting "Generic Drug User Fee Amendments of 2022";

(3) in subsection (a)(2), by striking "Not later than 30 calendar days after the end of the second quarter of fiscal year 2018, and not later than 30 calendar days after the end of each quarter of each fiscal year thereafter" and inserting "Not later than 30 calendar days after the end of each quarter of each fiscal year for which fees are collected under this part";

(4) in subsection (a)(3), by striking "Beginning with fiscal year 2020, the" and inserting "The";

(5) in subsection (b), by striking "Beginning with fiscal year 2018, not" and inserting "Not";

(6) in subsection (c), by striking "Beginning with fiscal year 2018, for" and inserting "For"; and

(7) in subsection (f)—

(A) in paragraph (1), in the matter preceding subparagraph (A), by striking "fiscal year 2022" and inserting "fiscal year 2027"; and

(B) in paragraph (5), by striking "January 15, 2022" and inserting "January 15, 2027".

SEC. 304. 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, 2027.

(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, 2028.

(c) PREVIOUS SUNSET PROVISION.—Effective October 1, 2022, subsections (a) and (b) of section 305 of the FDA Reauthorization Act of 2017 (Public Law 115–52) are repealed.

SEC. 305. EFFECTIVE DATE.

The amendments made by this title shall take effect on October 1, 2022, 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 (21 U.S.C. 379j–41 et seq.) shall be assessed for all abbreviated new drug applications received on or after October 1, 2022, regardless of the date of the enactment of this Act.

SEC. 306. 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 (21 U.S.C. 379j–41 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 abbreviated new drug applications (as defined in such part as of such day) that were received by the Food and Drug Administration within the meaning of section 505(j)(5)(A) of such Act (21 U.S.C. 355(j)(5)(A)), prior approval supplements that were submitted, and drug master files for Type II active pharmaceutical ingredients that were first referenced on or after October 1, 2017, but before October 1, 2022, with respect to assessing and collecting any fee required by such part for a fiscal year prior to fiscal year 2023.

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 2022".

(b) FINDING.—The Congress finds that the fees authorized by the amendments made by 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 (21 U.S.C. 379j–51 et seq.), 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-Arlington-Alexandria, DC–VA–MD–WV; Not Seasonally Adjusted; All items; Annual Index) for September of the preceding fiscal year divided by such Index for September 2011.".

(b) BIOSIMILAR BIOLOGICAL PRODUCT APPLICATION.—Section 744G(4)(B)(iii) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 379j–51(4)(B)(iii)) is amended—

(1) by striking subclause (II) (relating to an allergenic extract product); and

(2) by redesignating subclauses (III) and (IV) as subclauses (II) and (III), respectively.

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

(a) TYPES OF FEES.—

(1) IN GENERAL.—The matter preceding paragraph (1) in section 744H(a) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 379j–52(a)) is amended by striking "fiscal year 2018" and inserting "fiscal year 2023".

(2) INITIAL BIOSIMILAR BIOLOGICAL PRODUCT DEVELOPMENT FEE.—Clauses (iv)(I) and (v)(II) of section 744H(a)(1)(A) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 379j–52(a)(1)(A)) are each amended by striking "5 days" and inserting "7 days".

(3) ANNUAL BIOSIMILAR BIOLOGICAL PRODUCT DEVELOPMENT FEE.—Section 744H(a)(1)(B) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 379j–52(a)(1)(B)) is amended—

(A) in clause (i), by inserting before the period at the end the following: ", except where such product (including, where applicable, ownership of the relevant investigational new drug application) is transferred to a licensee, assignee, or successor of such person, and written notice of such transfer is provided to the Secretary, in which case such licensee, assignee, or successor shall pay the annual biosimilar biological product development fee";

(B) in clause (iii)—

(i) in subclause (I), by striking "or" at the end;

(ii) in subclause (II), by striking the period at the end and inserting "; or"; and

(iii) by adding at the end the following:

"(III) been administratively removed from the biosimilar biological product development program for the product under subparagraph (E)(v).."; and

(C) in clause (iv), by striking "is accepted for filing on or after October 1 of such fiscal year" and inserting "is subsequently accepted for filing".

(4) REACTIVATION FEE.—Section 744H(a)(1)(D) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 379j–52(a)(1)(D)) is amended to read as follows:

"(D) REACTIVATION FEE.—

"(i) IN GENERAL.—A person that has discontinued participation in the biosimilar biological product development program for a product under subparagraph (C), or who has been administratively removed from the biosimilar biological product development program for a product under subparagraph (E)(v), shall, if the person seeks to resume participation in such program, pay all annual biosimilar biological product development fees previously assessed for such product and still owed and a fee (referred to in this section as 'reactivation fee') by the earlier of the following:

"(I) Not later than 7 days after the Secretary grants a request by such person for a biosimilar biological product development meeting for the product (after the date on which such participation was discontinued or the date of administrative removal, as applicable).

"(II) Upon the date of submission (after the date on which such participation was discontinued or the date of administrative removal, as applicable) by such person of an investigational new drug application describing an investigation that the Secretary determines is intended to support a biosimilar biological product application for that product.

"(ii) APPLICATION OF ANNUAL FEE.—A person that pays a reactivation fee for a product shall pay for such product, beginning in the next fiscal year, the annual biosimilar biological product development fee under subparagraph (B), except where such product (including, where applicable, ownership of the relevant investigational new drug application) is transferred to a licensee, assignee, or successor of such person, and written notice of such transfer is provided to the Secretary, in which case such licensee, assignee, or successor shall pay the annual biosimilar biological product development fee.".

(5) EFFECT OF FAILURE TO PAY FEES.—Section 744H(a)(1)(E) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 379j–52(a)(1)(E)) is amended by adding at the end the following:

"(v) ADMINISTRATIVE REMOVAL FROM THE BIOSIMILAR BIOLOGICAL PRODUCT DEVELOPMENT PROGRAM.—If a person has failed to pay an annual biosimilar biological product development fee for a product as required under subparagraph (B) for a period of two consecutive fiscal years, the Secretary may administratively remove such person from the biosimilar biological product development program for the product. At least 30 days prior to administratively removing a person from the biosimilar biological product development program for a product under this clause, the Secretary shall provide written notice to such person of the intended administrative removal.".

(6) BIOSIMILAR BIOLOGICAL PRODUCT APPLICATION FEE.—Section 744H(a)(2)(D) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 379j–52(a)(2)(D)) is amended by inserting after "or was withdrawn" the following: "prior to approval".

(7) BIOSIMILAR BIOLOGICAL PRODUCT PROGRAM FEE.—Section 744H(a)(3) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 379j–52(a)(3)) is amended—

(A) in subparagraph (A)—

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

(ii) by redesignating clause (ii) as clause (iii); and

(iii) by inserting after clause (i) the following:

"(ii) may be dispensed only under prescription pursuant to section 503(b); and"; and

(B) by adding at the end the following:

"(E) MOVEMENT TO DISCONTINUED LIST.—

"(i) DATE OF INCLUSION.—If a written request to place a product on the list referenced in subparagraph (A) of discontinued biosimilar biological products is submitted to the Secretary on behalf of an applicant, and the request identifies the date the product is withdrawn from sale, then for purposes of assessing the biosimilar biological product program fee, the Secretary shall consider such product to have been included on such list on the later of—

"(I) the date such request was received; or

"(II) if the product will be withdrawn from sale on a future date, such future date when the product is withdrawn from sale.

"(ii) TREATMENT AS WITHDRAWN FROM SALE.—For purposes of clause (i), a product shall be considered withdrawn from sale once the applicant has ceased its own distribution of the product, whether or not the applicant has ordered recall of all previously distributed lots of the product, except that a routine, temporary interruption in supply shall not render a product withdrawn from sale.

"(iii) SPECIAL RULE.—If a biosimilar biological product that is identified in a biosimilar biological product application approved as of October 1 of a fiscal year appears, as of October 1 of such fiscal year, on the list referenced in subparagraph (A) of discontinued biosimilar biological products, and on any subsequent day during such fiscal year the biosimilar biological product does not appear on such list, then except as provided in subparagraph (D), each person who is named as the applicant in a biosimilar biological product application with respect to such product shall pay the annual biosimilar biological product program fee established for a fiscal year under subsection (c)(5) for such biosimilar biological product. Notwithstanding subparagraph (B), such fee shall be due on the last business day of such fiscal year and shall be paid only once for each such product for each fiscal year.".

(8) BIOSIMILAR BIOLOGICAL PRODUCT FEE.—Section 744H(a) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 379j–52(a)) is amended by striking paragraph (4).

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

(1) by striking paragraph (1);

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

(3) by amending paragraph (1) (as so redesignated) to read as follows:

"(1) IN GENERAL.—For each of the fiscal years 2023 through 2027, 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 (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 strategic hiring and retention adjustment (as determined under subsection (c)(2));

"(D) the dollar amount equal to the capacity planning adjustment for the fiscal year (as determined under subsection (c)(3));

"(E) the dollar amount equal to the operating reserve adjustment for the fiscal year, if applicable (as determined under subsection (c)(4));

"(F) for fiscal year 2023 an additional amount of $4,428,886; and

"(G) for fiscal year 2024 an additional amount of $320,569.";

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

(A) in the paragraph heading, by striking "; LIMITATIONS ON FEE AMOUNTS";

(B) by striking subparagraph (B); and

(C) by redesignating subparagraphs (C) and (D) as subparagraphs (B) and (C), respectively; and

(5) by amending paragraph (3) (as so redesignated) to read as follows:

"(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 2023, $43,376,922; and

"(B) for fiscal years 2024 through 2027, the dollar amount of the total revenue amount established under paragraph (1) for the previous fiscal year, excluding any adjustments to such revenue amount under subsection (c)(4).".

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

(1) in paragraph (1)—

(A) in subparagraph (A)—

(i) in the matter preceding clause (i), by striking "subsection (b)(2)(B)" and inserting "subsection (b)(1)(B)"; and

(ii) in clause (i), by striking "subsection (b)" and inserting "subsection (b)(1)(A)"; and

(B) in subparagraph (B)(ii), by striking "Washington-Baltimore, DC–MD–VA–WV" and inserting "Washington-Arlington-Alexandria, DC–VA–MD–WV";

(2) by striking paragraphs (2) through (4) and inserting the following:

"(2) STRATEGIC HIRING AND RETENTION ADJUSTMENT.—For each fiscal year, after the annual base revenue under subsection (b)(1)(A) is adjusted for inflation in accordance with paragraph (1), the Secretary shall further increase the fee revenue and fees by $150,000.

"(3) CAPACITY PLANNING ADJUSTMENT.—

"(A) IN GENERAL.—For each fiscal year, the Secretary shall, in addition to the adjustments under paragraphs (1) and (2), further adjust 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) METHODOLOGY.—For purposes of this paragraph, the Secretary shall employ the capacity planning methodology utilized by the Secretary in setting fees for fiscal year 2021, as described in the notice titled 'Biosimilar User Fee Rates for Fiscal Year 2021' published in the Federal Register on August 4, 2020 (85 Fed. Reg. 47220). The workload categories used in applying such methodology in forecasting shall include only the activities described in that notice and, as feasible, additional activities that are also directly related to the direct review of biosimilar biological product applications and supplements, including additional formal meeting types, the direct review of postmarketing commitments and requirements, the direct review of risk evaluation and mitigation strategies, and the direct review of annual reports for approved biosimilar biological products. Subject to the exceptions in the preceding sentence, the Secretary shall not include as workload categories in applying such methodology in forecasting any non-core review activities, including those activities that the Secretary referenced for potential future use in such notice but did not utilize in setting fees for fiscal year 2021.

"(C) LIMITATIONS.—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), (b)(1)(B) (the dollar amount of the inflation adjustment for the fiscal year), and (b)(1)(C) (the dollar amount of the strategic hiring and retention adjustment).

"(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.

"(4) OPERATING RESERVE ADJUSTMENT.—

"(A) INCREASE.—For fiscal year 2023 and subsequent fiscal years, the Secretary shall, in addition to adjustments under paragraphs (1), (2), and (3), further increase the fee revenue and fees if such an adjustment is necessary to provide for at least 10 weeks of operating reserves of carryover user fees for the process for the review of biosimilar biological product applications.

"(B) DECREASE.—

"(i) FISCAL YEAR 2023.—For fiscal year 2023, if the Secretary has carryover balances for such process in excess of 33 weeks of such operating reserves, the Secretary shall decrease such fee revenue and fees to provide for not more than 33 weeks of such operating reserves.

"(ii) FISCAL YEAR 2024.—For fiscal year 2024, if the Secretary has carryover balances for such process in excess of 27 weeks of such operating reserves, the Secretary shall decrease such fee revenue and fees to provide for not more than 27 weeks of such operating reserves.

"(iii) FISCAL YEAR 2025 AND SUBSEQUENT FISCAL YEARS.—For fiscal year 2025 and subsequent fiscal years, if the Secretary has carryover balances for such process in excess of 21 weeks of such operating reserves, the Secretary shall decrease such fee revenue and fees to provide for not more than 21 weeks of such operating reserves.

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

(3) in paragraph (5), in the matter preceding subparagraph (A), by striking "2018" and inserting "2023".

(e) CREDITING AND AVAILABILITY OF FEES.—Subsection (f)(3) of section 744H of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 379j–52(f)(3)) is amended by striking "2018 through 2022" and inserting "2023 through 2027".

(f) WRITTEN REQUESTS FOR WAIVERS AND RETURNS; DISPUTES CONCERNING FEES.—Section 744H(h) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 379j–52(h)) is amended to read as follows:

"(h) WRITTEN REQUESTS FOR WAIVERS AND RETURNS; DISPUTES CONCERNING FEES.—To qualify for consideration for a waiver under subsection (d), or for the return of any fee paid under this section, including if the fee is claimed to have been paid in error, a person shall submit to the Secretary a written request justifying such waiver or return and, except as otherwise specified in this section, such written request shall be submitted to the Secretary not later than 180 days after such fee is due. A request submitted under this paragraph shall include any legal authorities under which the request is made.".

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)(1), by striking "Beginning with fiscal year 2018, not" and inserting "Not";

(2) by striking "Biosimilar User Fee Amendments of 2017" each place it appears and inserting "Biosimilar User Fee Amendments of 2022";

(3) in subsection (a)(2), by striking "Beginning with fiscal year 2018, the" and inserting "The";

(4) in subsection (a)(3)(A), by striking "Not later than 30 calendar days after the end of the second quarter of fiscal year 2018, and not later than 30 calendar days after the end of each quarter of each fiscal year thereafter" and inserting "Not later than 30 calendar days after the end of each quarter of each fiscal year for which fees are collected under this part";

(5) in subsection (b), by striking "Not later than 120 days after the end of fiscal year 2018 and each subsequent fiscal year for which fees are collected under this part" and inserting "Not later than 120 days after the end of each fiscal year for which fees are collected under this part";

(6) in subsection (c), by striking "Beginning with fiscal year 2018, and for" and inserting "For"; and

(7) in subsection (f)—

(A) in paragraph (1), in the matter preceding subparagraph (A), by striking "fiscal year 2022" and inserting "fiscal year 2027"; and

(B) in paragraph (3), by striking "January 15, 2022" and inserting "January 15, 2027".

SEC. 405. SUNSET DATES.

(a) AUTHORIZATION.—Sections 744G and 744H of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 379j–51, 379j–52) shall cease to be effective October 1, 2027.

(b) REPORTING REQUIREMENTS.—Section 744I of the Federal Food, Drug, and Cosmetic Act shall cease to be effective January 31, 2028.

(c) PREVIOUS SUNSET PROVISION.—Effective October 1, 2022, subsections (a) and (b) of section 405 of the FDA Reauthorization Act of 2017 (Public Law 115–52) are repealed.

SEC. 406. EFFECTIVE DATE.

The amendments made by this title shall take effect on October 1, 2022, 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 (21 U.S.C. 379j–51 et seq.) shall be assessed for all biosimilar biological product applications received on or after October 1, 2022, 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 (21 U.S.C. 379j–51 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 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, 2017, but before October 1, 2022, with respect to assessing and collecting any fee required by such part for a fiscal year prior to fiscal year 2023.

TITLE V—IMPROVING DIVERSITY IN CLINICAL STUDIES

SEC. 501. DIVERSITY ACTION PLANS FOR CLINICAL STUDIES.

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

"(5)(A) In order for a new drug that is being studied in a phase 3 study, as defined in section 312.21(c) of title 21, Code of Federal Regulations (or successor regulations), or other pivotal study (other than bioavailability or bioequivalence studies), to be exempt pursuant to this subsection, the sponsor of a clinical investigation of such new drug shall submit to the Secretary a diversity action plan.

"(B) Such diversity action plan shall include—

"(i) the sponsor's goals for enrollment in such clinical study;

"(ii) the sponsor's rationale for such goals; and

"(iii) an explanation of how the sponsor intends to meet such goals.

"(C) The sponsor shall submit such diversity action plan in the form and manner specified in the guidance required by section 524B as soon as practicable but no later than when the sponsor seeks feedback regarding such a phase 3 study or other pivotal study of the drug.

"(D) The Secretary may waive the requirement in subparagraph (A) if the Secretary determines that a waiver is necessary based on what is known about the prevalence of the disease in terms of the patient population that may use the new drug.

"(E) No diversity action plan shall be required for a submission described in section 561.".

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

"(9)(A)(i) In order for a device in a clinical study for which submission of an application for an investigational device exemption is required to be exempt under this subsection, the sponsor of such study shall submit to the Secretary in such application a diversity action plan in the form and manner specified in the guidance required by section 524B.

"(ii) In order for a device in a clinical study for which submission of an application for an investigational device exemption is not required, except for a device being studied as described in section 812.2(c) of title 21, Code of Federal Regulations (or successor regulations), to be exempt under this subsection, the sponsor of such study shall develop and implement a diversity action plan. Such diversity action plan shall be submitted to the Secretary in any premarket notification under section 510(k), request for classification under section 513(f)(2), or application for premarket approval under section 515 for such device.

"(B) A diversity action plan under clause (i) or (ii) of subparagraph (A) shall include—

"(i) the sponsor's goals for enrollment in the clinical study;

"(ii) the sponsor's rationale for such goals; and

"(iii) an explanation of how the sponsor intends to meet such goals.

"(C) The Secretary may waive the requirement in subparagraph (A) or (B) if the Secretary determines that a waiver is necessary based on what is known about the prevalence of the disease in terms of the patient population that may use the device.

"(D) No diversity action plan shall be required for a submission described in section 561.".

(c) GUIDANCE.—Subchapter A of chapter V of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 351 et seq.) is amended by adding at the end the following:

"SEC. 524B. GUIDANCE ON DIVERSITY ACTION PLANS FOR CLINICAL STUDIES.

"(a) IN GENERAL.—The Secretary shall issue guidance relating to—

"(1) the format and content of the diversity action plans required by sections 505(i)(5) and 520(g)(9) pertaining to the sponsor's goals for clinical study enrollment, disaggregated by age group, sex, race, geographic location, socioeconomic status, and ethnicity, including with respect to—

"(A) the rationale for the sponsor's enrollment goals, which may include—

"(i) the estimated prevalence or incidence in the United States of the disease or condition for which the drug or device is being developed or investigated, if such estimated prevalence or incidence is known or can be determined based on available data;

"(ii) what is known about the disease or condition for which the drug or device is being developed or investigated;

"(iii) any relevant pharmacokinetic or pharmacogenomic data;

"(iv) what is known about the patient population for such disease or condition, including, to the extent data is available—

"(I) demographic information, including age group, sex, race, geographic location, socioeconomic status, and ethnicity;

"(II) non-demographic factors, including co-morbidities affecting the patient population; and

"(III) potential barriers to enrolling diverse participants, such as patient population size, geographic location, and socioeconomic status; and

"(v) any other data or information relevant to selecting appropriate enrollment goals, disaggregated by demographic subgroup, such as the inclusion of pregnant and lactating women;

"(B) an explanation for how the sponsor intends to meet such goals, including demographic-specific outreach and enrollment strategies, study-site selection, clinical study inclusion and exclusion practices, and any diversity training for study personnel; and

"(C) procedures for the public posting of key information from the diversity action plan that would be useful to patients and providers on the sponsor's website, as appropriate; and

"(2) how sponsors should include in regular reports to the Secretary—

"(A) the sponsor's progress in meeting the goals referred to in paragraph (1)(A); and

"(B) if the sponsor does not expect to meet such goals—

"(i) any updates needed to be made to a diversity action plan referred to in paragraph (1) to help meet such goals; and

"(ii) the sponsor's reasons for why the sponsor does not expect to meet such goals.

"(b) ISSUANCE.—The Secretary shall—

"(1) not later than 12 months after the date of enactment of this section, issue new draft guidance or update existing draft guidance described in subsection (a); and

"(2) not later than 9 months after closing the comment period on such draft guidance, finalize such guidance.".

(d) APPLICABILITY.—Sections 505(i)(5) and 520(g)(9) of the Federal Food, Drug, and Cosmetic Act, as added by subsections (a) and (b) of this section, apply only with respect to clinical investigations with respect to which enrollment commences after the date that is 180 days after the publication of final guidance under section 524B(b)(2) of the Federal Food, Drug, and Cosmetic Act, as added by subsection (c).

SEC. 502. EVALUATION OF THE NEED FOR FDA AUTHORITY TO MANDATE POSTAPPROVAL STUDIES OR POSTMARKET SURVEILLANCE DUE TO INSUFFICIENT DEMOGRAPHIC SUBGROUP DATA.

(a) IN GENERAL.—Not later than 2 years after the date of publication of final guidance pursuant to section 524B(b)(2) of the Federal Food, Drug, and Cosmetic Act, as added by section 501(c) of this Act, the Secretary of Health and Human Services shall commence an evaluation to assess whether additions or changes to statutes or regulations are warranted to ensure that sponsors conduct post-approval studies or postmarket surveillance where—

(1) premarket studies collected insufficient data for underrepresented subgroups according to the goals specified in the diversity action plans of such sponsors; and

(2) the Secretary has requested additional studies be conducted.

(b) DETERMINATION AND REPORTING.—Not later than 180 days after the commencement of the evaluation under subsection (a), the Secretary of Health and Human Services shall submit a report to the Congress on the outcome of such evaluation, including any recommendations related to additional needed authorities.

SEC. 503. PUBLIC WORKSHOPS TO ENHANCE CLINICAL STUDY DIVERSITY.

(a) IN GENERAL.—Not later than one year after the date of enactment of this Act, the Secretary of Health and Human Services, in consultation with drug sponsors, medical device manufacturers, patients, and other stakeholders, shall convene one or more public workshops to solicit input from stakeholders on increasing the enrollment of historically underrepresented populations in clinical studies and encouraging clinical study participation that reflects the prevalence of the disease or condition among demographic subgroups, where appropriate, and other topics, including—

(1) how and when to collect and present the prevalence or incidence data on a disease or condition by demographic subgroup, including possible sources for such data and methodologies for assessing such data;

(2) considerations for the dissemination, after approval, of information to the public on clinical study enrollment demographic data;

(3) the establishment of goals for enrollment in clinical trials, including the relevance of the estimated prevalence or incidence, as applicable, in the United States of the disease or condition for which the drug or device is being developed; and

(4) approaches to support inclusion of underrepresented populations and to encourage clinical study participation that reflects the population expected to use the drug or device under study, including with respect to—

(A) the establishment of inclusion and exclusion criteria for certain subgroups, such as pregnant and lactating women and individuals with disabilities, including intellectual or developmental disabilities or mental illness;

(B) considerations regarding informed consent with respect to individuals with intellectual or developmental disabilities or mental illness, including ethical and scientific considerations;

(C) the appropriate use of decentralized trials or digital health tools;

(D) clinical endpoints;

(E) biomarker selection; and

(F) studying analysis.

(b) PUBLIC DOCKET.—The Secretary of Health and Human Services shall establish a public comment period to receive written comments related to the topics addressed during each public workshop convened under this section. The public comment period shall remain open for 60 days following the date on which each public workshop is convened.

(c) REPORT.—Not later than 180 days after the close of the public comment period for each public workshop convened under this section, the Secretary of Health and Human Services shall make available on the public website of the Food and Drug Administration a report on the topics discussed at such workshop. The report shall include a summary of, and response to, recommendations raised in such workshop.

SEC. 504. ANNUAL SUMMARY REPORT ON PROGRESS TO INCREASE DIVERSITY IN CLINICAL STUDIES.

(a) IN GENERAL.—Beginning not later than 2 years after the date of enactment of this Act, and each year thereafter, the Secretary of Health and Human Services shall submit to the Congress, and publish on the public website of the Food and Drug Administration, a report that—

(1) summarizes, in aggregate, the diversity action plans received pursuant to section 505(i)(5) or 520(g)(9) of the Federal Food, Drug, and Cosmetic Act, as added by subsection (a) or (b) of section 501 of this Act; and

(2) contains information on—

(A) for drugs, biological products, and devices approved, licensed, cleared, or classified under section 505, 515, 510(k), or 513(f)(2) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355; 360e; 360(k); and 360(f)(2)), or section 351(a) of the Public Health Service Act (42 U.S.C. 262(a)), whether the clinical studies conducted with respect to such applications met the demographic subgroup enrollment goals from the diversity action plan submitted for such applications;

(B) the reasons provided for why enrollment goals from submitted diversity action plans were not met; and

(C) any postmarket studies of a drug or device in a demographic subgroup or subgroups required or recommended by the Secretary based on inadequate premarket clinical study diversity or based on other reasons where

a premarket study lacked adequate diversity, including the status and completion date of any such study.

(b) CONFIDENTIALITY.—Nothing in this section shall be construed as authorizing the Secretary of Health and Human Services to disclose any information that is a trade secret or confidential information subject to section 552(b)(4) of title 5, United States Code, or section 1905 of title 18, United States Code.

SEC. 505. PUBLIC MEETING ON CLINICAL STUDY FLEXIBILITIES INITIATED IN RESPONSE TO COVID–19 PANDEMIC.

(a) IN GENERAL.—Not later than 180 days after the date on which the COVID–19 emergency period ends, the Secretary of Health and Human Services shall convene a public meeting to discuss the recommendations provided by the Food and Drug Administration during the COVID–19 emergency period to mitigate disruption of clinical studies, including recommendations detailed in the guidance entitled "Conduct of Clinical Trials of Medical Products During the COVID–19 Public Health Emergency, Guidance for Industry, Investigators, and Institutional Review Boards", as updated on August 8, 2021, and by any subsequent updates to such guidance. The Secretary of Health and Human Services shall invite to such meeting representatives from the pharmaceutical and medical device industries who sponsored clinical studies during the COVID–19 emergency period and organizations representing patients.

(b) TOPICS.—Not later than 90 days after the date on which the public meeting under subsection (a) is convened, the Secretary of Health and Human Services shall make available on the public website of the Food and Drug Administration a report on the topics discussed at such meeting. Such topics shall include discussion of—

(1) the actions drug sponsors took to utilize such recommendations and the frequency at which such recommendations were employed;

(2) the characteristics of the sponsors, studies, and patient populations impacted by such recommendations;

(3) a consideration of how recommendations intended to mitigate disruption of clinical studies during the COVID–19 emergency period, including any recommendations to consider decentralized clinical studies when appropriate, may have affected access to clinical studies for certain patient populations, especially unrepresented racial and ethnic minorities; and

(4) recommendations for incorporating certain clinical study disruption mitigation recommendations into current or additional guidance to improve clinical study access and enrollment of diverse patient populations.

(c) COVID–19 EMERGENCY PERIOD DEFINED.—In this section, the term "COVID–19 emergency period" has the meaning given the term "emergency period" in section 1135(g)(1)(B) of the Social Security Act (42 U.S.C. 1320b–5(g)(1)(B)).

SEC. 506. DECENTRALIZED CLINICAL STUDIES.

(a) GUIDANCE.—The Secretary of Health and Human Services shall—

(1) not later than 12 months after the date of enactment of this Act, issue draft guidance that addresses considerations for decentralized clinical studies, including considerations regarding the engagement, enrollment, and retention of a meaningfully diverse clinical population, with respect to race, ethnicity, age, sex, and geographic location, when appropriate; and

(2) not later than 1 year after closing the comment period on such draft guidance, finalize such guidance.

(b) CONTENT OF GUIDANCE.—The guidance under subsection (a) shall address the following:

(1) Recommendations for how digital health technology or other remote assessment options, such as telehealth, could support decentralized clinical studies, including guidance on considerations for selecting technological platforms and mediums, data collection and use, data integrity and security, and communication to study participants through digital technology.

(2) Recommendations for subject recruitment and retention, including considerations for sponsors to minimize or reduce burdens for clinical study participants through the use of digital health technology, telehealth, local health care providers and laboratories, or other means.

(3) Recommendations with respect to the evaluation of data collected within a decentralized clinical study setting.

(c) DEFINITION.—In this section, the term "decentralized clinical study" means a clinical study in which some or all of the study-related activities occur at a location separate from the investigator's location.

TITLE VI—GENERIC DRUG COMPETITION

SEC. 601. INCREASING TRANSPARENCY IN GENERIC DRUG APPLICATIONS.

(a) IN GENERAL.—Section 505(j)(3) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(j)(3)) is amended by adding at the end the following:

"(H)(i) Upon request (in controlled correspondence or otherwise) by a person that has submitted or intends to submit an abbreviated application for a new drug under this subsection for which the Secretary has specified in regulation, including under section 314.94(a)(9), title 21, Code of Federal Regulations (or a successor regulation), or recommended in applicable guidance, certain qualitative or quantitative criteria with respect to an inactive ingredient, or on the Secretary's own initiative during the review of such abbreviated application, the Secretary shall inform the person whether such new drug is qualitatively and quantitatively the same as the listed drug.

"(ii) Notwithstanding section 301(j), if the Secretary determines that such new drug is not qualitatively or quantitatively the same as the listed drug, the Secretary shall identify and disclose to the person—

"(I) the ingredient or ingredients that cause the new drug not to be qualitatively or quantitatively the same as the listed drug; and

"(II) for any ingredient for which there is an identified quantitative deviation, the amount of such deviation.

"(iii) If the Secretary determines that such new drug is qualitatively and quantitatively the same as the listed drug, the Secretary shall not change or rescind such determination after the submission of an abbreviated application for such new drug under this subsection unless—

"(I) the formulation of the listed drug has been changed and the Secretary has determined that the prior listed drug formulation was withdrawn for reasons of safety or effectiveness; or

"(II) the Secretary makes a written determination that the prior determination must be changed because an error has been identified.

"(iv) If the Secretary makes a written determination described in clause (iii)(II), the Secretary shall provide notice and a copy of the written determination to the person making the request under clause (i).

"(v) The disclosures required by this subparagraph are disclosures authorized by law including for purposes of section 1905 of title 18, United States Code.".

(b) GUIDANCE.—

(1) IN GENERAL.—Not later than 1 year after the date of enactment of this Act, the Secretary of Health and Human Services shall issue draft guidance, or update guidance, describing how the Secretary will determine whether a new drug is qualitatively and quantitatively the same as the listed drug (as such terms are used in section 505(j)(3)(H) of the Federal Food, Drug, and Cosmetic Act, as added by subsection (a)), including with respect to assessing pH adjusters.

(2) PROCESS.—In issuing guidance as required by paragraph (1), the Secretary of Health and Human Services shall—

(A) publish draft guidance;

(B) provide a period of at least 60 days for comment on the draft guidance; and

(C) after considering any comments received, and not later than one year after the close of the comment period on the draft guidance, publish final guidance.

(c) APPLICABILITY.—Section 505(j)(3)(H) of the Federal Food, Drug, and Cosmetic Act, as added by subsection (a), applies beginning on the date of enactment of this Act, irrespective of the date on which the guidance required by subsection (b) is finalized.

SEC. 602. ENHANCING ACCESS TO AFFORDABLE MEDICINES.

Section 505(j)(10)(A) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(j)(10)(A)) is amended by striking clauses (i) through (iii) and inserting the following:

"(i) a revision to the labeling of the listed drug has been approved by the Secretary within 90 days of when the application is otherwise eligible for approval under this subsection;

"(ii) the sponsor of the application agrees to submit revised labeling for the drug that is the subject of the application not later than 60 days after approval under this subsection of the application;

"(iii) the labeling revision described under clause (i) does not include a change to the 'Warnings' section of the labeling; and".

TITLE VII—RESEARCH, DEVELOPMENT, AND SUPPLY CHAIN IMPROVEMENTS

Subtitle A—In General

SEC. 701. ANIMAL TESTING ALTERNATIVES.

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

(1) in subsection (b)(5)(B)(i)(II), by striking "animal" and inserting "nonclinical tests";

(2) in subsection (i)—

(A) in paragraph (1)(A), by striking "preclinical tests (including tests on animals)" and inserting "nonclinical tests"; and

(B) in paragraph (2)(B), by striking "animal" and inserting "nonclinical tests"; and

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

"(z) NONCLINICAL TEST DEFINED.—For purposes of this section, the term 'nonclinical test' means a test conducted in vitro, in silico, or in chemico, or a nonhuman in vivo test, that occurs before or during the clinical trial phase of the investigation of the safety and effectiveness of a drug. Such test may include the following:

"(1) Cell-based assays.

"(2) Organ chips and microphysiological systems.

"(3) Computer modeling.

"(4) Other nonhuman or human biology-based test methods.

"(5) Animal tests.".

SEC. 702. EMERGING TECHNOLOGY PROGRAM.

Chapter V of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 201 et seq.) is amended by inserting after section 566 of such Act (21 U.S.C. 360bbb–5) the following:

"SEC. 566A. EMERGING TECHNOLOGY PROGRAM.

"(a) PROGRAM ESTABLISHMENT.—

"(1) IN GENERAL.—The Secretary shall establish a program to support the adoption of, and improve the development of, innovative approaches to drug product design and manufacturing.

"(2) ACTIONS.—In carrying out the program under paragraph (1), the Secretary may—

"(A) facilitate and increase communication between public and private entities, consortia, and individuals with respect to innovative drug product design and manufacturing;

"(B) solicit information regarding, and conduct or support research on, innovative approaches to drug product design and manufacturing;

"(C) convene meetings with representatives of industry, academia, other Federal agencies, international agencies, and other interested persons, as appropriate;

"(D) convene working groups to support drug product design and manufacturing research and development;

"(E) support education and training for regulatory staff and scientists related to innovative approaches to drug product design and manufacturing;

"(F) advance regulatory science related to the development and review of innovative approaches to drug product design and manufacturing;

"(G) convene or participate in working groups to support the harmonization of international regulatory requirements related to innovative approaches to drug product design and manufacturing; and

"(H) award grants or contracts to carry out or support the program under paragraph (1).

"(3) GRANTS AND CONTRACTS.—To seek a grant or contract under this section, an entity shall submit an application—

"(A) in such form and manner as the Secretary may require; and

"(B) containing such information as the Secretary may require, including a description of—

"(i) how the entity will conduct the activities to be supported through the grant or contract; and

"(ii) how such activities will further research and development related to, or adoption of, innovative approaches to drug product design and manufacturing.

"(b) GUIDANCE.—The Secretary shall—

"(1) issue or update guidance to help facilitate the adoption of, and advance the development of, innovative approaches to drug product design and manufacturing; and

"(2) include in such guidance descriptions of—

"(A) any regulatory requirements related to the development or review of technologies related to innovative approaches to drug product design and manufacturing, including updates and improvements to such technologies after product approval; and

"(B) data that can be used to demonstrate the identity, safety, purity, and potency of drugs manufactured using such technologies.

"(c) REPORT TO CONGRESS.—Not later than 4 years after the date of enactment of this section, the Secretary shall submit to the Committee on Energy and Commerce of the House of Representatives and the Committee on Health, Education, Labor, and Pensions of the Senate a report containing—

"(1) an annual accounting of the allocation of funds made available to carry out this section;

"(2) a description of how Food and Drug Administration staff were utilized to carry out this section and, as applicable, any challenges or limitations related to staffing;

"(3) the number of public meetings held or participated in by the Food and Drug Administration pursuant to this section, including meetings convened as part of a working group described in subparagraph (D) or (G) of subsection (a)(2), and the topics of each such meeting; and

"(4) the number of drug products approved or licensed, after the date of enactment of this section, using an innovative approach to drug product design and manufacturing.

"(d) AUTHORIZATION OF APPROPRIATIONS.—To carry out this section, there is authorized to be appropriated $20,000,000 for each fiscal year 2023 through 2027.".

SEC. 703. IMPROVING THE TREATMENT OF RARE DISEASES AND CONDITIONS.

(a) REPORT ON ORPHAN DRUG PROGRAM.—

(1) IN GENERAL.—Not later than September 30, 2026, the Secretary shall submit to the Committee on Energy and Commerce of the House of Representatives and the Committee on Health, Education, Labor, and Pensions of the Senate a report summarizing the activities of the Food and Drug Administration related to designating drugs under section 526 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360bb) for a rare disease or condition and approving such drugs under section 505 of such Act (21 U.S.C. 355) or licensing such drugs under section 351 of the Public Health Service Act (42 U.S.C. 262), including—

(A) the number of applications for such drugs under section 505 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355) or section 351 of the Public Health Service Act (42 U.S.C. 262) received by the Food and Drug Administration, the number of such applications accepted and rejected for filing, and the number of such applications pending, approved, and disapproved by the Food and Drug Administration;

(B) a description of trends in drug approvals for rare diseases and conditions across review divisions at the Food and Drug Administration;

(C) the extent to which the Food and Drug Administration is consulting with external experts pursuant to section 569(a)(2) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360bbb–8(a)(2)) on topics pertaining to drugs for a rare disease or condition, including how and when any such consultation is occurring; and

(D) the Food and Drug Administration's efforts to promote best practices in the development of novel treatments for rare diseases, including—

(i) reviewer training on rare disease-related policies, methods, and tools; and

(ii) new regulatory science and coordinated support for patient and stakeholder engagement.

(2) PUBLIC AVAILABILITY.—The Secretary shall make the report under paragraph (1) available to the public, including by posting the report on the website of the Food and Drug Administration.

(3) INFORMATION DISCLOSURE.—Nothing in this subsection shall be construed to authorize the disclosure of information that is prohibited from disclosure under section 1905 of title 18, United States Code, or subject to withholding under paragraph (4) of section 552(b) of title 5, United States Code (commonly referred to as the "Freedom of Information Act").

(b) STUDY ON EUROPEAN UNION SAFETY AND EFFICACY REVIEWS OF DRUGS FOR RARE DISEASES AND CONDITIONS.—

(1) IN GENERAL.—The Secretary of Health and Human Services shall enter into a contract with an appropriate entity to conduct a study on processes for evaluating the safety and efficacy of drugs for rare diseases or conditions in the United States and the European Union, including—

(A) flexibilities, authorities, or mechanisms available to regulators in the United States and the European Union specific to rare diseases or conditions;

(B) the consideration and use of supplemental data submitted during review processes in the United States and the European Union, including data associated with open label extension studies and expanded access programs specific to rare diseases or conditions;

(C) an assessment of collaborative efforts between United States and European Union regulators related to—

(i) product development programs under review;

(ii) policies under development recently issued; and

(iii) scientific information related to product development or regulation; and

(D) recommendations for how Congress can support collaborative efforts described in subparagraph (C).

(2) CONSULTATION.—The contract under paragraph (1) shall provide for consultation with relevant stakeholders, including—

(A) representatives from the Food and Drug Administration and the European Medicines Agency;

(B) rare disease or condition patients; and

(C) patient groups that—

(i) represent rare disease or condition patients; and

(ii) have international patient outreach.

(3) REPORT.—The contract under paragraph (1) shall provide for, not later than 2 years after the date of entering into such contract—

(A) the completion of the study under paragraph (1); and

(B) the submission of a report on the results of such study to the Committee on Energy and Commerce of the House of Representatives and the Committee on Health, Education, Labor, and Pensions of the Senate.

(4) PUBLIC AVAILABILITY.—The contract under paragraph (1) shall provide for the appropriate entity referred to in paragraph (1) to make the report under paragraph (3) available to the public, including by posting the report on the website of the appropriate entity.

(c) PUBLIC MEETING.—

(1) IN GENERAL.—Not later than December 31, 2023, the Secretary of Health and Human Services, acting through the Commissioner of Food and Drugs, shall convene one or more public meetings to solicit input from stakeholders regarding the approaches described in paragraph (2).

(2) APPROACHES.—The public meeting or meetings under paragraph (1) shall address approaches to increasing and improving engagement with rare disease or condition patients, groups representing such patients, rare disease or condition experts, and experts on small population studies, in order to improve the understanding with respect to rare diseases or conditions of—

(A) patient burden;

(B) treatment options; and

(C) side effects of treatments, including—

(i) comparing the side effects of treatments; and

(ii) understanding the risks of side effects relative to the health status of the patient and the progression of the disease or condition.

(3) PUBLIC DOCKET.—The Secretary of Health and Human Services shall establish a public docket to receive written comments related to the approaches addressed during each public meeting under paragraph (1). Such public docket shall remain open for 60 days following the date of each such public meeting.

(4) REPORTS.—Not later than 180 days after each public meeting under paragraph (1), the Commissioner of Food and Drugs shall develop and publish on the website of the Food and Drug Administration a report on—

(A) the approaches discussed at the public meeting; and

(B) any related recommendations.

(d) CONSULTATION ON THE SCIENCE OF SMALL POPULATION STUDIES.—Section 569(a)(2) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360bbb–8(a)(2)) is amended by adding at the end the following:

"(C) SMALL POPULATION STUDIES.—The external experts on the list maintained pursuant to subparagraph (A) may include experts on the science of small population studies.".

(e) STUDY ON SUFFICIENCY AND USE OF FDA MECHANISMS FOR INCORPORATING THE PATIENT AND CLINICIAN PERSPECTIVE IN FDA PROCESSES RELATED TO APPLICATIONS CONCERNING DRUGS FOR RARE DISEASES OR CONDITIONS.—

(1) IN GENERAL.—The Comptroller General of the United States shall conduct a study on the use of Food and Drug Administration mechanisms and tools to ensure that patient and physician perspectives are considered and incorporated throughout the processes of the Food and Drug Administration—

(A) for approving or licensing under section 505 of the Federal Food, Drug, or Cosmetic Act (21 U.S.C. 355) or section 351 of the Public Health Service Act (42 U.S.C. 262) a drug designated as a drug for a rare disease or condition under section 526 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360bb); and

(B) in making any determination related to such a drug's approval, including assessment of the drug's—

(i) safety or effectiveness; or

(ii) postapproval safety monitoring.

(2) TOPICS.—The study under paragraph (1) shall—

(A) identify and compare the processes that the Food and Drug Administration has formally put in place and utilized to gather external expertise (including patients, patient groups, and physicians) related to applications for rare diseases or conditions;

(B) examine tools or mechanisms to improve efforts and initiatives of the Food and Drug Administration to collect and consider such external expertise with respect to applications for rare diseases or conditions throughout the application review and approval or licensure processes, including within internal benefit-risk assessments, advisory committee processes, and postapproval safety monitoring; and

(C) examine processes or alternatives to address or resolve conflicts of interest that impede the Food and Drug Administration in gaining external expert input on rare diseases or conditions with a limited set of clinical and research experts.

(3) REPORT.—Not later than 2 years after the date of enactment of this Act, the Comptroller General of the United States shall—

(A) complete the study under paragraph (1);

(B) submit a report on the results of such study to the Congress; and

(C) include in such report recommendations, if appropriate, for changes to the processes and authorities of the Food and Drug Administration to improve the collection and consideration of external expert opinions of patients, patient groups, and physicians with expertise in rare diseases or conditions.

(f) DEFINITION.—In this section, the term "rare disease or condition" has the meaning given such term in section 526(a)(2) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360bb(a)(2)).

SEC. 704. ANTIFUNGAL RESEARCH AND DEVELOPMENT.

(a) DRAFT GUIDANCE.—Not later than 3 years after the date of the enactment of this Act, the Secretary of Health and Human Services, acting through the Commissioner of Food and Drugs, shall issue draft guidance for industry for the purposes of assisting entities seeking approval under section 505 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355) or licensure under section 351 of the Public Health Service Act (42 U.S.C. 262) of antifungal therapies designed to treat coccidioidomycosis (commonly known as Valley Fever).

(b) FINAL GUIDANCE.—Not later than 18 months after the close of the public comment period on the draft guidance issued pursuant to subsection (a), the Secretary of Health and Human Services, acting through the Commissioner of Food and Drugs, shall finalize the draft guidance.

(c) WORKSHOP.—To assist entities developing preventive vaccines for fungal infections and coccidioidomycosis, the Secretary of Health and Human Services shall hold a public workshop.

SEC. 705. ADVANCING QUALIFIED INFECTIOUS DISEASE PRODUCT INNOVATION.

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

(1) in subsection (c)—

(A) in paragraph (2), by striking "or" at the end;

(B) in paragraph (3), by striking the period at the end and inserting "; or"; and

(C) by adding at the end the following:

"(4) an application pursuant to section 351(a) of the Public Health Service Act.";

(2) in subsection (d)(1), by inserting "of this Act or section 351(a) of the Public Health Service Act" after "section 505(b)"; and

(3) by amending subsection (g) to read as follows:

"(g) QUALIFIED INFECTIOUS DISEASE PRODUCT.—The term 'qualified infectious disease product' means a drug, including an antibacterial or antifungal drug or a biological product, for human use that—

"(1) acts directly on bacteria or fungi or on substances produced by such bacteria or fungi; and

"(2) is intended to treat a serious or life-threatening infection, including such an infection caused by—

"(A) an antibacterial or antifungal resistant pathogen, including novel or emerging infectious pathogens; or

"(B) qualifying pathogens listed by the Secretary under subsection (f).".

(b) PRIORITY REVIEW.—Section 524A(a) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360n–1(a)) is amended by inserting "of this Act or section 351(a) of the Public Health Service Act that requires clinical data (other than bioavailability studies) to demonstrate safety or effectiveness" before the period at the end.

SEC. 706. ADVANCED MANUFACTURING TECHNOLOGIES DESIGNATION PILOT PROGRAM.

Subchapter A of chapter V of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 351 et seq.) is amended by inserting after section 506J (21 U.S.C. 356j) the following:

"SEC. 506K. ADVANCED MANUFACTURING TECHNOLOGIES DESIGNATION PILOT PROGRAM.

"(a) IN GENERAL.—Not later than 1 year after the date of enactment of this section, the Secretary shall initiate a pilot program under which persons may request designation of an advanced manufacturing technology as described in subsection (b).

"(b) DESIGNATION PROCESS.—The Secretary shall establish a process for the designation under this section of methods of manufacturing drugs, including biological products, and active pharmaceutical ingredients of such drugs, as advanced manufacturing technologies. A method of manufacturing, or a combination of manufacturing methods, is eligible for designation as an advanced manufacturing technology if such method or combination of methods incorporates a novel technology, or uses an established technique or technology in a novel way, that will substantially improve the manufacturing process for a drug and maintain equivalent or provide superior drug quality, including by—

"(1) reducing development time for a drug using the designated manufacturing method; or

"(2) increasing or maintaining the supply of—

"(A) a drug that is described in section 506C(a) and is intended to treat a serious or life-threatening condition; or

"(B) a drug that is on the drug shortage list under section 506E.

"(c) EVALUATION AND DESIGNATION OF AN ADVANCED MANUFACTURING TECHNOLOGY.—

"(1) SUBMISSION.—A person who requests designation of a method of manufacturing as an advanced manufacturing technology under this section shall submit to the Secretary data or information demonstrating that the method of manufacturing meets the criteria described in subsection (b) in a particular context of use. The Secretary may facilitate the development and review of such data or information by—

"(A) providing timely advice to, and interactive communication with, such person regarding the development of the method of manufacturing; and

"(B) involving senior managers and experienced staff of the Food and Drug Administration, as appropriate, in a collaborative, cross-disciplinary review of the method of manufacturing, as applicable.

"(2) EVALUATION AND DESIGNATION.—Not later than 180 calendar days after the receipt of a request under paragraph (1), the Secretary shall determine whether to designate such method of manufacturing as an advanced manufacturing technology, in a particular context of use, based on the data and information submitted under paragraph (1) and the criteria described in subsection (b).

"(d) REVIEW OF ADVANCED MANUFACTURING TECHNOLOGIES.—If the Secretary designates a method of manufacturing as an advanced manufacturing technology, the Secretary shall—

"(1) expedite the development and review of an application submitted under section 505 of this Act or section 351 of the Public Health Service Act, including supplemental applications, for drugs that are manufactured using a designated advanced manufacturing technology and could help mitigate or prevent a short-

age or substantially improve manufacturing processes for a drug and maintain equivalent or provide superior drug quality, as described in subsection (b); and

"(2) allow the holder of an advanced technology designation, or a person authorized by the advanced manufacturing technology designation holder, to reference or rely upon, in an application submitted under section 505 of this Act or section 351 of the Public Health Service Act, including a supplemental application, data and information about the designated advanced manufacturing technology for use in manufacturing drugs in the same context of use for which the designation was granted.

"(e) IMPLEMENTATION AND EVALUATION OF ADVANCED MANUFACTURING TECHNOLOGIES PILOT.—

"(1) PUBLIC MEETING.—The Secretary shall publish in the Federal Register a notice of a public meeting, to be held not later than 180 days after the date of enactment of this section, to discuss and obtain input and recommendations from relevant stakeholders regarding—

"(A) the goals and scope of the pilot program, and a suitable framework, procedures, and requirements for such program; and

"(B) ways in which the Food and Drug Administration will support the use of advanced manufacturing technologies and other innovative manufacturing approaches for drugs.

"(2) PILOT PROGRAM GUIDANCE.—

"(A) IN GENERAL.—The Secretary shall—

"(i) not later than 180 days after the public meeting under paragraph (1), issue draft guidance regarding the goals and implementation of the pilot program under this section; and

"(ii) not later than 2 years after the date of enactment of this section, issue final guidance regarding the implementation of such program.

"(B) CONTENT.—The guidance described in subparagraph (A) shall address—

"(i) the process by which a person may request a designation under subsection (b);

"(ii) the data and information that a person requesting such a designation is required to submit under subsection (c), and how the Secretary intends to evaluate such submissions;

"(iii) the process to expedite the development and review of applications under subsection (d); and

"(iv) the criteria described in subsection (b) for eligibility for such a designation.

"(3) REPORT.—Not later than 3 years after the date of enactment of this section and annually thereafter, the Secretary shall publish on the website of the Food and Drug Administration and submit to the Committee on Health, Education, Labor, and Pensions of the Senate and the Committee on Energy and Commerce of the House of Representatives a report containing a description and evaluation of the pilot program being conducted under this section, including the types of innovative manufacturing approaches supported under the program. Such report shall include the following:

"(A) The number of persons that have requested designations and that have been granted designations.

"(B) The number of methods of manufacturing that have been the subject of designation requests and that have been granted designations.

"(C) The average number of calendar days for completion of evaluations under subsection (c)(2).

"(D) An analysis of the factors in data submissions that are relevant to determinations to designate and not to designate after evaluation under subsection (c)(2).

"(E) The number of applications received under section 505 of this Act or section 351 of the Public Health Service Act, including supplemental applications, that have included an advanced manufacturing technology designated under this section, and the number of such applications approved.

"(f) SUNSET.—The Secretary—

"(1) may not consider any requests for designation submitted under subsection (c) after October 1, 2029; and

"(2) may continue all activities under this section with respect to advanced manufacturing technologies that were designated pursuant to subsection (d) prior to such date, if the Secretary determines such activities are in the interest of the public health.".

SEC. 707. PUBLIC WORKSHOP ON CELL THERAPIES.

Not later than 3 years after the date of the enactment of this Act, the Secretary of Health and Human Services, acting through the Commissioner of Food and Drugs, shall convene a public workshop with relevant stakeholders to discuss best practices on generating scientific data necessary to further facilitate the development of certain human cell-, tissue-, and cellular-based medical products (and the latest scientific information about such products) that are regulated as drugs under the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 301 et seq.) and biological products under section 351 of the Public Health Service Act (42 U.S.C. 262), namely, stem-cell and other cellular therapies.

SEC. 708. REAUTHORIZATION OF BEST PHARMACEUTICALS FOR CHILDREN.

Section 409I(d)(1) of the Public Health Service Act (42 U.S.C. 284m(d)(1)) is amended by striking "2018 through 2022" and inserting "2023 through 2027".

SEC. 709. REAUTHORIZATION FOR HUMANITARIAN DEVICE EXEMPTION AND DEMONSTRATION GRANTS FOR IMPROVING PEDIATRIC AVAILABILITY.

(a) HUMANITARIAN DEVICE EXEMPTION.—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 "2022" and inserting "2027".

(b) PEDIATRIC MEDICAL DEVICE SAFETY AND IMPROVEMENT ACT.—Section 305(e) of the Pediatric Medical Device Safety and Improvement Act of 2007 (Public Law 110–85) is amended by striking "2018 through 2022" and inserting "2023 through 2027".

SEC. 710. REAUTHORIZATION OF PROVISION RELATED 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 "2022" and inserting "2027".

SEC. 711. REAUTHORIZATION OF THE CRITICAL PATH PUBLIC-PRIVATE PARTNERSHIP PROGRAM.

Section 566(f) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360bbb–5(f)) is amended by striking "$6,000,000 for each of fiscal years 2018 through 2022" and inserting "$10,000,000 for each of fiscal years 2023 through 2027".

SEC. 712. REAUTHORIZATION OF ORPHAN DRUG GRANTS.

Section 5 of the Orphan Drug Act (21 U.S.C. 360ee) is amended—

(1) in subsection (a)—

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

(B) by inserting before the period at the end the following: ", and (4) developing regulatory science pertaining to the chemistry, manufacturing, and controls of individualized medical products to treat individuals with rare diseases or conditions"; and

(2) in subsection (c), by striking "2018 through 2022" and inserting "2023 through 2027".

SEC. 713. RESEARCH INTO PEDIATRIC USES OF DRUGS; ADDITIONAL AUTHORITIES OF FOOD AND DRUG ADMINISTRATION REGARDING MOLECULARLY TARGETED CANCER DRUGS.

(a) IN GENERAL.—

(1) ADDITIONAL ACTIVE INGREDIENT FOR APPLICATION DRUG; LIMITATION REGARDING NOVEL-COMBINATION APPLICATION DRUG.—Section 505B(a)(3) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355c(a)(3)) is amended—

(A) by redesignating subparagraphs (B) and (C) as subparagraphs (C) and (D), respectively; and

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

"(A) IN GENERAL.—For purposes of paragraph (1)(B), the investigation described in this paragraph is (as determined by the Secretary) a molecularly targeted pediatric cancer investigation of—

"(i) the drug or biological product for which the application referred to in such paragraph is submitted; or

"(ii) such drug or biological product in combination with—

"(I) an active ingredient of a drug or biological product—

"(aa) for which an approved application under section 505(j) under this Act or under section 351(k) of the Public Health Service Act is in effect; and

"(bb) that is determined by the Secretary to be the standard of care for treating a pediatric cancer; or

"(II) an active ingredient of a drug or biological product—

"(aa) for which an approved application under section 505(b) of this Act or section 351(a) of the Public Health Service Act

to treat an adult cancer is in effect and is held by the same person submitting the application under paragraph (1)(B); and

"(bb) that is directed at a molecular target that the Secretary determines to be substantially relevant to the growth or progression of a pediatric cancer.

"(B) ADDITIONAL REQUIREMENTS.—

"(i) DESIGN OF INVESTIGATION.—A molecularly targeted pediatric cancer investigation referred to in subparagraph (A) shall be designed to yield clinically meaningful pediatric study data that is gathered using appropriate formulations for each age group for which the study is required, regarding dosing, safety, and preliminary efficacy to inform potential pediatric labeling.

"(ii) LIMITATION.—An investigation described in subparagraph (A)(ii) may be required only if the drug or biological product for which the application referred to in paragraph (1)(B) contains either—

"(I) a single new active ingredient; or

"(II) more than one active ingredient, if an application for the combination of active ingredients has not previously been approved but each active ingredient has been previously approved to treat an adult cancer.

"(iii) RESULTS OF ALREADY-COMPLETED PRECLINICAL STUDIES OF APPLICATION DRUG.—The Secretary may require that reports on an investigation required pursuant to paragraph (1)(B) include the results of all preclinical studies on which the decision to conduct such investigation was based.

"(iv) RULE OF CONSTRUCTION REGARDING INACTIVE INGREDIENTS.—With respect to a combination of active ingredients referred to in subparagraph (A)(ii), such subparagraph shall not be construed as addressing the use of inactive ingredients with such combination.".

(2) DETERMINATION OF APPLICABLE REQUIREMENTS.—Section 505B(e)(1) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355c(e)(1)) is amended by adding at the end the following: "The Secretary shall determine whether subparagraph (A) or (B) of subsection (a)(1) shall apply with respect to an application before the date on which the applicant is required to submit the initial pediatric study plan under paragraph (2)(A).".

(3) CLARIFYING APPLICABILITY.—Section 505B(a)(1) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355c(a)(1)) is amended by adding at the end the following:

"(C) RULE OF CONSTRUCTION.—No application that is subject to the requirements of subparagraph (B) shall be subject to the requirements of subparagraph (A), and no application (or supplement to an application) that is subject to the requirements of subparagraph (A) shall be subject to the requirements of subparagraph (B).".

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

(A) in paragraph (3)(C), as redesignated by paragraph (1)(A) of this subsection, by striking "investigations described in this paragraph" and inserting "investigations referred to in subparagraph (A)"; and

(B) in paragraph (3)(D), as redesignated by paragraph (1)(A) of this subsection, by striking "the assessments under paragraph (2)(B)" and inserting "the assessments required under paragraph (1)(A)".

(b) GUIDANCE.—The Secretary shall—

(1) not later than 6 months after the date of enactment of this Act, issue draft guidance on the implementation of the requirements in subsection (a); and

(2) not later than 12 months after closing the comment period on such draft guidance, finalize such guidance.

(c) APPLICABILITY.—The amendments made by this section apply with respect to any application under section 505(i) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(i)) and any application under section 351(a) of the Public Health Service Act (42 U.S.C. 262), that is submitted on or after the date that is 3 years after the date of enactment of this Act.

(d) REPORTS TO CONGRESS.—

(1) SECRETARY OF HEALTH AND HUMAN SERVICES.—Not later than 2 years after the date of enactment of this Act, the Secretary of Health and Human Services shall submit to the Committee on Energy and Commerce of the House of Representatives and the Committee on Health, Education, Labor, and Pensions of the Senate a report on the Secretary's efforts, in coordination with industry, to ensure implementation of the amendments made by subsection (a).

(2) GAO STUDY AND REPORT.—

(A) STUDY.—Not later than 2 years after the date of enactment of this Act, the Comptroller General of the United States shall conduct a study of the effectiveness of requiring assessments and investigations described in section 505B of the Federal Food, Drug, and Cosmetic Act (21 U.S.C.355c), as amended by subsection (a), in the development of drugs and biological products for pediatric cancer indications.

(B) FINDINGS.—Not later than 4 years after the date of enactment of this Act, the Comptroller General shall submit to the Committee on Energy and Commerce of the House of Representatives and the Committee on Health, Education, Labor, and Pensions of the Senate a report containing the findings of the study conducted under subparagraph (A).

Subtitle B—Inspections

SEC. 721. FACTORY INSPECTION.

(a) IN GENERAL.—Section 704(a)(1) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 374(a)(1)) is amended by striking "restricted devices" each place it appears and inserting "devices".

(b) RECORDS OR OTHER INFORMATION.—

(1) ESTABLISHMENTS.—Section 704(a)(4)(A) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 374(a)(4)(A)) is amended—

(A) by striking "an establishment that is engaged in the manufacture, preparation, propagation, compounding, or processing of a drug" and inserting "an establishment that is engaged in the manufacture, preparation, propagation, compounding, or processing of a drug or device, or that is subject to inspection under paragraph (5)(C),"; and

(B) by inserting after "a sufficient description of the records requested" the following: "and a rationale for requesting such records or other information in advance of, or in lieu of, an inspection".

(2) GUIDANCE.—

(A) IN GENERAL.—The Secretary of Health and Human Services shall issue or update guidance describing—

(i) circumstances in which the Secretary intends to issue requests for records or other information in advance of, or in lieu of, an inspection under section 704(a)(4) of the Federal Food, Drug, and Cosmetic Act, as amended by paragraph (1);

(ii) processes for responding to such requests electronically or in physical form; and

(iii) factors the Secretary intends to consider in evaluating whether such records and other information are provided within a reasonable timeframe, within reasonable limits, and in a reasonable manner, accounting for resource and other limitations that may exist, including for small businesses.

(B) TIMING.—The Secretary of Health and Human Services shall—

(i) not later than 1 year after the date of enactment of this Act, issue draft guidance under subparagraph (A); and

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

(c) BIORESEARCH MONITORING INSPECTIONS.—

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

"(5) BIORESEARCH MONITORING INSPECTIONS.—

"(A) IN GENERAL.—The Secretary may, to ensure the accuracy and reliability of studies and records or other information described in subparagraph (B) and to assess compliance with applicable requirements under this Act or the Public Health Service Act, enter sites and facilities specified in subparagraph (C) in order to inspect such records or other information.

"(B) INFORMATION SUBJECT TO INSPECTION.—An inspection under this paragraph shall extend to all records and other information related to the studies and submissions described in subparagraph (E), including records and information related to the conduct, results, and analyses of, and the protection of human and animal trial participants participating in, such studies.

"(C) SITES AND FACILITIES SUBJECT TO INSPECTION.—

"(i) SITES AND FACILITIES DESCRIBED.—The sites and facilities subject to inspection by the Secretary under this paragraph are those owned or operated by a person described in clause (ii) and which are (or were) utilized by such person in connection with—

"(I) developing an application or other submission to the Secretary under this Act or the Public Health Service Act related to marketing authorization for a product described in paragraph (1);

"(II) preparing, conducting, or analyzing the results of a study described in subparagraph (E); or

"(III) holding any records or other information described in subparagraph (B).

"(ii) PERSONS DESCRIBED.—A person described in this clause is—

"(I) the sponsor of an application or submission specified in subparagraph (E);

"(II) a person engaged in any activity described in clause (i) on behalf of such a sponsor, through a contract, grant, or other business arrangement with such sponsor;

"(III) an institutional review board, or other individual or entity, engaged by contract, grant, or other business arrangement with a nonsponsor in preparing, collecting, or analyzing records or other information described in subparagraph (B); or

"(IV) any person not otherwise described in this clause that conducts, or has conducted, a study described in subparagraph (E) yielding records or other information described in subparagraph (B).

"(D) CONDITIONS OF INSPECTION.—

"(i) ACCESS TO INFORMATION SUBJECT TO INSPECTION.—Subject to clause (ii), an entity that owns or operates any site or facility subject to inspection under this paragraph shall provide the Secretary with access to records and other information described in subparagraph (B) that is held by or under the control of such entity, including—

"(I) permitting the Secretary to record or copy such information for purposes of this paragraph;

"(II) providing the Secretary with access to any electronic information system utilized by such entity to hold, process, analyze, or transfer any records or other information described in subparagraph (B); and

"(III) permitting the Secretary to inspect the facilities, equipment, written procedures, processes, and conditions through which records or other information described in subparagraph (B) is or was generated, held, processed, analyzed, or transferred.

"(ii) NO EFFECT ON APPLICABILITY OF PROVISIONS FOR PROTECTION OF PROPRIETARY INFORMATION OR TRADE SECRETS.—Nothing in clause (i) shall negate, supersede, or otherwise affect the applicability of provisions, under this or any other Act, preventing or limiting the disclosure of confidential commercial information or other information considered proprietary or trade secret.

"(iii) REASONABLENESS OF INSPECTIONS.—An inspection under this paragraph shall be conducted at reasonable times and within reasonable limits and in a reasonable manner.

"(E) STUDIES AND SUBMISSIONS DESCRIBED.—The studies and submissions described in this subparagraph are each of the following:

"(i) Clinical and nonclinical studies submitted to the Secretary in support of, or otherwise related to, applications and other submissions to the Secretary under this Act or the Public Health Service Act for marketing authorization of a product described in paragraph (1).

"(ii) Postmarket safety activities conducted under this Act or the Public Health Service Act.

"(iii) Any other clinical investigation of—

"(I) a drug subject to section 505 or 512 of this Act or section 351 of the Public Health Service Act; or

"(II) a device subject to section 520(g).

"(iv) Any other submissions made under this Act or the Public Health Service Act with respect to which the Secretary determines an inspection under this paragraph is warranted in the interest of public health.

"(F) CLARIFICATION.—This paragraph clarifies the authority of the Secretary to conduct inspections of the type described in this paragraph and shall not be construed as a basis for inferring that, prior to the date of enactment of this paragraph, the Secretary lacked the authority to conduct such inspections, including under this Act or the Public Health Service Act.".

(2) REVIEW OF PROCESSES AND PRACTICES; GUIDANCE FOR INDUSTRY.—

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

(i) review processes and practices in effect as of the date of enactment of this Act applicable to inspections of foreign and domestic sites and facilities described in subparagraph (C)(i) of section 704(a)(5) of the Federal Food, Drug, and Cosmetic Act, as added by paragraph (1); and

(ii) evaluate whether any updates are needed to facilitate the consistency of such processes and practices.

(B) GUIDANCE.—

(i) IN GENERAL.—The Secretary of Health and Human Services shall issue guidance describing the processes and practices applicable to inspections of sites and facilities described in subparagraph (C)(i) of section 704(a)(5) of the Federal Food, Drug, and Cosmetic Act, as added by paragraph (1), including with respect to the types of records and information required to be provided, best practices for communication between the Food and Drug Administration and industry in advance of or during an inspection or request for records or other information, and other inspections-related conduct, to the extent not specified in existing publicly available Food and Drug Administration guides and manuals for such inspections.

(ii) TIMING.—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 under clause (i); and

(II) not later than 1 year after the close of the public comment period for such draft guidance, issue final guidance under clause (i).

SEC. 722. USES OF CERTAIN EVIDENCE.

Section 703 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 373) is amended by adding at the end the following:

"(c) APPLICABILITY.—The limitations on the Secretary's use of evidence obtained under this section, or any evidence which is directly or indirectly derived from such evidence, in a criminal prosecution of the person from whom such evidence was obtained shall not apply to evidence, including records or other information, obtained under authorities other than this section, unless such limitations are specifically incorporated by reference in such other authorities.".

SEC. 723. IMPROVING FDA INSPECTIONS.

(a) RISK FACTORS FOR ESTABLISHMENTS.—Section 510(h)(4) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360(h)(4)) is amended—

(1) by redesignating subparagraph (F) as subparagraph (G); and

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

"(F) The compliance history of establishments in the country or region in which the establishment is located that are subject to regulation under this Act, including the history of violations related to products exported from such country or region that are subject to such regulation.".

(b) USE OF RECORDS.—Section 704(a)(4) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 374(a)(4)) is amended—

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

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

"(C) The Secretary may rely on any records or other information that the Secretary may inspect under this section to satisfy requirements that may pertain to a preapproval or risk-based surveillance inspection, or to resolve deficiencies identified during such inspections, if applicable and appropriate.".

(c) RECOGNITION OF FOREIGN GOVERNMENT INSPECTIONS.—Section 809 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 384e) is amended—

(1) in subsection (a)(1), by inserting "preapproval or" before "risk-based inspections"; and

(2) by adding at the end the following:

"(c) PERIODIC REVIEW.—

"(1) IN GENERAL.—Beginning not later than 1 year after the date of the enactment of the Food and Drug Amendments of 2022, the Secretary shall periodically assess whether additional arrangements and agreements with a foreign government or an agency of a foreign government, as allowed under this section, are appropriate.

"(2) REPORTS TO CONGRESS.—Beginning not later than 4 years after the date of the enactment of the Food and Drug Amendments of 2022, and every 4 years thereafter, the Secretary shall submit to the Committee on Energy and Commerce of the House of Representatives and the Committee on Health, Education, Labor, and Pensions of the Senate a report describing the findings and conclusions of each review conducted under paragraph (1).".

SEC. 724. GAO REPORT ON INSPECTIONS OF FOREIGN ESTABLISHMENTS MANUFACTURING DRUGS.

(a) IN GENERAL.—Not later than 18 months after the date of the enactment of this Act, the Comptroller General of the United States shall submit to the Committee on Energy and Commerce of the House of Representatives and the Committee on Health, Education, Labor, and Pensions of the Senate a report on inspections conducted by—

(1) the Secretary of Health and Human Services (in this section referred to as the "Secretary") of foreign establishments pursuant to subsections (h) and (i) of section 510 and section 704 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360; 374); or

(2) a foreign government or an agency of a foreign government pursuant to section 809 of such Act (21 U.S.C. 384e).

(b) CONTENTS.—The report conducted under subsection (a) shall include—

(1) what alternative tools, including remote inspections or remote evaluations, other countries are utilizing to facilitate inspections of foreign establishments;

(2) how frequently trusted foreign regulators conduct inspections of foreign facilities that could be useful to the Food and Drug Administration to review in lieu of its own inspections;

(3) how frequently and under what circumstances, including for what types of inspections, the Secretary utilizes existing agreements or arrangements under section 809 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 384e) and whether the use of such agreements could be appropriately expanded;

(4) whether the Secretary has accepted reports of inspections of facilities in China and India conducted by entities with which they have entered into such an agreement or arrangement;

(5) what additional foreign governments or agencies of foreign governments the Secretary has considered entering into a mutual recognition agreement with and, if applicable, reasons why the Secretary declined to enter into a mutual recognition agreement with such foreign governments or agencies;

(6) what tools, if any, the Secretary used to facilitate inspections of domestic facilities that could also be effectively utilized to appropriately inspect foreign facilities;

(7) what steps the Secretary has taken to identify and evaluate tools and strategies the Secretary may use to continue oversight with respect to inspections when in-person inspections are disrupted;

(8) how the Secretary is considering incorporating alternative tools into the inspection activities conducted pursuant to the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 301 et seq.); and

(9) what steps the Secretary has taken to identify and evaluate how the Secretary may use alternative tools to address workforce shortages to carry out such inspection activities.

SEC. 725. UNANNOUNCED FOREIGN FACILITY INSPECTIONS PILOT PROGRAM.

(a) IN GENERAL.—The Secretary of Health and Human Services (referred to in this section as the "Secretary") shall conduct a pilot program under which the Secretary increases the conduct of unannounced surveillance inspections of foreign human drug establishments and evaluates the differences between such inspections of domestic and foreign human drug establishments, including the impact of announcing inspections to persons who own or operate foreign human drug establishments in advance of an inspection. Such pilot program shall evaluate—

(1) differences in the number and type of violations of section 501(a)(2)(B) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 351(a)(2)(B)) identified as a result of unannounced and announced inspections of foreign human drug establishments and any other significant differences between each type of inspection;

(2) costs and benefits associated with conducting announced and unannounced inspections of foreign human drug establishments;

(3) barriers to conducting unannounced inspections of foreign human drug establishments and any challenges to achieving parity between domestic and foreign human drug establishment inspections; and

(4) approaches for mitigating any negative effects of conducting announced inspections of foreign human drug establishments.

(b) PILOT PROGRAM SCOPE.—The inspections evaluated under the pilot program under this section shall be routine surveillance inspections and shall not include inspections conducted as part of the Secretary's evaluation of a request for approval to market a drug submitted under the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 301 et seq.) or the Public Health Service Act (42 U.S.C. 201 et seq.).

(c) PILOT PROGRAM INITIATION.—The Secretary shall initiate the pilot program under this section not later than 180 days after the date of enactment of this Act.

(d) REPORT.—The Secretary shall, not later than 180 days following the completion of the pilot program under this section, make available on the website of the Food and Drug Administration a final report on the pilot program under this section, including—

(1) findings and any associated recommendations with respect to the evaluation under subsection (a), including any recommendations to address identified barriers to conducting unannounced inspections of foreign human drug establishments;

(2) findings and any associated recommendations regarding how the Secretary may achieve parity between domestic and foreign human drug inspections; and

(3) the number of unannounced inspections during the pilot program that would not be unannounced under existing practices.

SEC. 726. 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 "2022" and inserting "2027".

SEC. 727. ENHANCING INTRA-AGENCY COORDINATION AND PUBLIC HEALTH ASSESSMENT WITH REGARD TO COMPLIANCE ACTIVITIES.

(a) COORDINATION.—Section 506D of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 356d) is amended by adding at the end the following:

"(g) COORDINATION.—The Secretary shall ensure timely and effective internal coordination and alignment among the field investigators of the Food and Drug Administration and the staff of the Center for Drug Evaluation and Research's Office of Compliance and Drug Shortage Program regarding—

"(1) the reviews of reports shared pursuant to section 704(b)(2); and

"(2) any feedback or corrective or preventive actions in response to such reports.".

(b) REPORTING.—

(1) IN GENERAL.—Section 506C–1(a)(2) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 356c–1(a)(2)) is amended to read as follows:

"(2)(A) describes the communication between the field investigators of the Food and Drug Administration and the staff of the Center for Drug Evaluation and Research's Office of Compliance and Drug Shortage Program, including the Food and Drug Administration's procedures for enabling and ensuring such communication;

"(B) provides the number of reports described in section 704(b)(2) that were required to be sent to the appropriate offices of the Food and Drug Administration and the number of such reports that were sent; and

"(C) describes the coordination and alignment activities undertaken pursuant to section 506D(g);".

(2) APPLICABILITY.—The amendment made by paragraph (1) shall apply with respect to reports submitted on or after March 31, 2023.

SEC. 728. REPORTING OF MUTUAL RECOGNITION AGREEMENTS FOR INSPECTIONS AND REVIEW ACTIVITIES.

(a) IN GENERAL.—Not later than December 31, 2022, and annually thereafter, the Secretary of Health and Human Services (referred to in this section as the "Secretary") shall publish a report on the public website of the Food and Drug Administration on the utilization of agreements entered into pursuant to section 809 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 384e) or otherwise entered into by the Secretary in the previous fiscal year to recognize inspections between drug regulatory authorities across countries and international regions with analogous review criteria to the Food and Drug Administration, such as the Pharmaceutical Inspection Co-Operation Scheme, the Mutual Recognition Agreement with the European Union, and the Australia-Canada-Singapore-Switzerland-United Kingdom Consortium.

(b) CONTENT.—The report under subsection (a) shall include each of the following:

(1) The total number of establishments that are registered under section 510(i) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360(i)), and the number of such establishments in each region of interest.

(2) The total number of inspections conducted at establishments described in paragraph (1), disaggregated by inspections conducted—

(A) pursuant to an agreement or other recognition described in subsection (a); and

(B) by employees or contractors of the Food and Drug Administration.

(3) Of the inspections described in paragraph (2), the total number of inspections in each region of interest.

(4) Of the inspections in each region of interest reported pursuant to paragraph (3), the number of inspections in each FDA inspection category.

(5) Of the number of inspections reported under each of paragraphs (3) and (4)—

(A) the number of inspections which have been conducted pursuant to an agreement or other recognition described in subsection (a); and

(B) the number of inspections which have been conducted by employees or contractors of the Food and Drug Administration.

(c) DEFINITIONS.—In this section:

(1) FDA INSPECTION CATEGORY.—The term "FDA inspection category" means the following inspection categories:

(A) Inspections to support approvals of changes to the manufacturing process of drugs approved under section 505 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355) or section 351 of the Public Health Service Act (42 U.S.C. 262).

(B) Surveillance inspections.

(C) For-cause inspections.

(2) REGION OF INTEREST.—The term "region of interest" means China, India, the European Union, and any other geographic region as the Secretary determines appropriate.

SEC. 729. ENHANCING TRANSPARENCY OF DRUG FACILITY INSPECTION TIMELINES.

Section 902 of the FDA Reauthorization Act of 2017 (21 U.S.C. 355 note) is amended to read as follows:

"SEC. 902. ANNUAL REPORT ON INSPECTIONS.

"Not later than 120 days after the end of each fiscal year, the Secretary of Health and Human Services shall post on the public website of the Food and Drug Administration information related to inspections of facilities necessary for approval of a drug under subsection (c) or (j) of section 505 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355), approval of a device under section 515 of such Act (21 U.S.C. 360e), or clearance of a device under section 510(k) of such Act (21 U.S.C. 360(k)) that were conducted during the previous fiscal year. Such information shall include the following:

"(1) The median time following a request from staff of the Food and Drug Administration reviewing an application or report to the beginning of the inspection, including—

"(A) the median time for drugs described in section 505(j)(11)(A)(i) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(j)(11)(A)(i));

"(B) the median time for drugs described in section 506C(a) of such Act (21 U.S.C. 356c(a)) only; and

"(C) the median time for drugs on the drug shortage list in effect under section 506E of such Act (21 U.S.C. 356e).

"(2) The median time from the issuance of a report pursuant to section 704(b) of such Act (21 U.S.C. 374(b)) to the sending of a warning letter, issuance of an import alert, or holding of a regulatory meeting for inspections for which the Secretary concluded that regulatory or enforcement action was indicated, including the median time for each category of drugs listed in subparagraphs (A) through (C) of paragraph (1).

"(3) The median time from the sending of a warning letter, issuance of an import alert, or holding of a regulatory meeting to resolution of the actions indicated to address the conditions or practices observed during an inspection.

"(4) The number of facilities that failed to implement adequate corrective or preventive actions following a report pursuant to such section 704(b), resulting in a withhold recommendation, including the number of such times for each category of drugs listed in subparagraphs (A) through (C) of paragraph (1).".

TITLE VIII—TRANSPARENCY, PROGRAM INTEGRITY, AND REGULATORY IMPROVEMENTS

SEC. 801. PROMPT REPORTS OF MARKETING STATUS BY HOLDERS OF APPROVED APPLICATIONS FOR BIOLOGICAL PRODUCTS.

(a) IN GENERAL.—Section 506I of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 356i) is amended—

(1) in subsection (a)—

(A) in the matter preceding paragraph (1), by striking "The holder of an application approved under subsection (c) or (j) of section 505" and inserting "The holder of an application approved under subsection (c) or (j) of section

505 of this Act or subsection (a) or (k) of section 351 of the Public Health Service Act";

(B) in paragraph (2), by striking "established name" and inserting "established name (for biological products, by proper name)"; and

(C) in paragraph (3), by striking "or abbreviated application number" and inserting ", abbreviated application number, or biologics license application number"; and

(2) in subsection (b)—

(A) in the matter preceding paragraph (1), by striking "The holder of an application approved under subsection (c) or (j)" and inserting "The holder of an application approved under subsection (c) or (j) of section 505 of this Act or subsection (a) or (k) of section 351 of the Public Health Service Act";

(B) in paragraph (1), by striking "established name" and inserting "established name (for biological products, by proper name)"; and

(C) in paragraph (2), by striking "or abbreviated application number" and inserting ", abbreviated application number, or biologics license application number".

(b) ADDITIONAL ONE-TIME REPORT.—Subsection (c) of section 506I of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 356i) is amended to read as follows:

"(c) ADDITIONAL ONE-TIME REPORT.—Within 180 days of the date of enactment of the Food and Drug Amendments of 2022, all holders of applications approved under subsection (a) or (k) of section 351 of the Public Health Service Act shall review the information in the list published under section 351(k)(9)(A) and shall submit a written notice to the Secretary—

"(1) stating that all of the application holder's biological products in the list published under section 351(k)(9)(A) that are not listed as discontinued are available for sale; or

"(2) including the information required pursuant to subsection (a) or (b), as applicable, for each of the application holder's biological products that are in the list published under section 351(k)(9)(A) and not listed as discontinued, but have been discontinued from sale or never have been available for sale.".

(c) PURPLE BOOK.—Section 506I of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 356i) is amended—

(1) by striking subsection (d) and inserting the following:

"(d) FAILURE TO MEET REQUIREMENTS.—If a holder of an approved application fails to submit the information required under subsection (a), (b), or (c), the Secretary may—

"(1) move the application holder's drugs from the active section of the list published under section 505(j)(7)(A) to the discontinued section of the list, except that the Secretary shall remove from the list in accordance with section 505(j)(7)(C) drugs the Secretary determines have been withdrawn from sale for reasons of safety or effectiveness; and

"(2) identify the application holder's biological products as discontinued in the list published under section 351(k)(9)(A) of the Public Health Service Act, except that the Secretary shall remove from the list in accordance with section 351(k)(9)(B) of such Act biological products for which the license has been revoked or suspended for reasons of safety, purity, or potency."; and

(2) in subsection (e)—

(A) by inserting after the first sentence the following: "The Secretary shall update the list published under section 351(k)(9)(A) of the Public Health Service Act based on information provided under subsections (a), (b), and (c) by identifying as discontinued biological products that are not available for sale, except that biological products for which the license has been revoked or suspended for safety, purity, or potency reasons shall be removed from the list in accordance with section 351(k)(9)(B) of the Public Health Service Act.";

(B) by striking "monthly updates to the list" and inserting "monthly updates to the lists referred to in the preceding sentences"; and

(C) by striking "and shall update the list based on" and inserting "and shall update such lists based on".

(d) TECHNICAL CORRECTIONS.—Section 506I(e) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 356i(e)) is amended—

(1) by striking "subsection 505(j)(7)(A)" and inserting "section 505(j)(7)(A)"; and

(2) by striking "subsection 505(j)(7)(C)" and inserting "section 505(j)(7)(C)".

SEC. 802. ENCOURAGING BLOOD DONATION.

(a) STREAMLINING PATIENT AND BLOOD DONOR INPUT.—Section 3003 of the 21st Century Cures Act (21 U.S.C. 360bbb–8c note) is amended to read as follows:

"SEC. 3003. STREAMLINING PATIENT AND BLOOD DONOR INPUT.

"Chapter 35 of title 44, United States Code, shall not apply to the collection of information to which a response is voluntary, to solicit—

"(1) the views and perspectives of patients under section 569C of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360bbb–8c) (as amended by section 3001) or section 3002; or

"(2) information from blood donors or potential blood donors to support the development of recommendations by the Secretary of Health and Human Services acting through the Commissioner of Food and Drugs concerning blood donation.".

(b) CLERICAL AMENDMENT.—The table of contents in section 1(b) of the 21st Century Cures Act is amended by striking the item relating to section 3003 and inserting the following:

"Sec. 3003. Streamlining patient and blood donor input.".

SEC. 803. REGULATION OF CERTAIN PRODUCTS AS DRUGS.

Section 503 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 353) is amended by adding at the end the following:

"(h)(1) Any contrast agent, radioactive drug, or OTC monograph drug shall be deemed to be a drug under section 201(g) and not a device under section 201(h).

"(2) For purposes of this subsection:

"(A) The term 'contrast agent' means an article that is intended for use in conjunction with a medical imaging device, and—

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

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

"(B) The term 'radioactive drug' has the meaning given such term in section 310.3(n) of title 21, Code of Federal Regulations (or any successor regulations), except that such term does not include—

"(i) an implant or article similar to an implant;

"(ii) an article that applies radiation from outside of the body; or

"(iii) the radiation source of an article described in clause (i) or (ii).

"(C) The term 'OTC monograph drug' has the meaning given such term in section 744L.

"(3) Nothing in this subsection shall be construed as allowing for the classification of a product as a drug (as defined in section 201(g)) if such product—

"(A) is not described in paragraph (1); and

"(B) meets the definition of a device under section 201(h),

unless another provision of this Act otherwise indicates a different classification.".

SEC. 804. POSTAPPROVAL STUDIES AND PROGRAM INTEGRITY FOR ACCELERATED APPROVAL DRUGS.

(a) IN GENERAL.—Section 506(c) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 356(c)) is amended—

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

"(2) LIMITATION.—

"(A) IN GENERAL.—Approval of a product under this subsection may be subject to 1 or both of the following requirements:

"(i) That the sponsor conduct an appropriate postapproval study or studies (which may be augmented or supported by real world evidence) to verify and describe the predicted effect on irreversible morbidity or mortality or other clinical benefit.

"(ii) That the sponsor submit copies of all promotional materials related to the product during the preapproval review period and, following approval and for such period thereafter as the Secretary determines to be appropriate, at least 30 days prior to dissemination of the materials.

"(B) STUDIES NOT REQUIRED.—If the Secretary does not require that the sponsor of a product approved under accelerated approval conduct a postapproval study under this paragraph, the Secretary shall publish on the website of the Food and Drug Administration the rationale for why such study is not appropriate or necessary.

"(C) POSTAPPROVAL STUDY CONDITIONS.—Not later than the time of approval of a product under accelerated approval, the Secretary shall specify the conditions for a postapproval study or studies required to be conducted under this paragraph with respect to such product, which may include en-

rollment targets, the study protocol, and milestones, including the target date of study completion.

"(D) STUDIES BEGUN BEFORE APPROVAL.—The Secretary may require such study or studies to be underway prior to approval."; and

(2) by striking paragraph (3) and inserting the following:

"(3) EXPEDITED WITHDRAWAL OF APPROVAL.—

"(A) IN GENERAL.—The Secretary may withdraw approval of a product approved under accelerated approval using expedited procedures described in subparagraph (B), if—

"(i) the sponsor fails to conduct any required postapproval study of the product with due diligence, including with respect to conditions specified by the Secretary under paragraph (2)(C);

"(ii) a study required to verify and describe the predicted effect on irreversible morbidity or mortality or other clinical benefit of the product fails to verify and describe such effect or benefit;

"(iii) other evidence demonstrates that the product is not shown to be safe or effective under the conditions of use; or

"(iv) the sponsor disseminates false or misleading promotional materials with respect to the product.

"(B) EXPEDITED PROCEDURES DESCRIBED.—Expedited procedures described in this subparagraph shall consist of, prior to the withdrawal of accelerated approval—

"(i) providing the sponsor with—

"(I) due notice;

"(II) an explanation for the proposed withdrawal;

"(III) an opportunity for a meeting with the Commissioner of Food and Drugs or the Commissioner's designee; and

"(IV) an opportunity for written appeal to—

"(aa) the Commissioner of Food and Drugs; or

"(bb) a designee of the Commissioner who has not participated in the proposed withdrawal of approval (other than a meeting pursuant to subclause (III)) and is not a subordinate of an individual (other than the Commissioner) who participated in such proposed withdrawal;

"(ii) providing an opportunity for public comment on the notice proposing to withdraw approval;

"(iii) the publication of a summary of the public comments received, and the Secretary's response to such comments, on the website of the Food and Drug Administration; and

"(iv) convening and consulting an advisory committee on issues related to the proposed withdrawal, if requested by the sponsor and if no such advisory committee has previously advised the Secretary on such issues with respect to the withdrawal of the product prior to the sponsor's request.

"(4) LABELING.—

"(A) IN GENERAL.—Subject to subparagraph (B), the labeling for a product approved under accelerated approval shall include—

"(i) a statement indicating that the product was approved under accelerated approval;

"(ii) a statement indicating that continued approval of the product is subject to postmarketing studies to verify clinical benefit;

"(iii) identification of the surrogate or intermediate endpoint or endpoints that supported approval and any known limitations of such surrogate or intermediate endpoint or endpoints in determining clinical benefit; and

"(iv) a succinct description of the product and any uncertainty about anticipated clinical benefit and a discussion of available evidence with respect to such clinical benefit.

"(B) APPLICABILITY.—The labeling requirements of subparagraph (A) shall apply only to products approved under accelerated approval for which the predicted effect on irreversible morbidity or mortality or other clinical benefit has not been verified.

"(C) RULE OF CONSTRUCTION.—With respect to any application pending before the Secretary on the date of enactment of the Food and Drug Amendments of 2022, the Secretary shall allow any applicable changes to the product labeling required to comply with subparagraph (A) to be made by supplement after the approval of such application.

"(5) REPORTING.—Not later than September 30, 2025, the Secretary shall submit to the Committee on Energy and Commerce of the House of Representatives

and the Committee on Health, Education, Labor, and Pensions of the Senate a report describing circumstances in which the Secretary considered real world evidence submitted to support postapproval studies required under this subsection that were completed after the date of enactment of the Food and Drug Amendments of 2022.".

(b) REPORTS OF POSTMARKETING STUDIES.—Section 506B(a) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 356b(a)) is amended—

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

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

"(2) ACCELERATED APPROVAL.—Notwithstanding paragraph (1), a sponsor of a drug approved under accelerated approval shall submit to the Secretary a report of the progress of any study required under section 506(c), including progress toward enrollment targets, milestones, and other information as required by the Secretary, not later than 180 days after the approval of such drug and not less frequently than every 180 days thereafter, until the study is completed or terminated.".

(c) GUIDANCE.—

(1) IN GENERAL.—The Secretary of Health and Human Services shall issue guidance describing—

(A) how sponsor questions related to the identification of novel surrogate or intermediate clinical endpoints may be addressed in early-stage development meetings with the Food and Drug Administration;

(B) the use of novel clinical trial designs that may be used to conduct appropriate postapproval studies as may be required under section 506(c)(2)(A) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 356(c)(2)(A)), as amended by subsection (a); and

(C) the expedited procedures described in section 506(c)(3)(B) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 356(c)(3)(B)).

(2) FINAL GUIDANCE.—The Secretary shall issue—

(A) draft guidance under paragraph (1) not later than 18 months after the date of enactment of this Act; and

(B) final guidance not later than 1 year after the close of the public comment period on such draft guidance.

(d) RARE DISEASE ENDPOINT ADVANCEMENT PILOT.—

(1) IN GENERAL.—The Secretary of Health and Human Services shall establish a pilot program under which the Secretary will establish procedures to provide increased interaction with sponsors of rare disease drug development programs for purposes of advancing the development of efficacy endpoints, including surrogate and intermediate endpoints, for drugs intended to treat rare diseases, including through—

(A) determining eligibility of participants for such a program; and

(B) developing and implementing a process for applying to, and participating in, such a program.

(2) PUBLIC WORKSHOPS.—The Secretary shall conduct up to 3 public workshops, which shall be completed not later than September 30, 2026, to discuss topics relevant to the development of endpoints for rare diseases, which may include discussions about—

(A) novel endpoints developed through the pilot program established under this subsection; and

(B) as appropriate, the use of real world evidence and real world data to support the validation of efficacy endpoints, including surrogate and intermediate endpoints, for rare diseases.

(3) REPORT.—Not later than September 30, 2027, the Secretary shall submit to the Committee on Energy and Commerce of the House of Representatives and the Committee on Health, Education, Labor, and Pensions of the Senate a report describing the outcomes of the pilot program established under this subsection.

(4) GUIDANCE.—Not later than September 30, 2027, the Secretary shall issue guidance describing best practices and strategies for development of efficacy endpoints, including surrogate and intermediate endpoints, for rare diseases.

(5) SUNSET.—The Secretary may not accept any new application or request to participate in the program established by this subsection on or after October 1, 2027.

SEC. 805. FACILITATING THE USE OF REAL WORLD EVIDENCE.

(a) GUIDANCE.—Not later than 1 year after the date of the enactment of this Act, the Secretary of Health and Human Services shall issue, or revise existing, guidance on considerations for the use of real world data and real world evidence to support regulatory decisionmaking, as follows:

(1) With respect to drugs, such guidance shall address—

(A) the use of such data and evidence to support the approval of a drug application under section 505 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355) or a biological product application under section 351 of the Public Health Service Act (42 U.S.C. 262), or to support an investigational use exemption under section 505(i) of the Federal Food, Drug, and Cosmetic Act or section 351(a)(3) of the Public Health Service Act; and

(B) the use of such data and evidence obtained as a result of the use of drugs authorized for emergency use under section 564 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360bbb–3) in such applications, submissions, or requests; and

(C) standards and methodologies which may be used for collection and analysis of real world evidence included in such applications, submissions, or requests, as appropriate.

(2) With respect to devices, such guidance shall address—

(A) the use of such data and evidence to support the approval, clearance, or classification of a device pursuant to an application or submission submitted under section 510(k), 513(f)(2), or 515 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360(k), 360c(f)(2), 360e), or to support an investigational use exemption under section 520(g) of such Act (21 U.S.C. 360j(g));

(B) the use of such data and evidence obtained as a result of the use of devices authorized for emergency use under section 564 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360bbb–3), in such applications, submissions, or requests; and

(C) standards and methodologies which may be used for collection and analysis of real world evidence included in such applications, submissions, or requests, as appropriate.

(b) REPORT TO CONGRESS.—Not later than 2 years after the termination of the public health emergency determination by the Secretary of Health and Human Services under section 564 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360bbb–3) on February 4, 2020, with respect to the Coronavirus Disease 2019 (COVID–19), the Secretary shall submit a report to the Committee on Energy and Commerce of the House of Representatives and the Committee on Health, Education, Labor, and Pensions of the Senate on—

(1) the number of applications, submissions, or requests submitted for clearance or approval under section 505, 510(k), 513(f)(2), or 515 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355, 360(k), 360c(f)(2), 360e) or section 351 of the Public Health Service Act, for which an authorization under section 564 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360bbb–3) was previously granted;

(2) of the number of applications so submitted, the number of such applications—

(A) for which real world evidence was submitted and used to support a regulatory decision; and

(B) for which real world evidence was submitted and determined to be insufficient to support a regulatory decision; and

(3) a summary explanation of why, in the case of applications described in paragraph (2)(B), real world evidence could not be used to support regulatory decisions.

(c) INFORMATION DISCLOSURE.—Nothing in this section shall be construed to authorize the disclosure of information that is prohibited from disclosure under section 1905 of title 18, United States Code, or subject to withholding under subsection (b)(4) of section 552 of title 5, United States Code (commonly referred to as the "Freedom of Information Act").

SEC. 806. DUAL SUBMISSION FOR CERTAIN DEVICES.

Section 513 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360c) is amended by adding at the end the following:

"(k) For a device authorized for emergency use under section 564 for which, in accordance with section 564(m), the Secretary has deemed a laboratory examination or procedure associated with such device to be in the category of examinations and procedures described in section 353(d)(3) of the Public Health Service Act, the sponsor of such device may, when submitting a request for classification under section 513(f)(2), submit a single submission containing—

"(1) the information needed for such a request; and

"(2) sufficient information to enable the Secretary to determine whether such laboratory examination or procedure satisfies the criteria to be categorized under section 353(d)(3) of the Public Health Service Act.".

SEC. 807. MEDICAL DEVICES ADVISORY COMMITTEE MEETINGS.

(a) IN GENERAL.—The Secretary shall convene one or more panels of the Medical Devices Advisory Committee not less than once per year for the purpose of providing advice to the Secretary on topics related to medical devices used in pandemic preparedness and response, including topics related to in vitro diagnostics.

(b) REQUIRED PANEL MEMBER.—A panel convened under subsection (a) shall include at least 1 population health-specific representative.

(c) SUNSET.—This section shall cease to be effective on October 1, 2027.

SEC. 808. ENSURING CYBERSECURITY OF MEDICAL DEVICES.

(a) IN GENERAL.—Subchapter A of chapter V of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 351 et seq.), as amended by section 501, is further amended by adding at the end the following:

"SEC. 524C. ENSURING CYBERSECURITY OF DEVICES.

"(a) IN GENERAL.—For purposes of ensuring cybersecurity throughout the lifecycle of a cyber device, any person who submits a premarket submission for the cyber device shall include such information as the Secretary may require to ensure that the cyber device meets such cybersecurity requirements as the Secretary determines to be appropriate to demonstrate a reasonable assurance of safety and effectiveness, including at a minimum the cybersecurity requirements under subsection (b).

"(b) CYBERSECURITY REQUIREMENTS.—At a minimum, the manufacturer of a cyber device shall meet the following cybersecurity requirements:

"(1) The manufacturer shall have a plan to appropriately monitor, identify, and address in a reasonable time postmarket cybersecurity vulnerabilities and exploits, including coordinated vulnerability disclosure and procedures.

"(2) The manufacturer shall design, develop, and maintain processes and procedures to ensure the device and related systems are cybersecure, and shall make available updates and patches to the cyber device and related systems throughout the lifecycle of the cyber device to address—

"(A) on a reasonably justified regular cycle, known unacceptable vulnerabilities; and

"(B) as soon as possible out of cycle, critical vulnerabilities that could cause uncontrolled risks.

"(3) The manufacturer shall provide in the labeling of the cyber device a software bill of materials, including commercial, open-source, and off-the-shelf software components.

"(4) The manufacturer shall comply with such other requirements as the Secretary may require to demonstrate reasonable assurance of the safety and effectiveness of the device for purposes of cybersecurity, which the Secretary may require by an order published in the Federal Register.

"(c) SUBSTANTIAL EQUIVALENCE.—In making a determination of substantial equivalence under section 513(i) for a cyber device, the Secretary may—

"(1) find that cybersecurity information for the cyber device described in the relevant premarket submission in the cyber device's use environment is inadequate; and

"(2) issue a nonsubstantial equivalence determination based on this finding.

"(d) DEFINITION.—In this section:

"(1) CYBER DEVICE.—The term 'cyber device' means a device that—

"(A) includes software, including software as or in a device;

"(B) has the ability to connect to the internet; or

"(C) contains any such technological characteristics that could be vulnerable to cybersecurity threats.

"(2) LIFECYCLE OF THE CYBER DEVICE.—The term 'lifecycle of the cyber device' includes the postmarket lifecycle of the cyber device.

"(3) PREMARKET SUBMISSION.—The term 'premarket submission' means any submission under section 510(k), 513, 515(c), 515(f), or 520(m).

"(e) EXEMPTION.—The Secretary may identify devices or types of devices that are exempt from meeting the cybersecurity requirements established by this section and regulations promulgated pursuant to this section. The Secretary shall publish in the Federal Register, and update, as appropriate, a list of the devices and types of devices so identified by the Secretary.".

(b) PROHIBITED ACT.—Section 301(q) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 331(q)) is amended by adding at the end the following:

"(3) The failure to comply with any requirement under section 524C (relating to ensuring device cybersecurity).".

(c) ADULTERATION.—Section 501 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 351) is amended by inserting after paragraph (j) the following:

"(k) If it is a device subject to the requirements set forth in section 524C (relating to ensuring device cybersecurity) and fails to comply with any requirement under that section.".

(d) MISBRANDING.—Section 502(t) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 352(t)) is amended—

(1) by striking "or (3)" and inserting "(3)"; and

(2) by inserting before the period at the end the following: ", or (4) to furnish a software bill of materials as required under section 524C (relating to ensuring device cybersecurity)".

SEC. 809. PUBLIC DOCKET ON PROPOSED CHANGES TO THIRD-PARTY VENDORS.

(a) IN GENERAL.—

(1) OPENING PUBLIC DOCKET.—Not later than 90 days after the date of enactment of this Act, the Secretary of Health and Human Services shall open a single public docket to solicit comments on factors that generally should be considered by the Secretary when reviewing requests from sponsors of drugs subject to risk evaluation and mitigation strategies to change third-party vendors engaged by sponsors to aid in implementation and management of the strategies.

(2) FACTORS.—Such factors include the potential effects of changes in third-party vendors on—

(A) patient access; and

(B) prescribing and administration of the drugs by health care providers.

(3) CLOSING PUBLIC DOCKET.—The Secretary of Health and Human Services may close such public docket not earlier than 90 days after such docket is opened.

(4) NO DELAY.—Nothing in this section shall delay agency action on any modification to a risk evaluation and mitigation strategy.

(b) GAO REPORT.—Not later than December 31, 2026, the Comptroller General of the United States shall submit to the Committee on Energy and Commerce of the House of Representatives and the Committee on Health, Education, Labor, and Pensions of the Senate a report on—

(1) the number of changes in third-party vendors (engaged by sponsors to aid implementation and management of risk evaluation and mitigation strategies) for an approved risk evaluation and mitigation strategy the Secretary of Health and Human Services has approved under section 505–1(h) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355–1(h));

(2) any issues affecting patient access to the drug that is subject to the strategy or considerations with respect to the administration or prescribing of such drug by health care providers that arose as a result of such modifications; and

(3) how such issues were resolved, as applicable.

SEC. 810. FACILITATING EXCHANGE OF PRODUCT INFORMATION PRIOR TO APPROVAL.

(a) IN GENERAL.—Section 502 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 352) is amended—

(1) in paragraph (a)—

(A) by striking "drugs for coverage" and inserting "drugs or devices for coverage"; and

(B) by striking "drug" each place it appears and inserting "drug or device", respectively;

(2) in paragraphs (a)(1) and (a)(2)(B), by striking "under section 505 or under section 351 of the Public Health Service Act" and inserting "under section 505, 510(k), 513(f)(2), or 515 of this Act or section 351 of the Public Health Service Act";

(3) in paragraph (a)(1)—

(A) by striking "under section 505 or under section 351(a) of the Public Health Service Act" and inserting "under section 505, 510(k), 513(f)(2), or 515 of this Act or section 351 of the Public Health Service Act"; and

(B) by striking "in section 505(a) or in subsections (a) and (k) of section 351 of the Public Health Service Act" and inserting "in section 505, 510(k), 513(f)(2), or 515 of this Act or section 351 of the Public Health Service Act"; and

(4) by adding at the end the following:

"(gg)(1) Unless its labeling bears adequate directions for use in accordance with paragraph (f), except that (in addition to drugs or devices that conform with exemptions pursuant to such paragraph) no drug or device shall be deemed to be misbranded under such paragraph through the provision of product information to a payor, formulary committee, or other similar entity with knowledge and expertise in the area of health care economic analysis carrying out its responsibilities for the selection of drugs or devices for coverage or reimbursement if the product information relates to an investigational drug or device or investigational use of a drug or

device that is approved, cleared, granted marketing authorization, or licensed under section 505, 510(k), 513(f)(2), or 515 of this Act or section 351 of the Public Health Service Act (as applicable), provided—

"(A) the product information includes—

"(i) a clear statement that the investigational drug or device or investigational use of a drug or device has not been approved, cleared, granted marketing authorization, or licensed under section 505, 510(k), 513(f)(2), or 515 of this Act or section 351 of the Public Health Service Act (as applicable) and that the safety and effectiveness of the drug or device or use has not been established;

"(ii) information related to the stage of development of the drug or device involved, such as—

"(I) the status of any study or studies in which the investigational drug or device or investigational use is being investigated;

"(II) how the study or studies relate to the overall plan for the development of the drug or device; and

"(III) whether an application, premarket notification, or request for classification for the investigational drug or device or investigational use has been submitted to the Secretary and when such a submission is planned;

"(iii) in the case of information that includes factual presentations of results from studies, which shall not be selectively presented, a description of—

"(I) all material aspects of study design, methodology, and results; and

"(II) all material limitations related to the study design, methodology, and results;

"(iv) where applicable, a prominent statement disclosing the indication or indications for which the Secretary has approved, granted marketing authorization, cleared, or licensed the product pursuant to section 505, 510(k), 513(f)(2), or 515 of this Act or section 351 of the Public Health Service Act, and a copy of the most current required labeling; and

"(v) updated information, if previously communicated information becomes materially outdated as a result of significant changes or as a result of new information regarding the product or its review status; and

"(B) the product information does not include—

"(i) information that represents that an unapproved product—

"(I) has been approved, cleared, granted marketing authorization, or licensed under section 505, 510(k), 513(f)(2), or 515 of this Act or section 351 of the Public Health Service Act (as applicable); or

"(II) has otherwise been determined to be safe or effective for the purpose or purposes for which the drug or device is being studied; or

"(ii) information that represents that an unapproved use of a drug or device that has been so approved, granted marketing authorization, cleared, or licensed—

"(I) is so approved, granted marketing authorization, cleared, or licensed; or

"(II) that the product is safe or effective for the use or uses for which the drug or device is being studied.

"(2) For purposes of this paragraph, the term 'product information' includes—

"(A) information describing the drug or device (such as drug class, device description, and features);

"(B) information about the indication or indications being investigated;

"(C) the anticipated timeline for a possible approval, clearance, marketing authorization, or licensure pursuant to section 505, 510(k), 513, or 515 of this Act or section 351 of the Public Health Service Act;

"(D) drug or device pricing information;

"(E) patient utilization projections;

"(F) product-related programs or services; and

"(G) factual presentations of results from studies that do not characterize or make conclusions regarding safety or efficacy.".

(b) GAO STUDY AND REPORT.—Beginning on the date that is 5 years and 6 months after the date of enactment of this Act, the Comptroller General of the United States shall conduct a study on the provision and use of information pursuant to section 502(gg) of the Federal Food, Drug, and Cosmetic Act, as added by this subsection (a), between manufacturers of drugs and devices (as defined in section 201 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321)) and entities described in such section 502(gg). Such study shall include an analysis of the following:

(1) The types of information communicated between such manufacturers and payors.

(2) The manner of communication between such manufacturers and payors.

(3)(A) Whether such manufacturers file an application for approval, marketing authorization, clearance, or licensing of a new drug or device or the new use of a drug or device that is the subject of communication between such manufacturers and payors under section 502(gg) of the Federal Food, Drug, and Cosmetic Act, as added by subsection (a).

(B) How frequently the Food and Drug Administration approves, grants marketing authorization, clears, or licenses the new drug or device or new use.

(C) The timeframe between the initial communications permitted under section 502(gg) of the Federal Food, Drug, and Cosmetic Act, as added by subsection (a), regarding an investigational drug or device or investigational use, and the initial marketing of such drug or device.

SEC. 811. BANS OF DEVICES FOR ONE OR MORE INTENDED USES.

(a) IN GENERAL.—Section 516(a) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360f(a)) is amended—

(1) in paragraph (1), by inserting "for one or more intended use" before the semicolon at the end; and

(2) in the matter following paragraph (2), by inserting "for any such intended use or uses. A device that is banned for one or more intended uses is not a legally marketed device under section 1006 when intended for such use or uses" after "banned device".

(b) SPECIFIC DEVICES DEEMED BANNED.—Section 516 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360f) is further amended by adding at the end the following:

"(c) SPECIFIC DEVICE BANNED.—Electrical stimulation devices that apply a noxious electrical stimulus to a person's skin intended to reduce or cease self-injurious behavior or aggressive behavior are deemed to be banned devices, as described in subsection (a).

"(d) REVERSAL BY REGULATION.—Devices banned under this section are banned devices unless or until the Secretary promulgates a regulation to make such devices or use of such devices no longer banned based on a finding that such devices or use of such devices does not present substantial deception or an unreasonable and substantial risk of illness or injury, or that such risk can be corrected or eliminated by labeling.".

SEC. 812. CLARIFYING APPLICATION OF EXCLUSIVE APPROVAL, CERTIFICATION, OR LICENSURE FOR DRUGS DESIGNATED FOR RARE DISEASES OR CONDITIONS.

(a) APPLICATION OF EXCLUSIVE APPROVAL, CERTIFICATION, OR LICENSURE FOR DRUGS DESIGNATED FOR RARE DISEASES OR CONDITIONS.—Section 527 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360cc) is amended—

(1) in subsection (a), in the matter following paragraph (2), by striking "same disease or condition" and inserting "same approved indication or use within such rare disease or condition";

(2) in subsection (b)—

(A) in the matter preceding paragraph (1), by striking "same rare disease or condition" and inserting "same indication or use for which the Secretary has approved or licensed such drug"; and

(B) in paragraph (1), by striking "with the disease or condition for which the drug was designated" and inserting "for whom the drug is indicated"; and

(3) in subsection (c), by striking "same rare disease or condition" and inserting "same indication or use".

(b) APPLICATION OF AMENDMENTS.—The amendments made by subsection (a) shall apply with respect to any drug designated under section 526 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360bb), regardless of the date on which the drug was so designated, and regardless of the date on which the drug was approved under section 505 of such Act (21 U.S.C. 355) or licensed under section 351 of the Public Health Service Act (42 U.S.C. 262).

SEC. 813. GAO REPORT ON THIRD-PARTY REVIEW.

Not later than September 30, 2026, the Comptroller General of the United States shall submit to the Committee on Energy and Commerce of the House of Representatives and the Committee on Health, Education, Labor, and Pensions of the Senate a report on the third-party review program described in section 523 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360m). Such report shall include—

(1) a description of the financial and staffing resources used to carry out such program;

(2) a description of actions taken by the Secretary pursuant section 523(b)(2)(C) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360m(b)(2)(C)); and

(3) the results of an audit of the performance of select persons accredited under such program.

SEC. 814. REPORTING ON PENDING GENERIC DRUG APPLICATIONS AND PRIORITY REVIEW APPLICATIONS.

Section 807 of the FDA Reauthorization Act of 2017 (Public Law 115–52) is amended, in the matter preceding paragraph (1), by striking "2022" and inserting "2027".

SEC. 815. FDA WORKFORCE IMPROVEMENTS.

Section 714A of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 379d–3a) is amended—

(1) in subsection (a), by striking "medical products" and inserting "products regulated by the Food and Drug Administration"; and

(2) by striking subsection (d) and inserting the following:

"(d) AGENCY-WIDE STRATEGIC WORKFORCE PLAN.—

"(1) IN GENERAL.—Not later than 1 year after the date of enactment of the Food and Drug Amendments of 2022, the Commissioner of Food and Drugs shall develop and begin implementation of an agency-wide strategic workforce plan at the Food and Drug Administration, which shall include—

"(A) agency-wide human capital goals and strategies;

"(B) performance measures, benchmarks, or other elements to facilitate the monitoring and evaluation of the progress made toward such goals and the effectiveness of such strategies; and

"(C) a process for updating such plan based on timely and relevant information on an ongoing basis.

"(2) REPORT TO CONGRESS.—Not later than 18 months after the date of enactment of the Food and Drug Amendments of 2022, the Secretary shall submit to the Committee on Energy and Commerce of the House of Representatives and the Committee on Health, Education, Labor, and Pensions of the Senate a report describing the plan under paragraph (1) and the status of its implementation.".

I. PURPOSE AND SUMMARY

H.R. 7667, the "Food and Drug Amendments of 2022," enables Food and Drug Administration (FDA) to continue to collect user fees from regulated industry to supplement Congressional appropriations for the premarket review and regulation of medical products. Specifically, the bill revises and reauthorizes provisions of the Prescription Drug User Fee Act (PDUFA), the Medical Device User Fee Amendments (MDUFA), the Generic Drug User Fee Amendments (GDUFA), and the Biosimilars User Fee Act (BsUFA) through 2027. The legislation also includes various provisions that will promote clinical trial diversity, encourage increased generic drug competition, preserve existing incentives for orphan drug development, facilitate a more resilient supply chain, and improve the review and regulation of medical products and the inspections of facilities that manufacture them.

II. BACKGROUND AND NEED FOR LEGISLATION

A. User Fees

Since 1992, pursuant to PDUFA, Congress has authorized FDA to collect fees from regulated industry to supplement Congressional appropriations. Revenues generated from these fees have been used on specific activities related to the review and regulation of medical products. FDA also commits to meeting certain performance goals, such as completing product reviews within specified timeframes. FDA's ability to collect such fees must be reauthorized every five years following a process laid out in statute that involves negotia-

tions between the agency and regulated industry and recommendations provided to Congress. The reauthorization process allows for input by other interested stakeholders, including patient and consumer groups, and provides opportunity for broader public comment.

Based in large part on the positive impact PDUFA had on expediting new drug product review times and improving related regulatory activities at FDA, Congress authorized FDA to collect medical device user fees in 2002 as part of the Medical Device User Fee and Modernization Act.[1] MDUFA user fees were reauthorized in 2007, 2012, and 2017, along with PDUFA.

Due to growing concerns from a wide range of stakeholders about the time it was taking FDA to review generic drug applications and the backlog of such applications pending at the agency, Congress passed the Generic Drug User Fee Amendments (GDUFA) in 2012 as part of the Food and Drug Administration Safety and Innovation Act (FDASIA).[2] Congress reauthorized GDUFA user fees in 2017.

As part of FDASIA, Congress also passed BsUFA in 2012 to authorize FDA to collect user fees from biosimilar product manufacturers. Congress reauthorized BsUFA in 2017.

Each of these four user fee programs is due to expire at the end of this fiscal year and must be reauthorized if FDA is to continue collecting fees to support review programs and other functions of the agency. H.R. 7667 would reauthorize all four user fee programs through 2027. The Committee also considered additional policies that would improve the regulation of certain medical products, a number of which are also included in the bill.

B. Improvements Across Product Areas

1. Clinical Study Diversity

Clinical studies—studies in human subjects—are fundamental to assessing whether medical products are safe and effective for a particular use and patient population.[3] FDA relies on these studies to assess whether medical products meet applicable premarket review standards, which determines whether they may be marketed, as well as what uses and patient populations they may be approved for, what labeling, including warnings and contraindications is required, and whether additional post-market studies are warranted, among other considerations. These studies also inform physician decisions regarding diagnosis and treatment, and providers and patients rely on FDA's premarket review and labeling determinations in their medical decision-making.

Neither diseases nor medical products affect everyone the same way. Certain demographic groups are at higher risk of developing certain illnesses or conditions than others; a product that poses little risk or is highly effective in some demographic groups may pose serious risks or provide little benefit to others.[4] Non-demographic

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[1] Pub. L. No. 107–250 (2002).

[2] Pub. L. No. 112–114 (2012).

[3] U.S. Food and Drug Administration, Step 3: *Clinical Research* (www.fda.gov/patients/drug-development-process/step-3-clinical-research) (Jan. 4, 2018).

[4] House Committee on Energy and Commerce, Subcommittee on Health, Testimony of Dr. Ruben Mesa, Executive Director, Mays Cancer Center at UT Health San Antonio MD Anderson, *Hearing on The Future of Medicine: Legislation to Encourage Innovation and Improve Oversight*, 117th Cong. (Mar. 17, 2022) (energycommerce.house.gov/sites/democrats.energycommerce.house.gov/files/documents/Witness%20Testimony_Mesa_HE_2022.03.17.pdf).

factors such as co-morbidities can also affect outcomes. Inclusion of diverse, representative populations in clinical studies can enable identification of these differences in risk and benefit across subgroups before a product comes to market,[5] which in turn can improve both regulatory and medical decision-making. It is thus critical that the participants that sponsors and investigators enroll in a clinical study are reflective of the patient population expected to use the medical product, both as a matter of health equity and as a matter of good science and medicine.[6]

At present, clinical studies often lack adequate diversity. Individuals from Black or African American, Hispanic/Latino, Indigenous and Native American, Asian, Native Hawaiian and other Pacific Islander populations and other persons of color "are frequently underrepresented in biomedical research despite having a disproportionate disease burden for certain diseases relative to their proportional representation in the general population."[7] For example, in an FDA analysis of nearly 300,000 people who participated in clinical studies between 2015 and 2019, only seven percent identified as African American and only 13 percent identified as Hispanic or Latino,[8] despite these groups making up 13.4 percent and 18.5 percent of the United States population, respectively.[9] There are various reasons for this lack of adequate representation. On the sponsor side, there may be challenges to including subpopulations where expanding enrollment may require additional time or resources.[10] On the participant side, barriers include lack of awareness of open studies, mistrust of research, financial and language barriers, and lack of diversity among those conducting the studies.[11]

Title V of H.R. 7667 addresses both sides of this problem. Under section 501, the legislation requires sponsors of phase 3 or other pivotal studies of drugs and biological products, and sponsors of clinical studies of devices, to develop, implement, and submit to FDA diversity action plans that include the sponsor's goals for study enrollment, a rationale for such goals, and an explanation of how these goals will be met. Section 501 also requires FDA to update its guidance to address sponsor diversity goals, disaggregated by age group, sex, race, geographic location, socioeconomic status, and ethnicity, and how sponsors will publicly post key information from their plans on their website. Building on some of the experience gained during the current coronavirus disease 2019 (COVID–19) pandemic, the legislation also requires guidance addressing decentralized study enrollment, including the engagement, enrollment, and retention of a meaningfully diverse study population and recommendations for sponsors to reduce burdens for participants

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[5] Food and Drug Administration, Draft Guidance, *Diversity Plans to Improve Enrollment of Participants from Underrepresented Racial and Ethnic Populations in Clinical Trials* (April 2022) (www.fda.gov/regulatory-information/search-fda-guidance-documents/diversity-plans-improve-enrollment-participants-underrepresented-racial-and-ethnic-populations).

[6] See note 4; National Academies of Sciences, Engineering, and Medicine, *Improving Representation in Clinical Trials and Research: Building Research Equity for Women and Underrepresented Groups* (2022) (nap.nationalacademies.org/download/26479).

[7] *See* note 4.

[8] Food and Drug Administration, *2015–2019 Drug Trials Snapshots Summary Report* (www.fda.gov/media/143592/download).

[9] Census Bureau, *QuickFacts* (www.census.gov/quickfacts/fact/table/US/PST045221) (accessed May 24, 2022).

[10] *See* note 6 at 134–35.

[11] *See* note 4.

through digital health technology, telehealth, local providers and laboratories, or other means.

To further advance the goal of robust diverse participation, the legislation requires FDA to further study and discuss these issues. Section 502 requires FDA to evaluate whether there is a need for additional authorities to assure that sponsors conduct post-approval studies or postmarket surveillance in certain circumstances where premarket studies collect insufficient data for underrepresented subgroups. Section 503 requires public workshops to discuss how study enrollment of historically underrepresented populations may be increased and how participation reflective of the prevalence of a disease among subgroups may be encouraged, the creation of a docket for public comment regarding such information, and the publication of an FDA report on such workshops on its website. Section 504 requires an annual report from FDA to Congress summarizing the diversity action plans received, whether goals were met, and the reasons given why any goals were not met. The report also must include any postmarket studies required or recommended by FDA based on its existing authority and the premarket study lacked adequate diversity. Section 505 requires a public meeting regarding the clinical study flexibilities initiated in response to the COVID–19 pandemic, including how such flexibilities, such as those relating to study decentralization, may have affected access to studies by unrepresented or underrepresented populations, including racial and ethnic minorities, and how they may help improve clinical study access and diverse enrollment in the future. Finally, Section 506 requires FDA to issue guidance recommending how digital health technology or other remote assessment options could support decentralized clinical studies, as well as considerations for sponsors to minimize or reduce burdens for clinical study participants, thus encouraging the retention of a meaningfully diverse clinical population.

2. Inspections

The COVID–19 pandemic and an increasing reliance on drugs manufactured overseas has illustrated the need for updates and clarification with respect to FDA's inspectional authorities for medical products, in particular with respect to certain aspects of foreign inspections, bioresearch monitoring inspections, and inspections of records both in-person and remotely.

Concerns have been raised in recent years regarding FDA's inspections of foreign medical product facilities, including with respect to its practice of preannouncing most of these inspections. For example, in 2019 the Government Accountability Office (GAO) reported:

> FDA investigators identified persistent challenges conducting foreign inspections, raising questions about the equivalence of foreign to domestic inspections. For example, while domestic inspections are almost always unannounced, FDA's practice of preannouncing foreign inspections up to 12 weeks in advance may give manufacturers the opportunity to fix problems [before the investigator arrives]. Investigators from FDA's China and India offices do conduct some unannounced inspections, but they are in-

volved in a small percentage of inspections in these countries (27 percent and 10 percent, respectively).[12]

On the other hand, FDA investigators reported some benefits to preannouncing foreign inspections, including avoiding wasting agency resources, better preparation of establishment records and staff, and ensuring the safety of investigators in the foreign country,[13] which has become more of a concern during the COVID–19 public health emergency. FDA also reported a lack of data that would enable it to assess the relative merits of unannounced and preannounced inspections.[14] GAO more recently reported that FDA plans to implement two pilot programs to help address challenges related to preannounced inspections and language barriers, which will include gathering data that can be used to evaluate differences between announced and unannounced inspections.[15] However, FDA has not yet finalized the design of these pilots due to the COVID–19 pandemic.[16]

H.R. 7667 addresses these issues in several ways. Section 725 requires FDA to initiate a pilot program within 180 days of enactment in which FDA increases the conduct of unannounced surveillance inspections of foreign drug establishments, evaluates the differences between such inspections of domestic and foreign establishments, including the impact of announcing inspections, and posts a report of its findings and recommendations on the FDA website. Section 721 requires FDA to review its processes and practices applicable to bioresearch monitoring inspections in the United States and in foreign countries, evaluate whether updates are needed to facilitate consistency, and issue guidance describing the conduct of such inspections. Section 723 provides for FDA consideration of the compliance history of other FDA-regulated establishments in the country or region in which an establishment is located as a factor in establishing a schedule for risk-based inspections and requires a periodic assessment of whether additional arrangements with foreign governments pertaining to recognition of foreign government inspections of foreign establishments are appropriate. Currently, FDA has these arrangements in place with the European Union and the United Kingdom; however, the agency's inspection capabilities may benefit from assessing whether additional arrangements with countries with robust regulatory systems and drug safety protocols, such as Israel, Japan, or others, are appropriate, taking into account public health and safety, and any differences with regard to how these systems operate. Section 728 requires FDA to annually publish on its website a report on the utilization of these and other agreements entered into with foreign governments with review criteria analogous to those of FDA.

Building on the lessons learned during the COVID–19 pandemic, which has made in-person inspections more difficult, section 721

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[12] House Committee on Energy and Commerce, Subcommittee on Oversight and Investigations, Testimony of Mary Denigan-Macauley, Director, U.S. Government Accountability Office, *Hearing on Securing the U.S. Drug Supply Chain: Oversight of FDA's Foreign Inspection Program, Preliminary Findings Indicate Persistent Challenges with FDA Foreign Inspections*, 116th Cong. (Dec. 10, 2019) (www.gao.gov/assets/gao-20-262t.pdf).

[13] *Id.*

[14] *Id.*

[15] Government Accountability Office, GAO–22–103611, *Drug Safety: FDA Should Take Additional Steps to Improve its Foreign Inspection Program* (Jan. 2022) (www.gao.gov/assets/gao-22–103611.pdf).

[16] *Id.*

clarifies that FDA's authority to inspect records, among other things, applies not only to restricted devices but to all devices, and that FDA's authority to require records in advance or in lieu of an inspection applies not only to drugs but devices as well. Section 721 also codifies and clarifies FDA authority to inspect clinical study sites, also known as bioresearch monitoring inspections, including with respect to records. Section 723 clarifies that FDA may rely on any records or other information inspected to satisfy requirements that may pertain to a preapproval or risk-based surveillance inspection, or to resolve deficiencies found in such inspections, if applicable and appropriate. Finally, section 727 requires FDA to ensure timely and effective internal coordination and alignment among field investigators and staff regarding the reviews of inspection reports and any feedback or corrective actions in response to such reports and requires FDA reporting to Congress regarding such coordination and feedback and regarding certain drug shortage reports.

3. Appropriate and Consistent Regulation of Certain Products as Drugs

FDA has consistently regulated contrast agents as drugs for decades. However, a 2021 decision by the Court of Appeals for the District of Columbia Circuit created uncertainty as to whether these products, as well as certain therapeutic radioactive products and certain products that have been regulated under over-the-counter drug monographs, could be regulated by FDA as drugs or medical devices.[17] Devices have different standards for premarket review and different regulatory requirements from drugs. Without a legislative remedy, sponsors of contrast agents and certain other products who went through the drug approval process may be unnecessarily subject to new regulatory regimes.

This court-mandated change raises concerns about fairness and potential negative consequences for patients. The uncertainty and determinations regarding which products may transition, the timing and process by which they would transition, and how they would be regulated as devices would impose additional costs on sponsors and the agency. Section 803 of H.R. 7667 addresses these concerns by preserving the longstanding status quo of regulation of these products as drugs, as they have been regulated for decades.

4. Real World Evidence

Real-world evidence (RWE) has been playing an increasing role in health care and regulatory decision-making in recent years, for example with respect to clinical practice guidelines, improving clinical study designs, and postmarket safety monitoring.[18] While RWE holds great promise for further advancing the study, regulation, and use of medical products, further understanding and development of RWE and RWE generation practices is needed. At least one example in which RWE played a significant role in premarket drug review, for a product used in combination with other immunosuppressant drugs to prevent organ rejection in lung trans-

[17] *Genus Med. Techs., LLC* v. *FDA*, 994 F.3d 631 (D.C. Cir. 2021).
[18] Food and Drug Administration, *Real-World Evidence* (www.fda.gov/science-research/science-and-research-special-topics/real-world-evidence) (accessed May 24, 2022).

plant recipients, illustrates this point.[19] First, while FDA relied on RWE in its approval of a new indication for Prograf (tacrolimus), it has not yet approved a new molecular entity primarily relying on RWE; second, the observed clinical benefit was so large that it was highly unlikely that the outcomes could be explained by bias; and third, in addition to RWE, the approval was also supported by randomized controlled trials of the drug in other settings, which provided confirmatory evidence of effectiveness, and additional clinical trial evidence from research publications, which supported the independent contribution of the drug as part of a multidrug regimen.[20]

There is hope that RWE will not only reduce medical product development costs, speed patient access, and lower prices, but also provide greater confidence in their safety and effectiveness. Thus, it is important to advance the development, study, and regulatory application of RWE, while being careful to recognize that at the present time "randomized and other types of clinical trials are still generally the most reliable way to assess the potential effectiveness of a drug and these trials will remain a critical part of the drug development process."[21]

Section 805 of H.R. 7667 aims to improve the understanding of the potential uses and limitations of RWE in the premarket review of medical products by requiring FDA to issue guidance addressing the use of RWE, including that obtained through COVID–19 emergency use authorizations, to support drug and device approvals and clearances. This section also advances this goal by requiring FDA to report to Congress regarding the number of applications including RWE submitted for products for which an emergency use authorization was granted and whether such evidence was sufficient to support a regulatory decision. Additionally, section 804 clarifies that RWE may augment or support appropriate postapproval studies required by FDA, including such conditions as the Secretary may require, to verify clinical benefit for drugs approved through accelerated approval.

5. Pre-Approval Information Exchange

Information about a drug or device being studied in clinical investigations can be used to inform payors, formulary committees, and other entities responsible for the selection of drugs or devices for coverage or reimbursement as they plan for and make coverage and reimbursement decisions. In its guidance on these communications, FDA has explained that the important impact these decisions have for many patients renders it critical that the information drug and device sponsors provide to payors about their products be truthful and not misleading, and that appropriate background and context be provided so that this sophisticated audience will understand its limitations and be able to make informed decisions.[22]

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[19] Food and Drug Administration, *FDA Approval Demonstrates the Role of Real-World Evidence in Regulatory Decision-Making on Drug Effectiveness* (Aug. 4, 2021) (www.fda.gov/drugs/news-events-human-drugs/fda-approval-demonstrates-role-real-world-evidence-regulatory-decision-making-drug-effectiveness).

[20] *Id.*

[21] *Id.*

[22] Food and Drug Administration, *Drug and Device Manufacturer Communications with Payors, Formulary Committees, and Similar Entities, Questions and Answers* (final guidance) (June 2018) (www.fda.gov/media/133620/download).

In the interest of facilitating the provision of this information to these specific audiences and ensuring its accuracy and comprehensiveness, section 810 of H.R. 7667 essentially codifies FDA's guidance on preapproval information exchange.[23] Section 810 of H.R. 7667 amends section 502 of the Federal Food, Drug, and Cosmetic Act (FFDCA) (21 U.S.C. §352) to clarify that no drug or device shall be misbranded as a result of providing information regarding investigational drugs or devices or uses to payors, formulary committees, or other similar entities under specified conditions. It requires the information to include a clear statement that the drug or device discussed has not been approved, and that the safety and efficacy of the drug or device has not been established. Additional required disclosures to help ensure the information is not misleading include information about the studies the product is undergoing, whether an application for the drug or device has been submitted to FDA, and if not, when such submission is planned.

6. Hiring

FDA needs to be able to hire and retain a highly-skilled workforce with various types of specialized expertise in order to successfully carry out its mission to promote the public health by promptly and efficiently reviewing clinical research and taking appropriate action on the marketing of regulated products in a timely manner; and to protect the public health by ensuring that foods are safe, wholesome, sanitary, and properly labeled; human and veterinary drugs are safe and effective; there is reasonable assurance of the safety and effectiveness of devices intended for human use; cosmetics are safe and properly labeled; and public health and safety are protected from electronic product radiation.[24] As the science behind the products FDA regulates becomes more complex and specialized, so too must the skills and expertise of its staff.[25]

To advance this end with respect to the development, review, and regulation of medical products, in 2016 Congress provided FDA specific hiring authority in the 21st Century Cures Act, which added section 714A to the FFDCA (21 U.S.C. §379d–3a).[26] This authority has enabled FDA to simplify and expedite the hiring process for certain scientific, technical, and professional positions and set higher rates of pay for these positions to enable it to better compete with the private sector in the recruitment and retention of outstanding, highly qualified candidates.[27]

FDA's need for highly skilled employees with specialized expertise is not limited to its regulation of human drugs, biological products, and devices. The successful regulation of food, veterinary medicine, tobacco, cosmetics, and electronic products also demands the hiring and retention of such highly qualified and trained individuals. Section 815 of H.R. 7667 accomplishes this goal by extending the hiring and pay authority Congress granted to FDA in 2016 to the hiring of outstanding candidates for scientific, technical, or professional positions across the entire agency. This section also provides accountability by requiring FDA to develop and implement

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[23] *Id.*

[24] Section 1003(b) of the FFDCA (21 U.S.C. § 393(b)).

[25] Food and Drug Administration, *21st Century Cures Workforce Planning Report to Congress* (June 2018) (www.fda.gov/media/114163/download).

[26] Pub. L. No. 114–255 (2016).

[27] *See* note 25.

a strategic workforce plan, as recommended by GAO, and report to Congress regarding such implementation.

C. Improvements to Drug Regulation

1. Accelerated Approval Integrity

Initiated by FDA through regulation in 1992 in response to the HIV/AIDS crisis and codified in section 506(c) of the FFDCA (21 U.S.C. § 356(c)) by Congress in 2012, the accelerated approval premarket review pathway for new drugs has expedited the approvals of hundreds of drugs and biologics in several disease areas, most of which have been for oncology and hematology indications; as a result, patients with no alternative options have had access to life-extending treatments for cancer and other serious diseases years earlier than they would have had without accelerated approval.[28] Drugs approved via accelerated approval must meet the same "safe and effective" review standard as other drugs, including substantial evidence of effectiveness, but rather than having to prove clinical benefit in the same way as drugs reviewed under the traditional pathway, sponsors of drugs reviewed under accelerated approval can demonstrate effect on a surrogate or intermediate endpoint reasonably likely to predict clinical benefit. This enables shorter studies and earlier approvals, but this greater uncertainty regarding benefit to patients requires postapproval studies to confirm such benefit. If a sponsor fails to conduct such a required study with due diligence, such a study fails to verify benefit, or if the drug is otherwise not shown to be safe and effective, FDA may withdraw approval. If a sponsor fails to complete such a postapproval study, this violates section 505(p) of the FFDCA (21 U.S.C. § 355(p)) and distribution of the drug in interstate commerce is prohibited.

While many in the patient community, among others, have touted the success of this program,[29] others, including some patient and provider groups, have criticized various aspects of it, such as the uncertainty of clinical benefit; delays in postapproval study initiation, conduct, and completion; inadequacy of postapproval study design; inadequacy of postapproval study reporting and transparency; inadequacy of labeling information for providers and patients; and the fact that FDA has not withdrawn approvals for a number of drugs where confirmatory studies failed to verify benefit, which some argue is due to a cumbersome and time-consuming process.[30]

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[28] Julia A. Beaver, et al., *A 25-Year Experience of US Food and Drug Administration Accelerated Approval of Malignant Hematology and Oncology Drugs and Biologics: A Review*, JAMA Oncology (June 1, 2018); Food and Drug Administration, *Project Confirm, Promoting the transparency of Accelerated Approval for oncology indications* (www.fda.gov/about-fda/oncology-center-excellence/project-confirm).

[29] House Committee on Energy and Commerce, Subcommittee on Health, Testimony of Jeff Allen, Ph.D., President and CEO, Friends of Cancer Research, *Hearing on The Future of Medicine: Legislation to Encourage Innovation and Improve Oversight*, 117th Cong. (March 17, 2022) (energycommerce.house.gov/sites/democrats.energycommerce.house.gov/files/documents/Witness%20Testimony_Allen_HE_2022.03.17.pdf).

[30] See Bishal Gyawali, M.D., Ph.D., et al., *Assessment of the Clinical Benefit of Cancer Drugs Receiving Accelerated Approval*, JAMA Internal Medicine (May 28, 2019) (jamanetwork.com/journals/jamainternalmedicine/fullarticle/2733561); House Committee on Energy and Commerce, Subcommittee on Health, Testimony of Reshma Ramachandran, M.D., M.P.P., Yale School of Medicine, *Hearing on The Future of Medicine: Legislation to Encourage Innovation and Improve Oversight*, 117th Cong. (March 17, 2022) (energycommerce.house.gov/sites/democrats.energycommerce.house.gov/files/documents/

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Section 804 of H.R. 7667 aims to improve the integrity and performance of this valuable pathway by addressing some of these concerns. In the interest of enhancing the quality and timeliness of postapproval studies, it requires FDA to specify the conditions for such studies, which may include enrollment targets and the target date for study completion as well as other milestones, by the time the drug is approved, requires more frequent reporting of postapproval study progress, and makes clear that FDA may require postapproval studies to be underway at the time of approval and may withdraw approval where the conditions it specified at the time of approval are not satisfied. It also clarifies that postapproval studies, which FDA regulation requires to be adequate, well controlled, and carried out with due diligence, may be supported or augmented by real world evidence.[31] To promote accurate provider and patient understanding of the limitations of accelerated approvals, section 804 requires the labeling of drugs approved under this pathway to include certain information, such as the uncertainty regarding benefit, the endpoints used in premarket studies, and the fact that continued approval depends on the ability of a postapproval study to verify benefit.

H.R. 7667 also ensures FDA can expeditiously withdraw approval where a postapproval study fails to verify patient benefit or if any of the other grounds for withdrawal apply, while still providing the sponsor due process by which to challenge a proposed withdrawal. The informal hearing required by the current process can be cumbersome and time-consuming, requires a meeting of an advisory committee even if the same committee previously met to discuss the same issues regarding withdrawal of the drug's approval, and enables a drug sponsor to continue marketing a drug long after a postapproval study fails to verify any benefit to patients.[32] Section 804 replaces the requirement for an informal hearing with an opportunity for written appeal to the Commissioner of Food and Drugs, which should significantly streamline the withdrawal process, while allowing sponsors to present the same case against withdrawal they may currently present to the Commissioner. In the interest of fairness and transparency, section 804 also requires FDA to provide an explanation for the withdrawal, an opportunity for a meeting with the Commissioner, a public comment period and responses to public comments, and an advisory committee meeting, if one was not held previously, to discuss the issues that have led to the determination that the product should be withdrawn.

2. Drugs for Rare Diseases, Pediatric Populations, and Certain Infectious Diseases

Significant progress has been made in recent decades with respect to the treatment of rare diseases, also known as orphan products, thanks in part to the Orphan Drug Act of 1983. Before the

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Witness%20Testimony_Ramachandran_HE_2022.03.17.pdf); National Organization for Rare Diseases, *FDA's Accelerated Approval Pathway: A Rare Disease Perspective* (2021) (rarediseases.org/wp-content/uploads/2021/06/NRD-2182-Policy-Report_Accelerated-Approval_FNL.pdf).

[31] See 21 C.F.R. § 314.510.

[32] House Committee on Energy and Commerce, Subcommittee on Health, Testimony of Patrizia Cavazzoni, Director, Center for Drug Evaluation and Research, U.S. Food and Drug Administration, Hearing on *FDA User Fee Reauthorization: Ensuring Safe and Effective Drugs and Biologics* (Feb. 3, 2022).

enactment of this law, only 38 orphan products existed; between 1983 and 2020, FDA approved 599 orphan products to treat rare diseases.[33] However, there is still a long way to go; together rare diseases affect more than 25 million Americans, 90 percent of these diseases continue not to have an FDA-approved treatment, and numerous obstacles to the investment in research and development of these drugs remain.[34]

A recent decision of the 11th Circuit Court of Appeals upended FDA's longstanding interpretation of seven-year orphan drug exclusivity under section 527 of the FFDCA (21 U.S.C. § 360cc).[35] Under FDA's implementation of section 527, orphan drug exclusivity blocks approval of the same drug only for the same use or indication that FDA previously approved, which may be in a small subgroup affected by the disease. This incentivizes companies to continue to study and obtain approval for other uses within the designated disease, such as a pediatric indication for a drug approved for adults.[36]

As a result of the court's decision, which held that exclusivity applies to the entire designated disease regardless of the specific indications for which a drug is actually approved, sponsors would have incentive to obtain approval for the smallest, easiest-to-study subpopulation and block approval for any other populations or indications within the rare disease for seven years.[37] Were this interpretation to stand, there could be a chilling effect on investment in studying and obtaining approval for these drugs in different subpopulations, which could be especially harmful to populations that tend to be studied later in drug development, such as children, the elderly, and patients with co-morbidities. The ruling also creates uncertainty regarding existing approvals for a number of brand-name and generic drugs and could block approval of drugs in late-stage development or for which premarket review is pending. This problem will grow over time for the hundreds of existing terms of orphan exclusivity that would be subject to the broad scope resulting from the *Catalyst* decision.[38]

Section 812 of H.R. 7667 will prevent the potential negative consequences of this decision from occurring by amending section 527 of the FFDCA (21 U.S.C. § 360cc) to clearly provide that orphan exclusivity applies only to the specific indication or use approved by FDA under this section, not the entire rare disease or condition for which a drug is designated, consistent with FDA's long-held interpretation of the law.[39]

Section 703 of H.R. 7667 further seeks to advance the development of drugs for rare diseases by requiring FDA to study processes for evaluating drugs for rare diseases in the United States and the European Union, convene a public meeting to solicit input

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[33] National Organization for Rare Disorders, *Orphan Drugs in the United States: An Examination of Patents and Orphan Drug Exclusivity* (March 25, 2021) (https://rarediseases.org/wp-content/uploads/2021/03/NORD-Avalere-Report-2021_FNL-1.pdf).

[34] *Id.*; Food and Drug Administration, *Remarks by Acting Commissioner Woodcock to the 2021 NORD Breakthrough Summit* (Oct. 19, 2021) (www.fda.gov/news-events/speeches-fda-officials/remarks-acting-commissioner-woodcock-2021-nord-breakthrough-summit-10192021).

[35] *Catalyst Pharms., Inc.* v. *Becerra*, 14 F.4th 1299 (11th Cir. 2021).

[36] Food and Drug Administration, *Overview of Catalyst Pharms., Inc.* v. *Becerra* (www.fda.gov/industry/developing-products-rare-diseases-conditions/fdas-overview-catalyst-pharms-inc-v-becerra) (accessed May 24, 2022).

[37] *Id.*

[38] *Id.*

[39] 21 CFR 316.

from stakeholders regarding approaches to improving engagement with patients, patient groups, and experts, and submit a report to Congress summarizing its activities relating to designating, approving, and licensing drugs used to treat rare diseases. Section 703 also requires GAO to conduct a study on the use of FDA tools to ensure that patient and physician perspectives are incorporated throughout FDA processes for approving and licensing drugs and making determinations related to a drug's approval.

Section 804 addresses the need for further rare disease development by requiring FDA to establish a rare disease endpoint advancement pilot program and issue guidance on novel surrogate endpoints and trial designs, and section 712 does so by reauthorizing orphan drug grants and allowing such grants to be used to develop regulatory science pertaining to the chemistry, manufacturing, and controls of rare disease drugs.

Although there has been progress in the treatment of pediatric cancer in recent years, particularly with respect to the most common malignancy, little improvement has been made in the treatment of certain other types of childhood cancer. High development costs and the relatively smaller number of pediatric patients limit investment in treatments for this population; as a result, few cancer drugs have obtained FDA approval for pediatric indications and the need for more clinical studies in children persists.[40]

The FDA Reauthorization Act of 2017 sought to facilitate development of appropriate new therapies for pediatric cancer patients by requiring pediatric investigations of certain adult cancer drugs with new active ingredients directed at a molecular target FDA determines to be substantially relevant to the growth or progression of a pediatric cancer, unless FDA waives or defers the requirement.[41] Section 713 of H.R. 7667 takes this mandate a step further, clarifying that the required pediatric investigations may be of the new drug for which approval is sought or such drug used in combination with a previously-approved drug or biological product that meets certain conditions. This section also requires FDA to issue guidance and report to Congress on its implementation of this section, and a GAO report on its success.

As antibiotic resistance continues to rise throughout the world and remains one of the biggest threats to public health, there continues to be a critical need for new antibiotic and antifungal treatments.[42] The Generating Antibiotic Incentives Now (GAIN) provisions of the FDA Safety and Innovation Act of 2012 promoted the development and approval of such treatments for serious or life-threatening infections by allowing a drug designated by FDA as a Qualified Infectious Disease Product (QIDP) to be eligible for market exclusivity, priority review for the first application submitted for approval, and fast-track designation upon request. Section 705 of H.R. 7667 broadens QIDP designation to antibiotic and antifungal biological products, which renders them eligible for fast-track designation and provides for priority review for the first application for an innovative biological antifungal or antibiotic QIDP

[40] Theodore W. Laetsch, et al., *Opportunities and Challenges in Drug Development for Pediatric Cancers*, Cancer Discovery (Mar. 2, 2021) (aacrjournals.org/cancerdiscovery/article/11/3/545/3017/Opportunities-and-Challenges-in-Drug-Development).

[41] Pub. L. No. 115–52 (2017).

[42] World Health Organization, *Antibiotic Resistance* (www.who.int/news-room/fact-sheets/detail/antibiotic-resistance) (accessed May 24, 2002).

that requires clinical data to demonstrate safety or effectiveness. This section does not extend QIDP exclusivity to biological products.

H.R. 7667 also addresses the specific need for antifungal treatments for coccidioidomycosis, commonly known as Valley Fever, which is a serious fungal lung infection that afflicts about 15,000 patients in the United States each year, mostly in Arizona and California.[43] Section 704 attempts to advance the development of antifungal therapies for this illness by requiring FDA to issue guidance assisting entities seeking approval for such treatments and to hold a public workshop to assist entities developing vaccines for fungal infections, including Valley Fever.

3. Generic Drug and Biosimilar Competition

For a generic drug to be approved by FDA, it generally must have the same inactive ingredients in the same concentration (within a certain range) as the listed drug.[44] Currently, generic drug sponsors often have to engage in trial and error before they successfully match the same inactive ingredients in the same proportions as the listed drug in order to obtain approval.[45] This is a costly, burdensome, and inefficient process for both the agency and these sponsors, and more importantly, can delay patient access to cost-saving generic drugs.[46] Section 601 of H.R. 7667 fixes this problem by requiring FDA to provide this information to generic sponsors of certain drugs upon request, which will avoid this unnecessary back-and-forth and enable patients to have access to more affordable drugs sooner, which will reduce costs for patients and the health system. This section makes clear this information is not protected under the Trade Secrets Act.

An NDA holder for a listed drug can also attempt to block competition from generics by changing the labeling of its drug shortly before a generic is approved and prepared to enter the market. Because generic drug labeling must generally match that of the listed drug, any change in a listed drug's labeling can temporarily block a generic drug market entry. Section 505(j)(10)(A) of the FFDCA (21 U.S.C. § 355(j)(10)(A)) addresses this issue by enabling FDA to approve a generic drug despite differences between its proposed labeling and that of the listed drug, other than differences in the "Warnings" section, resulting from revisions made to the labeling of the listed drug approved by FDA within 60 days of when the generic could be approved. Section 602 of H.R. 7667 extends this protection to 90 days, which will help cost-saving generic drugs get to market sooner in certain circumstances, saving patients money.

Timely, accurate information regarding which drugs are on the market, and which are not, can help generic drug manufacturers and policymakers identify circumstances where generic competition is lacking, which can help spur competition and help identify any

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[43] Centers for Disease Control and Prevention, *Valley Fever Awareness* (www.cdc.gov/fungal/features/valley-fever.html) (accessed May 24, 2022).

[44] 21 C.F.R. § 314.94(a)(9).

[45] House Committee on Energy and Commerce, Subcommittee on Health, Testimony of David R. Gaugh, RPh, Senior Vice President, Sciences & Regulatory Affairs, Association for Accessible Medicines, *Hearing on The Future of Medicine: Legislation to Encourage Innovation and Improve Oversight*, 117th Cong. (Mar. 17, 2022) (energycommerce.house.gov/sites/democrats.energycommerce.house.gov/files/documents/Witness%20Testimony_Gaugh_HE_2022.03.17.pdf).

[46] *Id.*

policy changes that may be appropriate to address these circumstances.[47] This information can also be useful to providers, payors, pharmacies, and patients. Congress addressed this issue in the FDA Reauthorization Act of 2017, which added section 506I to the FFDCA (21 U.S.C. § 356i), requiring all drug application holders to report to FDA certain information regarding the marketing status of approved drug products. Section 801 of H.R. 7667 extends these requirements and benefits to biological products, including biosimilars.

4. Advanced and Innovative Manufacturing for Drugs

The COVID–19 public health emergency has exposed gaps in the United States manufacturing supply chain and has reinforced the need to develop and implement manufacturing technologies that improve drug supply chain resilience, reduce time to market, or increase manufacturing capacity.[48] Advanced manufacturing, which is a collective term for new medical product manufacturing technologies and approaches that can improve drug quality, address shortages of medicines, and speed time-to-market, is a key component of the overall United States strategy to strengthen domestic drug manufacturing and increase the domestic supply of quality medical products for consumers.[49] Patients with diseases including cystic fibrosis, HIV, breast cancer, leukemia, and asthma are already benefitting from medications manufactured in newer, more expedient, and more flexible ways.[50] Innovations in this area promise to rapidly scale manufacturing capabilities for vaccines and other medical countermeasures to enable faster responses in public health emergencies, shorten supply chains and increase manufacturing resilience to disruption by creating reserve capacity in network of small manufacturing sites, accelerate therapy development for rare diseases by improving the cost-efficiency of small-scale manufacturing processes, speed availability of emerging therapies, and provide new tools to address drug shortages and other challenges, including pharmaceutical quality.[51]

Section 706 of H.R. 7667 fosters expanded creation and use of these methods by requiring FDA to initiate a pilot program for the designation of advanced manufacturing technologies. A method of manufacturing is eligible for designation if such method incorporates a novel technology or novel use of technology, will at least maintain equivalent drug quality, and will substantially improve the manufacturing process, for example by reducing development time or increasing or maintaining the supply of certain drugs on the shortage list or drugs for serious diseases the manufacture of

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[47] Food and Drug Administration, *Statement from FDA Commissioner Scott Gottlieb, M.D., on the agency's efforts to enhance the utility of the Orange Book to foster drug competition* (Jan. 30, 2019) (www.fda.gov/news-events/press-announcements/statement-fda-commissioner-scott-gottlieb-md-agencys-efforts-enhance-utility-orange-book-foster-drug).

[48] Manufacturing x Digital (MxD) and the International Academy of Automation Engineering (IAAE), *Analysis of the Advantages of and Barriers to Adoption of Smart Manufacturing for Medical Products—Focus on Response to Emerging and Pandemic Threats such as SARS–CoV–2*, FDA-funded study (June 30, 2021) (www.fda.gov/media/152569/download).

[49] Food and Drug Administration, *Advanced Manufacturing* (www.fda.gov/emergency-preparedness-and-response/mcm-issues/advanced-manufacturing) (accessed May 24, 2022).

[50] *Id.*

[51] *Id.*; Food and Drug Administration, *FDA's Advanced Manufacturing Initiatives Helping to Provide Quality Human Drugs for Patients* (www.fda.gov/news-events/fda-voices/fdas-advanced-manufacturing-initiatives-helping-provide-quality-human-drugs-patients) (accessed May 24, 2022).

which has been interrupted or discontinued. Designated technologies qualify for expedited application development and review and allow the holder or their designee to reference or rely upon data and information about the designated technology for use in manufacturing drugs in the same context of use as the designation. This section also encourages advanced manufacturing utilization by requiring FDA to hold a public meeting, issue guidance, and report to Congress regarding this pilot.

These goals are further advanced through section 702 of H.R. 7667, which codifies FDA's Emerging Technologies Program. This is a collaborative program wherein industry representatives, academics, and others can meet with FDA officials to support the adoption and improve the development of innovative approaches to drug design and manufacturing. This section also authorizes FDA to make grants, provides FDA $20 million annually to carry out the program, and requires FDA to issue guidance regarding such innovative approaches. It also requires a report to Congress detailing the effectiveness of the program.

5. Animal Testing

Animal studies have long been critical to the development of safe and effective medical products. For example, scientists have relied heavily on animal studies to determine whether a drug is toxic before testing it in humans; such studies have shown great accuracy in predicting safe doses and determining appropriate monitoring for adverse effects.[52] Conversely, although animal testing is still necessary in many situations, it is expensive and time-consuming, and does not always predict toxic effects in humans.[53] Some have also raised ethical concerns.[54] Advances in recent years, for example in the use of stem cells, engineered tissues, and mathematical modeling, have led to the development of alternative testing models that promise to improve the predictive ability of pre-clinical testing in conjunction with more traditional approaches.[55] While most current alternative methods cannot yet predict effects in highly complex interacting systems, they hold the potential to reduce and refine animal testing, and potentially someday replace it.[56]

Recognizing these advances and this potential for expanded use of non-animal testing, section 701 of H.R. 7667 amends certain provisions of the FFDCA pertaining to drug studies to allow for the possible use of non-animal nonclinical testing in certain circumstances as appropriate. It broadens the purpose of a certain type of FDA-sponsor meeting in situations where human efficacy studies are not ethical or feasible to include reaching agreement on the design of "nonclinical tests" intended to support effectiveness, so that non-animal nonclinical studies may be included in these meetings. This section also broadens references to animal testing in section 505(i) regarding investigational new drug exemptions to "nonclinical tests," defined to include cell-based assays, organ chips

[52] Food and Drug Administration, *Advancing New Alternative Methodologies at FDA* (Jan. 2021) (www.fda.gov/media/144891/download).
[53] *Id.*
[54] Stephanie Liou, *The Ethics of Animal Experimentation*, Huntington's Outreach Project for Education at Stanford (July 6, 2010) (hopes.stanford.edu/animal-research/).
[55] *See* note 52.
[56] Food and Drug Administration, *Advancing Alternative Methods at FDA* (www.fda.gov/science-research/about-science-research-fda/advancing-alternative-methods-fda) (accessed May 24, 2022).

and microphysiological systems, computer modeling, other nonhuman or human biology-based test methods, and animal tests.

6. Addressing Third-Party Vendor Issues

In the wake of recent FDA-approved changes to the risk evaluation and mitigation strategies (REMS) programs for clozapine and isotretinoin, users have experienced problems such as long wait times and difficulties obtaining certain authorizations. To attempt to avoid such problems in the future, section 809 of H.R. 7667 requires FDA to provide a single public comment period regarding patient access and provider administration when a proposed modification to an approved REMS is reviewed under section 505–1(h) of the FFDCA (21 U.S.C. § 355–1). This section makes clear that it shall not delay any agency action on any modification to a REMS. It also requires a GAO study on how any third-party vendor changes have impacted patient access to drugs subject to the modified REMS and how those access issues were resolved.

7. Encouraging Blood Donation

To facilitate FDA collection of certain information pertaining to blood donation and ultimately encourage broad donation of blood to assure adequate supply, section 802 exempts from Paperwork Reduction Act requirements FDA information gathering regarding patient perspectives during medical product development and solicitation of information from blood donors and potential blood donors to inform recommendations regarding blood donation.

8. Cell and Gene Therapy Workshop

In the interest of advancing the understanding of certain human cell-, tissue-, and cellular-based medical products and the latest scientific information about such products and providing a public forum for discussion of related issues, section 707 requires FDA to convene a public workshop on generating the scientific data necessary to further facilitate development of these products.

D. Improvements for Device Regulation

1. Cybersecurity

As cyberattacks generally, and on the health care sector in particular, have become more widespread and more sophisticated in recent years, medical device cybersecurity is more important than ever.[57] Connected, networked systems that leverage wireless technologies provide many advantages in health care delivery, but also leave systems more vulnerable to cyberattacks. For example, recent ransomware attacks on hospitals have rendered medical devices and hospital networks inoperable, necessitated moving patients to other hospitals, and prevented access to patient records, putting patients at risk and imposing substantial financial costs on the

[57] Cybersecurity and Infrastructure Security Agency, *Stop Ransomware Resources, Sector Risk Management Agencies, Healthcare and the Public Sector* (www.cisa.gov/stopransomware/healthcare-and-public-health-sector) (accessed May 24, 2022); Cybersecurity and Infrastructure Security Agency, Federal Bureau of Investigation, and Department of Health and Human Services, *Alert AA20–302A, Ransomware Activity Targeting the Healthcare and Public Health Sector* (Oct. 28, 2020) (www.cisa.gov/uscert/ncas/alerts/aa20–302a).

health care system.[58] Without adequate cybersecurity across all components of larger medical device systems, which can include health care facility networks, various individual devices, and software update servers, a cybersecurity threat can compromise the safety or effectiveness of a device by compromising any component in the system.[59]

Section 808 of H.R. 7667 imposes crucial requirements that will improve the cybersecurity of medical devices and thereby improve the cybersecurity of our entire health care system. It requires manufacturers of all cyber devices, defined as any device that includes software, can connect to the internet, or otherwise could be vulnerable to cybersecurity threats, to develop processes to ensure their devices are secure, have plans to identify and address cybersecurity vulnerabilities, and provide a software bill of materials in their labeling so that users can more easily identify threats and vulnerabilities. This section also provides that this information, as well as any other information pertaining to cybersecurity that FDA determines to be appropriate to demonstrate a reasonable assurance of safety and effectiveness, must be submitted in any premarket submissions and authorizes FDA to deny 510(k) clearance if cybersecurity information is inadequate. To enable enforcement of these requirements, it makes failure to comply a prohibited act.

2. Bans of Devices for Specific Intended Use(s)

In 2020, FDA, pursuant to section 516 of the FFDCA (21 U.S.C. § 360f), issued a final rule banning electric shock devices intended to aversively condition patients against self-injurious and aggressive behavior.[60] In 2021, the Court of Appeals for the District of Columbia Circuit, without weighing in on the reasons for FDA's decision to ban such devices, overturned the ban, finding that banning a device for a particular use interferes with the practice of medicine in contravention of section 1006 of the FFDCA (21 U.S.C. § 396).[61] This section makes two legislative changes to address this court decision: one to clarify FDA's authority to ban a device, in appropriate circumstances where the longstanding banning standard is met, regardless of whether it includes other devices that are technologically similar but have different intended uses within the scope of the ban, and another to effectuate FDA's ban of this particular device, including its particular intended use.

Since the Medical Device Amendments of 1976, FDA has had the authority under section 516 of the FFDCA (21 U.S.C. § 360f) to ban medical devices that present an unreasonable and substantial risk of illness or injury. For an even longer time—since Congress first gave FDA authority over devices in the FFDCA of 1938—the regulatory status of a product as a "device" under section 201(h) of the FFDCA (21 U.S.C. § 321(h)) has been dependent on its intended use; whereas a technology for one use may not be FDA-regulated, the same technology for a different use may be a "device." How a device is classified, its premarket pathway, labeling, and other re-

[58] *Id.*; Food and Drug Administration, *Cybersecurity in Medical Devices: Quality System Considerations and Content of Premarket Submissions* (draft guidance) (April 8, 2022) (www.fda.gov/media/119933/download).

[59] *Id.*

[60] Food and Drug Administration, *Banned Devices: Electrical Stimulation Devices for Self-Injurious or Aggressive Behavior*, 85 Fed. Reg. 13312 (Mar. 6, 2020).

[61] *Judge Rotenberg Educ. Ctr., Inc. v. FDA,* 3 F.4th 390 (D.C. Cir. 2021).

quirements very much depend on its intended use; a device that is safe and effective for one use may be unsafe and ineffective for a different use or different population.[62] Section 811 of H.R. 7667 makes clear that the same principle applies to FDA's banning authority, so that FDA may ban a device intended for one particular use. Without this change, FDA would either have to ban a technology for all uses, which could prevent patient access to safe and effective devices, or not ban a device that presents a substantial and unreasonable risk of illness or injury for a certain use or population, depriving those individuals of the protection Congress intended the banning authority to provide for over 45 years.

FDA's ban applied to shock devices intended for use on a particularly vulnerable patient population—individuals who engage in self-injurious and aggressive behavior, conditions that present in individuals with intellectual and developmental disabilities, such as Autism spectrum disorder, Down syndrome, and Tourette's syndrome.[63] FDA determined that these devices intended for this use present an unreasonable and substantial risk of illness or injury based on the serious risks they pose, the inadequacy of data to show effectiveness, and the positive benefit-risk profiles of behavioral and pharmacological alternatives developed in recent decades to treat patients with these conditions.[64]

Specifically, in its final rule imposing the ban, FDA cited medical literature that found that the use of these devices included risks of physical harms, including pain, skin burns, and tissue damage, as well as serious psychological harms, including depression, posttraumatic stress disorder (PTSD), suicidality, chronic stress, anxiety, fear, panic, and substitution of other negative behaviors.[65] FDA issued the final rule after an extensive process spanning nearly a decade over two administrations, with multiple opportunities for stakeholder input, including an outside expert advisory committee meeting in 2014, a proposed rule in 2016, meetings with the affected company and other stakeholders, consideration of tens of thousands of pages of scientific literature, state court proceedings, and over 1,500 comments, which were overwhelmingly supportive of the ban.[66] Section 811 of H.R. 7667 would reinstitute this ban without the need for additional time-consuming and resource-intensive proceedings.

3. Public Health Emergency Diagnostic Testing

One of the lessons learned from the COVID–19 public health emergency regards the value that external expertise and experience can provide to FDA regarding medical devices that are essential during such an emergency, such as personal protective equipment and diagnostic tests, including with respect to the use of such tests in the detection of an emerging threat and its spread across the nation and globe. It can be difficult to obtain such expertise in the middle of an emergency, given the focus of public health resources on other aspects of emergency response. Section 807 of H.R. 7667 aims to address this issue by requiring at least one panel of

[62] Sections 513(a)(1), 513(a)(2) and 513(i) of the FFDCA (21 U.S.C. §§ 360c(a)(1), 360c(a)(2), 360c(i)).
[63] See note 60.
[64] *Id.*
[65] *Id.*
[66] *Id.*

FDA's Medical Device Advisory Committee, which shall include at least one population-health representative, to meet at least once per year to discuss topics related to device use in pandemic preparedness and response, including with respect to in vitro diagnostics.

Looking ahead to a post-pandemic world, section 806 of H.R. 7667 will streamline FDA premarket review and categorization under the Clinical Laboratory Improvement Amendments (CLIA) for certain diagnostic tests that were granted an emergency use authorization during the COVID–19 emergency. More specifically, sponsors of such tests that were deemed to be CLIA-waived under section 564(m) of the FFDCA (21 U.S.C. § 360bbb–3) as part of such authorization that submit requests for de novo classification of their test under section 513(f)(2) (21 U.S.C. § 360c(f)(2)) of the FFDCA may submit a request for CLIA categorization together with their de novo request in a single submission.

III. COMMITTEE HEARINGS

For the purposes of section 3(c) of rule XIII of the Rules of the House of Representatives, the following hearings were used to develop and consider H.R. 7667:

The Subcommittee on Health held a legislative hearing on February 3, 2022, entitled "FDA User Fee Reauthorization: Ensuring Safe and Effective Drugs and Biologics." The Subcommittee received testimony from the following witnesses:

Panel I:

- Patrizia Cavazzoni, M.D., Director, Center for Drug Evaluation and Research, Food and Drug Administration; and
- Peter Marks, M.D., Ph.D., Director, Center for Biologics Evaluation and Research, Food and Drug Administration.

Panel II:

- Cartier Esham, Ph.D., Chief Scientific Officer, Executive Vice President, Emerging Companies, Biotechnology Innovation Organization;
- David Gaugh, Senior Vice President, Sciences and Regulatory Affairs, Association for Accessible Medicines;
- Reshma Ramachandran, M.D., Chair, Doctors for America FDA Task Force, Physician-Fellow, Yale National Clinician Scholars Program, Yale School of Medicine;
- Juliana M. Reed, Executive Director, Biosimilars Forum; and
- Lucy Vereshchagina, Ph.D., Vice President, Science and Regulatory Advocacy. Pharmaceutical Research and Manufacturers of America.

The Subcommittee on Health held a hearing on March 17, 2022, entitled "The Future of Medicine: Legislation to Encourage Innovation and Improve Oversight." The Subcommittee received testimony from the following witnesses:

- Jeff Allen, Ph.D., President and CEO, Friends of Cancer Research;
- Cartier Esham, Ph.D., Chief Scientific Officer, Executive Vice President, Emerging Companies, Biotechnology Innovation Organization;
- David Gaugh, Senior Vice President, Sciences and Regulatory Affairs, Association for Accessible Medicines;

- Ruben Mesa, M.D., Executive Director, Mays Cancer Center, UT Health San Antonio MD Anderson;
- Reshma Ramachandran, M.D., Chair, Doctors for America FDA Task Force, Physician-Fellow, Yale National Clinician Scholars Program, Yale School of Medicine; and
- Lucy Vereshchagina, Ph.D., Vice President, Science and Regulatory Advocacy. Pharmaceutical Research and Manufacturers of America.

The Subcommittee on Health held a legislative hearing on March 30, 2022, entitled "FDA User Fee Reauthorization: Ensuring Safe and Effective Medical Devices." The Subcommittee received testimony from the following witnesses:

Panel I:

- Jeff Shuren, M.D., Director, Center for Devices and Radiological Health, Food and Drug Administration.

Panel II:

- Richard J. Kovacs, M.D., Q.E. and Sally Russell Professor of Medicine, Indiana University School of Medicine, Chief Medical Officer, American College of Cardiology;
- Mark Leahey, President & CEO, Medical Device Manufacturers Association;
- Janet Trunzo, Senior Executive Vice President, Technology and Regulatory Affairs, Advanced Medical Technology Association (AdvaMed); and
- Diane Wurzburger, Executive of Regulatory Affairs, GE Healthcare.

IV. Committee Consideration

H.R. 7667, the "Food and Drug Amendments of 2022," was introduced on May 6, 2022, by Representatives Eshoo (D–CA), Guthrie (R–KY), Pallone (D–NJ), and Rodgers (R–WA) and referred to the Committee on Energy and Commerce. Subsequently, on May 9, 2022, the bill was referred to the Subcommittee on Health.

On May 11, 2022, the Subcommittee on Health met in open markup session, pursuant to notice, to consider H.R. 7667 and five other bills. During consideration of the bill, an amendment in the nature of a substitute (AINS) offered by Representative Eshoo was agreed to by a voice vote. Upon conclusion of consideration of the bill, the Subcommittee on Health agreed to report the bill favorably to the full Committee, amended, by a roll call vote of 30 yeas to zero nays.

On May 18, 2022, the full Committee met in open markup session, pursuant to notice, to consider H.R. 7667 and five other bills. An AINS offered by Representative Guthrie was agreed to by a voice vote. An amendment to the AINS offered by Representative Butterfield (D–NC) was agreed to by a voice vote. Upon conclusion of consideration of the bill, the full Committee agreed to a motion on final passage offered by Representative Pallone, Chairman of the Committee, to order H.R. 7667 reported favorably to the House, amended, by a roll call vote of 55 yeas to zero nays.

V. Committee Votes

Clause 3(b) of rule XIII of the Rules of the House of Representatives requires the Committee to list each record vote on the motion

to report legislation and amendments thereto. The Committee advises that there were two record votes taken on H.R. 7667, including a motion by Mr. Pallone ordering H.R. 7667 favorably reported to the House, amended. The motion on final passage of the bill was approved by a record vote of 55 yeas to zero nays. The following are the record votes taken during Committee consideration, including the names of those members voting for and against:

Committee on Energy and Commerce
117th Congress

Subcommittee on Health
(ratio: 19-15)
ROLL CALL VOTE #1

Bill: **H.R. 7667**, the "Food and Drug Amendments of 2022"

Motion: A motion by Ms. Eshoo of California to order **H.R. 7667** transmitted favorably to the full Committee, amended (Final Passage).

Disposition: **AGREED TO** by a roll call vote of 30 yeas to 0 nays

REPRESENTATIVE	YEAS	NAYS	PRESENT	REPRESENTATIVE	YEAS	NAYS	PRESENT
Ms. Eshoo	X			Mr. Guthrie	X		
Mr. Butterfield				Mr. Upton	X		
Ms. Matsui	X			Mr. Burgess	X		
Ms. Castor	X			Mr. Griffith	X		
Mr. Sarbanes	X			Mr. Bilirakis	X		
Mr. Welch				Mr. Long	X		
Mr. Schrader	X			Mr. Bucshon	X		
Mr. Cárdenas	X			Mr. Mullin	X		
Mr. Ruiz	X			Mr. Hudson	X		
Mrs. Dingell	X			Mr. Carter			
Ms. Kuster	X			Mr. Dunn	X		
Ms. Kelly	X			Mr. Curtis	X		
Ms. Barragán	X			Mr. Crenshaw	X		
Ms. Blunt Rochester	X			Mr. Joyce	X		
Ms. Craig	X			Mrs. Rodgers	X		
Ms. Schrier	X						
Ms. Trahan	X						
Ms. Fletcher	X						
Mr. Pallone	X						

05/11/22

Committee on Energy and Commerce
117th Congress

Full Committee
(ratio: 32-26)
ROLL CALL VOTE #119

Bill: **H.R. 7667**, the "Food and Drug Amendments of 2022"

Vote: Final Passage

Disposition: **AGREED TO** by a roll call vote of 55 yeas to 0 nays

REPRESENTATIVE	YEAS	NAYS	PRESENT	REPRESENTATIVE	YEAS	NAYS	PRESENT
Mr. Pallone	X			Mrs. Rodgers	X		
Mr. Rush	X			Mr. Upton	X		
Ms. Eshoo	X			Mr. Burgess	X		
Ms. DeGette	X			Mr. Scalise			
Mr. Doyle	X			Mr. Latta	X		
Ms. Schakowsky	X			Mr. Guthrie	X		
Mr. Butterfield	X			Mr. McKinley	X		
Ms. Matsui	X			Mr. Kinzinger	X		
Ms. Castor	X			Mr. Griffith	X		
Mr. Sarbanes	X			Mr. Bilirakis	X		
Mr. McNerney	X			Mr. Johnson	X		
Mr. Welch				Mr. Long	X		
Mr. Tonko	X			Mr. Bucshon	X		
Ms. Clarke	X			Mr. Mullin	X		
Mr. Schrader	X			Mr. Hudson	X		
Mr. Cárdenas	X			Mr. Walberg	X		
Mr. Ruiz	X			Mr. Carter	X		
Mr. Peters	X			Mr. Duncan	X		
Mrs. Dingell	X			Mr. Palmer	X		
Mr. Veasey	X			Mr. Dunn	X		
Ms. Kuster	X			Mr. Curtis	X		
Ms. Kelly	X			Ms. Lesko	X		
Ms. Barragán	X			Mr. Pence	X		
Mr. McEachin				Mr. Crenshaw	X		
Ms. Blunt Rochester	X			Mr. Joyce	X		
Mr. Soto	X			Mr. Armstrong	X		
Mr. O'Halleran	X						
Ms. Rice	X						
Ms. Craig	X						
Ms. Schrier	X						
Ms. Trahan	X						
Ms. Fletcher	X						

VI. Oversight Findings

Pursuant to clause 3(c)(1) of rule XIII and clause 2(b)(1) of rule X of the Rules of the House of Representatives, the oversight findings and recommendations of the Committee are reflected in the descriptive portion of the report.

VII. New Budget Authority, Entitlement Authority, and Tax Expenditures

Pursuant to 3(c)(2) of rule XIII of the Rules of the House of Representatives, the Committee adopts as its own the estimate of new budget authority, entitlement authority, or tax expenditures or revenues contained in the cost estimate prepared by the Director of the Congressional Budget Office pursuant to section 402 of the Congressional Budget Act of 1974.

The Committee has requested but not received from the Director of the Congressional Budget Office a statement as to whether this bill contains any new budget authority, spending authority, credit authority, or an increase or decrease in revenues or tax expenditures.

VIII. Federal Mandates Statement

The Committee adopts as its own the estimate of Federal mandates prepared by the Director of the Congressional Budget Office pursuant to section 423 of the Unfunded Mandates Reform Act.

IX. Statement of General Performance Goals and Objectives

Pursuant to clause 3(c)(4) of rule XIII, the general performance goal or objective of this legislation is to reauthorize important FDA user fee programs and to improve the review and regulation of products regulated by FDA.

X. Duplication of Federal Programs

Pursuant to clause 3(c)(5) of rule XIII, no provision of H.R. 7667 is known to be duplicative of another Federal program, including any program that was included in a report to Congress pursuant to section 21 of Public Law 111–139 or the most recent Catalog of Federal Domestic Assistance.

XI. Committee Cost Estimate

Pursuant to clause 3(d)(1) of rule XIII, the Committee adopts as its own the cost estimate prepared by the Director of the Congressional Budget Office pursuant to section 402 of the Congressional Budget Act of 1974.

XII. Earmarks, Limited Tax Benefits, and Limited Tariff Benefits

Pursuant to clause 9(e), 9(f), and 9(g) of rule XXI, the Committee finds that H.R. 7667 contains no earmarks, limited tax benefits, or limited tariff benefits.

XIII. Advisory Committee Statement

No advisory committee within the meaning of section 5(b) of the Federal Advisory Committee Act was created by this legislation.

XIV. Applicability to Legislative Branch

The Committee finds that the legislation does not relate to the terms and conditions of employment or access to public services or accommodations within the meaning of section 102(b)(3) of the Congressional Accountability Act.

XV. Section-by-Section Analysis of the Legislation

TITLE I—FEES RELATING TO DRUGS

Section 101. Short title; finding

Section 101 establishes a short title for Title I—the "Prescription Drug User Fee Amendments of 2022"—and provides that the fees authorized in the title will be dedicated to expediting the drug development and review processes, including postmarket drug safety activities, as set forth in the commitment letter submitted to the Congressional Record.

Sec. 102. Definitions

Section 102 adds to the definition of human drug application certain applications with respect to allergenic extract products, adds to the definition of prescription drug product certain allergenic extract products, details how product withdrawn from sale may be considered discontinued for purposes of the prescription drug program fee, and adds a definition for skin-test diagnostic products.

Sec. 103. Authority to assess and use drug fees

Section 103 reauthorizes FDA's prescription drug user fee program through 2027, maintains the existing fee structure, and increases and adjusts fees, including a new strategic hiring and a reserve adjustment. This section also excepts skin-test diagnostic products from human drug application fees, provides a special rule for products that are no longer discontinued, and provides program fee exceptions for certain large volume parenteral products, products that are pharmaceutically equivalent to certain other products, and skin-test diagnostic products.

Sec. 104. Reauthorization; reporting requirements

Section 104 reauthorizes and updates requirements for FDA reporting to Congress and requires reporting regarding certain requests for in-person face-to-face meetings in fiscal years 2023 and 2024.

Sec 105. Sunset dates

Section 105 sunsets the authority to collect prescription drug user fees on October 1, 2027, and sunsets reporting requirements on January 31, 2028.

Sec 106. Effective date

Section 106 clarifies that the effective date of this title is October 1, 2022, or the date of enactment, whichever is later, except that

the fees in FFDCA apply to applications received on or after October 1, 2022, regardless of the date of enactment.

Sec. 107. Savings clause

Section 107 clarifies that the prescription drug user fees in effect before enactment continue to apply to human drug applications and supplements accepted by FDA for filing before October 1, 2022.

TITLE II—FEES RELATING TO DEVICES

Sec. 201. Short title; finding

Section 201 establishes a short title for Title II—the "Medical Device User Fee Amendments of 2022"—and provides that the fees authorized in the title will be dedicated to expediting the process for device review and assuring device safety and effectiveness, as set forth in the commitment letter submitted to the Congressional Record.

Sec. 202. Definitions

Section 202 amends the definition of "process for the review of device applications" to include de novo classification requests.

Sec. 203. Authority to assess and use device fees

Section 203 reauthorizes FDA's medical device user fee program through 2027, maintains the existing fee structure, and increases and adjusts fees, including a new strategic hiring adjustment, operating reserve adjustment, and performance improvement adjustment that provides for increased fees in later years if FDA meets review goal timelines.

Sec. 204. Reauthorization; reporting requirements

Section 204 reauthorizes and updates requirements for FDA reporting to Congress.

Sec. 205. Conformity assessment pilot program

Section 205 reauthorizes a pilot program for accreditation of testing laboratories to assess conformance of a device with certain recognized standards and continuation of program after completion of pilot.

Sec. 206. Reauthorization of third-party review program

Section 206 reauthorizes third party 510(k) review of certain devices.

Sec. 207. Sunset dates

Section 209 sunsets the authority to collect medical device user fees on October 1, 2027, and sunsets reporting requirements on January 31, 2028.

Sec. 208. Effective date

Section 208 clarifies that the effective date of this title is October 1, 2022, or the date of enactment, whichever is later, except that the fees in FFDCA apply to submissions received on or after October 1, 2022, regardless of the date of enactment.

Sec. 209. Savings clause

Section 207 clarifies that the medical device user fees in effect before enactment continue to apply to device submissions received by FDA before October 1, 2022.

TITLE III—FEES RELATING TO GENERIC DRUGS

Sec. 301. Short title; finding

Section 301 establishes a short title for Title III—the "Generic Drug User Fee Amendments of 2022"—and provides that the fees authorized in the title will be dedicated to human generic drug activities, as set forth in the commitment letter submitted to the Congressional Record.

Sec. 302. Authority to assess and use human generic drug fees

Section 302 reauthorizes FDA's generic drug user fee program through 2027, maintains existing fee structure, and increases and adjusts fees, including capacity planning and operating reserve adjustments.

Sec. 303. Reauthorization; reporting requirements

Section 303 reauthorizes and updates requirements for FDA reporting to Congress.

Sec. 304. Sunset dates

Section 304 sunsets the authority to collect generic drug user fees on October 1, 2027, and sunsets reporting requirements on January 31, 2028.

Sec. 305. Effective date

Section 305 clarifies that the effective date of this title is October 1, 2022, or the date of enactment, whichever is later, except that the fees in FFDCA apply to applications received on or after October 1, 2022, regardless of the date of enactment.

Sec. 306. Savings clause

Section 306 clarifies that the generic drug user fees in effect before enactment continue to apply to new drug applications and prior approval supplements received by FDA before October 1, 2022, and drug master files for Type II active pharmaceutical ingredients first referenced before October 1, 2022.

TITLE IV—FEES RELATING TO BIOSIMILAR BIOLOGICAL PRODUCTS

Sec. 401. Short title; finding

Section 401 establishes a short title for Title IV—the "Biosimilar User Fee Amendments of 2022"—and provides that the fees authorized in the title will be dedicated to expediting the review of biosimilar biological product applications, including postmarket drug safety activities, as set forth in the commitment letter submitted to the Congressional Record.

Sec. 402. Definitions

Section 402 defines adjustment factor and removes the exclusion of allergenic extract product applications from the definition of biosimilar biological product application.

Sec. 403. Authority to assess and use biosimilar fees

Section 403 reauthorizes the biosimilar user fee program through 2027, maintains the existing fee structure, and increases and adjusts fees, including a strategic hiring and retention adjustment. Section 403 also adds provisions regarding removal from the biosimilar development program for failure to pay fees under certain circumstances, requests for movement to the list of discontinued biosimilar biological products, and a special rule for products that are no longer discontinued.

Sec. 404. Reauthorization; reporting requirements

Section 404 reauthorizes and updates requirements for FDA reporting to Congress.

Sec. 405. Sunset dates

Section 405 sunsets the authority to collect biosimilar user fees on October 1, 2027, and sunsets reporting requirements on January 31, 2028.

Sec. 406. Effective date

Section 406 clarifies that the effective date of this title is October 1, 2022, or the date of enactment, whichever is later, except that the fees in FFDCA apply to applications received on or after October 1, 2022, regardless of the date of enactment.

Sec. 407. Savings clause

Section 407 clarifies that the biosimilar user fees in effect before enactment continue to apply to biosimilar biological product applications and supplements accepted by FDA for filing before October 1, 2022.

TITLE V—IMPROVING DIVERSITY IN CLINICAL STUDIES

Sec. 501. Diversity action plans for clinical studies

Section 501 requires sponsors of phase 3 and other pivotal studies of new drugs (and biological products that are also drugs) and sponsors of studies of devices (including biological products that are also devices) except those excepted under 21 C.F.R. § 812.3(c), to develop and implement a diversity action plan. Such plan must include the sponsor's goals for enrollment in the clinical studies, the sponsor's rationale for such goals, and an explanation for how the sponsor intends to meet such goals. FDA may waive this requirement for certain drugs and devices based on a determination that submission of a diversity action plan is not necessary based on what is known about the prevalence of the disease in terms of the patient population that may use the drug. Submissions under section 561 of the FFDCA (21 U.S.C. § 360bbb) are exempt from this requirement. This section requires drug sponsors to submit their plans to FDA in the form and manner specified in the guidance required by this section as soon as practicable but no later than when

the sponsor seeks feedback from FDA regarding a phase 3 study or other pivotal study of the drug.

The timing and manner of diversity action plan submission to FDA for device studies is dependent upon whether submission of an application for investigational device exemption (IDE) to FDA is required under FDA regulations. FDA regulations, 21 C.F.R. § 812.20(a), require submission of an IDE application for studies of significant risk devices, studies involving exceptions from informed consent, and studies for which FDA notifies the sponsor an application is required. Under 21 C.F.R. § 812.2(b), non-significant risk studies are considered to have approved IDE applications, without sponsor submission of such, as long as the sponsor complies with certain abbreviated requirements and FDA does not notify the sponsor that IDE application submission is required. Section 501 of H.R. 7667 provides that device sponsors must submit their diversity action plan in their IDE application, if one is required; if one is not required, sponsors must submit their plans in any premarket notification, application for premarket approval, or request for de novo classification the sponsor may submit to FDA. Diversity action plans would also be subject to inspection by FDA.

The requirement to submit diversity action plans becomes effective six months after publication of the final guidance required by this section; sponsors of studies for which enrollment has begun after such date must comply. Failure to comply prevents a drug or device to which this requirement is applicable from being exempt under section 505(i) or 520(g) of the FFDCA (21 U.S.C. §§ 355(i), 360j(g)) from other applicable requirements. For non-significant risk devices, at the time the study is being conducted, failure to develop or implement a plan as required by this section would prevent the device from being exempt under section 520(g) of the FFDCA; at the time of any submission for premarket review to FDA, failure to submit the diversity action plan to FDA would render the device adulterated under section 501(i) of the FFDCA.

This section also requires FDA to issue new draft guidance or update existing draft guidance within 12 months of enactment, and to finalize such guidance no later than nine months after the close of the comment period. The guidance must specify the form and content of diversity action plans regarding the sponsor's goals for study enrollment, disaggregated into certain demographic categories, including with respect to the rationale for enrollment goals, an explanation for how the sponsor will meet such goals, and how the sponsor will publicly post key information from the plan that would be useful to patients and providers on its website.

Sec. 502. Evaluation of the need for FDA authority to mandate post-approval studies or postmarket surveillance due to insufficient demographic subgroup data

Section 502 requires FDA to evaluate, not later than two years after the publication of the final guidance required by section 501, whether regulations or additional authorities are warranted to ensure that sponsors conduct post-approval studies or postmarket surveillance where premarket studies collected insufficient data for underrepresented subgroups according to the sponsor's goals and FDA has requested additional studies to be conducted.

Sec. 503. Public workshops to enhance clinical study diversity

Section 503 requires FDA, in consultation with drug sponsors, medical device manufacturers, patients, and other stakeholders, not later than one year after enactment, to convene one or more public workshops to solicit input from stakeholders on increasing the enrollment of historically underrepresented populations in clinical studies.

Sec. 504. Annual summary report on progress to increase diversity in clinical studies

Section 504 requires FDA, not later than two years after the enactment of the Food and Drug Amendments of 2022, and annually thereafter, to submit to Congress, and publish on the public website of FDA, a report that summarizes the diversity action plans received pursuant to section 501 and contains information on whether studies for approved and cleared drugs and devices met diversity action plan goals, the reasons given whenever sponsors failed to meet their goals, and any postmarket studies requested or required by FDA where there was inadequate premarket study diversity.

Sec. 505. Public meeting on clinical study flexibilities initiated in response to COVID–19 pandemic

Section 505 requires FDA, not later than 180 days after the date on which the COVID–19 public health emergency period ends, to convene a public meeting to discuss recommendations provided during the COVID–19 public health emergency to mitigate disruption of clinical studies. Such meeting shall discuss incorporating certain clinical study disruption mitigation recommendations into current or additional guidance to improve clinical study access and enrollment of diverse patient populations.

Sec. 506. Decentralized clinical studies

Section 506 requires FDA, not later than 12 months after the enactment of the Food and Drug Amendments of 2022, to issue draft guidance that addresses considerations for decentralized clinical studies, including regarding the engagement, enrollment, and retention of a meaningfully diverse clinical population with respect to race, ethnicity, age, sex, and geographic location, when appropriate. FDA is required to finalize this guidance no later than one year after the public comment period for the draft guidance ends.

TITLE VI—GENERIC DRUG COMPETITION

Sec. 601. Increasing transparency in generic drug applications

Section 601 requires FDA to provide generic drug sponsors, upon request, information regarding any qualitative or quantitative differences in ingredients between their generic drug and the reference listed drug to which they are compared, to facilitate generic drug development and review. This section makes clear these disclosures are authorized by law, including under section 1905 of title 18, United States Code. This section also requires FDA to issue guidance explaining how it determines whether a generic drug is qualitatively and quantitatively the same as the listed drug.

Sec. 602. Enhancing access to affordable medicines

Section 602 provides that a generic drug is eligible for approval notwithstanding differences between its proposed labeling and that of the listed drug due to revisions made to the labeling of the listed drug approved by FDA within 90 days of when the generic application is otherwise eligible for approval. This section preserves the provisions requiring that the revisions not be to the "Warnings" section of the labeling, the generic sponsor must submit revised labeling within 60 days of approval, and the applicable otherwise meet applicable requirements for approval.

TITLE VII—RESEARCH, DEVELOPMENT, AND SUPPLY CHAIN IMPROVEMENTS

SUBTITLE A—IN GENERAL

Sec. 701. Animal testing alternatives

Section 701 clarifies one of the purposes of a certain type of meeting FDA is required to have with sponsors of drug studies and applicants for drug approval, upon reasonable written request, in situations where human efficacy studies are not ethical or feasible. Section 701 broadens the purpose from reaching agreement on the design and size of "animal and any associated clinical trials" intended to support effectiveness to reaching agreement on the design and size of "nonclinical tests and any associated clinical trials" intended to support effectiveness, so that non-animal nonclinical studies would be included in these meetings in the event that such studies may be sufficient to provide substantial evidence of effectiveness in these situations. This section also broadens references to animal testing in section 505(i) regarding investigational new drug exemptions to "nonclinical tests." Section 701 also defines "nonclinical test" and clarifies that it includes cell-based assays, organ chips and microphysiological systems, computer modeling, other nonhuman or human biology-based test methods, and animal tests.

Sec. 702. Emerging technology program

Section 702 authorizes the Emerging Technologies Program at FDA, a collaborative program wherein industry representatives, academics, and others can meet with FDA officials to support the adoption and improve the development of innovative approaches to drug design and manufacturing. This section requires FDA to issue guidance regarding requirements related to such approaches and report to Congress regarding allocation of funds and staff utilization in this program. It authorizes FDA to make grants and authorizes $20 million each year for fiscal years 2023 through 2027 to carry out the program.

Sec. 703. Improving the treatment of rare diseases and conditions

Section 703 requires FDA to submit a report summarizing its activities relating to designating, approving, and licensing drugs used to treat rare diseases no later than September 30, 2026. This section also requires FDA to study processes for evaluating drugs for rare diseases in the United States and the European Union and to convene one or more public meetings to solicit input from stake-

holders regarding approaches to improving engagement with rare disease condition patients, patient groups, and experts. Section 703 also requires the Government Accountability Office (GAO) to conduct a study on the use of FDA tools and mechanisms to ensure that patient and physician perspectives are considered and incorporated throughout FDA processes for approving and licensing drugs and making determinations related to a drug's approval.

Sec. 704. Antifungal research and development

Section 704 requires the Secretary to issue guidance for industry to assist entities seeking approval or licensure for antifungal therapies intended to treat coccidioidomycosis, commonly known as Valley Fever, and to hold a public workshop to assist entities developing preventative vaccines for fungal infections and Valley Fever.

Sec. 705. Advancing qualified infectious disease product innovation

Section 705 allows a biological product to qualify as a Qualified Infectious Disease Product (QIDP) under Section 505E of the FFDCA (21 U.S.C. § 355f), which renders it eligible for fast track designation, and provides for priority review for the first application for an innovative biological antifungal or antibiotic QIDP that requires clinical data to demonstrate safety or effectiveness. This section does not extend QIDP exclusivity to biological products.

Sec. 706. Advanced manufacturing technologies designation pilot program

Section 706 requires FDA to initiate a pilot program for designating methods of manufacturing as advanced manufacturing technologies. A method of manufacturing is eligible for designation if such method both: incorporates a novel technology or uses an established technology in a novel way and will substantially improve the manufacturing process and maintain equivalent or superior drug quality. Designated technologies qualify for expedited application development and review and allow the holder of such designation, or a person authorized by the designation holder, to reference or rely upon, in a drug or biologic application, data and information about the designated technology for use in manufacturing drugs in the same context of use for which FDA granted the designation. This section also requires FDA to hold a public meeting, issue guidance, and report to Congress regarding this pilot, which sunsets on October 1, 2029.

Sec. 707. Public workshop on cell therapies

Section 707 requires FDA to convene a public workshop on best practices on generating scientific data necessary to further facilitate development of certain human cell-, tissue-, and cellular-based medical products, and the latest scientific information about such products.

Sec. 708. Reauthorization of best pharmaceuticals for children

Section 708 reauthorizes the Best Pharmaceuticals for Children Act through 2027, which allows the National Institutes of Health to fund studies of off-patent drugs in children.

Sec. 709. Reauthorization for humanitarian device exemption and demonstration grants for improving pediatric availability

Section 709 reauthorizes through 2027 the exemption, subject to certain conditions, from the profit limitation on devices granted a humanitarian device exemption under section 520(m) of the FFDCA (21 U.S.C. § 360j(m)). Such devices, which are designed to treat or diagnose a disease or condition that affects 8,000 or fewer individuals in the United States, are exempt from certain requirements if they meet certain criteria. Section 709 also reauthorizes demonstration grants for improving development of pediatric medical devices through 2027.

Sec. 710. Reauthorization of provision related to exclusivity of certain drugs containing single enantiomers

Section 710 reauthorizes the provision allowing for exclusivity for certain single enantiomer drugs under certain conditions through 2027.

Sec. 711. Reauthorization of the critical path public-private partnership program

Section 711 reauthorizes the Critical Path Public-Private Partnership at $10 million annually through 2027.

Sec. 712. Reauthorization of orphan drug grants

Section 712 reauthorizes orphan drug grants through 2027 and expands uses of such grants to include the development of regulatory science pertaining to manufacturing and controls related to individualized medical products to treat those with rare diseases or conditions.

Sec. 713. Research into pediatric uses of drugs; additional authorities of Food and Drug Administration regarding molecularly targeted cancer drugs

This section builds on the requirement included in Section 504 of the FDA Reauthorization Act of 2017 for pediatric studies by sponsors of certain adult cancer drugs with new active ingredients directed at a molecular target FDA determines to be substantially relevant to the growth or progression of a pediatric cancer. Such required pediatric studies shall be designed to yield clinically meaningful data regarding dosing, safety, and preliminary efficacy to inform potential pediatric labeling. The section also clarifies that the required pediatric study may be of the new drug for which approval is sought or such drug used in combination with a previously approved drug or biological product that meets certain conditions. Additionally, Section 713 requires FDA to issue guidance and report to Congress on its implementation of this section not later than two years after enactment, and a GAO report on its success in the development of drugs and biological products for pediatric cancer indications.

SUBTITLE B—INSPECTIONS

Sec. 721. Factory inspection

Section 721 clarifies that the scope of FDA inspectional authority extending to all things in a factory, warehouse, establishment, or

consulting laboratory applies to such places that manufacture, process, pack, or hold non-restricted devices as well as ones that do so with respect to restricted devices. This section also extends the requirement for the provision, to FDA, of records requested in advance or in lieu of an inspection to persons that own or operate establishments engaged in the manufacture, preparation, propagation, compounding, or processing of devices. FDA will have to provide a rationale for requesting such records and issue guidance regarding such requests.

Section 721 also codifies and clarifies FDA authority to inspect clinical study sites, also known as bioresearch monitoring inspections. It requires FDA to review its processes and practices applicable to such inspections in the United States and in foreign countries, evaluate whether updates are needed to facilitate consistency, and issue guidance describing the conduct of such inspections.

Sec. 722. Uses of certain evidence

Section 722 clarifies that the limitation on FDA's use of certain evidence regarding product movement in interstate commerce obtained from carriers and receivers does not apply to information obtained under other authorities such as those authorizing inspections unless such limitations are specifically incorporated.

Sec. 723. Improving FDA inspections

Section 723 provides for FDA consideration of the compliance history of other FDA-regulated establishments in the country or region in which an establishment is located as a factor in establishing a schedule for risk-based inspections. It clarifies that FDA may rely on any records or other information inspected to satisfy requirements that may pertain to a preapproval or risk-based surveillance inspection, or to resolve deficiencies found in such inspections, if applicable and appropriate. It provides that FDA may enter into agreements with foreign governments to recognize inspections of foreign establishments to facilitate preapproval inspections and requires a periodic assessment of whether additional arrangements with foreign governments are appropriate.

Sec. 724. GAO report on inspections of foreign establishments manufacturing drugs

Section 724 requires GAO to report on FDA and recognized foreign government inspections of foreign establishments manufacturing drugs.

Sec. 725. Unannounced foreign facility inspections pilot program

Section 725 requires FDA to conduct a pilot program in which FDA increases the conduct of unannounced surveillance inspections of foreign drug establishments, evaluates the differences between such inspections of domestic and foreign establishments, including the impact of announcing inspections, and post a report of its findings and recommendations on the FDA website.

Sec. 726. Reauthorization of inspection program

Section 726 reauthorizes the third-party inspection program until October 1, 2027.

Sec. 727. Enhancing intra-agency coordination and public health assessment with regard to compliance activities

Section 727 amends section 506D of the FFDCA (21 U.S.C. § 356d) to require FDA to ensure timely and effective internal coordination and alignment among field investigators and staff of CDER's Office of Compliance and Drug Shortage Program regarding the reviews of inspection reports and any feedback or corrective actions in response to such reports. It also requires FDA reporting to Congress regarding certain drug shortage reports and the internal coordination and alignment required by this section.

Sec. 728. Reporting of mutual recognition agreements for inspections and review activities

Section 728 requires FDA to publish on its website a report, no later than the end of calendar year 2022 and annually thereafter, on the utilization of agreements entered into pursuant to section 809 of the FFDCA (21 U.S.C. § 384e) or otherwise entered into to recognize inspections across countries and international regions by drug regulatory authorities with analogous review criteria to the FDA.

Sec. 729. Enhancing transparency of drug facility inspection timelines

Section 729 amends the information FDA must annually report regarding inspections on its website pursuant to section 902 of the FDA Reauthorization Act of 2017, including by adding to this information the time between a request from FDA and the beginning of an inspection for certain generic drugs, drugs subject to discontinuance reporting, and drugs on the shortage list.

TITLE VIII—TRANSPARENCY, PROGRAM INTEGRITY, AND REGULATORY IMPROVEMENTS

Sec. 801. Prompt reports of marketing status by holders of approved applications for biological products

Section 801 requires all holders of approved Biologics License Applications to submit a one-time notification to FDA indicating whether their products listed in the Purple Book are still available for sale and to report to FDA on an ongoing basis when withdrawing a product from the market.

Sec. 802. Encouraging blood donation

Section 802 exempts from Paperwork Reduction Act requirements FDA information collections to solicit patient perspectives during medical product development and to solicit information from blood donors and potential blood donors to inform recommendations regarding blood donation.

Sec. 803. Regulation of certain products as drugs

Section 803 deems all contrast agents and products under over-the-counter drug monographs, and certain radioactive products, to be drugs and not medical devices.

Sec. 804. Postapproval studies and program integrity for accelerated approval drugs

Section 804 requires FDA to specify conditions for required postapproval studies for drugs approved under accelerated approval, which may include enrollment targets and milestones, including the target date for study completion, by the time the drug is approved. This section also authorizes FDA to require postapproval studies to be underway at the time of approval for such drugs, requires FDA to explain any instances where it does not require such studies, and provides that postapproval studies may be augmented or supported by real world evidence. This section clarifies that existing authority to withdraw approvals where sponsors fail to conduct studies with due diligence applies with respect to the approval conditions and streamlines the procedures for withdrawal of approval. To withdraw an accelerated approval, it requires FDA to provide an explanation for the withdrawal, an opportunity for written appeal, a meeting with the Commissioner or their designee, responses to public comment, and, upon request, an advisory committee meeting if there was not previously one on the withdrawal. Section 804 codifies labeling requirements for accelerated approval and requires more frequent reports on postapproval study progress. It also requires FDA to report to Congress on the use of real world evidence to support postapproval studies, issue guidance on novel surrogate endpoints and trial designs, and establish a rare disease endpoint advancement pilot program.

Sec. 805. Facilitating the use of real world evidence

Section 805 requires FDA to issue guidance addressing the use of real world evidence and real world data, including that obtained for drugs and devices authorized for emergency use during the COVID–19 public health emergency, to support drug and device approvals and clearances. It requires FDA to report to Congress regarding the number of applications submitted for products for which an emergency use authorization was previously granted and, of such applications, how many included real world evidence and whether such evidence was sufficient to support a regulatory decision.

Sec. 806. Dual submission for certain devices

Section 806 provides that sponsors of diagnostic tests that have been deemed to be CLIA-waived under section 564(m) of the FFDCA (21 U.S.C. § 360j(m)) as part of a COVID–19 emergency use authorization that submit requests for de novo classification of their test under section 513(f)(2) of the FFDCA (21 U.S.C. § 360c(f)(2)) may submit such request together with sufficient information to enable FDA to determine whether the test satisfies the criteria for CLIA categorization under section 353(d)(3) of the Public Health Service Act (42 U.S.C. § 263a(d)(3)) in a single submission.

Sec. 807. Medical devices advisory committee meetings

Section 807 requires the Medical Device Advisory Committee to meet at least once a year through 2027 to provide FDA advice on topics related to medical devices in pandemic preparedness and response, including issues related to in vitro diagnostics.

Sec. 808. Ensuring cybersecurity of medical devices

Section 808 requires manufacturers of cyber devices to develop processes to ensure their devices are secure, have plans to identify and address cybersecurity vulnerabilities, provide a software bill of materials in their labeling, and submit this information to FDA in any premarket submissions. It defines cyber devices as devices that have software, connect to the internet, or otherwise could be vulnerable to cybersecurity threats. Section 808 authorizes FDA to deny 510(k) clearance if cyber security information is inadequate and to exempt types of devices from these requirements. It makes failure to comply with these requirements a prohibited act.

Sec. 809. Public docket on proposed changes to third-party vendors

Section 809 requires FDA to provide a public comment period regarding patient access and provider administration when a proposed modification to an approved risk evaluation and mitigation strategy (REMS) is reviewed under section 505–1(h) of the FFDCA (21 U.S.C. § 355 1(h)). This section makes clear that it shall not delay any agency action on any modification to a REMS.

Sec. 810. Facilitating exchange of product information prior to approval

Section 810 provides that no drug or device shall be considered misbranded as a result of the provision of information regarding investigational drugs or devices or uses to payors, formulary committees, or other similar entities under specified conditions. It requires the information to include a clear statement that the drug or device it discusses has not been approved and that the safety and efficacy of the drug or device has not been established. Additional required disclosures include information about studies the drug or device is undergoing, how the studies relate to the overall plan for the development of the drug or device, whether an application for the drug or device has been submitted to FDA, and if not, when such submission is planned.

Sec. 811. Bans of devices for one or more intended uses

Section 811 amends section 516 of the FFDCA (21 U.S.C. § 360f) to make clear that FDA is authorized to ban a medical device intended for a particular use. A ban may apply to devices intended for more than one use, but in a situation where there are devices with the same or similar technological characteristics and different intended uses, FDA may ban one and not the other. Section 811 also bans electrical stimulation devices intended for self-injurious and aggressive behavior, which renders such devices adulterated under section 501(g) of the FFDCA (21 U.S.C. § 351(g)).

Sec. 812. Clarifying application of exclusive approval, certification, or licensure for drugs designated for rare disease or conditions

Section 812 amends section 527 of the FFDCA (21 U.S.C. § 360cc) regarding orphan drugs to provide clarity that orphan exclusivity applies only to the specific indication or use approved by FDA under this section, not the entire rare disease or condition for which the drug was designated, consistent with FDA's long-held interpretation of the law.

Sec. 813. GAO report on third-party review

Section 813 requires GAO to report on the program for accredited third-party review of 510(k) premarket notifications for medical devices.

Sec. 814. Reporting on pending generic drug applications and priority review applications

Section 814 reauthorizes reporting on certain pending generic drug applications and priority review applications through 2027.

Sec. 815. FDA workforce improvements

Section 815 extends the authority Congress granted to FDA in the 21st Century Cures Act of 2016 to facilitate the hiring and retention of outstanding candidates for scientific, technical, or professional positions that support the development and regulation of medical products to the hiring of candidates for such positions to support the regulation of products across the entire agency. This section also requires FDA to develop and begin implementation of a strategic workforce plan and report to Congress regarding such plan.

XVI. CHANGES IN EXISTING LAW MADE BY THE BILL, AS REPORTED

In compliance with clause 3(e) of rule XIII of the Rules of the House of Representatives, changes in existing law made by the bill, as reported, are shown as follows (existing law proposed to be omitted is enclosed in black brackets, new matter is printed in italics, and existing law in which no change is proposed is shown in roman):

FEDERAL FOOD, DRUG, AND COSMETIC ACT

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CHAPTER III—PROHIBITED ACTS AND PENALTIES

PROHIBITED ACTS

SEC. 301. The following acts and the causing thereof are hereby prohibited:

(a) The introduction or delivery for introduction into interstate commerce of any food, drug, device, tobacco product, or cosmetic that is adulterated or misbranded.

(b) The adulteration or misbranding of any food, drug, device, tobacco product, or cosmetic in interstate commerce.

(c) The receipt in interstate commerce of any food, drug, device, tobacco product, or cosmetic that is adulterated or misbranded, and the delivery or proffered delivery thereof for pay or otherwise.

(d) The introduction or delivery for introduction into interstate commerce of any article in violation of section 404, 415, 505, or 564.

(e) The refusal to permit access to or copying of any record as required by section 412, 414, 417(j), 416, 504, 564, 703, 704(a), 760, or 761; or the failure to establish or maintain any record, or make any report, required under section 412, 414(b), 417, 416, 504, 505 (i) or (k), 512(a)(4)(C), 512 (j), (l) or (m), 572(i), 515(f), 519, 564,

760, 761, 909, or 920 or the refusal to permit access to or verification or copying of any such required record; or the violation of any recordkeeping requirement under section 204 of the FDA Food Safety Modernization Act (except when such violation is committed by a farm).

(f) The refusal to permit entry or inspection as authorized by section 704.

(g) The manufacture within any Territory of any food, drug, device, tobacco product, or cosmetic that is adulterated or misbranded.

(h) The giving of a guaranty or undertaking referred to in section 303(c)(2), which guaranty or undertaking is false, except by a person who relied upon a guaranty or undertaking to the same effect signed by, and containing the name and address of, the person residing in the United States from whom he received in good faith the food, drug, device, tobacco product, or cosmetic; or the giving of a guaranty or undertaking referred to in section 303(c)(3), which guaranty or undertaking is false.

(i)(1) Forging, counterfeiting, simulating, or falsely representing, or without proper authority using any mark, stamp, tag, label, or other identification device authorized or required by regulations promulgated under the provisions of section 404 or 721.

(2) Making, selling, disposing of, or keeping in possession, control, or custody, or concealing any punch, die, plate, stone, or other thing designed to print, imprint, or reproduce the trademark, trade name, or other identifying mark, imprint, or device of another or any likeness of any of the foregoing upon any drug or container or labeling thereof so as to render such drugs a counterfeit drug.

(3) The doing of any act which causes a drug to be a counterfeit drug, or the sale or dispensing, or the holding for sale or dispensing, of a counterfeit drug.

(j) The using by any person to his own advantage, or revealing, other than to the Secretary or officers or employees of the Department, or to the courts when relevant in any judicial proceeding under this Act, any information acquired under authority of section 404, 409, 412, 414, 505, 510, 512, 513, 514, 515, 516, 518, 519, 520, 571, 572, 573, 704, 708, 721, 904, 905, 906, 907, 908, 909, or 920(b) concerning any method or process which as a trade secret is entitled to protection; or the violating of section 408(i)(2) or any regulation issued under that section.. This paragraph does not authorize the withholding of information from either House of Congress or from, to the extent of matter within its jurisdiction, any committee or subcommittee of such committee or any joint committee of Congress or any subcommittee of such joint committee.

(k) The alteration, mutilation, destruction, obliteration, or removal of the whole or any part of the labeling of, or the doing of any other act with respect to, a food, drug, device, tobacco product, or cosmetic, if such act is done while such article is held for sale (whether or not the first sale) after shipment in interstate commerce and results in such article being adulterated or misbranded.

(m) The sale or offering for sale of colored oleomargarine or colored margarine, or the possession or serving of colored oleomargarine or colored margarine in violation of section 407(b) or 407(c).

(n) The using, in labeling, advertising or other sales promotion of any reference to any report or analysis furnished in compliance with section 704.

(o) In the case of a prescription drug distributed or offered for sale in interstate commerce, the failure of the manufacturer, packer, or distributor thereof to maintain for transmittal, or to transmit, to any practitioner licensed by applicable State law to administer such drug who makes written request for information as to such drug, true and correct copies of all printed matter which is required to be included in any package in which that drug is distributed or sold, or such other printed matter as is approved by the Secretary. Nothing in this paragraph shall be construed to exempt any person from any labeling requirement imposed by or under other provisions of this Act.

(p) The failure to register in accordance with section 510 or 905, the failure to provide any information required by section 510(j), 510(k), 905(i), or 905(j), or the failure to provide a notice required by section 510(j)(2) or 905(i)(3).

(q)(1) The failure or refusal—

(A) to comply with any requirement prescribed under section 518, 520(g), 903(b), 907, 908, or 915;

(B) to furnish any notification or other material or information required by or under section 519, 520(g), 904, 909, or 920; or

(C) to comply with a requirement under section 522 or 913.

(2) With respect to any device or tobacco product, the submission of any report that is required by or under this Act that is false or misleading in any material respect.

(3) The failure to comply with any requirement under section 524C (relating to ensuring device cybersecurity).

(r) The movement of a device, drug, or tobacco product in violation of an order under section 304(g) or the removal or alteration of any mark or label required by the order to identify the device, drug, or tobacco product as detained.

(s) The failure to provide the notice required by section 412(c) or 412(e), the failure to make the reports required by section 412(f)(1)(B), the failure to retain the records required by section 412(b)(4), or the failure to meet the requirements prescribed under section 412(f)(3).

(t) The importation of a drug in violation of section 801(d)(1), the sale, purchase, or trade of a drug or drug sample or the offer to sell, purchase, or trade a drug or drug sample in violation of section 503(c), the sale, purchase, or trade of a coupon, the offer to sell, purchase, or trade such a coupon, or the counterfeiting of such a coupon in violation of section 503(c)(2), the distribution of a drug sample in violation of section 503(d) or the failure to otherwise comply with the requirements of section 503(d), the distribution of drugs in violation of section 503(e), failure to comply with the requirements under section 582, the failure to comply with the requirements under section 584, as applicable, or the failure to otherwise comply with the requirements of section 503(e).

(u) The failure to comply with any requirements of the provisions of, or any regulations or orders of the Secretary, under section 512(a)(4)(A), 512(a)(4)(D), or 512(a)(5).

(v) The introduction or delivery for introduction into interstate commerce of a dietary supplement that is unsafe under section 413.

(w) The making of a knowingly false statement in any statement, certificate of analysis, record, or report required or requested under section 801(d)(3); the failure to submit a certificate of analysis as required under such section; the failure to maintain records or to submit records or reports as required by such section; the release into interstate commerce of any article or portion thereof imported into the United States under such section or any finished product made from such article or portion, except for export in accordance with section 801(e) or 802, or with section 351(h) of the Public Health Service Act; or the failure to so export or to destroy such an article or portions thereof, or such a finished product.

(x) The falsification of a declaration of conformity submitted under section 514(c) or the failure or refusal to provide data or information requested by the Secretary under paragraph (3) of such section.

(y) In the case of a drug, device, or food—

(1) the submission of a report or recommendation by a person accredited under section 523 that is false or misleading in any material respect;

(2) the disclosure by a person accredited under section 523 of confidential commercial information or any trade secret without the express written consent of the person who submitted such information or secret to such person; or

(3) the receipt by a person accredited under section 523 of a bribe in any form or the doing of any corrupt act by such person associated with a responsibility delegated to such person under this Act.

(z) The dissemination of information in violation of section 551.

(aa) The importation of a prescription drug in violation of section 804, the falsification of any record required to be maintained or provided to the Secretary under such section, or any other violation of regulations under such section.

(bb) The transfer of an article of food in violation of an order under section 304(h), or the removal or alteration of any mark or label required by the order to identify the article as detained.

(cc) The importing or offering for import into the United States of an article of food or a drug by, with the assistance of, or at the direction of, a person debarred from such activity under section 306(b)(3).

(dd) The failure to register in accordance with section 415.

(ee) The importing or offering for import into the United States of an article of food in violation of the requirements under section 801(m).

(ff) The importing or offering for import into the United States of a drug or device with respect to which there is a failure to comply with a request of the Secretary to submit to the Secretary a statement under section 801(o).

(gg) The knowing failure to comply with paragraph (7)(E) of section 704(g); the knowing inclusion by a person accredited under paragraph (2) of such section of false information in an inspection report under paragraph (7)(A) of such section; or the knowing failure of such a person to include material facts in such a report.

(hh) The failure by a shipper, carrier by motor vehicle or rail vehicle, receiver, or any other person engaged in the transportation of food to comply with the sanitary transportation practices prescribed by the Secretary under section 416.

(ii) The falsification of a report of a serious adverse event submitted to a responsible person (as defined under section 760 or 761) or the falsification of a serious adverse event report (as defined under section 760 or 761) submitted to the Secretary.

(jj)(1) The failure to submit the certification required by section 402(j)(5)(B) of the Public Health Service Act, or knowingly submitting a false certification under such section.

(2) The failure to submit clinical trial information required under subsection (j) of section 402 of the Public Health Service Act.

(3) The submission of clinical trial information under subsection (j) of section 402 of the Public Health Service Act that is false or misleading in any particular under paragraph (5)(D) of such subsection (j).

(kk) The dissemination of a television advertisement without complying with section 503B.

(ll) The introduction or delivery for introduction into interstate commerce of any food to which has been added a drug approved under section 505, a biological product licensed under section 351 of the Public Health Service Act, or a drug or a biological product for which substantial clinical investigations have been instituted and for which the existence of such investigations has been made public, unless—

(1) such drug or such biological product was marketed in food before any approval of the drug under section 505, before licensure of the biological product under such section 351, and before any substantial clinical investigations involving the drug or the biological product have been instituted;

(2) the Secretary, in the Secretary's discretion, has issued a regulation, after notice and comment, approving the use of such drug or such biological product in the food;

(3) the use of the drug or the biological product in the food is to enhance the safety of the food to which the drug or the biological product is added or applied and not to have independent biological or therapeutic effects on humans, and the use is in conformity with—

(A) a regulation issued under section 409 prescribing conditions of safe use in food;

(B) a regulation listing or affirming conditions under which the use of the drug or the biological product in food is generally recognized as safe;

(C) the conditions of use identified in a notification to the Secretary of a claim of exemption from the premarket approval requirements for food additives based on the notifier's determination that the use of the drug or the biological product in food is generally recognized as safe, provided that the Secretary has not questioned the general recognition of safety determination in a letter to the notifier;

(D) a food contact substance notification that is effective under section 409(h); or

(E) such drug or biological product had been marketed for smoking cessation prior to the date of the enactment of the Food and Drug Administration Amendments Act of 2007; or

(4) the drug is a new animal drug whose use is not unsafe under section 512.

(mm) The failure to submit a report or provide a notification required under section 417(d).

(nn) The falsification of a report or notification required under section 417(d).

(oo) The sale of tobacco products in violation of a no-tobacco-sale order issued under section 303(f).

(pp) The introduction or delivery for introduction into interstate commerce of a tobacco product in violation of section 911.

(qq)(1) Forging, counterfeiting, simulating, or falsely representing, or without proper authority using any mark, stamp (including tax stamp), tag, label, or other identification device upon any tobacco product or container or labeling thereof so as to render such tobacco product a counterfeit tobacco product.

(2) Making, selling, disposing of, or keeping in possession, control, or custody, or concealing any punch, die, plate, stone, or other item that is designed to print, imprint, or reproduce the trademark, trade name, or other identifying mark, imprint, or device of another or any likeness of any of the foregoing upon any tobacco product or container or labeling thereof so as to render such tobacco product a counterfeit tobacco product.

(3) The doing of any act that causes a tobacco product to be a counterfeit tobacco product, or the sale or dispensing, or the holding for sale or dispensing, of a counterfeit tobacco product.

(rr) The charitable distribution of tobacco products.

(ss) The failure of a manufacturer or distributor to notify the Attorney General and the Secretary of the Treasury of their knowledge of tobacco products used in illicit trade.

(tt) Making any express or implied statement or representation directed to consumers with respect to a tobacco product, in a label or labeling or through the media or advertising, that either conveys, or misleads or would mislead consumers into believing, that—

(1) the product is approved by the Food and Drug Administration;

(2) the Food and Drug Administration deems the product to be safe for use by consumers;

(3) the product is endorsed by the Food and Drug Administration for use by consumers; or

(4) the product is safe or less harmful by virtue of—

(A) its regulation or inspection by the Food and Drug Administration; or

(B) its compliance with regulatory requirements set by the Food and Drug Administration;

including any such statement or representation rendering the product misbranded under section 903.

(uu) The operation of a facility that manufactures, processes, packs, or holds food for sale in the United States if the owner, operator, or agent in charge of such facility is not in compliance with section 418.

(vv) The failure to comply with the requirements under section 419.

(ww) The failure to comply with section 420.

(xx) The refusal or failure to follow an order under section 423.

(yy) The knowing and willful failure to comply with the notification requirement under section 417(h).

(zz) The importation or offering for importation of a food if the importer (as defined in section 805) does not have in place a foreign supplier verification program in compliance with such section 805.

(aaa) The failure to register in accordance with section 801(s).

(bbb) The failure to notify the Secretary in violation of section 568.

(ccc)(1) The resale of a compounded drug that is labeled "not for resale" in accordance with section 503B.

(2) With respect to a drug to be compounded pursuant to section 503A or 503B, the intentional falsification of a prescription, as applicable.

(3) The failure to report drugs or adverse events by an entity that is registered in accordance with subsection (b) of section 503B.

(ddd)(1) The manufacture or the introduction or delivery for introduction into interstate commerce of a rinse-off cosmetic that contains intentionally-added plastic microbeads.

(2) In this paragraph—

(A) the term "plastic microbead" means any solid plastic particle that is less than five millimeters in size and is intended to be used to exfoliate or cleanse the human body or any part thereof; and

(B) the term "rinse-off cosmetic" includes toothpaste.

(eee) The failure to comply with any order issued under section 569D.

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CHAPTER V—DRUGS AND DEVICES

SUBCHAPTER A—DRUGS AND DEVICES

ADULTERATED DRUGS AND DEVICES

SEC. 501. A drug or device shall be deemed to be adulterated—

(a)(1) If it consists in whole or in part of any filthy, putrid, or decomposed substance; or (2)(A) if it has been prepared, packed, or held under insanitary conditions whereby it may have been contaminated with filth, or whereby it may have been rendered injurious to health; or (B) if it is a drug and the methods used in, or the facilities or controls used for, its manufacture, processing, packing, or holding do not conform to or are not operated or administered in conformity with current good manufacturing practice to assure that such drug meets the requirements of this Act as to safety and has the identity and strength, and meets the quality and purity characteristics, which it purports or is represented to possess; or (C) if it is a compounded positron emission tomography drug and the methods used in, or the facilities and controls used for, its compounding, processing, packing, or holding do not conform to or are not operated or administered in conformity with the positron emission tomography compounding standards and the official

monographs of the United States Pharmacopoeia to assure that such drug meets the requirements of this Act as to safety and has the identity and strength, and meets the quality and purity characteristics, that it purports or is represented to possess; or (3) if its container is composed, in whole or in part, of any poisonous or deleterious substance which may render the contents injurious to health; or (4) if (A) it bears or contains, for purposes of coloring only, a color additive which is unsafe within the meaning of section 721(a), or (B) it is a color additive the intended use of which in or on drugs or devices is for purposes of coloring only and is unsafe within the meaning of section 721(a); or (5) if it is a new animal drug which is unsafe within the meaning of section 512; or (6) if it is an animal feed bearing or containing a new animal drug, and such animal feed is unsafe within the meaning of section 512.

(b) If it purports to be or is represented as a drug the name of which is recognized in an official compendium, and its strength differs from, or its quality or purity falls below, the standards set forth in such compendium. Such determination as to strength, quality, or purity shall be made in accordance with the tests or methods of assay set forth in such compendium, except that whenever tests or methods of assay have not been prescribed in such compendium, or such tests or methods of assay as are prescribed are, in the judgment of the Secretary, insufficient for the making of such determination, the Secretary shall bring such fact to the attention of the appropriate body charged with the revision of such compendium, and if such body fails within a reasonable time to prescribe tests or methods of assay which, in the judgment of the Secretary, are sufficient for purposes of this paragraph, then the Secretary shall promulgate regulations prescribing appropriate tests or methods of assay in accordance with which such determination as to strength, quality, or purity shall be made. No drug defined in an official compendium shall be deemed to be adulterated under this paragraph because it differs from the standard of strength, quality, or purity therefor set forth in such compendium, if its difference in strength, quality, or purity from such standards is plainly stated on its label. Whenever a drug is recognized in both the United States Pharmacopeia and the Homeopathic Pharmacopeia of the United States it shall be subject to the requirements of the United States Pharmacopeia unless it is labeled and offered for sale as a homeopathic drug, in which case it shall be subject to the provisions of the Homeopathic Pharmacopeia of the United States and not to those of the United States Pharmacopeia.

(c) If it is not subject to the provisions of paragraph (b) of this section and its strength differs from, or its purity or quality falls below, that which it purports or is represented to possess.

(d) If it is a drug and any substance has been (1) mixed or packed therewith so as to reduce its quality or strength or (2) substituted wholly or in part therefor.

(e)(1) If it is, or purports to be or is represented as, a device which is subject to a performance standard established under section 514, unless such device is in all respects in conformity with such standard.

(2) If it is declared to be, purports to be, or is represented as, a device that is in conformity with any standard recognized under

section 514(c) unless such device is in all respects in conformity with such standard.

(f)(1) If it is a class III device—

(A)(i) which is required by an order issued under subsection (b) of section 515 to have an approval under such section of an application for premarket approval and which is not exempt from section 515 under section 520(g), and

(ii)(I) for which an application for premarket approval or a notice of completion of a product development protocol was not filed with the Secretary within the ninety-day period beginning on the date of the issuance of such order, or

(II) for which such an application was filed and approval of the application has been denied, suspended, or withdrawn, or such a notice was filed and has been declared not completed or the approval of the device under the protocol has been withdrawn;

(B)(i) which was classified under section 513(f) into class III, which under section 515(a) is required to have in effect an approved application for premarket approval, and which is not exempt from section 515 under section 520(g), and

(ii) which has an application which has been suspended or is otherwise not in effect; or

(C) which was classified under section 520(l) into class III, which under such section is required to have in effect an approved application under section 515, and which has an application which has been suspended or is otherwise not in effect.

(2)(A) In the case of a device classified under section 513(f) into class III and intended solely for investigational use, paragraph (1)(B) shall not apply with respect to such device during the period ending on the ninetieth day after the date of the promulgation of the regulations prescribing the procedures and conditions required by section 520(g)(2).

(B) In the case of a device subject to an order issued under subsection (b) of section 515, paragraph (1) shall not apply with respect to such device during the period ending—

(i) on the last day of the thirtieth calendar month beginning after the month in which the classification of the device in class III became effective under section 513, or

(ii) on the ninetieth day after the date of the issuance of such order,

whichever occurs later.

(3) In the case of a device with respect to which a regulation was promulgated under section 515(b) prior to the date of enactment of the Food and Drug Administration Safety and Innovation Act, a reference in this subsection to an order issued under section 515(b) shall be deemed to include such regulation.

(g) If it is a banned device.

(h) If it is a device and the methods used in, or the facilities or controls used for, its manufacture, packing, storage, or installation are not in conformity with applicable requirements under section 520(f)(1) or an applicable condition prescribed by an order under section 520(f)(2).

(i) If it is a device for which an exemption has been granted under section 520(g) for investigational use and the person who was granted such exemption or any investigator who uses such de-

vice under such exemption fails to comply with a requirement prescribed by or under such section.

(j) If it is a drug or device and it has been manufactured, processed, packed, or held in any factory, warehouse, or establishment and the owner, operator, or agent of such factory, warehouse, or establishment delays, denies, or limits an inspection, or refuses to permit entry or inspection.

For purposes of paragraph (a)(2)(B), the term "current good manufacturing practice" includes the implementation of oversight and controls over the manufacture of drugs to ensure quality, including managing the risk of and establishing the safety of raw materials, materials used in the manufacturing of drugs, and finished drug products.

(k) If it is a device subject to the requirements set forth in section 524C (relating to ensuring device cybersecurity) and fails to comply with any requirement under that section.

MISBRANDED DRUGS AND DEVICES

SEC. 502. A drug or device shall be deemed to be misbranded—

(a)(1) If its labeling is false or misleading in any particular. Health care economic information provided to a payor, formulary committee, or other similar entity with knowledge and expertise in the area of health care economic analysis, carrying out its responsibilities for the selection of [drugs for coverage] *drugs or devices for coverage* or reimbursement, shall not be considered to be false or misleading under this paragraph if the health care economic information relates to an indication approved [under section 505 or under section 351(a) of the Public Health Service Act] *under section 505, 510(k), 513(f)(2), or 515 of this Act or section 351 of the Public Health Service Act* for such [drug] *drug or device*, is based on competent and reliable scientific evidence, and includes, where applicable, a conspicuous and prominent statement describing any material differences between the health care economic information and the labeling approved for the [drug] *drug or device* [under section 505 or under section 351 of the Public Health Service Act] *under section 505, 510(k), 513(f)(2), or 515 of this Act or section 351 of the Public Health Service Act*. The requirements set forth [in section 505(a) or in subsections (a) and (k) of section 351 of the Public Health Service Act] *in section 505, 510(k), 513(f)(2), or 515 of this Act or section 351 of the Public Health Service Act* shall not apply to health care economic information provided to such a payor, committee, or entity in accordance with this paragraph. Information that is relevant to the substantiation of the health care economic information presented pursuant to this paragraph shall be made available to the Secretary upon request.

(2)(A) For purposes of this paragraph, the term "health care economic information" means any analysis (including the clinical data, inputs, clinical or other assumptions, methods, results, and other components underlying or comprising the analysis) that identifies, measures, or describes the economic consequences, which may be based on the separate or aggregated clinical consequences of the represented health outcomes, of the use of a [drug] *drug or device*. Such analysis may be comparative to the use of another [drug] *drug or device*, to another health care intervention, or to no intervention.

(B) Such term does not include any analysis that relates only to an indication that is not approved [under section 505 or under section 351 of the Public Health Service Act] *under section 505, 510(k), 513(f)(2), or 515 of this Act or section 351 of the Public Health Service Act* for such [drug] *drug or device*.

(b) If in a package form unless it bears a label containing (1) the name and place of business of the manufacturer, packer, or distributor; and (2) an accurate statement of the quantity of the contents in terms of weight, measure, or numerical count: *Provided,* That under clause (2) of this paragraph reasonable variations shall be permitted, and exemptions as to small packages shall be established, by regulations prescribed by the Secretary.

(c) If any word, statement, or other information required by or under authority of this Act to appear on the label or labeling is not prominently placed thereon with such conspicuousness (as compared with other words, statements, designs, or devices, in the labeling) and in such terms as to render it likely to be read and understood by the ordinary individual under customary conditions of purchase and use.

(e)(1)(A) If it is a drug, unless its label bears, to the exclusion of any other nonproprietary name (except the applicable systematic chemical name or the chemical formula)—

(i) the established name (as defined in subparagraph (3)) of the drug, if there is such a name;

(ii) the established name and quantity or, if determined to be appropriate by the Secretary, the proportion of each active ingredient, including the quantity, kind, and proportion of any alcohol, and also including whether active or not the established name and quantity or if determined to be appropriate by the Secretary, the proportion of any bromides, ether, chloroform, acetanilide, acetophenetidin, amidopyrine, antipyrine, atropine, hyoscine, hyoscyamine, arsenic, digitalis, digitalis glucosides, mercury, ouabain, strophanthin, strychnine, thyroid, or any derivative or preparation of any such substances, contained therein, except that the requirement for stating the quantity of the active ingredients, other than the quantity of those specifically named in this subclause, shall not apply to nonprescription drugs not intended for human use; and

(iii) the established name of each inactive ingredient listed in alphabetical order on the outside container of the retail package and, if determined to be appropriate by the Secretary, on the immediate container, as prescribed in regulation promulgated by the Secretary, except that nothing in this subclause shall be deemed to require that any trade secret be divulged, and except that the requirements of this subclause with respect to alphabetical order shall apply only to nonprescription drugs that are not also cosmetics and that this subclause shall not apply to nonprescription drugs not intended for human use.

(B) For any prescription drug the established name of such drug or ingredient, as the case may be, on such label (and on any labeling on which a name for such drug or ingredient is used) shall be printed prominently and in type at least half as large as that used thereon for any proprietary name or designation for such drug or ingredient, except that to the extent that compliance with the re-

quirements of subclause (ii) or (iii) of clause (A) or this clause is impracticable, exemptions shall be established by regulations promulgated by the Secretary.

(2) If it is a device and it has an established name, unless its label bears, to the exclusion of any other nonproprietary name, its established name (as defined in subparagraph (4)) prominently printed in type at least half as large as that used thereon for any proprietary name or designation for such device, except that to the extent compliance with the requirements of this subparagraph is impracticable, exemptions shall be established by regulations promulgated by the Secretary.

(3) As used in subparagraph (1), the term "established name", with respect to a drug or ingredient thereof, means (A) the applicable official name designated pursuant to section 508, or (B) if there is no such name and such drug, or such ingredient, is an article recognized in an official compendium, then the official title thereof in such compendium, or (C) if neither clause (A) nor clause (B) of this subparagraph applies, then the common or usual name, if any, of such drug or of such ingredient, except that where clause (B) of this subparagraph applies to an article recognized in the United States Pharmacopeia and in the Homeopathic Pharmacopeia under different official titles, the official title used in the United States Pharmacopeia shall apply unless it is labeled and offered for sale as a homeopathic drug, in which case the official title used in the Homeopathic Pharmacopeia shall apply.

(4) As used in subparagraph (2), the term "established name" with respect to a device means (A) the applicable official name of the device designated pursuant to section 508, (B) if there is no such name and such device is an article recognized in an official compendium, then the official title thereof in such compendium, or (C) if neither clause (A) nor clause (B) of this subparagraph applies, then any common or usual name of such device.

(f) Unless its labeling bears (1) adequate directions for use; and (2) such adequate warnings against use in those pathological conditions or by children where its use may be dangerous to health, or against unsafe dosage or methods or duration of administration or application, in such manner and form, as are necessary for the protection of users, except that where any requirement of clause (1) of this paragraph, as applied to any drug or device, is not necessary for the protection of the public health, the Secretary shall promulgate regulations exempting such drug or device from such requirement. Required labeling for prescription devices intended for use in health care facilities or by a health care professional and required labeling for in vitro diagnostic devices intended for use by health care professionals or in blood establishments may be made available solely by electronic means, provided that the labeling complies with all applicable requirements of law, and that the manufacturer affords such users the opportunity to request the labeling in paper form, and after such request, promptly provides the requested information without additional cost.

(g) If it purports to be a drug the name of which is recognized in an official compendium, unless it is packaged and labeled as prescribed therein. The method of packing may be modified with the consent of the Secretary. Whenever a drug is recognized in both the United States Pharmacopeia and the Homeopathic Pharmacopeia

of the United States, it shall be subject to the requirements of the United States Pharmacopeia with respect to packaging, and labeling unless it is labeled and offered for sale as a homeopathic drug, in which case it shall be subject to the provisions of the Homeopathic Pharmacopeia of the United States, and not to those of the United States Pharmacopeia, except that in the event of inconsistency between the requirements of this paragraph and those of paragraph (e) as to the name by which the drug or its ingredients shall be designated, the requirements of paragraph (e) shall prevail.

(h) If it has been found by the Secretary to be a drug liable to deterioration, unless it is packaged in such form and manner, and its label bears a statement of such precautions, as the Secretary shall by regulations require as necessary for the protection of the public health. No such regulation shall be established for any drug recognized in an official compendium until the Secretary shall have informed the appropriate body charged with the revision of such compendium of the need for such packaging or labeling requirements and such body shall have failed within a reasonable time to prescribe such requirements.

(i)(1) If it is a drug and its container is so made, formed, or filled as to be misleading; or (2) if it is an imitation of another drug; or (3) if it is offered for sale under the name of another drug.

(j) If it is dangerous to health when used in the dosage or manner; or with the frequency or duration prescribed, recommended, or suggested in the labeling thereof.

(m) If it is a color additive the intended use of which is for the purpose of coloring only, unless its packaging and labeling are in conformity with such packaging and labeling requirements applicable to such color additive, as may be contained in regulations issued under section 721.

(n) In the case of any prescription drug distributed or offered for sale in any State, unless the manufacturer, packer, or distributor thereof includes in all advertisements and other descriptive printed matter issued or caused to be issued by the manufacturer, packer, or distributor with respect to that drug a true statement of (1) the established name as defined in section 502(e), printed prominently and in type at least half as large as that used for any trade or brand name thereof, (2) the formula showing quantitatively each ingredient of such drug to the extent required for labels under section 502(e), and (3) such other information in brief summary relating to side effects, contraindications, and effectiveness as shall be required in regulations which shall be issued by the Secretary in accordance with section 701(a), and in the case of published direct-to-consumer advertisements the following statement printed in conspicuous text: "You are encouraged to report negative side effects of prescription drugs to the FDA. Visit www.fda.gov/medwatch, or call 1–800-FDA-1088.", except that (A) except in extraordinary circumstances, no regulation issued under this paragraph shall require prior approval by the Secretary of the content of any advertisement, and (B) no advertisement of a prescription drug, published after the effective date of regulations issued under this paragraph applicable to advertisements of prescription drugs, shall, with respect to the matters specified in this paragraph or covered by such regulations, be subject to the provisions of sections 12

through 17 of the Federal Trade Commission Act, as amended (15 U.S.C. 52–57). This paragraph (n) shall not be applicable to any printed matter which the Secretary determines to be labeling as defined in section 201(m) of this Act. Nothing in the Convention on Psychotropic Substances, signed at Vienna, Austria, on February 21, 1971, shall be construed to prevent drug price communications to consumers. In the case of an advertisement for a drug subject to section 503(b)(1) presented directly to consumers in television or radio format and stating the name of the drug and its conditions of use, the major statement relating to side effects and contraindications shall be presented in a clear, conspicuous, and neutral manner.

(o) If it was manufactured, prepared, propagated, compounded, or processed in an establishment not duly registered under section 510, if it is a drug and was imported or offered for import by a commercial importer of drugs not duly registered under section 801(s), if it was not included in a list required by section 510(j), if a notice or other information respecting it was not provided as required by such section or section 510(k), or if it does not bear such symbols from the uniform system for identification of devices prescribed under section 510(e) as the Secretary by regulation requires.

(p) If it is a drug and its packaging or labeling is in violation of an applicable regulation issued pursuant to section 3 or 4 of the Poison Prevention Packaging Act of 1970.

(q) In the case of any restricted device distributed or offered for sale in any State, if (1) its advertising is false or misleading in any particular, or (2) it is sold, distributed, or used in violation of regulations prescribed under section 520(e).

(r) In the case of any restricted device distributed or offered for sale in any State, unless the manufacturer, packer, or distributor thereof includes in all advertisements and other descriptive printed matter issued or caused to be issued by the manufacturer, packer, or distributor with respect to that device (1) a true statement of the device's established name as defined in section 502(e), printed prominently and in type at least half as large as that used for any trade or brand name thereof, and (2) a brief statement of the intended uses of the device and relevant warnings, precautions, side effects, and contraindications and, in the case of specific devices made subject to a finding by the Secretary after notice and opportunity for comment that such action is necessary to protect the public health, a full description of the components of such device or the formula showing quantitatively each ingredient of such device to the extent required in regulations which shall be issued by the Secretary after an opportunity for a hearing. Except in extraordinary circumstances, no regulation issued under this paragraph shall require prior approval by the Secretary of the content of any advertisement and no advertisement of a restricted device, published after the effective date of this paragraph shall, with respect to the matters specified in this paragraph or covered by regulations issued hereunder, be subject to the provisions of sections 12 through 15 of the Federal Trade Commission Act (15 U.S.C. 52–55). This paragraph shall not be applicable to any printed matter which the Secretary determines to be labeling as defined in section 201(m).

(s) If it is a device subject to a performance standard established under section 514, unless it bears such labeling as may be prescribed in such performance standard.

(t) If it is a device and there was a failure or refusal (1) to comply with any requirement prescribed under section 518 respecting the device, (2) to furnish any material or information required by or under section 519 respecting the device, [or (3)] *(3)* to comply with a requirement under section 522*, or (4) to furnish a software bill of materials as required under section 524C (relating to ensuring device cybersecurity)*.

(u)(1) Subject to paragraph (2), if it is a reprocessed single-use device, unless it, or an attachment thereto, prominently and conspicuously bears the name of the manufacturer of the reprocessed device, a generally recognized abbreviation of such name, or a unique and generally recognized symbol identifying such manufacturer.

(2) If the original device or an attachment thereto does not prominently and conspicuously bear the name of the manufacturer of the original device, a generally recognized abbreviation of such name, or a unique and generally recognized symbol identifying such manufacturer, a reprocessed device may satisfy the requirements of paragraph (1) through the use of a detachable label on the packaging that identifies the manufacturer and is intended to be affixed to the medical record of a patient.

(v) If it is a reprocessed single-use device, unless all labeling of the device prominently and conspicuously bears the statement "Reprocessed device for single use. Reprocessed by ____." The name of the manufacturer of the reprocessed device shall be placed in the space identifying the person responsible for reprocessing.

(w) If it is a new animal drug—

(1) that is conditionally approved under section 571 and its labeling does not conform with the approved application or section 571(f), or that is not conditionally approved under section 571 and its label bears the statement set forth in section 571(f)(1)(A);

(2) that is indexed under section 572 and its labeling does not conform with the index listing under section 572(e) or 572(h), or that has not been indexed under section 572 and its label bears the statement set forth in section 572(h); or

(3) for which an application has been approved under section 512 and the labeling of such drug does not include the application number in the format: "Approved by FDA under (A)NADA # xxx–xxx", except that this subparagraph shall not apply to representative labeling required under section 514.1(b)(3)(v)(b) of title 21, Code of Federal Regulations (or any successor regulation) for animal feed bearing or containing a new animal drug.

(x) If it is a nonprescription drug (as defined in section 760) that is marketed in the United States, unless the label of such drug includes a domestic address or domestic phone number through which the responsible person (as described in section 760) may receive a report of a serious adverse event (as defined in section 760) with such drug.

(y) If it is a drug subject to an approved risk evaluation and mitigation strategy pursuant to section 505(p) and the responsible per-

son (as such term is used in section 505–1) fails to comply with a requirement of such strategy provided for under subsection (d), (e), or (f) of section 505–1.

(z) If it is a drug, and the responsible person (as such term is used in section 505(o)) is in violation of a requirement established under paragraph (3) (relating to postmarket studies and clinical trials) or paragraph (4) (relating to labeling) of section 505(o) with respect to such drug.

(aa) If it is a drug, or an active pharmaceutical ingredient, and it was manufactured, prepared, propagated, compounded, or processed in a facility for which fees have not been paid as required by section 744B(a)(4) or for which identifying information required by section 744B(f) has not been submitted, or it contains an active pharmaceutical ingredient that was manufactured, prepared, propagated, compounded, or processed in such a facility.

(bb) If the advertising or promotion of a compounded drug is false or misleading in any particular.

(cc) If it is a drug and it fails to bear the product identifier as required by section 582.

(dd) If it is an antimicrobial drug, as defined in section 511A(f), and its labeling fails to conform with the requirements under section 511A(d).

(ee) If it is a nonprescription drug that is subject to section 505G, is not the subject of an application approved under section 505, and does not comply with the requirements under section 505G.

(ff) If it is a drug and it was manufactured, prepared, propagated, compounded, or processed in a facility for which fees have not been paid as required by section 744M.

(gg)(1) Unless its labeling bears adequate directions for use in accordance with paragraph (f), except that (in addition to drugs or devices that conform with exemptions pursuant to such paragraph) no drug or device shall be deemed to be misbranded under such paragraph through the provision of product information to a payor, formulary committee, or other similar entity with knowledge and expertise in the area of health care economic analysis carrying out its responsibilities for the selection of drugs or devices for coverage or reimbursement if the product information relates to an investigational drug or device or investigational use of a drug or device that is approved, cleared, granted marketing authorization, or licensed under section 505, 510(k), 513(f)(2), or 515 of this Act or section 351 of the Public Health Service Act (as applicable), provided—

(A) the product information includes—

(i) a clear statement that the investigational drug or device or investigational use of a drug or device has not been approved, cleared, granted marketing authorization, or licensed under section 505, 510(k), 513(f)(2), or 515 of this Act or section 351 of the Public Health Service Act (as applicable) and that the safety and effectiveness of the drug or device or use has not been established;

(ii) information related to the stage of development of the drug or device involved, such as—

(I) the status of any study or studies in which the investigational drug or device or investigational use is being investigated;

(II) how the study or studies relate to the overall plan for the development of the drug or device; and

(III) whether an application, premarket notification, or request for classification for the investigational drug or device or investigational use has been submitted to the Secretary and when such a submission is planned;

(iii) in the case of information that includes factual presentations of results from studies, which shall not be selectively presented, a description of—

(I) all material aspects of study design, methodology, and results; and

(II) all material limitations related to the study design, methodology, and results;

(iv) where applicable, a prominent statement disclosing the indication or indications for which the Secretary has approved, granted marketing authorization, cleared, or licensed the product pursuant to section 505, 510(k), 513(f)(2), or 515 of this Act or section 351 of the Public Health Service Act, and a copy of the most current required labeling; and

(v) updated information, if previously communicated information becomes materially outdated as a result of significant changes or as a result of new information regarding the product or its review status; and

(B) the product information does not include—

(i) information that represents that an unapproved product—

(I) has been approved, cleared, granted marketing authorization, or licensed under section 505, 510(k), 513(f)(2), or 515 of this Act or section 351 of the Public Health Service Act (as applicable); or

(II) has otherwise been determined to be safe or effective for the purpose or purposes for which the drug or device is being studied; or

(ii) information that represents that an unapproved use of a drug or device that has been so approved, granted marketing authorization, cleared, or licensed—

(I) is so approved, granted marketing authorization, cleared, or licensed; or

(II) that the product is safe or effective for the use or uses for which the drug or device is being studied.

(2) For purposes of this paragraph, the term "product information" includes—

(A) information describing the drug or device (such as drug class, device description, and features);

(B) information about the indication or indications being investigated;

(C) the anticipated timeline for a possible approval, clearance, marketing authorization, or licensure pursuant to section 505, 510(k), 513, or 515 of this Act or section 351 of the Public Health Service Act;

(D) drug or device pricing information;

(E) patient utilization projections;

(F) product-related programs or services; and

(G) factual presentations of results from studies that do not characterize or make conclusions regarding safety or efficacy.

EXEMPTIONS AND CONSIDERATION FOR CERTAIN DRUGS, DEVICES, AND BIOLOGICAL PRODUCTS

SEC. 503. (a) The Secretary is hereby directed to promulgate regulations exempting from any labeling or packaging requirement of this Act drugs and devices which are, in accordance with the practice of the trade, to be processed, labeled, or repacked in substantial quantities at establishments other than those where originally processed or packed, on condition that such drugs and devices are not adulterated or misbranded, under the provisions of this Act upon removal from such processing, labeling, or repacking establishment.

(b)(1) A drug intended for use by man which—

(A) because of its toxicity or other potentiality for harmful effect, or the method of its use, or the collateral measures necessary to its use, is not safe for use except under the supervision of a practitioner licensed by law to administer such drug; or

(B) is limited by an approved application under section 505 to use under the professional supervision of a practitioner licensed by law to administer such drug;

shall be dispensed only (i) upon a written prescription of a practitioner licensed by law to administer such drug, or (ii) upon an oral prescription of such practitioner which is reduced promptly to writing and filed by the pharmacist, or (iii) by refilling any such written or oral prescription if such refilling is authorized by the prescriber either in the original prescription or by oral order which is reduced promptly to writing and filed by the pharmacist. The act of dispensing a drug contrary to the provisions of this paragraph shall be deemed to be an act which results in the drug being misbranded while held for sale.

(2) Any drug dispensed by filling or refilling a written or oral prescription of a practitioner licensed by law to administer such drug shall be exempt from the requirements of section 502, except paragraphs (a), (i) (2) and (3), (k), and (l), and the packaging requirements of paragraphs (g), (h), and (p), if the drug bears a label containing the name and address of the dispenser, the serial number and date of the prescription or of its filling, the name of the prescriber, and, if stated in the prescription, the name of the patient, and the directions for use and cautionary statements, if any, contained in such prescription. This exemption shall not apply to any drug dispensed in the course of the conduct of a business of dispensing drugs pursuant to diagnosis by mail, or to a drug dispensed in violation of paragraph (1) of this subsection.

(3) The Secretary may by regulation remove drugs subject to section 505 from the requirements of paragraph (1) of this subsection when such requirements are not necessary for the protection of the public health.

(4)(A) A drug that is subject to paragraph (1) shall be deemed to be misbranded if at any time prior to dispensing the label of the drug fails to bear, at a minimum, the symbol "Rx only".

(B) A drug to which paragraph (1) does not apply shall be deemed to be misbranded if at any time prior to dispensing the label of the drug bears the symbol described in subparagraph (A).

(5) Nothing in this subsection shall be construed to relieve any person from any requirement prescribed by or under authority of law with respect to drugs now included or which may hereafter be included within the classifications stated in section 3220 of the Internal Revenue Code (26 U.S.C. 3220), or to marihuana as defined in section 3238(b) of the Internal Revenue Code (26 U.S.C. 3238(b)).

(c)(1) No person may sell, purchase, or trade or offer to sell, purchase, or trade any drug sample. For purposes of this paragraph and subsection (d), the term "drug sample" means a unit of a drug, subject to subsection (b), which is not intended to be sold and is intended to promote the sale of the drug. Nothing in this paragraph shall subject an officer or executive of a drug manufacturer or distributor to criminal liability solely because of a sale, purchase, trade, or offer to sell, purchase, or trade in violation of this paragraph by other employees of the manufacturer or distributor.

(2) No person may sell, purchase, or trade, offer to sell, purchase, or trade, or counterfeit any coupon. For purposes of this paragraph, the term "coupon" means a form which may be redeemed, at no cost or at a reduced cost, for a drug which is prescribed in accordance with subsection (b).

(3)(A) No person may sell, purchase, or trade, or offer to sell, purchase, or trade, any drug—

(i) which is subject to subsection (b), and

(ii)(I) which was purchased by a public or private hospital or other health care entity, or

(II) which was donated or supplied at a reduced price to a charitable organization described in section 501(c)(3) of the Internal Revenue Code of 1954.

(B) Subparagraph (A) does not apply to—

(i) the purchase or other acquisition by a hospital or other health care entity which is a member of a group purchasing organization of a drug for its own use from the group purchasing organization or from other hospitals or health care entities which are members of such organization,

(ii) the sale, purchase, or trade of a drug or an offer to sell, purchase, or trade a drug by an organization described in subparagraph (A)(ii)(II) to a nonprofit affiliate of the organization to the extent otherwise permitted by law,

(iii) a sale, purchase, or trade of a drug or an offer to sell, purchase, or trade a drug among hospitals or other health care entities which are under common control,

(iv) a sale, purchase, or trade of a drug or an offer to sell, purchase, or trade a drug for emergency medical reasons, or

(v) a sale, purchase, or trade of a drug, an offer to sell, purchase, or trade a drug, or the dispensing of a drug pursuant to a prescription executed in accordance with subsection (b).

For purposes of this paragraph, the term "entity" does not include a wholesale distributor of drugs or a retail pharmacy licensed under State law and the term "emergency medical reasons" includes transfers of a drug between health care entities or from a health care entity to a retail pharmacy undertaken to alleviate

temporary shortages of the drug arising from delays in or interruptions of regular distribution schedules.

(d)(1) Except as provided in paragraphs (2) and (3), no person may distribute any drug sample. For purposes of this subsection, the term "distribute" does not include the providing of a drug sample to a patient by a—

(A) practitioner licensed to prescribe such drug,

(B) health care professional acting at the direction and under the supervision of such a practitioner, or

(C) pharmacy of a hospital or of another health care entity that is acting at the direction of such a practitioner and that received such sample pursuant to paragraph (2) or (3).

(2)(A) The manufacturer or authorized distributor of record of a drug subject to subsection (b) may, in accordance with this paragraph, distribute drug samples by mail or common carrier to practitioners licensed to prescribe such drugs or, at the request of a licensed practitioner, to pharmacies of hospitals or other health care entities. Such a distribution of drug samples may only be made—

(i) in response to a written request for drug samples made on a form which meets the requirements of subparagraph (B), and

(ii) under a system which requires the recipient of the drug sample to execute a written receipt for the drug sample upon its delivery and the return of the receipt to the manufacturer or authorized distributor of record.

(B) A written request for a drug sample required by subparagraph (A)(i) shall contain—

(i) the name, address, professional designation, and signature of the practitioner making the request,

(ii) the identity of the drug sample requested and the quantity requested,

(iii) the name of the manufacturer of the drug sample requested, and

(iv) the date of the request.

(C) Each drug manufacturer or authorized distributor of record which makes distributions by mail or common carrier under this paragraph shall maintain, for a period of 3 years, the request forms submitted for such distributions and the receipts submitted for such distributions and shall maintain a record of distributions of drug samples which identifies the drugs distributed and the recipients of the distributions. Forms, receipts, and records required to be maintained under this subparagraph shall be made available by the drug manufacturer or authorized distributor of record to Federal and State officials engaged in the regulation of drugs and in the enforcement of laws applicable to drugs.

(3) The manufacturer or authorized distributor of record of a drug subject to subsection (b) may, by means other than mail or common carrier, distribute drug samples only if the manufacturer or authorized distributor of record makes the distributions in accordance with subparagraph (A) and carries out the activities described in subparagraphs (B) through (F) as follows:

(A) Drug samples may only be distributed—

(i) to practitioners licensed to prescribe such drugs if they make a written request for the drug samples, or

(ii) at the written request of such a licensed practitioner, to pharmacies of hospitals or other health care entities.

A written request for drug samples shall be made on a form which contains the practitioner's name, address, and professional designation, the identity of the drug sample requested, the quantity of drug samples requested, the name of the manufacturer or authorized distributor of record of the drug sample, the date of the request and signature of the practitioner making the request.

(B) Drug manufacturers or authorized distributors of record shall store drug samples under conditions that will maintain their stability, integrity, and effectiveness and will assure that the drug samples will be free of contamination, deterioration, and adulteration.

(C) Drug manufacturers or authorized distributors of record shall conduct, at least annually, a complete and accurate inventory of all drug samples in the possession of representatives of the manufacturer or authorized distributor of record. Drug manufacturers or authorized distributors of record shall maintain lists of the names and address of each of their representatives who distribute drug samples and of the sites where drug samples are stored. Drug manufacturers or authorized distributors of record shall maintain records for at least 3 years of all drug samples distributed, destroyed, or returned to the manufacturer or authorized distributor of record, of all inventories maintained under this subparagraph, of all thefts or significant losses of drug samples, and of all requests made under subparagraph (A) for drug samples. Records and lists maintained under this subparagraph shall be made available by the drug manufacturer or authorized distributor of record to the Secretary upon request.

(D) Drug manufacturers or authorized distributors of record shall notify the Secretary of any significant loss of drug samples and any known theft of drug samples.

(E) Drug manufacturers or authorized distributors of record shall report to the Secretary any conviction of their representatives for violations of subsection (c)(1) or a State law because of the sale, purchase, or trade of a drug sample or the offer to sell, purchase, or trade a drug sample.

(F) Drug manufacturers or authorized distributors of record shall provide to the Secretary the name and telephone number of the individual responsible for responding to a request for information respecting drug samples.

(4) In this subsection, the term "authorized distributors of record" means those distributors with whom a manufacturer has established an ongoing relationship to distribute such manufacturer's products.

(e)

(1) REQUIREMENT.—Subject to section 583:

(A) IN GENERAL.—No person may engage in wholesale distribution of a drug subject to subsection (b)(1) in any State unless such person—

(i)(I) is licensed by the State from which the drug is distributed; or

(II) if the State from which the drug is distributed has not established a licensure requirement, is licensed by the Secretary; and

(ii) if the drug is distributed interstate, is licensed by the State into which the drug is distributed if the State into which the drug is distributed requires the licensure of a person that distributes drugs into the State.

(B) STANDARDS.—Each Federal and State license described in subparagraph (A) shall meet the standards, terms, and conditions established by the Secretary under section 583.

(2) REPORTING AND DATABASE.—

(A) REPORTING.—Beginning January 1, 2015, any person who owns or operates an establishment that engages in wholesale distribution shall—

(i) report to the Secretary, on an annual basis pursuant to a schedule determined by the Secretary—

(I) each State by which the person is licensed and the appropriate identification number of each such license; and

(II) the name, address, and contact information of each facility at which, and all trade names under which, the person conducts business; and

(ii) report to the Secretary within a reasonable period of time and in a reasonable manner, as determined by the Secretary, any significant disciplinary actions, such as the revocation or suspension of a wholesale distributor license, taken by a State or the Federal Government during the reporting period against the wholesale distributor.

(B) DATABASE.—Not later than January 1, 2015, the Secretary shall establish a database of authorized wholesale distributors. Such database shall—

(i) identify each authorized wholesale distributor by name, contact information, and each State where such wholesale distributor is appropriately licensed to engage in wholesale distribution;

(ii) be available to the public on the Internet Web site of the Food and Drug Administration; and

(iii) be regularly updated on a schedule determined by the Secretary.

(C) COORDINATION.—The Secretary shall establish a format and procedure for appropriate State officials to access the information provided pursuant to subparagraph (A) in a prompt and secure manner.

(D) CONFIDENTIALITY.—Nothing in this paragraph shall be construed as authorizing the Secretary to disclose any information that is a trade secret or confidential information subject to section 552(b)(4) of title 5, United States Code, or section 1905 of title 18, United States Code.

(3) COSTS.—

(A) AUTHORIZED FEES OF SECRETARY.—If a State does not establish a licensing program for persons engaged in the wholesale distribution of a drug subject to subsection

(b), the Secretary shall license a person engaged in wholesale distribution located in such State and may collect a reasonable fee in such amount necessary to reimburse the Secretary for costs associated with establishing and administering the licensure program and conducting periodic inspections under this section. The Secretary shall adjust fee rates as needed on an annual basis to generate only the amount of revenue needed to perform this service. Fees authorized under this paragraph shall be collected and available for obligation only to the extent and in the amount provided in advance in appropriations Acts. Such fees are authorized to remain available until expended. Such sums as may be necessary may be transferred from the Food and Drug Administration salaries and expenses appropriation account without fiscal year limitation to such appropriation account for salaries and expenses with such fiscal year limitation.

(B) STATE LICENSING FEES.—Nothing in this Act shall prohibit States from collecting fees from wholesale distributors in connection with State licensing of such distributors.

(4) For the purposes of this subsection and subsection (d), the term "wholesale distribution" means the distribution of a drug subject to subsection (b) to a person other than a consumer or patient, or receipt of a drug subject to subsection (b) by a person other than the consumer or patient, but does not include—

(A) intracompany distribution of any drug between members of an affiliate or within a manufacturer;

(B) the distribution of a drug, or an offer to distribute a drug among hospitals or other health care entities which are under common control;

(C) the distribution of a drug or an offer to distribute a drug for emergency medical reasons, including a public health emergency declaration pursuant to section 319 of the Public Health Service Act, except that, for purposes of this paragraph, a drug shortage not caused by a public health emergency shall not constitute an emergency medical reason;

(D) the dispensing of a drug pursuant to a prescription executed in accordance with subsection (b)(1);

(E) the distribution of minimal quantities of drug by a licensed retail pharmacy to a licensed practitioner for office use;

(F) the distribution of a drug or an offer to distribute a drug by a charitable organization to a nonprofit affiliate of the organization to the extent otherwise permitted by law;

(G) the purchase or other acquisition by a dispenser, hospital, or other health care entity of a drug for use by such dispenser, hospital, or other health care entity;

(H) the distribution of a drug by the manufacturer of such drug;

(I) the receipt or transfer of a drug by an authorized third-party logistics provider provided that such third-

party logistics provider does not take ownership of the drug;

(J) a common carrier that transports a drug, provided that the common carrier does not take ownership of the drug;

(K) the distribution of a drug, or an offer to distribute a drug by an authorized repackager that has taken ownership or possession of the drug and repacks it in accordance with section 582(e);

(L) salable drug returns when conducted by a dispenser;

(M) the distribution of a collection of finished medical devices, which may include a product or biological product, assembled in kit form strictly for the convenience of the purchaser or user (referred to in this subparagraph as a "medical convenience kit") if—

(i) the medical convenience kit is assembled in an establishment that is registered with the Food and Drug Administration as a device manufacturer in accordance with section 510(b)(2);

(ii) the medical convenience kit does not contain a controlled substance that appears in a schedule contained in the Comprehensive Drug Abuse Prevention and Control Act of 1970;

(iii) in the case of a medical convenience kit that includes a product, the person that manufacturers the kit—

(I) purchased such product directly from the pharmaceutical manufacturer or from a wholesale distributor that purchased the product directly from the pharmaceutical manufacturer; and

(II) does not alter the primary container or label of the product as purchased from the manufacturer or wholesale distributor; and

(iv) in the case of a medical convenience kit that includes a product, the product is—

(I) an intravenous solution intended for the replenishment of fluids and electrolytes;

(II) a product intended to maintain the equilibrium of water and minerals in the body;

(III) a product intended for irrigation or reconstitution;

(IV) an anesthetic;

(V) an anticoagulant;

(VI) a vasopressor; or

(VII) a sympathomimetic;

(N) the distribution of an intravenous drug that, by its formulation, is intended for the replenishment of fluids and electrolytes (such as sodium, chloride, and potassium) or calories (such as dextrose and amino acids);

(O) the distribution of an intravenous drug used to maintain the equilibrium of water and minerals in the body, such as dialysis solutions;

(P) the distribution of a drug that is intended for irrigation, or sterile water, whether intended for such purposes or for injection;

(Q) the distribution of medical gas, as defined in section 575;

(R) facilitating the distribution of a product by providing solely administrative services, including processing of orders and payments; or

(S) the transfer of a product by a hospital or other health care entity, or by a wholesale distributor or manufacturer operating at the direction of the hospital or other health care entity, to a repackager described in section 581(16)(B) and registered under section 510 for the purpose of repackaging the drug for use by that hospital, or other health care entity and other health care entities that are under common control, if ownership of the drug remains with the hospital or other health care entity at all times.

(5) THIRD-PARTY LOGISTICS PROVIDERS.—Notwithstanding paragraphs (1) through (4), each entity that meets the definition of a third-party logistics provider under section 581(22) shall obtain a license as a third-party logistics provider as described in section 584(a) and is not required to obtain a license as a wholesale distributor if the entity never assumes an ownership interest in the product it handles.

(6) AFFILIATE.—For purposes of this subsection, the term "affiliate" means a business entity that has a relationship with a second business entity if, directly or indirectly—

(A) one business entity controls, or has the power to control, the other business entity; or

(B) a third party controls, or has the power to control, both of the business entities.

(f)(1)(A) A drug intended for use by animals other than man, other than a veterinary feed directive drug intended for use in animal feed or an animal feed bearing or containing a veterinary feed directive drug, which—

(i) because of its toxicity or other potentiality for harmful effect, or the method of its use, or the collateral measures necessary for its use, is not safe for animal use except under the professional supervision of a licensed veterinarian, or

(ii) is limited by an approved application under subsection (b) of section 512, a conditionally-approved application under section 571, or an index listing under section 572 to use under the professional supervision of a licensed veterinarian,

shall be dispensed only by or upon the lawful written or oral order of a licensed veterinarian in the course of the veterinarian's professional practice.

(B) For purposes of subparagraph (A), an order is lawful if the order—

(i) is a prescription or other order authorized by law,

(ii) is, if an oral order, promptly reduced to writing by the person lawfully filling the order, and filed by that person, and

(iii) is refilled only if authorized in the original order or in a subsequent oral order promptly reduced to writing by the person lawfully filling the order, and filed by that person.

(C) The act of dispensing a drug contrary to the provisions of this paragraph shall be deemed to be an act which results in the drug being misbranded while held for sale.

(2) Any drug when dispensed in accordance with paragraph (1) of this subsection—

(A) Shall be exempt from the requirements of section 502, except subsections (a), (g), (h), (i)(2), (i)(3), and (p) of such section, and

(B) shall be exempt from the packaging requirements of subsections (g), (h), and (p) of such section, if—

(i) when dispensed by a licensed veterinarian, the drug bears a label containing the name and address of the practitioner and any directions for use and cautionary statements specified by the practitioner, or

(ii) when dispensed by filling the lawful order of a licensed veterinarian, the drug bears a label containing the name and address of the dispenser, the serial number and date of the order or of its filing, the name of the licensed veterinarian, and the directions for use and cautionary statements, if any, contained in such order.

The preceding sentence shall not apply to any drug dispensed in the course of the conduct of a business of dispensing drugs pursuant to diagnosis by mail.

(3) The Secretary may by regulation exempt drugs for animals other than man subject to section 512, 571, or 572 from the requirements of paragraph (1) when such requirements are not necessary for the protection of the public health.

(4) A drug which is subject to paragraph (1) shall be deemed to be misbranded if at any time prior to dispensing its label fails to bear the statement "Caution: Federal law restricts this drug to use by or on the order of a licensed veterinarian.". A drug to which paragraph (1) does not apply shall be deemed to be misbranded if at any time prior to dispensing its label bears the statement specified in the preceding sentence.

(g)(1)(A) The Secretary shall, in accordance with this subsection, assign a primary agency center to regulate products that constitute a combination of a drug, device, or biological product.

(B) The Secretary shall conduct the premarket review of any combination product under a single application, whenever appropriate.

(C) For purposes of this subsection, the term "primary mode of action" means the single mode of action of a combination product expected to make the greatest contribution to the overall intended therapeutic effects of the combination product.

(D) The Secretary shall determine the primary mode of action of the combination product. If the Secretary determines that the primary mode of action is that of—

(i) a drug (other than a biological product), the agency center charged with premarket review of drugs shall have primary jurisdiction;

(ii) a device, the agency center charged with premarket review of devices shall have primary jurisdiction; or

(iii) a biological product, the agency center charged with premarket review of biological products shall have primary jurisdiction.

(E) In determining the primary mode of action of a combination product, the Secretary shall not determine that the primary mode of action is that of a drug or biological product solely because the

combination product has any chemical action within or on the human body.

(F) If a sponsor of a combination product disagrees with the determination under subparagraph (D)—

(i) such sponsor may request, and the Secretary shall provide, a substantive rationale to such sponsor that references scientific evidence provided by the sponsor and any other scientific evidence relied upon by the Secretary to support such determination; and

(ii)(I) the sponsor of the combination product may propose one or more studies (which may be nonclinical, clinical, or both) to establish the relevance, if any, of the chemical action in achieving the primary mode of action of such product;

(II) if the sponsor proposes any such studies, the Secretary and the sponsor of such product shall collaborate and seek to reach agreement, within a reasonable time of such proposal, not to exceed 90 calendar days, on the design of such studies; and

(III) if an agreement is reached under subclause (II) and the sponsor conducts one or more of such studies, the Secretary shall consider the data resulting from any such study when reevaluating the determination of the primary mode of action of such product, and unless and until such reevaluation has occurred and the Secretary issues a new determination, the determination of the Secretary under subparagraph (D) shall remain in effect.

(2)(A)(i) To establish clarity and certainty for the sponsor, the sponsor of a combination product may request a meeting on such combination product. If the Secretary concludes that a determination of the primary mode of action pursuant to paragraph (1)(D) is necessary, the sponsor may request such meeting only after the Secretary makes such determination. If the sponsor submits a written meeting request, the Secretary shall, not later than 75 calendar days after receiving such request, meet with the sponsor of such combination product.

(ii) A meeting under clause (i) may—

(I) address the standards and requirements for market approval or clearance of the combination product;

(II) address other issues relevant to such combination product, such as requirements related to postmarket modification of such combination product and good manufacturing practices applicable to such combination product; and

(III) identify elements under subclauses (I) and (II) that may be more appropriate for discussion and agreement with the Secretary at a later date given that scientific or other information is not available, or agreement is otherwise not feasible regarding such elements, at the time a request for such meeting is made.

(iii) Any agreement under this subparagraph shall be in writing and made part of the administrative record by the Secretary.

(iv) Any such agreement shall remain in effect, except—

(I) upon the written agreement of the Secretary and the sponsor or applicant; or

(II) pursuant to a decision by the director of the reviewing division of the primary agency center, or a person more senior

than such director, in consultation with consulting centers and the Office, as appropriate, that an issue essential to determining whether the standard for market clearance or other applicable standard under this Act or the Public Health Service Act applicable to the combination product has been identified since the agreement was reached, or that deviating from the agreement is otherwise justifiable based on scientific evidence, for public health reasons.

(3) For purposes of conducting the premarket review of a combination product that contains an approved constituent part described in paragraph (4), the Secretary may require that the sponsor of such combination product submit to the Secretary only data or information that the Secretary determines is necessary to meet the standard for clearance or approval, as applicable, under this Act or the Public Health Service Act, including any incremental risks and benefits posed by such combination product, using a risk-based approach and taking into account any prior finding of safety and effectiveness or substantial equivalence for the approved constituent part relied upon by the applicant in accordance with paragraph (5).

(4) For purposes of paragraph (3), an approved constituent part is—

(A) a drug constituent part of a combination product being reviewed in a single application or request under section 515, 510(k), or 513(f)(2) (submitted in accordance with paragraph (5)), that is an approved drug, provided such application or request complies with paragraph (5);

(B) a device constituent part approved under section 515 that is referenced by the sponsor and that is available for use by the Secretary under section 520(h)(4); or

(C) any constituent part that was previously approved, cleared, or classified under section 505, 510(k), 513(f)(2), or 515 of this Act for which the sponsor has a right of reference or any constituent part that is a nonprescription drug, as defined in section 760(a)(2).

(5)(A) If an application is submitted under section 515 or 510(k) or a request is submitted under section 513(f)(2), consistent with any determination made under paragraph (1)(D), for a combination product containing as a constituent part an approved drug—

(i) the application or request shall include the certification or statement described in section 505(b)(2); and

(ii) the applicant or requester shall provide notice as described in section 505(b)(3).

(B) For purposes of this paragraph and paragraph (4), the term "approved drug" means an active ingredient—

(i) that was in an application previously approved under section 505(c);

(ii) where such application is relied upon by the applicant submitting the application or request described in subparagraph (A);

(iii) for which full reports of investigations that have been made to show whether such drug is safe for use and whether such drug is effective in use were not conducted by or for the applicant submitting the application or request described in subparagraph (A); and

(iv) for which the applicant submitting the application or request described in subparagraph (A) has not obtained a right of reference or use from the person by or for whom the investigations described in clause (iii) were conducted.

(C) The following provisions shall apply with respect to an application or request described in subparagraph (A) to the same extent and in the same manner as if such application or request were an application described in section 505(b)(2) that referenced the approved drug:

(i) Subparagraphs (A), (B), (C), and (D) of section 505(c)(3).

(ii) Clauses (ii), (iii), and (iv) of section 505(c)(3)(E).

(iii) Subsections (b) and (c) of section 505A.

(iv) Section 505E(a).

(v) Section 527(a).

(D) Notwithstanding any other provision of this subsection, an application or request for classification for a combination product described in subparagraph (A) shall be considered an application submitted under section 505(b)(2) for purposes of section 271(e)(2)(A) of title 35, United States Code.

(6) Nothing in this subsection shall be construed as prohibiting a sponsor from submitting separate applications for the constituent parts of a combination product, unless the Secretary determines that a single application is necessary.

(7) Nothing in this subsection shall prevent the Secretary from using any agency resources of the Food and Drug Administration necessary to ensure adequate review of the safety, effectiveness, or substantial equivalence of an article.

(8)(A) Not later than 60 days after the date of the enactment of this paragraph, the Secretary shall establish within the Office of the Commissioner of Food and Drugs an office to ensure the prompt assignment of combination products to agency centers, the timely and effective premarket review of such products, and consistent and appropriate postmarket regulation of like products subject to the same statutory requirements to the extent permitted by law. Additionally, the office shall, in determining whether a product is to be designated a combination product, consult with the component within the Office of the Commissioner of Food and Drugs that is responsible for such determinations. Such office (referred to in this paragraph as the "Office") shall have appropriate scientific and medical expertise, and shall be headed by a director.

(B) In carrying out this subsection, the Office shall, for each combination product, promptly assign an agency center with primary jurisdiction in accordance with paragraph (1) for the premarket review of such product.

(C)(i) In carrying out this subsection, the Office shall help to ensure timely and effective premarket review that involves more than one agency center by coordinating such reviews, overseeing the timeliness of such reviews, and overseeing the alignment of feedback regarding such reviews.

(ii) In order to ensure the timeliness and alignment of the premarket review of a combination product, the agency center with primary jurisdiction for the product, and the consulting agency center, shall be responsible to the Office with respect to the timeliness and alignment of the premarket review.

(iii) The Office shall ensure that, with respect to a combination product, a designated person or persons in the primary agency center is the primary point or points of contact for the sponsor of such combination product. The Office shall also coordinate communications to and from any consulting center involved in such premarket review, if requested by such primary agency center or any such consulting center. Agency communications and commitments, to the extent consistent with other provisions of law and the requirements of all affected agency centers, from the primary agency center shall be considered as communication from the Secretary on behalf of all agency centers involved in the review.

(iv) The Office shall, with respect to the premarket review of a combination product—

(I) ensure that any meeting between the Secretary and the sponsor of such product is attended by each agency center involved in the review, as appropriate;

(II) ensure that each consulting agency center has completed its premarket review and provided the results of such review to the primary agency center in a timely manner; and

(III) ensure that each consulting center follows the guidance described in clause (vi) and advises, as appropriate, on other relevant regulations, guidances, and policies.

(v) In seeking agency action with respect to a combination product, the sponsor of such product—

(I) shall identify the product as a combination product; and

(II) may request in writing the participation of representatives of the Office in meetings related to such combination product, or to have the Office otherwise engage on such regulatory matters concerning the combination product.

(vi) Not later than 4 years after the date of enactment of the 21st Century Cures Act, and after a public comment period of not less than 60 calendar days, the Secretary shall issue a final guidance that describes—

(I) the structured process for managing pre-submission interactions with sponsors developing combination products;

(II) the best practices for ensuring that the feedback in such pre-submission interactions represents the Agency's best advice based on the information provided during such pre-submission interactions;

(III) the information that is required to be submitted with a meeting request under paragraph (2), how such meetings relate to other types of meetings in the Food and Drug Administration, and the form and content of any agreement reached through a meeting under such paragraph (2);

(D) In carrying out this subsection, the Office shall ensure the consistency and appropriateness of postmarket regulation of like products subject to the same statutory requirements to the extent permitted by law.

(E)(i) Any dispute regarding the timeliness of the premarket review of a combination product may be presented to the Office for resolution, unless the dispute is clearly premature.

(ii) During the review process, any dispute regarding the substance of the premarket review may be presented to the Commissioner of Food and Drugs after first being considered by the agency center with primary jurisdiction of the premarket review, under the

scientific dispute resolution procedures for such center. The Commissioner of Food and Drugs shall consult with the Director of the Office in resolving the substantive dispute.

(F) The Secretary, acting through the Office, shall review each agreement, guidance, or practice of the Secretary that is specific to the assignment of combination products to agency centers and shall determine whether the agreement, guidance, or practice is consistent with the requirements of this subsection. In carrying out such review, the Secretary shall consult with stakeholders and the directors of the agency centers. After such consultation, the Secretary shall determine whether to continue in effect, modify, revise, or eliminate such agreement, guidance, or practice, and shall publish in the Federal Register a notice of the availability of such modified or revised agreement, guidance or practice. Nothing in this paragraph shall be construed as preventing the Secretary from following each agreement, guidance, or practice until continued, modified, revised, or eliminated.

(G) Not later than one year after the date of the enactment of this paragraph (except with respect to clause (iv), beginning not later than one year after the date of the enactment of the 21st Century Cures Act) and annually thereafter, the Secretary shall report to the appropriate committees of Congress on the activities and impact of the Office. The report shall include provisions—

(i) describing the numbers and types of combination products under review and the timeliness in days of such assignments, reviews, and dispute resolutions;

(ii) identifying the number of premarket reviews of such products that involved a consulting agency center;

(iii) describing improvements in the consistency of postmarket regulation of combination products; and

(iv) identifying the percentage of combination products for which a dispute resolution, with respect to premarket review, was requested by the combination product's sponsor.

(H) Nothing in this paragraph shall be construed to limit the regulatory authority of any agency center.

(9) As used in this subsection:

(A) The term "agency center" means a center or alternative organizational component of the Food and Drug Administration.

(B) The term "biological product" has the meaning given the term in section 351(i) of the Public Health Service Act (42 U.S.C. 262(i)).

(C) The term "market clearance" includes—

(i) approval of an application under section 505, 507, 515, or 520(g);

(ii) a finding of substantial equivalence under this subchapter;

(iii) approval of a biologics license application under subsection (a) of section 351 of the Public Health Service Act (42 U.S.C. 262); and

(iv) de novo classification under section 513(a)(1).

(D) The terms "premarket review" and "reviews" include all activities of the Food and Drug Administration conducted prior to approval or clearance of an application, notification, or request for classification submitted under section 505, 510(k),

513(f)(2), 515, or 520 of this Act or under section 351 of the Public Health Service Act, including with respect to investigational use of the product.

(h)(1) Any contrast agent, radioactive drug, or OTC monograph drug shall be deemed to be a drug under section 201(g) and not a device under section 201(h).

(2) For purposes of this subsection:

(A) The term "contrast agent" means an article that is intended for use in conjunction with a medical imaging device, and—

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

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

(B) The term 'radioactive drug' has the meaning given such term in section 310.3(n) of title 21, Code of Federal Regulations (or any successor regulations), except that such term does not include—

(i) an implant or article similar to an implant;

(ii) an article that applies radiation from outside of the body; or

(iii) the radiation source of an article described in clause (i) or (ii).

(C) The term 'OTC monograph drug' has the meaning given such term in section 744L.

(3) Nothing in this subsection shall be construed as allowing for the classification of a product as a drug (as defined in section 201(g)) if such product—

(A) is not described in paragraph (1); and

(B) meets the definition of a device under section 201(h),

unless another provision of this Act otherwise indicates a different classification.

* * * * * * *

NEW DRUGS

SEC. 505. (a) No person shall introduce or deliver for introduction into interstate commerce any new drug, unless an approval of an application filed pursuant to subsection (b) or (j) is effective with respect to such drug.

(b)

(b)(1)(A) Any person may file with the Secretary an application with respect to any drug subject to the provisions of subsection (a). Such persons shall submit to the Secretary as part of the application—

(i) full reports of investigations which have been made to show whether such drug is safe for use and whether such drug is effective in use;

(ii) a full list of the articles used as components of such drug;

(iii) a full statement of the composition of such drug;

(iv) a full description of the methods used in, and the facilities and controls used for, the manufacture, processing, and packing of such drug;

(v) such samples of such drug and of the articles used as components thereof as the Secretary may require;

(vi) specimens of the labeling proposed to be used for such drug;

(vii) any assessments required under section 505B; and

(viii) the patent number and expiration date of each patent for which a claim of patent infringement could reasonably be asserted if a person not licensed by the owner of the patent engaged in the manufacture, use, or sale of the drug, and that—

(I) claims the drug for which the applicant submitted the application and is a drug substance (active ingredient) patent or a drug product (formulation or composition) patent; or

(II) claims a method of using such drug for which approval is sought or has been granted in the application.

(B) If an application is filed under this subsection for a drug, and a patent of the type described in subparagraph (A)(viii) is issued after the filing date but before approval of the application, the applicant shall amend the application to include the patent number and expiration date.

(2) An application submitted under paragraph (1) for a drug for which the investigations described in clause (A) of such paragraph and relied upon by the applicant for approval of the application were not conducted by or for the applicant and for which the applicant has not obtained a right of reference or use from the person by or for whom the investigations were conducted shall also include—

(A) a certification, in the opinion of the applicant and to the best of his knowledge, with respect to each patent which claims the drug for which such investigations were conducted or which claims a use for such drug for which the applicant is seeking approval under this subsection and for which information is required to be filed under paragraph (1) or subsection (c)—

(i) that such patent information has not been filed,

(ii) that such patent has expired,

(iii) of the date on which such patent will expire, or

(iv) that such patent is invalid or will not be infringed by the manufacture, use, or sale of the new drug for which the application is submitted; and

(B) if with respect to the drug for which investigations described in paragraph (1)(A) were conducted information was filed under paragraph (1) or subsection (c) for a method of use patent which does not claim a use for which the applicant is seeking approval under this subsection, a statement that the method of use patent does not claim such a use.

(3) NOTICE OF OPINION THAT PATENT IS INVALID OR WILL NOT BE INFRINGED.—

(A) AGREEMENT TO GIVE NOTICE.—An applicant that makes a certification described in paragraph (2)(A)(iv) shall include in the application a statement that the applicant will give notice as required by this paragraph.

(B) TIMING OF NOTICE.—An applicant that makes a certification described in paragraph (2)(A)(iv) shall give notice as required under this paragraph—

(i) if the certification is in the application, not later than 20 days after the date of the postmark on the notice with which the Secretary informs the applicant that the application has been filed; or

(ii) if the certification is in an amendment or supplement to the application, at the time at which the applicant submits the amendment or supplement, regardless of whether the applicant has already given notice with respect to another such certification contained in the application or in an amendment or supplement to the application.

(C) RECIPIENTS OF NOTICE.—An applicant required under this paragraph to give notice shall give notice to—

(i) each owner of the patent that is the subject of the certification (or a representative of the owner designated to receive such a notice); and

(ii) the holder of the approved application under this subsection for the drug that is claimed by the patent or a use of which is claimed by the patent (or a representative of the holder designated to receive such a notice).

(D) CONTENTS OF NOTICE.—A notice required under this paragraph shall—

(i) state that an application that contains data from bioavailability or bioequivalence studies has been submitted under this subsection for the drug with respect to which the certification is made to obtain approval to engage in the commercial manufacture, use, or sale of the drug before the expiration of the patent referred to in the certification; and

(ii) include a detailed statement of the factual and legal basis of the opinion of the applicant that the patent is invalid or will not be infringed.

(4)(A) An applicant may not amend or supplement an application referred to in paragraph (2) to seek approval of a drug that is a different drug than the drug identified in the application as submitted to the Secretary.

(B) With respect to the drug for which such an application is submitted, nothing in this subsection or subsection (c)(3) prohibits an applicant from amending or supplementing the application to seek approval of a different strength.

(5)(A) The Secretary shall issue guidance for the individuals who review applications submitted under paragraph (1) or under section 351 of the Public Health Service Act, which shall relate to promptness in conducting the review, technical excellence, lack of bias and conflict of interest, and knowledge of regulatory and scientific standards, and which shall apply equally to all individuals who review such applications.

(B) The Secretary shall meet with a sponsor of an investigation or an applicant for approval for a drug under this subsection or section 351 of the Public Health Service Act if the sponsor or applicant makes a reasonable written request for a meeting for the purpose of reaching agreement on the design and size—

(i)(I) of clinical trials intended to form the primary basis of an effectiveness claim; or

(II) in the case where human efficacy studies are not ethical or feasible, of [animal] *nonclinical tests* and any associated clinical trials which, in combination, are intended to form the primary basis of an effectiveness claim; or

(ii) with respect to an application for approval of a biological product under section 351(k) of the Public Health Service Act, of any necessary clinical study or studies.

The sponsor or applicant shall provide information necessary for discussion and agreement on the design and size of the clinical trials. Minutes of any such meeting shall be prepared by the Secretary and made available to the sponsor or applicant upon request.

(C) Any agreement regarding the parameters of the design and size of clinical trials of a new drug under this paragraph that is reached between the Secretary and a sponsor or applicant shall be reduced to writing and made part of the administrative record by the Secretary. Such agreement shall not be changed after the testing begins, except—

(i) with the written agreement of the sponsor or applicant; or

(ii) pursuant to a decision, made in accordance with subparagraph (D) by the director of the reviewing division, that a substantial scientific issue essential to determining the safety or effectiveness of the drug has been identified after the testing has begun.

(D) A decision under subparagraph (C)(ii) by the director shall be in writing and the Secretary shall provide to the sponsor or applicant an opportunity for a meeting at which the director and the sponsor or applicant will be present and at which the director will document the scientific issue involved.

(E) The written decisions of the reviewing division shall be binding upon, and may not directly or indirectly be changed by, the field or compliance division personnel unless such field or compliance division personnel demonstrate to the reviewing division why such decision should be modified.

(F) No action by the reviewing division may be delayed because of the unavailability of information from or action by field personnel unless the reviewing division determines that a delay is necessary to assure the marketing of a safe and effective drug.

(G) For purposes of this paragraph, the reviewing division is the division responsible for the review of an application for approval of a drug under this subsection or section 351 of the Public Health Service Act (including all scientific and medical matters, chemistry, manufacturing, and controls).

(6) An application submitted under this subsection shall be accompanied by the certification required under section 402(j)(5)(B) of the Public Health Service Act. Such certification shall not be considered an element of such application.

(c)(1) Within one hundred and eighty days after the filing of an application under subsection (b), or such additional period as may be agreed upon by the Secretary and the applicant, the Secretary shall either—

(A) approve the application if he then finds that none of the grounds for denying approval specified in subsection (d) applies, or

(B) give the applicant notice of an opportunity for a hearing before the Secretary under subsection (d) on the question whether such application is approvable. If the applicant elects to accept the opportunity for hearing by written request within thirty days after such notice, such hearing shall commence not more than ninety days after the expiration of such thirty days unless the Secretary and the applicant otherwise agree. Any such hearing shall thereafter be conducted on an expedited basis and the Secretary's order thereon shall be issued within ninety days after the date fixed by the Secretary for filing final briefs.

(2) Not later than 30 days after the date of approval of an application submitted under subsection (b), the holder of the approved application shall file with the Secretary the patent number and the expiration date of any patent described in subsection (b)(1)(A)(viii), except that a patent that is identified as claiming a method of using such drug shall be filed only if the patent claims a method of use approved in the application. If a patent described in subsection (b)(1)(A)(viii) is issued after the date of approval of an application submitted under subsection (b), the holder of the approved application shall, not later than 30 days after the date of issuance of the patent, file the patent number and the expiration date of the patent, except that a patent that claims a method of using such drug shall be filed only if approval for such use has been granted in the application. If the patent information described in subsection (b) could not be filed with the submission of an application under subsection (b) because the application was filed before the patent information was required under subsection (b) or a patent was issued after the application was approved under such subsection, the holder of an approved application shall file with the Secretary, the patent number and the expiration date of any patent described in subsection (b)(1)(A)(viii). If the holder of an approved application could not file patent information under subsection (b) because it was not required at the time the application was approved, the holder shall file such information under this subsection not later than thirty days after the date of the enactment of this sentence, and if the holder of an approved application could not file patent information under subsection (b) because no patent of the type for which information is required to be submitted in subsection (b)(1)(A)(viii) had been issued when an application was filed or approved, the holder shall file such information under this subsection not later than thirty days after the date the patent involved is issued. Upon the submission of patent information under this subsection, the Secretary shall publish it. Patent informationthat is not the type of patent information requiredby subsection (b)(1)(A)(viii) shall not be submitted underthis paragraph.

(3) The approval of an application filed under subsection (b) which contains a certification required by paragraph (2) of such subsection shall be made effective on the last applicable date determined by applying the following to each certification made under subsection (b)(2)(A):

(A) If the applicant only made a certification described in clause (i) or (ii) of subsection (b)(2)(A) or in both such clauses, the approval may be made effective immediately.

(B) If the applicant made a certification described in clause (iii) of subsection (b)(2)(A), the approval may be made effective on the date certified under clause (iii).

(C) If the applicant made a certification described in clause (iv) of subsection (b)(2)(A), the approval shall be made effective immediately unless, before the expiration of 45 days after the date on which the notice described in subsection (b)(3) is received, an action is brought for infringement of the patent that is the subject of the certification and for which information was submitted to the Secretary under paragraph (2) or subsection (b)(1) before the date on which the application (excluding an amendment or supplement to the application) was submitted. If such an action is brought before the expiration of such days, the approval may be made effective upon the expiration of the thirty-month period beginning on the date of the receipt of the notice provided under subsection (b)(3) or such shorter or longer period as the court may order because either party to the action failed to reasonably cooperate in expediting the action, except that—

(i) if before the expiration of such period the district court decides that the patent is invalid or not infringed (including any substantive determination that there is no cause of action for patent infringement or invalidity), the approval shall be made effective on—

(I) the date on which the court enters judgment reflecting the decision; or

(II) the date of a settlement order or consent decree signed and entered by the court stating that the patent that is the subject of the certification is invalid or not infringed;

(ii) if before the expiration of such period the district court decides that the patent has been infringed—

(I) if the judgment of the district court is appealed, the approval shall be made effective on—

(aa) the date on which the court of appeals decides that the patent is invalid or not infringed (including any substantive determination that there is no cause of action for patent infringement or invalidity); or

(bb) the date of a settlement order or consent decree signed and entered by the court of appeals stating that the patent that is the subject of the certification is invalid or not infringed; or

(II) if the judgment of the district court is not appealed or is affirmed, the approval shall be made effective on the date specified by the district court in a court order under section 271(e)(4)(A) of title 35, United States Code;

(iii) if before the expiration of such period the court grants a preliminary injunction prohibiting the applicant from engaging in the commercial manufacture or sale of the drug until the court decides the issues of patent valid-

ity and infringement and if the court decides that such patent is invalid or not infringed, the approval shall be made effective as provided in clause (i); or

(iv) if before the expiration of such period the court grants a preliminary injunction prohibiting the applicant from engaging in the commercial manufacture or sale of the drug until the court decides the issues of patent validity and infringement and if the court decides that such patent has been infringed, the approval shall be made effective as provided in clause (ii).

In such an action, each of the parties shall reasonably cooperate in expediting the action.

(D) CIVIL ACTION TO OBTAIN PATENT CERTAINTY.—

(i) DECLARATORY JUDGMENT ABSENT INFRINGEMENT ACTION.—

(I) IN GENERAL.—No action may be brought under section 2201 of title 28, United States Code, by an applicant referred to in subsection (b)(2) for a declaratory judgment with respect to a patent which is the subject of the certification referred to in subparagraph (C) unless—

(aa) the 45-day period referred to in such subparagraph has expired;

(bb) neither the owner of such patent nor the holder of the approved application under subsection (b) for the drug that is claimed by the patent or a use of which is claimed by the patent brought a civil action against the applicant for infringement of the patent before the expiration of such period; and

(cc) in any case in which the notice provided under paragraph (2)(B) relates to noninfringement, the notice was accompanied by a document described in subclause (III).

(II) FILING OF CIVIL ACTION.—If the conditions described in items (aa), (bb), and as applicable, (cc) of subclause (I) have been met, the applicant referred to in such subclause may, in accordance with section 2201 of title 28, United States Code, bring a civil action under such section against the owner or holder referred to in such subclause (but not against any owner or holder that has brought such a civil action against the applicant, unless that civil action was dismissed without prejudice) for a declaratory judgment that the patent is invalid or will not be infringed by the drug for which the applicant seeks approval, except that such civil action may be brought for a declaratory judgment that the patent will not be infringed only in a case in which the condition described in subclause (I)(cc) is applicable. A civil action referred to in this subclause shall be brought in the judicial district where the defendant has its principal place of business or a regular and established place of business.

(III) OFFER OF CONFIDENTIAL ACCESS TO APPLICATION.—For purposes of subclause (I)(cc), the document

described in this subclause is a document providing an offer of confidential access to the application that is in the custody of the applicant referred to in subsection (b)(2) for the purpose of determining whether an action referred to in subparagraph (C) should be brought. The document providing the offer of confidential access shall contain such restrictions as to persons entitled to access, and on the use and disposition of any information accessed, as would apply had a protective order been entered for the purpose of protecting trade secrets and other confidential business information. A request for access to an application under an offer of confidential access shall be considered acceptance of the offer of confidential access with the restrictions as to persons entitled to access, and on the use and disposition of any information accessed, contained in the offer of confidential access, and those restrictions and other terms of the offer of confidential access shall be considered terms of an enforceable contract. Any person provided an offer of confidential access shall review the application for the sole and limited purpose of evaluating possible infringement of the patent that is the subject of the certification under subsection (b)(2)(A)(iv) and for no other purpose, and may not disclose information of no relevance to any issue of patent infringement to any person other than a person provided an offer of confidential access. Further, the application may be redacted by the applicant to remove any information of no relevance to any issue of patent infringement.

(ii) COUNTERCLAIM TO INFRINGEMENT ACTION.—

(I) IN GENERAL.—If an owner of the patent or the holder of the approved application under subsection (b) for the drug that is claimed by the patent or a use of which is claimed by the patent brings a patent infringement action against the applicant, the applicant may assert a counterclaim seeking an order requiring the holder to correct or delete the patent information submitted by the holder under subsection (b) or this subsection on the ground that the patent does not claim either—

(aa) the drug for which the application was approved; or

(bb) an approved method of using the drug.

(II) NO INDEPENDENT CAUSE OF ACTION.—Subclause (I) does not authorize the assertion of a claim described in subclause (I) in any civil action or proceeding other than a counterclaim described in subclause (I).

(iii) NO DAMAGES.—An applicant shall not be entitled to damages in a civil action under clause (i) or a counterclaim under clause (ii).

(E)

(ii) If an application submitted under subsection (b) for a drug, no active moiety (as defined by the Secretary in section

314.3 of title 21, Code of Federal Regulations (or any successor regulations)) of which has been approved in any other application under subsection (b), is approved after the date of the enactment of this clause, no application which refers to the drug for which the subsection (b) application was submitted and for which the investigations described in subsection (b)(1)(A)(i) and relied upon by the applicant for approval of the application were not conducted by or for the applicant and for which the applicant has not obtained a right of reference or use from the person by or for whom the investigations were conducted may be submitted under subsection (b) before the expiration of five years from the date of the approval of the application under subsection (b), except that such an application may be submitted under subsection (b) after the expiration of four years from the date of the approval of the subsection (b) application if it contains a certification of patent invalidity or noninfringement described in clause (iv) of subsection (b)(2)(A). The approval of such an application shall be made effective in accordance with this paragraph except that, if an action for patent infringement is commenced during the one-year period beginning forty-eight months after the date of the approval of the subsection (b) application, the thirty-month period referred to in subparagraph (C) shall be extended by such amount of time (if any) which is required for seven and one-half years to have elapsed from the date of approval of the subsection (b) application.

(iii) If an application submitted under subsection (b) for a drug, which includes an active moiety (as defined by the Secretary in section 314.3 of title 21, Code of Federal Regulations (or any successor regulations)) that has been approved in another application approved under subsection (b), is approved after the date of the enactment of this clause and if such application contains reports of new clinical investigations (other than bioavailability studies) essential to the approval of the application and conducted or sponsored by the applicant, the Secretary may not make the approval of an application submitted under subsection (b) for the conditions of approval of such drug in the approved subsection (b) application effective before the expiration of three years from the date of the approval of the application under subsection (b) if the investigations described in subsection (b)(1)(A)(i) and relied upon by the applicant for approval of the application were not conducted by or for the applicant and if the applicant has not obtained a right of reference or use from the person by or for whom the investigations were conducted.

(iv) If a supplement to an application approved under subsection (b) is approved after the date of enactment of this clause and the supplement contains reports of new clinical investigations (other than bioavailabilty studies) essential to the approval of the supplement and conducted or sponsored by the person submitting the supplement, the Secretary may not make the approval of an application submitted under subsection (b) for a change approved in the supplement effective before the expiration of three years from the date of the approval of the supplement under subsection (b) if the investiga-

tions described in subsection (b)(1)(A)(i) and relied upon by the applicant for approval of the application were not conducted by or for the applicant and if the applicant has not obtained a right of reference or use from the person by or for whom the investigations were conducted.

(v) If an application (or supplement to an application) submitted under subsection (b) for a drug, which includes anactive moiety (as defined by the Secretary in section 314.3 of title 21, Code of Federal Regulations (or any successor regulations)) that has been approved in another application under subsection (b), was approved during the period beginning January 1, 1982, and ending on the date of the enactment of this clause, the Secretary may not make the approval of an application submitted under this subsection and for which the investigations described in subsection (b)(1)(A)(i) and relied upon by the applicant for approval of the application were not conducted by or for the applicant and for which the applicant has not obtained a right of reference or use from the person by or for whom the investigations were conducted and which refers to the drug for which the subsection (b) application was submitted effective before the expiration of two years from the date of enactment of this clause.

(4) A drug manufactured in a pilot or other small facility may be used to demonstrate the safety and effectiveness of the drug and to obtain approval for the drug prior to manufacture of the drug in a larger facility, unless the Secretary makes a determination that a full scale production facility is necessary to ensure the safety or effectiveness of the drug.

(5)(A) The Secretary may rely upon qualified data summaries to support the approval of a supplemental application, with respect to a qualified indication for a drug, submitted under subsection (b), if such supplemental application complies with subparagraph (B).

(B) A supplemental application is eligible for review as described in subparagraph (A) only if—

(i) there is existing data available and acceptable to the Secretary demonstrating the safety of the drug; and

(ii) all data used to develop the qualified data summaries are submitted to the Secretary as part of the supplemental application.

(C) The Secretary shall post on the Internet website of the Food and Drug Administration and update annually—

(i) the number of applications reviewed solely under subparagraph (A) or section 351(a)(2)(E) of the Public Health Service Act;

(ii) the average time for completion of review under subparagraph (A) or section 351(a)(2)(E) of the Public Health Service Act;

(iii) the average time for review of supplemental applications where the Secretary did not use review flexibility under subparagraph (A) or section 351(a)(2)(E) of the Public Health Service Act; and

(iv) the number of applications reviewed under subparagraph (A) or section 351(a)(2)(E) of the Public Health Service Act for which the Secretary made use of full data sets in addition to the qualified data summary.

(D) In this paragraph—

(i) the term "qualified indication" means an indication for a drug that the Secretary determines to be appropriate for summary level review under this paragraph; and

(ii) the term "qualified data summary" means a summary of clinical data that demonstrates the safety and effectiveness of a drug with respect to a qualified indication.

(d) If the Secretary finds, after due notice to the applicant in accordance with subsection (c) and giving him an opportunity for a hearing, in accordance with said subsection, that (1) the investigations, reports of which are required to be submitted to the Secretary pursuant to subsection (b), do not include adequate tests by all methods reasonably applicable to show whether or not such drug is safe for use under the conditions prescribed, recommended, or suggested in the proposed labeling thereof; (2) the results of such tests show that such drug is unsafe for use under such conditions or do not show that such drug is safe for use under such conditions; (3) the methods used in, and the facilities and controls used for, the manufacture, processing, and packing of such drug are inadequate to preserve its identity, strength, quality, and purity; (4) upon the basis of the information submitted to him as part of the application, or upon the basis of any other information before him with respect to such drug, he has insufficient information to determine whether such drug is safe for use under such conditions; or (5) evaluated on the basis of the information submitted to him as part of the application and any other information before him with respect to such drug, there is a lack of substantial evidence that the drug will have the effect it purports or is represented to have under the conditions of use prescribed, recommended, or suggested in the proposed labeling thereof; or (6) the application failed to contain the patent information prescribed by subsection (b); or (7) based on a fair evaluation of all material facts, such labeling is false or misleading in any particular; he shall issue an order refusing to approve the application. If, after such notice and opportunity for hearing, the Secretary finds that clauses (1) through (6) do not apply, he shall issue an order approving the application. As used in this subsection and subsection (e), the term "substantial evidence" means evidence consisting of adequate and well-controlled investigations, including clinical investigations, by experts qualified by scientific training and experience to evaluate the effectiveness of the drug involved, on the basis of which it could fairly and responsibly be concluded by such experts that the drug will have the effect it purports or is represented to have under the conditions of use prescribed, recommended, or suggested in the labeling or proposed labeling thereof. If the Secretary determines, based on relevant science, that data from one adequate and well-controlled clinical investigation and confirmatory evidence (obtained prior to or after such investigation) are sufficient to establish effectiveness, the Secretary may consider such data and evidence to constitute substantial evidence for purposes of the preceding sentence. The Secretary shall implement a structured risk-benefit assessment framework in the new drug approval process to facilitate the balanced consideration of benefits and risks, a consistent and systematic approach to the discussion and regulatory decisionmaking, and the communication of the benefits and risks of new drugs. Nothing

in the preceding sentence shall alter the criteria for evaluating an application for marketing approval of a drug.

(e) The Secretary shall, after due notice and opportunity for hearing to the applicant, withdraw approval of an application with respect to any drug under this section if the Secretary finds (1) that clinical or other experience, tests, or other scientific data show that such drug is unsafe for use under the conditions of use upon the basis of which the application was approved; (2) that new evidence of clinical experience, not contained in such application or not available to the Secretary until after such application was approved, or tests by new methods, or tests by methods not deemed reasonably applicable when such application was approved, evaluated together with the evidence available to the Secretary when the application was approved, shows that such drug is not shown to be safe for use under the conditions of use upon the basis of which the application was approved; or (3) on the basis of new information before him with respect to such drug, evaluated together with the evidence available to him when the application was approved, that there is a lack of substantial evidence that the drug will have the effect it purports or is represented to have under the conditions of use prescribed, recommended, or suggested in the labeling thereof; or (4) the patent information prescribed by subsection (c) was not filed within thirty days after the receipt of written notice from the Secretary specifying the failure to file such information; or (5) that the application contains any untrue statement of a material fact: *Provided,* That if the Secretary (or in his absence the officer acting as Secretary) finds that there is an imminent hazard to the public health, he may suspend the approval of such application immediately, and give the applicant prompt notice of his action and afford the applicant the opportunity for an expedited hearing under this subsection; but the authority conferred by this proviso to suspend the approval of an application shall not be delegated. The Secretary may also, after due notice and opportunity for hearing to the applicant, withdraw the approval of an application submitted under subsection (b) or (j) with respect to any drug under this section if the Secretary finds (1) that the applicant has failed to establish a system for maintaining required records, or has repeatedly or deliberately failed to maintain such records or to make required reports, in accordance with a regulation or order under subsection (k) or to comply with the notice requirements of section 510(k)(2), or the applicant has refused to permit access to, or copying or verification of, such records as required by paragraph (2) of such subsection; or (2) that on the basis of new information before him, evaluated together with the evidence before him when the application was approved, the methods used in, or the facilities and controls used for, the manufacture, processing, and packing of such drug are inadequate to assure and preserve its identity, strength, quality, and purity and were not made adequate within a reasonable time after receipt of written notice from the Secretary specifying the matter complained of; or (3) that on the basis of new information before him, evaluated together with the evidence before him when the application was approved, the labeling of such drug, based on a fair evaluation of all material facts, is false or misleading in any particular and was not corrected within a reasonable time after receipt of written notice from the Secretary speci-

fying the matter complained of. Any order under this subsection shall state the findings upon which it is based. The Secretary may withdraw the approval of an application submitted under this section, or suspend the approval of such an application, as provided under this subsection, without first ordering the applicant to submit an assessment of the approved risk evaluation and mitigation strategy for the drug under section 505–1(g)(2)(D).

(f) Whenever the Secretary finds that the facts so require, he shall revoke any previous order under subsection (d) or (e) refusing, withdrawing, or suspending approval of an application and shall approve such application or reinstate such approval, as may be appropriate.

(g) Orders of the Secretary issued under this section shall be served (1) in person by any officer or employee of the Department designated by the Secretary or (2) by mailing the order by registered mail or by certified mail addressed to the applicant or respondent at his last-known address in the records of the Secretary.

(h) An appeal may be taken by the applicant from an order of the Secretary refusing or withdrawing approval of an application under this section. Such appeal shall be taken by filing in the United States court of appeals for the circuit wherein such applicant resides or has his principal place of business, or in the United States Court of Appeals for the District of Columbia Circuit, within sixty days after the entry of such order, a written petition praying that the order of the Secretary be set aside. A copy of such petition shall be forthwith transmitted by the clerk of the court to the Secretary, or any officer designated by him for that purpose, and thereupon the Secretary shall certify and file in the court the record upon which the order complained of was entered, as provided in section 2112 of title 28, United States Code. Upon the filing of such petition such court shall have exclusive jurisdiction to affirm or set aside such order, except that until the filing of the record the Secretary may modify or set aside his order. No objection to the order of the Secretary shall be considered by the court unless such objection shall have been urged before the Secretary or unless there were reasonable grounds for failure so to do. The finding of the Secretary as to the facts, if supported by substantial evidence, shall be conclusive. If any person shall apply to the court for leave to adduce additional evidence, and shall show to the satisfaction of the court that such additional evidence is material and that there were reasonable grounds for failure to adduce such evidence in the proceeding before the Secretary, the court may order such additional evidence to be taken before the Secretary and to be adduced upon the hearing in such manner and upon such terms and conditions as to the court may seem proper. The Secretary may modify his findings as to the facts by reason of the additional evidence so taken, and he shall file with the court such modified findings which, if supported by substantial evidence, shall be conclusive, and his recommendation, if any, for the setting aside of the original order. The judgment of the court affirming or setting aside any such order of the Secretary shall be final, subject to review by the Supreme Court of the United States upon certiorari or certification as provided in section 1254 of title 28 of the United States Code. The commencement of proceedings under this subsection

shall not, unless specifically ordered by the court to the contrary, operate as a stay of the Secretary's order.

(i)(1) The Secretary shall promulgate regulations for exempting from the operation of the foregoing subsections of this section drugs intended solely for investigational use by experts qualified by scientific training and experience to investigate the safety and effectiveness of drugs. Such regulations may, within the discretion of the Secretary, among other conditions relating to the protection of the public health, provide for conditioning such exemption upon—

(A) the submission to the Secretary, before any clinical testing of a new drug is undertaken, of reports, by the manufacturer or the sponsor of the investigation of such drug, or **[**preclinical tests (including tests on animals)**]** *nonclinical tests* of such drug adequate to justify the proposed clinical testing;

(B) the manufacturer or the sponsor of the investigation of a new drug proposed to be distributed to investigators for clinical testing obtaining a signed agreement from each of such investigators that patients to whom the drug is administered will be under his personal supervision, or under the supervision of investigators responsible to him, and that he will not supply such drug to any other investigator, or to clinics, for administration to human beings;

(C) the establishment and maintenance of such records, and the making of such reports to the Secretary, by the manufacturer or the sponsor of the investigation of such drug, of data (including but not limited to analytical reports by investigators) obtained as the result of such investigational use of such drug, as the Secretary finds will enable him to evaluate the safety and effectiveness of such drug in the event of the filing of an application pursuant to subsection (b); and

(D) the submission to the Secretary by the manufacturer or the sponsor of the investigation of a new drug of a statement of intent regarding whether the manufacturer or sponsor has plans for assessing pediatric safety and efficacy.

(2) Subject to paragraph (3), a clinical investigation of a new drug may begin 30 days after the Secretary has received from the manufacturer or sponsor of the investigation a submission containing such information about the drug and the clinical investigation, including—

(A) information on design of the investigation and adequate reports of basic information, certified by the applicant to be accurate reports, necessary to assess the safety of the drug for use in clinical investigation; and

(B) adequate information on the chemistry and manufacturing of the drug, controls available for the drug, and primary data tabulations from **[**animal**]** *nonclinical tests* or human studies.

(3)(A) At any time, the Secretary may prohibit the sponsor of an investigation from conducting the investigation (referred to in this paragraph as a "clinical hold") if the Secretary makes a determination described in subparagraph (B). The Secretary shall specify the basis for the clinical hold, including the specific information available to the Secretary which served as the basis for such clinical hold, and confirm such determination in writing.

(B) For purposes of subparagraph (A), a determination described in this subparagraph with respect to a clinical hold is that—

(i) the drug involved represents an unreasonable risk to the safety of the persons who are the subjects of the clinical investigation, taking into account the qualifications of the clinical investigators, information about the drug, the design of the clinical investigation, the condition for which the drug is to be investigated, and the health status of the subjects involved; or

(ii) the clinical hold should be issued for such other reasons as the Secretary may by regulation establish (including reasons established by regulation before the date of the enactment of the Food and Drug Administration Modernization Act of 1997).

(C) Any written request to the Secretary from the sponsor of an investigation that a clinical hold be removed shall receive a decision, in writing and specifying the reasons therefor, within 30 days after receipt of such request. Any such request shall include sufficient information to support the removal of such clinical hold.

(4) Regulations under paragraph (1) shall provide that such exemption shall be conditioned upon the manufacturer, or the sponsor of the investigation, requiring that experts using such drugs for investigational purposes certify to such manufacturer or sponsor that they will inform any human beings to whom such drugs, or any controls used in connection therewith, are being administered, or their representatives, that such drugs are being used for investigational purposes and will obtain the consent of such human beings or their representatives, except where it is not feasible, it is contrary to the best interests of such human beings, or the proposed clinical testing poses no more than minimal risk to such human beings and includes appropriate safeguards as prescribed to protect the rights, safety, and welfare of such human beings. Nothing in this subsection shall be construed to require any clinical investigator to submit directly to the Secretary reports on the investigational use of drugs. The Secretary shall update such regulations to require inclusion in the informed consent documents and process a statement that clinical trial information for such clinical investigation has been or will be submitted for inclusion in the registry data bank pursuant to subsection (j) of section 402 of the Public Health Service Act.

(5)(A) In order for a new drug that is being studied in a phase 3 study, as defined in section 312.21(c) of title 21, Code of Federal Regulations (or successor regulations), or other pivotal study (other than bioavailability or bioequivalence studies), to be exempt pursuant to this subsection, the sponsor of a clinical investigation of such new drug shall submit to the Secretary a diversity action plan.

(B) Such diversity action plan shall include—

(i) the sponsor's goals for enrollment in such clinical study;

(ii) the sponsor's rationale for such goals; and

(iii) an explanation of how the sponsor intends to meet such goals.

(C) The sponsor shall submit such diversity action plan in the form and manner specified in the guidance required by section 524B as soon as practicable but no later than when the sponsor seeks feedback regarding such a phase 3 study or other pivotal study of the drug.

(D) The Secretary may waive the requirement in subparagraph (A) if the Secretary determines that a waiver is necessary based on what is known about the prevalence of the disease in terms of the patient population that may use the new drug.

(E) No diversity action plan shall be required for a submission described in section 561.

(j)(1) Any person may file with the Secretary an abbreviated application for the approval of a new drug.

(2)(A) An abbreviated application for a new drug shall contain—

(i) information to show that the conditions of use prescribed, recommended, or suggested in the labeling proposed for the new drug have been previously approved for a drug listed under paragraph (7) (hereinafter in this subsection referred to as a "listed drug");

(ii)(I) if the listed drug referred to in clause (i) has only one active ingredient, information to show that the active ingredient of the new drug is the same as that of the listed drug;

(II) if the listed drug referred to in clause (i) has more than one active ingredient, information to show that the active ingredients of the new drug are the same as those of the listed drug, or

(III) if the listed drug referred to in clause (i) has more than one active ingredient and if one of the active ingredients of the new drug is different and the application is filed pursuant to the approval of a petition filed under subparagraph (C), information to show that the other active ingredients of the new drug are the same as the active ingredients of the listed drug, information to show that the different active ingredient is an active ingredient of a listed drug or of a drug which does not meet the requirements of section 201(p), and such other information respecting the different active ingredient with respect to which the petition was filed as the Secretary may require;

(iii) information to show that the route of administration, the dosage form, and the strength of the new drug are the same as those of the listed drug referred to in clause (i) or, if the route of administration, the dosage form, or the strength of the new drug is different and the application is filed pursuant to the approval of a petition filed under subparagraph (C), such information respecting the route of administration, dosage form, or strength with respect to which the petition was filed as the Secretary may require;

(iv) information to show that the new drug is bioequivalent to the listed drug referred to in clause (i), except that if the application is filed pursuant to the approval of a petition filed under subparagraph (C), information to show that the active ingredients of the new drug are of the same pharmacological or therapeutic class as those of the listed drug referred to in clause (i) and the new drug can be expected to have the same therapeutic effect as the listed drug when administered to patients for a condition of use referred to in clause (i);

(v) information to show that the labeling proposed for the new drug is the same as the labeling approved for the listed drug referred to in clause (i) except for changes required because of differences approved under a petition filed under sub-

paragraph (C) or because the new drug and the listed drug are produced or distributed by different manufacturers;

(vi) the items specified in clauses (ii) through (vi) of subsection (b)(1)(A);

(vii) a certification, in the opinion of the applicant and to the best of his knowledge, with respect to each patent which claims the listed drug referred to in clause (i) or which claims a use for such listed drug for which the applicant is seeking approval under this subsection and for which information is required to be filed under subsection (b) or (c)—

(I) that such patent information has not been filed,

(II) that such patent has expired,

(III) of the date on which such patent will expire, or

(IV) that such patent is invalid or will not be infringed by the manufacture, use, or sale of the new drug for which the application is submitted; and

(viii) if with respect to the listed drug referred to in clause (i) information was filed under subsection (b) or (c) for a method of use patent which does not claim a use for which the applicant is seeking approval under this subsection, a statement that the method of use patent does not claim such a use.

The Secretary may not require that an abbreviated application contain information in addition to that required by clauses (i) through (viii).

(B) NOTICE OF OPINION THAT PATENT IS INVALID OR WILL NOT BE INFRINGED.—

(i) AGREEMENT TO GIVE NOTICE.—An applicant that makes a certification described in subparagraph (A)(vii)(IV) shall include in the application a statement that the applicant will give notice as required by this subparagraph.

(ii) TIMING OF NOTICE.—An applicant that makes a certification described in subparagraph (A)(vii)(IV) shall give notice as required under this subparagraph—

(I) if the certification is in the application, not later than 20 days after the date of the postmark on the notice with which the Secretary informs the applicant that the application has been filed; or

(II) if the certification is in an amendment or supplement to the application, at the time at which the applicant submits the amendment or supplement, regardless of whether the applicant has already given notice with respect to another such certification contained in the application or in an amendment or supplement to the application.

(iii) RECIPIENTS OF NOTICE.—An applicant required under this subparagraph to give notice shall give notice to—

(I) each owner of the patent that is the subject of the certification (or a representative of the owner designated to receive such a notice); and

(II) the holder of the approved application under subsection (b) for the drug that is claimed by the patent or a use of which is claimed by the patent (or a representative of the holder designated to receive such a notice).

(iv) CONTENTS OF NOTICE.—A notice required under this subparagraph shall—

(I) state that an application that contains data from bioavailability or bioequivalence studies has been submitted under this subsection for the drug with respect to which the certification is made to obtain approval to engage in the commercial manufacture, use, or sale of the drug before the expiration of the patent referred to in the certification; and

(II) include a detailed statement of the factual and legal basis of the opinion of the applicant that the patent is invalid or will not be infringed.

(C) If a person wants to submit an abbreviated application for a new drug which has a different active ingredient or whose route of administration, dosage form, or strength differ from that of a listed drug, such person shall submit a petition to the Secretary seeking permission to file such an application. The Secretary shall approve or disapprove a petition submitted under this subparagraph within ninety days of the date the petition is submitted. The Secretary shall approve such a petition unless the Secretary finds—

(i) that investigations must be conducted to show the safety and effectiveness of the drug or of any of its active ingredients, the route of administration, the dosage form, or strength which differ from the listed drug; or

(ii) that any drug with a different active ingredient may not be adequately evaluated for approval as safe and effective on the basis of the information required to be submitted in an abbreviated application.

(D)(i) An applicant may not amend or supplement an application to seek approval of a drug referring to a different listed drug from the listed drug identified in the application as submitted to the Secretary.

(ii) With respect to the drug for which an application is submitted, nothing in this subsection prohibits an applicant from amending or supplementing the application to seek approval of a different strength.

(iii) Within 60 days after the date of the enactment of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003, the Secretary shall issue guidance defining the term "listed drug" for purposes of this subparagraph.

(3)(A) The Secretary shall issue guidance for the individuals who review applications submitted under paragraph (1), which shall relate to promptness in conducting the review, technical excellence, lack of bias and conflict of interest, and knowledge of regulatory and scientific standards, and which shall apply equally to all individuals who review such applications.

(B) The Secretary shall meet with a sponsor of an investigation or an applicant for approval for a drug under this subsection if the sponsor or applicant makes a reasonable written request for a meeting for the purpose of reaching agreement on the design and size of bioavailability and bioequivalence studies needed for approval of such application. The sponsor or applicant shall provide information necessary for discussion and agreement on the design and size of such studies. Minutes of any such meeting shall be prepared by the Secretary and made available to the sponsor or applicant.

(C) Any agreement regarding the parameters of design and size of bioavailability and bioequivalence studies of a drug under this paragraph that is reached between the Secretary and a sponsor or applicant shall be reduced to writing and made part of the administrative record by the Secretary. Such agreement shall not be changed after the testing begins, except—

(i) with the written agreement of the sponsor or applicant; or

(ii) pursuant to a decision, made in accordance with subparagraph (D) by the director of the reviewing division, that a substantial scientific issue essential to determining the safety or effectiveness of the drug has been identified after the testing has begun.

(D) A decision under subparagraph (C)(ii) by the director shall be in writing and the Secretary shall provide to the sponsor or applicant an opportunity for a meeting at which the director and the sponsor or applicant will be present and at which the director will document the scientific issue involved.

(E) The written decisions of the reviewing division shall be binding upon, and may not directly or indirectly be changed by, the field or compliance office personnel unless such field or compliance office personnel demonstrate to the reviewing division why such decision should be modified.

(F) No action by the reviewing division may be delayed because of the unavailability of information from or action by field personnel unless the reviewing division determines that a delay is necessary to assure the marketing of a safe and effective drug.

(G) For purposes of this paragraph, the reviewing division is the division responsible for the review of an application for approval of a drug under this subsection (including scientific matters, chemistry, manufacturing, and controls).

(H)(i) Upon request (in controlled correspondence or otherwise) by a person that has submitted or intends to submit an abbreviated application for a new drug under this subsection for which the Secretary has specified in regulation, including under section 314.94(a)(9), title 21, Code of Federal Regulations (or a successor regulation), or recommended in applicable guidance, certain qualitative or quantitative criteria with respect to an inactive ingredient, or on the Secretary's own initiative during the review of such abbreviated application, the Secretary shall inform the person whether such new drug is qualitatively and quantitatively the same as the listed drug.

(ii) Notwithstanding section 301(j), if the Secretary determines that such new drug is not qualitatively or quantitatively the same as the listed drug, the Secretary shall identify and disclose to the person—

(I) the ingredient or ingredients that cause the new drug not to be qualitatively or quantitatively the same as the listed drug; and

(II) for any ingredient for which there is an identified quantitative deviation, the amount of such deviation.

(iii) If the Secretary determines that such new drug is qualitatively and quantitatively the same as the listed drug, the Secretary shall not change or rescind such determination after the sub-

mission of an abbreviated application for such new drug under this subsection unless—

(I) the formulation of the listed drug has been changed and the Secretary has determined that the prior listed drug formulation was withdrawn for reasons of safety or effectiveness; or

(II) the Secretary makes a written determination that the prior determination must be changed because an error has been identified.

(iv) If the Secretary makes a written determination described in clause (iii)(II), the Secretary shall provide notice and a copy of the written determination to the person making the request under clause (i).

(v) The disclosures required by this subparagraph are disclosures authorized by law including for purposes of section 1905 of title 18, United States Code.

(4) Subject to paragraph (5), the Secretary shall approve an application for a drug unless the Secretary finds—

(A) the methods used in, or the facilities and controls used for, the manufacture, processing, and packing of the drug are inadequate to assure and preserve its identity, strength, quality, and purity;

(B) information submitted with the application is insufficient show that each of the proposed conditions of use have been previously approved for the listed drug referred to in the application;

(C)(i) if the listed drug has only one active ingredient, information submitted with the application is insufficient to show that the active ingredient is the same as that of the listed drug;

(ii) if the listed drug has more than one active ingredient, information submitted with the application is insufficient to show that the active ingredients are the same as the active ingredients of the listed drug, or

(iii) if the listed drug has more than one active ingredient and if the application is for a drug which has an active ingredient different from the listed drug, information submitted with the application is insufficient to show—

(I) that the other active ingredients are the same as the active ingredients of the listed drug, or

(II) that the different active ingredient is an active ingredient of a listed drug or a drug which does not meet the requirements of section 201(p),

or no petition to file an application for the drug with the different ingredient was approved under paragraph (2)(C);

(D)(i) if the application is for a drug whose route of administration, dosage form, or strength of the drug is the same as the route of administration, dosage form, or strength of the listed drug referred to in the application, information submitted in the application is insufficient to show that the route of administration, dosage form, or strength is the same as that of the listed drug, or

(ii) if the application is for a drug whose route of administration, dosage form, or strength of the drug is different from that of the listed drug referred to in the application, no petition to file an application for the drug with the different route of ad-

ministration, dosage form, or strength was approved under paragraph (2)(C);

(E) if the application was filed pursuant to the approval of a petition under paragraph (2)(C), the application did not contain the information required by the Secretary respecting the active ingredient, route of administration, dosage form, or strength which is not the same;

(F) information submitted in the application is insufficient to show that the drug is bioequivalent to the listed drug referred to in the application or, if the application was filed pursuant to a petition approved under paragraph (2)(C), information submitted in the application is insufficient to show that the active ingredients of the new drug are of the same pharmacological or therapeutic class as those of the listed drug referred to in paragraph (2)(A)(i) and that the new drug can be expected to have the same therapeutic effect as the listed drug when administered to patients for a condition of use referred to in such paragraph;

(G) information submitted in the application is insufficient to show that the labeling proposed for the drug is the same as the labeling approved for the listed drug referred to in the application except for changes required because of differences approved under a petition filed under paragraph (2)(C) or because the drug and the listed drug are produced or distributed by different manufacturers;

(H) information submitted in the application or any other information available to the Secretary shows that (i) the inactive ingredients of the drug are unsafe for use under the conditions prescribed, recommended, or suggested in the labeling proposed for the drug, or (ii) the composition of the drug is unsafe under such conditions because of the type or quantity of inactive ingredients included or the manner in which the inactive ingredients are included;

(I) the approval under subsection (c) of the listed drug referred to in the application under this subsection has been withdrawn or suspended for grounds described in the first sentence of subsection (e), the Secretary has published a notice of opportunity for hearing to withdraw approval of the listed drug under subsection (c) for grounds described in the first sentence of subsection (e), the approval under this subsection of the listed drug referred to in the application under this subsection has been withdrawn or suspended under paragraph (6), or the Secretary has determined that the listed drug has been withdrawn from sale for safety or effectiveness reasons;

(J) the application does not meet any other requirement of paragraph (2)(A); or

(K) the application contains an untrue statement of material fact.

(5)(A) Within one hundred and eighty days of the initial receipt of an application under paragraph (2) or within such additional period as may be agreed upon by the Secretary and the applicant, the Secretary shall approve or disapprove the application.

(B) The approval of an application submitted under paragraph (2) shall be made effective on the last applicable date determined

by applying the following to each certification made under paragraph (2)(A)(vii):

(i) If the applicant only made a certification described in subclause (I) or (II) of paragraph (2)(A)(vii) or in both such subclauses, the approval may be made effective immediately.

(ii) If the applicant made a certification described in subclause (III) of paragraph (2)(A)(vii), the approval may be made effective on the date certified under subclause (III).

(iii) If the applicant made a certification described in subclause (IV) of paragraph (2)(A)(vii), the approval shall be made effective immediately unless, before the expiration of 45 days after the date on which the notice described in paragraph (2)(B) is received, an action is brought for infringement of the patent that is the subject of the certification and for which information was submitted to the Secretary under subsection (b)(1) or (c)(2) before the date on which the application (excluding an amendment or supplement to the application), which the Secretary later determines to be substantially complete, was submitted. If such an action is brought before the expiration of such days, the approval shall be made effective upon the expiration of the thirty-month period beginning on the date of the receipt of the notice provided under paragraph (2)(B)(i) or such shorter or longer period as the court may order because either party to the action failed to reasonably cooperate in expediting the action, except that—

(I) if before the expiration of such period the district court decides that the patent is invalid or not infringed (including any substantive determination that there is no cause of action for patent infringement or invalidity), the approval shall be made effective on—

(aa) the date on which the court enters judgment reflecting the decision; or

(bb) the date of a settlement order or consent decree signed and entered by the court stating that the patent that is the subject of the certification is invalid or not infringed;

(II) if before the expiration of such period the district court decides that the patent has been infringed—

(aa) if the judgment of the district court is appealed, the approval shall be made effective on—

(AA) the date on which the court of appeals decides that the patent is invalid or not infringed (including any substantive determination that there is no cause of action for patent infringement or invalidity); or

(BB) the date of a settlement order or consent decree signed and entered by the court of appeals stating that the patent that is the subject of the certification is invalid or not infringed; or

(bb) if the judgment of the district court is not appealed or is affirmed, the approval shall be made effective on the date specified by the district court in a court order under section 271(e)(4)(A) of title 35, United States Code;

(III) if before the expiration of such period the court grants a preliminary injunction prohibiting the applicant from engaging in the commercial manufacture or sale of the drug until the court decides the issues of patent validity and infringement and if the court decides that such patent is invalid or not infringed, the approval shall be made effective as provided in subclause (I); or

(IV) if before the expiration of such period the court grants a preliminary injunction prohibiting the applicant from engaging in the commercial manufacture or sale of the drug until the court decides the issues of patent validity and infringement and if the court decides that such patent has been infringed, the approval shall be made effective as provided in subclause (II).

In such an action, each of the parties shall reasonably cooperate in expediting the action.

(iv) 180-DAY EXCLUSIVITY PERIOD.—

(I) EFFECTIVENESS OF APPLICATION.—Subject to subparagraph (D), if the application contains a certification described in paragraph (2)(A)(vii)(IV) and is for a drug for which a first applicant has submitted an application containing such a certification, the application shall be made effective on the date that is 180 days after the date of the first commercial marketing of the drug (including the commercial marketing of the listed drug) by any first applicant.

(II) DEFINITIONS.—In this paragraph:

(aa) 180-DAY EXCLUSIVITY PERIOD.—The term "180-day exclusivity period" means the 180-day period ending on the day before the date on which an application submitted by an applicant other than a first applicant could become effective under this clause.

(bb) FIRST APPLICANT.—As used in this subsection, the term "first applicant" means an applicant that, on the first day on which a substantially complete application containing a certification described in paragraph (2)(A)(vii)(IV) is submitted for approval of a drug, submits a substantially complete application that contains and lawfully maintains a certification described in paragraph (2)(A)(vii)(IV) for the drug.

(cc) SUBSTANTIALLY COMPLETE APPLICATION.—As used in this subsection, the term "substantially complete application" means an application under this subsection that on its face is sufficiently complete to permit a substantive review and contains all the information required by paragraph (2)(A).

(dd) TENTATIVE APPROVAL.—

(AA) IN GENERAL.—The term "tentative approval" means notification to an applicant by the Secretary that an application under this subsection meets the requirements of paragraph (2)(A), but cannot receive effective approval because the application does not meet the requirements of this subparagraph, there is a period of exclusivity for the listed drug under subparagraph

(F) or section 505A, or there is a 7-year period of exclusivity for the listed drug under section 527.

(BB) LIMITATION.—A drug that is granted tentative approval by the Secretary is not an approved drug and shall not have an effective approval until the Secretary issues an approval after any necessary additional review of the application.

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

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

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

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

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

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

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

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

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

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

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

(C) CIVIL ACTION TO OBTAIN PATENT CERTAINTY.—

(i) DECLARATORY JUDGMENT ABSENT INFRINGEMENT ACTION.—

(I) IN GENERAL.—No action may be brought under section 2201 of title 28, United States Code, by an applicant under paragraph (2) for a declaratory judgment with respect to a patent which is the subject of the certification referred to in subparagraph (B)(iii) unless—

(aa) the 45-day period referred to in such subparagraph has expired;

(bb) neither the owner of such patent nor the holder of the approved application under subsection (b) for the drug that is claimed by the patent or a use of which is claimed by the patent brought a civil action against the applicant for infringement of the patent before the expiration of such period; and

(cc) in any case in which the notice provided under paragraph (2)(B) relates to noninfringement, the notice was accompanied by a document described in subclause (III).

(II) FILING OF CIVIL ACTION.—If the conditions described in items (aa), (bb), and as applicable, (cc) of subclause (I) have been met, the applicant referred to in such subclause may, in accordance with section 2201 of title 28, United States Code, bring a civil action under such section against the owner or holder referred to in such subclause (but not against any owner or holder that has brought such a civil action against the applicant, unless that civil action was dismissed without prejudice) for a declaratory judgment that the patent is invalid or will not be infringed by the drug for which the applicant seeks approval, except that such civil action may be brought for a declaratory judgment that the patent will not be infringed only in a case in which the condition described in subclause (I)(cc) is applicable. A civil action referred to in this subclause shall be brought in the judicial district where the defendant has its principal place of business or a regular and established place of business.

(III) OFFER OF CONFIDENTIAL ACCESS TO APPLICATION.—For purposes of subclause (I)(cc), the document described in this subclause is a document providing an offer of confidential access to the application that is in the custody of the applicant under paragraph (2) for the purpose of determining whether an action referred to in subparagraph (B)(iii) should be brought. The document providing the offer of confidential access shall contain such restrictions as to persons entitled to access, and on the use and disposition of any information accessed, as would apply had a protective order been entered for the purpose of protecting trade secrets and other confidential business information. A request for access to an application under an offer of confidential access shall be considered acceptance of the offer of confidential access with the restrictions as to persons entitled to access, and on the use and disposition of any information accessed, contained in the offer of confidential access, and those restrictions and other terms of the offer of confidential access shall be considered terms of an enforceable contract. Any person provided an offer of confidential access shall review the application for the sole and limited purpose of evaluating pos-

sible infringement of the patent that is the subject of the certification under paragraph (2)(A)(vii)(IV) and for no other purpose, and may not disclose information of no relevance to any issue of patent infringement to any person other than a person provided an offer of confidential access. Further, the application may be redacted by the applicant to remove any information of no relevance to any issue of patent infringement.

(ii) COUNTERCLAIM TO INFRINGEMENT ACTION.—

(I) IN GENERAL.—If an owner of the patent or the holder of the approved application under subsection (b) for the drug that is claimed by the patent or a use of which is claimed by the patent brings a patent infringement action against the applicant, the applicant may assert a counterclaim seeking an order requiring the holder to correct or delete the patent information submitted by the holder under subsection (b) or (c) on the ground that the patent does not claim either—

(aa) the drug for which the application was approved; or

(bb) an approved method of using the drug.

(II) NO INDEPENDENT CAUSE OF ACTION.—Subclause (I) does not authorize the assertion of a claim described in subclause (I) in any civil action or proceeding other than a counterclaim described in subclause (I).

(iii) NO DAMAGES.—An applicant shall not be entitled to damages in a civil action under clause (i) or a counterclaim under clause (ii).

(D) FORFEITURE OF 180-DAY EXCLUSIVITY PERIOD.—

(i) DEFINITION OF FORFEITURE EVENT.—In this subparagraph, the term "forfeiture event", with respect to an application under this subsection, means the occurrence of any of the following:

(I) FAILURE TO MARKET.—The first applicant fails to market the drug by the later of—

(aa) the earlier of the date that is—

(AA) 75 days after the date on which the approval of the application of the first applicant is made effective under subparagraph (B)(iii); or

(BB) 30 months after the date of submission of the application of the first applicant; or

(bb) with respect to the first applicant or any other applicant (which other applicant has received tentative approval), the date that is 75 days after the date as of which, as to each of the patents with respect to which the first applicant submitted and lawfully maintained a certification qualifying the first applicant for the 180-day exclusivity period under subparagraph (B)(iv), at least 1 of the following has occurred:

(AA) In an infringement action brought against that applicant with respect to the patent or in a declaratory judgment action

brought by that applicant with respect to the patent, a court enters a final decision from which no appeal (other than a petition to the Supreme Court for a writ of certiorari) has been or can be taken that the patent is invalid or not infringed.

(BB) In an infringement action or a declaratory judgment action described in subitem (AA), a court signs a settlement order or consent decree that enters a final judgment that includes a finding that the patent is invalid or not infringed.

(CC) The patent information submitted under subsection (b) or (c) is withdrawn by the holder of the application approved under subsection (b).

(II) WITHDRAWAL OF APPLICATION.—The first applicant withdraws the application or the Secretary considers the application to have been withdrawn as a result of a determination by the Secretary that the application does not meet the requirements for approval under paragraph (4).

(III) AMENDMENT OF CERTIFICATION.—The first applicant amends or withdraws the certification for all of the patents with respect to which that applicant submitted a certification qualifying the applicant for the 180-day exclusivity period.

(IV) FAILURE TO OBTAIN TENTATIVE APPROVAL.—The first applicant fails to obtain tentative approval of the application within 30 months after the date on which the application is filed, unless the failure is caused by a change in or a review of the requirements for approval of the application imposed after the date on which the application is filed.

(V) AGREEMENT WITH ANOTHER APPLICANT, THE LISTED DRUG APPLICATION HOLDER, OR A PATENT OWNER.—The first applicant enters into an agreement with another applicant under this subsection for the drug, the holder of the application for the listed drug, or an owner of the patent that is the subject of the certification under paragraph (2)(A)(vii)(IV), the Federal Trade Commission or the Attorney General files a complaint, and there is a final decision of the Federal Trade Commission or the court with regard to the complaint from which no appeal (other than a petition to the Supreme Court for a writ of certiorari) has been or can be taken that the agreement has violated the antitrust laws (as defined in section 1 of the Clayton Act (15 U.S.C. 12), except that the term includes section 5 of the Federal Trade Commission Act (15 U.S.C. 45) to the extent that that section applies to unfair methods of competition).

(VI) EXPIRATION OF ALL PATENTS.—All of the patents as to which the applicant submitted a certification

qualifying it for the 180-day exclusivity period have expired.

(ii) FORFEITURE.—The 180-day exclusivity period described in subparagraph (B)(iv) shall be forfeited by a first applicant if a forfeiture event occurs with respect to that first applicant.

(iii) SUBSEQUENT APPLICANT.—If all first applicants forfeit the 180-day exclusivity period under clause (ii)—

(I) approval of any application containing a certification described in paragraph (2)(A)(vii)(IV) shall be made effective in accordance with subparagraph (B)(iii); and

(II) no applicant shall be eligible for a 180-day exclusivity period.

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

(E) If the Secretary decides to disapprove an application, the Secretary shall give the applicant notice of an opportunity for a hearing before the Secretary on the question of whether such application is approvable. If the applicant elects to accept the opportunity for hearing by written request within thirty days after such notice, such hearing shall commence not more than ninety days after the expiration of such thirty days unless the Secretary and the applicant otherwise agree. Any such hearing shall thereafter be conducted on an expedited basis and the Secretary's order thereon shall be issued within ninety days after the date fixed by the Secretary for filing final briefs.

(F)

(ii) If an application submitted under subsection (b) for a drug, no active moiety (as defined by the Secretary in section 314.3 of title 21, Code of Federal Regulations (or any successor regulations)) of which has been approved in any other application under subsection (b), is approved after the date of the enactment of this subsection, no application may be submitted under this subsection which refers to the drug for which the subsection (b) application was submitted before the expiration of five years from the date of the approval of the application under subsection (b), except that such an application may be submitted under this subsection after the expiration of four years from the date of the approval of the subsection (b) application if it contains a certification of patent invalidity or noninfringement described in subclause (IV) of paragraph (2)(A)(vii). The approval of such an application shall be made effective in accordance with subparagraph (B) except that, if an action for patent infringement is commenced during the one-year period beginning forty-eight months after the date of the approval of the subsection (b) application, the thirty-month period referred to in subparagraph (B)(iii) shall be extended by such amount of time (if any) which is required for seven and one-half years to have elapsed from the date of approval of the subsection (b) application.

(iii) If an application submitted under subsection (b) for a drug, which includes an active moiety (as defined by the Secretary in section 314.3 of title 21, Code of Federal Regulations (or any successor regulations)) that has been approved in another application approved under subsection (b), is approved after the date of enactment of this subsection and if such application contains reports of new clinical investigations (other than bioavailability studies) essential to the approval of the application and conducted or sponsored by the applicant, the Secretary may not make the approval of an application submitted under this subsection for the conditions of approval of such drug in the subsection (b) application effective before the expiration of three years from the date of the approval of the application under subsection (b) for such drug.

(iv) If a supplement to an application approved under subsection (b) is approved after the date of enactment of this subsection and the supplement contains reports of new clinical investigations (other than bioavailability studies) essential to the approval of the supplement and conducted or sponsored by the person submitting the supplement, the Secretary may not make the approval of an application submitted under this subsection for a change approved in the supplement effective before the expiration of three years from the date of the approval of the supplement under subsection (b).

(v) If an application (or supplement to an application) submitted under subsection (b) for a drug, which includes an active moiety (as defined by the Secretary in section 314.3 of title 21, Code of Federal Regulations (or any successor regulations)) that has been approved in another application under subsection (b), was approved during the period beginning January 1, 1982, and ending on the date of the enactment of this subsection, the Secretary may not make the approval of an application submitted under this subsection which refers to the drug for which the subsection (b) application was submitted or which refers to a change approved in a supplement to the subsection (b) application effective before the expiration of two years from the date of enactment of this subsection.

(6) If a drug approved under this subsection refers in its approved application to a drug the approval of which was withdrawn or suspended for grounds described in the first sentence of subsection (e) or was withdrawn or suspended under this paragraph or which, as determined by the Secretary, has been withdrawn from sale for safety or effectiveness reasons, the approval of the drug under this subsection shall be withdrawn or suspended—

(A) for the same period as the withdrawal or suspension under subsection (e) or this paragraph, or

(B) if the listed drug has been withdrawn from sale, for the period of withdrawal from sale or, if earlier, the period ending on the date the Secretary determines that the withdrawal from sale is not for safety or effectiveness reasons.

(7)(A)(i) Within sixty days of the date of the enactment of this subsection, the Secretary shall publish and make available to the public—

(I) a list in alphabetical order of the official and proprietary name of each drug which has been approved for safety and effectiveness under subsection (c) before the date of the enactment of this subsection;

(II) the date of approval if the drug is approved after 1981 and the number of the application which was approved; and

(III) whether in vitro or in vivo bioequivalence studies, or both such studies, are required for applications filed under this subsection which will refer to the drug published.

(ii) Every thirty days after the publication of the first list under clause (i) the Secretary shall revise the list to include each drug which has been approved for safety and effectiveness under subsection (c) or approved under this subsection during the thirty-day period.

(iii) When patent information submitted under subsection (c) respecting a drug included on the list is to be published by the Secretary, the Secretary shall, in revisions made under clause (ii), include such information for such drug.

(iv) For each drug included on the list, the Secretary shall specify any exclusivity period that is applicable, for which the Secretary has determined the expiration date, and for which such period has not yet expired, under—

(I) clause (ii), (iii), or (iv) of subsection (c)(3)(E);
(II) clause (iv) or (v) of paragraph (5)(B);
(III) clause (ii), (iii), or (iv) of paragraph (5)(F);
(IV) section 505A;
(V) section 505E;
(VI) section 527(a); or
(VII) subsection (u).

(B) A drug approved for safety and effectiveness under subsection (c) or approved under this subsection shall, for purposes of this subsection, be considered to have been published under subparagraph (A) on the date of its approval or the date of enactment, whichever is later.

(C) If the approval of a drug was withdrawn or suspended for grounds described in the first sentence of subsection (e) or was withdrawn or suspended under paragraph (6) or if the Secretary determines that a drug has been withdrawn from sale for safety or effectiveness reasons, it may not be published in the list under subparagraph (A) or, if the withdrawal or suspension occurred after its publication in such list, it shall be immediately removed from such list—

(i) for the same period as the withdrawal or suspension under subsection (e) or paragraph (6), or

(ii) if the listed drug has been withdrawn from sale, for the period of withdrawal from sale or, if earlier, the period ending on the date the Secretary determines that the withdrawal from sale is not for safety or effectiveness reasons.

A notice of the removal shall be published in the Federal Register.

(D) In the case of a listed drug for which the list under subparagraph (A)(i) includes a patent for such drug, and any claim of the patent has been cancelled or invalidated pursuant to a final decision issued by the Patent Trial and Appeal Board of the United States Patent and Trademark Office or by a court, from which no appeal has been, or can be, taken, if the holder of the applicable application approved under subsection (c) determines that a patent for such drug, or any patent information for such drug, no longer meets the listing requirements under this section—

(i) the holder of such approved application shall notify the Secretary, in writing, within 14 days of such decision of such cancellation or invalidation and request that such patent or patent information, as applicable, be amended or withdrawn in accordance with the decision issued by the Patent Trial and Appeal Board or a court;

(ii) the holder of such approved application shall include in any notification under clause (i) information related to such patent cancellation or invalidation decision and submit such information, including a copy of such decision, to the Secretary; and

(iii) the Secretary shall, in response to a notification under clause (i), amend or remove patent or patent information in accordance with the relevant decision from the Patent Trial and Appeals Board or court, as applicable, except that the Secretary shall not remove from the list any patent or patent information before the expiration of any 180-day exclusivity period under paragraph (5)(B)(iv) that relies on a certification described in paragraph (2)(A)(vii)(IV).

(8) For purposes of this subsection:

(A)(i) The term "bioavailability" means the rate and extent to which the active ingredient or therapeutic ingredient is absorbed from a drug and becomes available at the site of drug action.

(ii) For a drug that is not intended to be absorbed into the bloodstream, the Secretary may assess bioavailability by scientifically valid measurements intended to reflect the rate and extent to which the active ingredient or therapeutic ingredient becomes available at the site of drug action.

(B) A drug shall be considered to be bioequivalent to a listed drug if—

(i) the rate and extent of absorption of the drug do not show a significant difference from the rate and extent of absorption of the listed drug when administered at the same molar dose of the therapeutic ingredient under similar experimental conditions in either a single dose or multiple doses; or

(ii) the extent of absorption of the drug does not show a significant difference from the extent of absorption of the listed drug when administered at the same molar dose of the therapeutic ingredient under similar experimental conditions in either a single dose or multiple doses and the difference from the listed drug in the rate of absorption of the drug is intentional, is reflected in its proposed labeling, is not essential to the attainment of effective body drug concentrations on chronic use, and is considered medically insignificant for the drug.

(C) For a drug that is not intended to be absorbed into the bloodstream, the Secretary may establish alternative, scientifically valid methods to show bioequivalence if the alternative methods are expected to detect a significant difference between the drug and the listed drug in safety and therapeutic effect.

(9) The Secretary shall, with respect to each application submitted under this subsection, maintain a record of—

(A) the name of the applicant,

(B) the name of the drug covered by the application,

(C) the name of each person to whom the review of the chemistry of the application was assigned and the date of such assignment, and

(D) the name of each person to whom the bioequivalence review for such application was assigned and the date of such assignment.

The information the Secretary is required to maintain under this paragraph with respect to an application submitted under this subsection shall be made available to the public after the approval of such application.

(10)(A) If the proposed labeling of a drug that is the subject of an application under this subsection differs from the listed drug due to a labeling revision described under clause (i), the drug that is the subject of such application shall, notwithstanding any other provision of this Act, be eligible for approval and shall not be considered misbranded under section 502 if—

[(i) the application is otherwise eligible for approval under this subsection but for expiration of patent, an exclusivity period, or of a delay in approval described in paragraph (5)(B)(iii), and a revision to the labeling of the listed drug has been approved by the Secretary within 60 days of such expiration;

[(ii) the labeling revision described under clause (i) does not include a change to the "Warnings" section of the labeling;

[(iii) the sponsor of the application under this subsection agrees to submit revised labeling of the drug that is the subject of such application not later than 60 days after the notification of any changes to such labeling required by the Secretary; and**]**

(i) a revision to the labeling of the listed drug has been approved by the Secretary within 90 days of when the application is otherwise eligible for approval under this subsection;

(ii) the sponsor of the application agrees to submit revised labeling for the drug that is the subject of the application not later than 60 days after approval under this subsection of the application;

(iii) the labeling revision described under clause (i) does not include a change to the "Warnings" section of the labeling; and

(iv) such application otherwise meets the applicable requirements for approval under this subsection.

(B) If, after a labeling revision described in subparagraph (A)(i), the Secretary determines that the continued presence in interstate commerce of the labeling of the listed drug (as in effect before the revision described in subparagraph (A)(i)) adversely impacts the safe use of the drug, no application under this subsection shall be eligible for approval with such labeling.

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

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

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

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

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

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

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

(13) Upon the request of an applicant regarding one or more specified pending applications under this subsection, the Secretary shall, as appropriate, provide review status updates indicating the categorical status of the applications by each relevant review discipline.

(k)(1) In the case of any drug for which an approval of an application filed under subsection (b) or (j) is in effect, the applicant shall establish and maintain such records, and make such reports to the Secretary, of data relating to clinical experience and other data or information, received or otherwise obtained by such applicant with respect to such drug, as the Secretary may by general regulation, or by order with respect to such application, prescribe on the basis of a finding that such records and reports are necessary in order to enable the Secretary to determine, or facilitate a determination, whether there is or may be ground for invoking subsection (e) of this section. Regulations and orders issued under this subsection and under subsection (i) shall have due regard for the professional ethics of the medical profession and the interests of patients and shall provide, where the Secretary deems it to be appropriate, for the examination, upon request, by the persons to whom such regulations or orders are applicable, of similar information received or otherwise obtained by the Secretary.

(2) Every person required under this section to maintain records, and every person in charge or custody thereof, shall, upon request of an officer or employee designated by the Secretary, permit such officer or employee at all reasonable times to have access to and copy and verify such records.

(3) ACTIVE POSTMARKET RISK IDENTIFICATION.—

(A) DEFINITION.—In this paragraph, the term "data" refers to information with respect to a drug approved under this section or under section 351 of the Public Health Service Act, including claims data, patient survey data, standardized analytic files that allow for the pooling and analysis of data from disparate data environments, and any other data deemed appropriate by the Secretary.

(B) DEVELOPMENT OF POSTMARKET RISK IDENTIFICATION AND ANALYSIS METHODS.—The Secretary shall, not later than 2 years after the date of the enactment of the Food and Drug Administration Amendments Act of 2007, in collaboration with public, academic, and private entities—

(i) develop methods to obtain access to disparate data sources including the data sources specified in subparagraph (C);

(ii) develop validated methods for the establishment of a postmarket risk identification and analysis system to link and analyze safety data from multiple sources, with the goals of including, in aggregate—

(I) at least 25,000,000 patients by July 1, 2010; and

(II) at least 100,000,000 patients by July 1, 2012; and

(iii) convene a committee of experts, including individuals who are recognized in the field of protecting data privacy and security, to make recommendations to the Secretary on the development of tools and methods for the ethical and scientific uses for, and communication of, postmarketing data specified under subparagraph (C), including recommendations on the development of effective research methods for the study of drug safety questions.

(C) ESTABLISHMENT OF THE POSTMARKET RISK IDENTIFICATION AND ANALYSIS SYSTEM.—

(i) IN GENERAL.—The Secretary shall, not later than 1 year after the development of the risk identification and analysis methods under subparagraph (B), establish and maintain procedures—

(I) for risk identification and analysis based on electronic health data, in compliance with the regulations promulgated under section 264(c) of the Health Insurance Portability and Accountability Act of 1996, and in a manner that does not disclose individually identifiable health information in violation of paragraph (4)(B);

(II) for the reporting (in a standardized form) of data on all serious adverse drug experiences (as defined in section 505–1(b)) submitted to the Secretary under paragraph (1), and those adverse

events submitted by patients, providers, and drug sponsors, when appropriate;

(III) to provide for active adverse event surveillance using the following data sources, as available:

(aa) Federal health-related electronic data (such as data from the Medicare program and the health systems of the Department of Veterans Affairs);

(bb) private sector health-related electronic data (such as pharmaceutical purchase data and health insurance claims data); and

(cc) other data as the Secretary deems necessary to create a robust system to identify adverse events and potential drug safety signals;

(IV) to identify certain trends and patterns with respect to data accessed by the system;

(V) to provide regular reports to the Secretary concerning adverse event trends, adverse event patterns, incidence and prevalence of adverse events, and other information the Secretary determines appropriate, which may include data on comparative national adverse event trends; and

(VI) to enable the program to export data in a form appropriate for further aggregation, statistical analysis, and reporting.

(ii) TIMELINESS OF REPORTING.—The procedures established under clause (i) shall ensure that such data are accessed, analyzed, and reported in a timely, routine, and systematic manner, taking into consideration the need for data completeness, coding, cleansing, and standardized analysis and transmission.

(iii) PRIVATE SECTOR RESOURCES.—To ensure the establishment of the active postmarket risk identification and analysis system under this subsection not later than 1 year after the development of the risk identification and analysis methods under subparagraph (B), as required under clause (i), the Secretary may, on a temporary or permanent basis, implement systems or products developed by private entities.

(iv) COMPLEMENTARY APPROACHES.—To the extent the active postmarket risk identification and analysis system under this subsection is not sufficient to gather data and information relevant to a priority drug safety question, the Secretary shall develop, support, and participate in complementary approaches to gather and analyze such data and information, including—

(I) approaches that are complementary with respect to assessing the safety of use of a drug in domestic populations not included, or underrepresented, in the trials used to approve the drug (such as older people, people with comorbidities, pregnant women, or children); and

(II) existing approaches such as the Vaccine Adverse Event Reporting System and the Vaccine Safety Datalink or successor databases.

(v) AUTHORITY FOR CONTRACTS.—The Secretary may enter into contracts with public and private entities to fulfill the requirements of this subparagraph.

(4) ADVANCED ANALYSIS OF DRUG SAFETY DATA.—

(A) PURPOSE.—The Secretary shall establish collaborations with public, academic, and private entities, which may include the Centers for Education and Research on Therapeutics under section 912 of the Public Health Service Act, to provide for advanced analysis of drug safety data described in paragraph (3)(C) and other information that is publicly available or is provided by the Secretary, in order to—

(i) improve the quality and efficiency of postmarket drug safety risk-benefit analysis;

(ii) provide the Secretary with routine access to outside expertise to study advanced drug safety questions; and

(iii) enhance the ability of the Secretary to make timely assessments based on drug safety data.

(B) PRIVACY.—Such analysis shall not disclose individually identifiable health information when presenting such drug safety signals and trends or when responding to inquiries regarding such drug safety signals and trends.

(C) PUBLIC PROCESS FOR PRIORITY QUESTIONS.—At least biannually, the Secretary shall seek recommendations from the Drug Safety and Risk Management Advisory Committee (or any successor committee) and from other advisory committees, as appropriate, to the Food and Drug Administration on—

(i) priority drug safety questions; and

(ii) mechanisms for answering such questions, including through—

(I) active risk identification under paragraph (3); and

(II) when such risk identification is not sufficient, postapproval studies and clinical trials under subsection (o)(3).

(D) PROCEDURES FOR THE DEVELOPMENT OF DRUG SAFETY COLLABORATIONS.—

(i) IN GENERAL.—Not later than 180 days after the date of the establishment of the active postmarket risk identification and analysis system under this subsection, the Secretary shall establish and implement procedures under which the Secretary may routinely contract with one or more qualified entities to—

(I) classify, analyze, or aggregate data described in paragraph (3)(C) and information that is publicly available or is provided by the Secretary;

(II) allow for prompt investigation of priority drug safety questions, including—

(aa) unresolved safety questions for drugs or classes of drugs; and

(bb) for a newly-approved drugs, safety signals from clinical trials used to approve the drug and other preapproval trials; rare, serious drug side effects; and the safety of use in domestic populations not included, or underrepresented, in the trials used to approve the drug (such as older people, people with comorbidities, pregnant women, or children);

(III) perform advanced research and analysis on identified drug safety risks;

(IV) focus postapproval studies and clinical trials under subsection (o)(3) more effectively on cases for which reports under paragraph (1) and other safety signal detection is not sufficient to resolve whether there is an elevated risk of a serious adverse event associated with the use of a drug; and

(V) carry out other activities as the Secretary deems necessary to carry out the purposes of this paragraph.

(ii) REQUEST FOR SPECIFIC METHODOLOGY.—The procedures described in clause (i) shall permit the Secretary to request that a specific methodology be used by the qualified entity. The qualified entity shall work with the Secretary to finalize the methodology to be used.

(E) USE OF ANALYSES.—The Secretary shall provide the analyses described in this paragraph, including the methods and results of such analyses, about a drug to the sponsor or sponsors of such drug.

(F) QUALIFIED ENTITIES.—

(i) IN GENERAL.—The Secretary shall enter into contracts with a sufficient number of qualified entities to develop and provide information to the Secretary in a timely manner.

(ii) QUALIFICATION.—The Secretary shall enter into a contract with an entity under clause (i) only if the Secretary determines that the entity has a significant presence in the United States and has one or more of the following qualifications:

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

(II) An information technology infrastructure in place to support electronic data and operational standards to provide security for such data.

(III) Experience with, and expertise on, the development of drug safety and effectiveness research using electronic population data.

(IV) An understanding of drug development or risk/benefit balancing in a clinical setting.

(V) Other expertise which the Secretary deems necessary to fulfill the activities under this paragraph.

(G) CONTRACT REQUIREMENTS.—Each contract with a qualified entity under subparagraph (F)(i) shall contain the following requirements:

(i) ENSURING PRIVACY.—The qualified entity shall ensure that the entity will not use data under this subsection in a manner that—

(I) violates the regulations promulgated under section 264(c) of the Health Insurance Portability and Accountability Act of 1996;

(II) violates sections 552 or 552a of title 5, United States Code, with regard to the privacy of individually-identifiable beneficiary health information; or

(III) discloses individually identifiable health information when presenting drug safety signals and trends or when responding to inquiries regarding drug safety signals and trends.

Nothing in this clause prohibits lawful disclosure for other purposes.

(ii) COMPONENT OF ANOTHER ORGANIZATION.—If a qualified entity is a component of another organization—

(I) the qualified entity shall establish appropriate security measures to maintain the confidentiality and privacy of such data; and

(II) the entity shall not make an unauthorized disclosure of such data to the other components of the organization in breach of such confidentiality and privacy requirement.

(iii) TERMINATION OR NONRENEWAL.—If a contract with a qualified entity under this subparagraph is terminated or not renewed, the following requirements shall apply:

(I) CONFIDENTIALITY AND PRIVACY PROTECTIONS.—The entity shall continue to comply with the confidentiality and privacy requirements under this paragraph with respect to all data disclosed to the entity.

(II) DISPOSITION OF DATA.—The entity shall return any data disclosed to such entity under this subsection to which it would not otherwise have access or, if returning the data is not practicable, destroy the data.

(H) COMPETITIVE PROCEDURES.—The Secretary shall use competitive procedures (as defined in section 4(5) of the Federal Procurement Policy Act) to enter into contracts under subparagraph (G).

(I) REVIEW OF CONTRACT IN THE EVENT OF A MERGER OR ACQUISITION.—The Secretary shall review the contract with a qualified entity under this paragraph in the event of a merger or acquisition of the entity in order to ensure

that the requirements under this paragraph will continue to be met.

(J) COORDINATION.—In carrying out this paragraph, the Secretary shall provide for appropriate communications to the public, scientific, public health, and medical communities, and other key stakeholders, and to the extent practicable shall coordinate with the activities of private entities, professional associations, or other entities that may have sources of drug safety data.

(5) The Secretary shall—

(A) conduct regular screenings of the Adverse Event Reporting System database and post a quarterly report on the Adverse Event Reporting System Web site of any new safety information or potential signal of a serious risk identified by Adverse Event Reporting System within the last quarter; and

(B) on an annual basis, review the entire backlog of postmarket safety commitments to determine which commitments require revision or should be eliminated, report to the Congress on these determinations, and assign start dates and estimated completion dates for such commitments; and

(C) make available on the Internet website of the Food and Drug Administration—

(i) guidelines, developed with input from experts qualified by scientific training and experience to evaluate the safety and effectiveness of drugs, that detail best practices for drug safety surveillance using the Adverse Event Reporting System; and

(ii) criteria for public posting of adverse event signals.

(l)(1) Safety and effectiveness data and information which has been submitted in an application under subsection (b) for a drug and which has not previously been disclosed to the public shall be made available to the public, upon request, unless extraordinary circumstances are shown—

(A) if no work is being or will be undertaken to have the application approved,

(B) if the Secretary has determined that the application is not approvable and all legal appeals have been exhausted,

(C) if approval of the application under subsection (c) is withdrawn and all legal appeals have been exhausted,

(D) if the Secretary has determined that such drug is not a new drug, or

(E) upon the effective date of the approval of the first application under subsection (j) which refers to such drug or upon the date upon which the approval of an application under subsection (j) which refers to such drug could be made effective if such an application had been submitted.

(2) ACTION PACKAGE FOR APPROVAL.—

(A) ACTION PACKAGE.—The Secretary shall publish the action package for approval of an application under subsection (b) or section 351 of the Public Health Service Act on the Internet Web site of the Food and Drug Administration—

(i) not later than 30 days after the date of approval of such applications—

(I) for a drug, no active moiety (as defined by the Secretary in section 314.3 of title 21, Code of Federal Regulations (or any successor regulations)) of which has been approved in any other application under this section; or

(II) for a biological product, no active ingredient of which has been approved in any other application under section 351 of the Public Health Service Act; and

(ii) not later than 30 days after the third request for such action package for approval received under section 552 of title 5, United States Code, for any other drug or biological product.

(B) IMMEDIATE PUBLICATION OF SUMMARY REVIEW.—Notwithstanding subparagraph (A), the Secretary shall publish, on the Internet Web site of the Food and Drug Administration, the materials described in subparagraph (C)(iv) not later than 48 hours after the date of approval of the drug, except where such materials require redaction by the Secretary.

(C) CONTENTS.—An action package for approval of an application under subparagraph (A) shall be dated and shall include the following:

(i) Documents generated by the Food and Drug Administration related to review of the application.

(ii) Documents pertaining to the format and content of the application generated during drug development.

(iii) Labeling submitted by the applicant.

(iv) A summary review that documents conclusions from all reviewing disciplines about the drug, noting any critical issues and disagreements with the applicant and within the review team and how they were resolved, recommendations for action, and an explanation of any nonconcurrence with review conclusions.

(v) The Division Director and Office Director's decision document which includes—

(I) a brief statement of concurrence with the summary review;

(II) a separate review or addendum to the review if disagreeing with the summary review; and

(III) a separate review or addendum to the review to add further analysis.

(vi) Identification by name of each officer or employee of the Food and Drug Administration who—

(I) participated in the decision to approve the application; and

(II) consents to have his or her name included in the package.

(D) REVIEW.—A scientific review of an application is considered the work of the reviewer and shall not be altered by management or the reviewer once final.

(E) CONFIDENTIAL INFORMATION.—This paragraph does not authorize the disclosure of any trade secret, confidential commercial or financial information, or other matter listed in section 552(b) of title 5, United States Code.

(m) For purposes of this section, the term "patent" means a patent issued by the United States Patent and Trademark Office.

(n)(1) For the purpose of providing expert scientific advice and recommendations to the Secretary regarding a clinical investigation of a drug or the approval for marketing of a drug under section 505 or section 351 of the Public Health Service Act, the Secretary shall establish panels of experts or use panels of experts established before the date of enactment of the Food and Drug Administration Modernization Act of 1997, or both.

(2) The Secretary may delegate the appointment and oversight authority granted under section 1004 to a director of a center or successor entity within the Food and Drug Administration.

(3) The Secretary shall make appointments to each panel established under paragraph (1) so that each panel shall consist of—

(A) members who are qualified by training and experience to evaluate the safety and effectiveness of the drugs to be referred to the panel and who, to the extent feasible, possess skill and experience in the development, manufacture, or utilization of such drugs;

(B) members with diverse expertise in such fields as clinical and administrative medicine, pharmacy, pharmacology, pharmacoeconomics, biological and physical sciences, and other related professions;

(C) a representative of consumer interests, and a representative of interests of the drug manufacturing industry not directly affected by the matter to be brought before the panel; and

(D) two or more members who are specialists or have other expertise in the particular disease or condition for which the drug under review is proposed to be indicated.

Scientific, trade, and consumer organizations shall be afforded an opportunity to nominate individuals for appointment to the panels. No individual who is in the regular full-time employ of the United States and engaged in the administration of this Act may be a voting member of any panel. The Secretary shall designate one of the members of each panel to serve as chairman thereof.

(4) The Secretary shall, as appropriate, provide education and training to each new panel member before such member participates in a panel's activities, including education regarding requirements under this Act and related regulations of the Secretary, and the administrative processes and procedures related to panel meetings.

(5) Panel members (other than officers or employees of the United States), while attending meetings or conferences of a panel or otherwise engaged in its business, shall be entitled to receive compensation for each day so engaged, including traveltime, at rates to be fixed by the Secretary, but not to exceed the daily equivalent of the rate in effect for positions classified above grade GS–15 of the General Schedule. While serving away from their homes or regular places of business, panel members may be allowed travel expenses (including per diem in lieu of subsistence) as authorized by section 5703 of title 5, United States Code, for persons in the Government service employed intermittently.

(6) The Secretary shall ensure that scientific advisory panels meet regularly and at appropriate intervals so that any matter to

be reviewed by such a panel can be presented to the panel not more than 60 days after the matter is ready for such review. Meetings of the panel may be held using electronic communication to convene the meetings.

(7) Within 90 days after a scientific advisory panel makes recommendations on any matter under its review, the Food and Drug Administration official responsible for the matter shall review the conclusions and recommendations of the panel, and notify the affected persons of the final decision on the matter, or of the reasons that no such decision has been reached. Each such final decision shall be documented including the rationale for the decision.

(o) POSTMARKET STUDIES AND CLINICAL TRIALS; LABELING.—

(1) IN GENERAL.—A responsible person may not introduce or deliver for introduction into interstate commerce the new drug involved if the person is in violation of a requirement established under paragraph (3) or (4) with respect to the drug.

(2) DEFINITIONS.—For purposes of this subsection:

(A) RESPONSIBLE PERSON.—The term "responsible person" means a person who—

(i) has submitted to the Secretary a covered application that is pending; or

(ii) is the holder of an approved covered application.

(B) COVERED APPLICATION.—The term "covered application" means—

(i) an application under subsection (b) for a drug that is subject to section 503(b); and

(ii) an application under section 351 of the Public Health Service Act.

(C) NEW SAFETY INFORMATION; SERIOUS RISK.—The terms "new safety information", "serious risk", and "signal of a serious risk" have the meanings given such terms in section 505–1(b).

(3) STUDIES AND CLINICAL TRIALS.—

(A) IN GENERAL.—For any or all of the purposes specified in subparagraph (B), the Secretary may, subject to subparagraph (D), require a responsible person for a drug to conduct a postapproval study or studies of the drug, or a postapproval clinical trial or trials of the drug, on the basis of scientific data deemed appropriate by the Secretary, including information regarding chemically-related or pharmacologically-related drugs.

(B) PURPOSES OF STUDY OR CLINICAL TRIAL.—The purposes referred to in this subparagraph with respect to a postapproval study or postapproval clinical trial are the following:

(i) To assess a known serious risk related to the use of the drug involved.

(ii) To assess signals of serious risk related to the use of the drug.

(iii) To identify an unexpected serious risk when available data indicates the potential for a serious risk.

(C) ESTABLISHMENT OF REQUIREMENT AFTER APPROVAL OF COVERED APPLICATION.—The Secretary may require a postapproval study or studies or postapproval clinical trial

or trials for a drug for which an approved covered application is in effect as of the date on which the Secretary seeks to establish such requirement only if the Secretary becomes aware of new safety information.

(D) DETERMINATION BY SECRETARY.—

(i) POSTAPPROVAL STUDIES.—The Secretary may not require the responsible person to conduct a study under this paragraph, unless the Secretary makes a determination that the reports under subsection (k)(1) and the active postmarket risk identification and analysis system as available under subsection (k)(3) will not be sufficient to meet the purposes set forth in subparagraph (B).

(ii) POSTAPPROVAL CLINICAL TRIALS.—The Secretary may not require the responsible person to conduct a clinical trial under this paragraph, unless the Secretary makes a determination that a postapproval study or studies will not be sufficient to meet the purposes set forth in subparagraph (B).

(E) NOTIFICATION; TIMETABLES; PERIODIC REPORTS.—

(i) NOTIFICATION.—The Secretary shall notify the responsible person regarding a requirement under this paragraph to conduct a postapproval study or clinical trial by the target dates for communication of feedback from the review team to the responsible person regarding proposed labeling and postmarketing study commitments as set forth in the letters described in section 101(c) of the Food and Drug Administration Amendments Act of 2007.

(ii) TIMETABLE; PERIODIC REPORTS.—For each study or clinical trial required to be conducted under this paragraph, the Secretary shall require that the responsible person submit a timetable for completion of the study or clinical trial. With respect to each study required to be conducted under this paragraph or otherwise undertaken by the responsible person to investigate a safety issue, the Secretary shall require the responsible person to periodically report to the Secretary on the status of such study including whether any difficulties in completing the study have been encountered. With respect to each clinical trial required to be conducted under this paragraph or otherwise undertaken by the responsible person to investigate a safety issue, the Secretary shall require the responsible person to periodically report to the Secretary on the status of such clinical trial including whether enrollment has begun, the number of participants enrolled, the expected completion date, whether any difficulties completing the clinical trial have been encountered, and registration information with respect to the requirements under section 402(j) of the Public Health Service Act. If the responsible person fails to comply with such timetable or violates any other requirement of this subparagraph, the responsible person shall be considered in violation of this subsection,

unless the responsible person demonstrates good cause for such noncompliance or such other violation. The Secretary shall determine what constitutes good cause under the preceding sentence.

(F) DISPUTE RESOLUTION.—The responsible person may appeal a requirement to conduct a study or clinical trial under this paragraph using dispute resolution procedures established by the Secretary in regulation and guidance.

(4) SAFETY LABELING CHANGES REQUESTED BY SECRETARY.—

(A) NEW SAFETY OR NEW EFFECTIVENESS INFORMATION.—If the Secretary becomes aware of new information, including any new safety information or information related to reduced effectiveness, that the Secretary determines should be included in the labeling of the drug, the Secretary shall promptly notify the responsible person or, if the same drug approved under section 505(b) is not currently marketed, the holder of an approved application under 505(j).

(B) RESPONSE TO NOTIFICATION.—Following notification pursuant to subparagraph (A), the responsible person or the holder of the approved application under section 505(j) shall within 30 days—

(i) submit a supplement proposing changes to the approved labeling to reflect the new safety information, including changes to boxed warnings, contraindications, warnings, precautions, or adverse reactions, or new effectiveness information; or

(ii) notify the Secretary that the responsible person or the holder of the approved application under section 505(j) does not believe a labeling change is warranted and submit a statement detailing the reasons why such a change is not warranted.

(C) REVIEW.—Upon receipt of such supplement, the Secretary shall promptly review and act upon such supplement. If the Secretary disagrees with the proposed changes in the supplement or with the statement setting forth the reasons why no labeling change is necessary, the Secretary shall initiate discussions to reach agreement on whether the labeling for the drug should be modified to reflect the new safety or new effectiveness information, and if so, the contents of such labeling changes.

(D) DISCUSSIONS.—Such discussions shall not extend for more than 30 days after the response to the notification under subparagraph (B), unless the Secretary determines an extension of such discussion period is warranted.

(E) ORDER.—Within 15 days of the conclusion of the discussions under subparagraph (D), the Secretary may issue an order directing the responsible person or the holder of the approved application under section 505(j) to make such a labeling change as the Secretary deems appropriate to address the new safety or new effectiveness information. Within 15 days of such an order, the responsible person or the holder of the approved application under section 505(j) shall submit a supplement containing the labeling change.

(F) DISPUTE RESOLUTION.—Within 5 days of receiving an order under subparagraph (E), the responsible person or the holder of the approved application under section 505(j) may appeal using dispute resolution procedures established by the Secretary in regulation and guidance.

(G) VIOLATION.—If the responsible person or the holder of the approved application under section 505(j) has not submitted a supplement within 15 days of the date of such order under subparagraph (E), and there is no appeal or dispute resolution proceeding pending, the responsible person or holder shall be considered to be in violation of this subsection. If at the conclusion of any dispute resolution procedures the Secretary determines that a supplement must be submitted and such a supplement is not submitted within 15 days of the date of that determination, the responsible person or holder shall be in violation of this subsection.

(H) PUBLIC HEALTH THREAT.—Notwithstanding subparagraphs (A) through (F), if the Secretary concludes that such a labeling change is necessary to protect the public health, the Secretary may accelerate the timelines in such subparagraphs.

(I) RULE OF CONSTRUCTION.—This paragraph shall not be construed to affect the responsibility of the responsible person or the holder of the approved application under section 505(j) to maintain its label in accordance with existing requirements, including subpart B of part 201 and sections 314.70 and 601.12 of title 21, Code of Federal Regulations (or any successor regulations).

(5) NON-DELEGATION.—Determinations by the Secretary under this subsection for a drug shall be made by individuals at or above the level of individuals empowered to approve a drug (such as division directors within the Center for Drug Evaluation and Research).

(p) RISK EVALUATION AND MITIGATION STRATEGY.—

(1) IN GENERAL.—A person may not introduce or deliver for introduction into interstate commerce a new drug if—

(A)(i) the application for such drug is approved under subsection (b) or (j) and is subject to section 503(b); or

(ii) the application for such drug is approved under section 351 of the Public Health Service Act; and

(B) a risk evaluation and mitigation strategy is required under section 505–1 with respect to the drug and the person fails to maintain compliance with the requirements of the approved strategy or with other requirements under section 505–1, including requirements regarding assessments of approved strategies.

(2) CERTAIN POSTMARKET STUDIES.—The failure to conduct a postmarket study under section 506, subpart H of part 314, or subpart E of part 601 of title 21, Code of Federal Regulations (or any successor regulations), is deemed to be a violation of paragraph (1).

(q) PETITIONS AND CIVIL ACTIONS REGARDING APPROVAL OF CERTAIN APPLICATIONS.—

(1) IN GENERAL.—

(A) DETERMINATION.—The Secretary shall not delay approval of a pending application submitted under subsection (b)(2) or (j) of this section or section 351(k) of the Public Health Service Act because of any request to take any form of action relating to the application, either before or during consideration of the request, unless—

(i) the request is in writing and is a petition submitted to the Secretary pursuant to section 10.30 or 10.35 of title 21, Code of Federal Regulations (or any successor regulations); and

(ii) the Secretary determines, upon reviewing the petition, that a delay is necessary to protect the public health.

Consideration of the petition shall be separate and apart from review and approval of any application.

(B) NOTIFICATION.—If the Secretary determines under subparagraph (A) that a delay is necessary with respect to an application, the Secretary shall provide to the applicant, not later than 30 days after making such determination, the following information:

(i) Notification of the fact that a determination under subparagraph (A) has been made.

(ii) If applicable, any clarification or additional data that the applicant should submit to the docket on the petition to allow the Secretary to review the petition promptly.

(iii) A brief summary of the specific substantive issues raised in the petition which form the basis of the determination.

(C) FORMAT.—The information described in subparagraph (B) shall be conveyed via either, at the discretion of the Secretary—

(i) a document; or

(ii) a meeting with the applicant involved.

(D) PUBLIC DISCLOSURE.—Any information conveyed by the Secretary under subparagraph (C) shall be considered part of the application and shall be subject to the disclosure requirements applicable to information in such application.

(E) DENIAL BASED ON INTENT TO DELAY.—If the Secretary determines that a petition or a supplement to the petition was submitted with the primary purpose of delaying the approval of an application and the petition does not on its face raise valid scientific or regulatory issues, the Secretary may deny the petition at any point based on such determination. The Secretary may issue guidance to describe the factors that will be used to determine under this subparagraph whether a petition is submitted with the primary purpose of delaying the approval of an application.

(F) FINAL AGENCY ACTION.—The Secretary shall take final agency action on a petition not later than 150 days after the date on which the petition is submitted. The Secretary shall not extend such period for any reason, including—

(i) any determination made under subparagraph (A);

(ii) the submission of comments relating to the petition or supplemental information supplied by the petitioner; or

(iii) the consent of the petitioner.

(G) EXTENSION OF 30-MONTH PERIOD.—If the filing of an application resulted in first-applicant status under subsection (j)(5)(D)(i)(IV) and approval of the application was delayed because of a petition, the 30-month period under such subsection is deemed to be extended by a period of time equal to the period beginning on the date on which the Secretary received the petition and ending on the date of final agency action on the petition (inclusive of such beginning and ending dates), without regard to whether the Secretary grants, in whole or in part, or denies, in whole or in part, the petition.

(H) CERTIFICATION.—The Secretary shall not consider a petition for review unless the party submitting such petition does so in written form and the subject document is signed and contains the following certification: "I certify that, to my best knowledge and belief: (a) this petition includes all information and views upon which the petition relies; (b) this petition includes representative data and/or information known to the petitioner which are unfavorable to the petition; and (c) I have taken reasonable steps to ensure that any representative data and/or information which are unfavorable to the petition were disclosed to me. I further certify that the information upon which I have based the action requested herein first became known to the party on whose behalf this petition is submitted on or about the following date: _____. If I received or expect to receive payments, including cash and other forms of consideration, to file this information or its contents, I received or expect to receive those payments from the following persons or organizations: _____. I verify under penalty of perjury that the foregoing is true and correct as of the date of the submission of this petition.", with the date on which such information first became known to such party and the names of such persons or organizations inserted in the first and second blank space, respectively.

(I) VERIFICATION.—The Secretary shall not accept for review any supplemental information or comments on a petition unless the party submitting such information or comments does so in written form and the subject document is signed and contains the following verification: "I certify that, to my best knowledge and belief: (a) I have not intentionally delayed submission of this document or its contents; and (b) the information upon which I have based the action requested herein first became known to me on or about _____. If I received or expect to receive payments, including cash and other forms of consideration, to file this information or its contents, I received or expect to receive those payments from the following persons or organizations: _____. I verify under penalty of

perjury that the foregoing is true and correct as of the date of the submission of this petition.", with the date on which such information first became known to the party and the names of such persons or organizations inserted in the first and second blank space, respectively.

(2) EXHAUSTION OF ADMINISTRATIVE REMEDIES.—

(A) FINAL AGENCY ACTION WITHIN 150 DAYS.—The Secretary shall be considered to have taken final agency action on a petition if—

(i) during the 150-day period referred to in paragraph (1)(F), the Secretary makes a final decision within the meaning of section 10.45(d) of title 21, Code of Federal Regulations (or any successor regulation); or

(ii) such period expires without the Secretary having made such a final decision.

(B) DISMISSAL OF CERTAIN CIVIL ACTIONS.—If a civil action is filed against the Secretary with respect to any issue raised in the petition before the Secretary has taken final agency action on the petition within the meaning of subparagraph (A), the court shall dismiss without prejudice the action for failure to exhaust administrative remedies.

(C) ADMINISTRATIVE RECORD.—For purposes of judicial review related to the approval of an application for which a petition under paragraph (1) was submitted, the administrative record regarding any issue raised by the petition shall include—

(i) the petition filed under paragraph (1) and any supplements and comments thereto;

(ii) the Secretary's response to such petition, if issued; and

(iii) other information, as designated by the Secretary, related to the Secretary's determinations regarding the issues raised in such petition, as long as the information was considered by the agency no later than the date of final agency action as defined under subparagraph (2)(A), and regardless of whether the Secretary responded to the petition at or before the approval of the application at issue in the petition.

(3) ANNUAL REPORT ON DELAYS IN APPROVALS PER PETITIONS.—The Secretary shall annually submit to the Congress a report that specifies—

(A) the number of applications that were approved during the preceding 12-month period;

(B) the number of such applications whose effective dates were delayed by petitions referred to in paragraph (1) during such period;

(C) the number of days by which such applications were so delayed; and

(D) the number of such petitions that were submitted during such period.

(4) EXCEPTIONS.—

(A) This subsection does not apply to—

(i) a petition that relates solely to the timing of the approval of an application pursuant to subsection (j)(5)(B)(iv); or

(ii) a petition that is made by the sponsor of an application and that seeks only to have the Secretary take or refrain from taking any form of action with respect to that application.

(B) Paragraph (2) does not apply to a petition addressing issues concerning an application submitted pursuant to section 351(k) of the Public Health Service Act.

(5) DEFINITIONS.—

(A) APPLICATION.—For purposes of this subsection, the term "application" means an application submitted under subsection (b)(2) or (j) of this section or section 351(k) of the Public Health Service Act.

(B) PETITION.—For purposes of this subsection, other than paragraph (1)(A)(i), the term "petition" means a request described in paragraph (1)(A)(i).

(r) POSTMARKET DRUG SAFETY INFORMATION FOR PATIENTS AND PROVIDERS.—

(1) ESTABLISHMENT.—Not later than 1 year after the date of the enactment of the Food and Drug Administration Amendments Act of 2007, the Secretary shall improve the transparency of information about drugs and allow patients and health care providers better access to information about drugs by developing and maintaining an Internet Web site that—

(A) provides links to drug safety information listed in paragraph (2) for prescription drugs that are approved under this section or licensed under section 351 of the Public Health Service Act; and

(B) improves communication of drug safety information to patients and providers.

(2) INTERNET WEB SITE.—The Secretary shall carry out paragraph (1) by—

(A) developing and maintaining an accessible, consolidated Internet Web site with easily searchable drug safety information, including the information found on United States Government Internet Web sites, such as the United States National Library of Medicine's Daily Med and Medline Plus Web sites, in addition to other such Web sites maintained by the Secretary;

(B) ensuring that the information provided on the Internet Web site is comprehensive and includes, when available and appropriate—

(i) patient labeling and patient packaging inserts;

(ii) a link to a list of each drug, whether approved under this section or licensed under such section 351, for which a Medication Guide, as provided for under part 208 of title 21, Code of Federal Regulations (or any successor regulations), is required;

(iii) a link to the registry and results data bank provided for under subsections (i) and (j) of section 402 of the Public Health Service Act;

(iv) the most recent safety information and alerts issued by the Food and Drug Administration for drugs

approved by the Secretary under this section, such as product recalls, warning letters, and import alerts;

(v) publicly available information about implemented RiskMAPs and risk evaluation and mitigation strategies under subsection (o);

(vi) guidance documents and regulations related to drug safety; and

(vii) other material determined appropriate by the Secretary;

(C) providing access to summaries of the assessed and aggregated data collected from the active surveillance infrastructure under subsection (k)(3) to provide information of known and serious side-effects for drugs approved under this section or licensed under such section 351;

(D) preparing and making publicly available on the Internet website established under paragraph (1) best practices for drug safety surveillance activities for drugs approved under this section or section 351 of the Public Health Service Act;

(E) enabling patients, providers, and drug sponsors to submit adverse event reports through the Internet Web site;

(F) providing educational materials for patients and providers about the appropriate means of disposing of expired, damaged, or unusable medications; and

(G) supporting initiatives that the Secretary determines to be useful to fulfill the purposes of the Internet Web site.

(3) POSTING OF DRUG LABELING.—The Secretary shall post on the Internet Web site established under paragraph (1) the approved professional labeling and any required patient labeling of a drug approved under this section or licensed under such section 351 not later than 21 days after the date the drug is approved or licensed, including in a supplemental application with respect to a labeling change.

(4) PRIVATE SECTOR RESOURCES.—To ensure development of the Internet Web site by the date described in paragraph (1), the Secretary may, on a temporary or permanent basis, implement systems or products developed by private entities.

(5) AUTHORITY FOR CONTRACTS.—The Secretary may enter into contracts with public and private entities to fulfill the requirements of this subsection.

(6) REVIEW.—The Advisory Committee on Risk Communication under section 567 shall, on a regular basis, perform a comprehensive review and evaluation of the types of risk communication information provided on the Internet Web site established under paragraph (1) and, through other means, shall identify, clarify, and define the purposes and types of information available to facilitate the efficient flow of information to patients and providers, and shall recommend ways for the Food and Drug Administration to work with outside entities to help facilitate the dispensing of risk communication information to patients and providers.

(s) REFERRAL TO ADVISORY COMMITTEE.—The Secretary shall—

(1) refer a drug or biological product to a Food and Drug Administration advisory committee for review at a meeting of

such advisory committee prior to the approval of such drug or biological if it is—

(A) a drug, no active moiety (as defined by the Secretary in section 314.3 of title 21, Code of Federal Regulations (or any successor regulations)) of which has been approved in any other application under this section; or

(B) a biological product, no active ingredient of which has been approved in any other application under section 351 of the Public Health Service Act; or

(2) if the Secretary does not refer a drug or biological product described in paragraph (1) to a Food and Drug Administration advisory committee prior to such approval, provide in the action letter on the application for the drug or biological product a summary of the reasons why the Secretary did not refer the drug or biological product to an advisory committee prior to approval.

(t) DATABASE FOR AUTHORIZED GENERIC DRUGS.—

(1) IN GENERAL.—

(A) PUBLICATION.—The Commissioner shall—

(i) not later than 9 months after the date of the enactment of the Food and Drug Administration Amendments Act of 2007, publish a complete list on the Internet Web site of the Food and Drug Administration of all authorized generic drugs (including drug trade name, brand company manufacturer, and the date the authorized generic drug entered the market); and

(ii) update the list quarterly to include each authorized generic drug included in an annual report submitted to the Secretary by the sponsor of a listed drug during the preceding 3-month period.

(B) NOTIFICATION.—The Commissioner shall notify relevant Federal agencies, including the Centers for Medicare & Medicaid Services and the Federal Trade Commission, when the Commissioner first publishes the information described in subparagraph (A) that the information has been published and that the information will be updated quarterly.

(2) INCLUSION.—The Commissioner shall include in the list described in paragraph (1) each authorized generic drug included in an annual report submitted to the Secretary by the sponsor of a listed drug after January 1, 1999.

(3) AUTHORIZED GENERIC DRUG.—In this section, the term "authorized generic drug" means a listed drug (as that term is used in subsection (j)) that—

(A) has been approved under subsection (c); and

(B) is marketed, sold, or distributed directly or indirectly to retail class of trade under a different labeling, packaging (other than repackaging as the listed drug in blister packs, unit doses, or similar packaging for use in institutions), product code, labeler code, trade name, or trade mark than the listed drug.

(u) CERTAIN DRUGS CONTAINING SINGLE ENANTIOMERS.—

(1) IN GENERAL.—For purposes of subsections (c)(3)(E)(ii) and (j)(5)(F)(ii), if an application is submitted under subsection (b)

for a non-racemic drug containing as an active moiety (as defined by the Secretary in section 314.3 of title 21, Code of Federal Regulations (or any successor regulations)) a single enantiomer that is contained in a racemic drug approved in another application under subsection (b), the applicant may, in the application for such non-racemic drug, elect to have the single enantiomer not be considered the same active moiety as that contained in the approved racemic drug, if—

(A)(i) the single enantiomer has not been previously approved except in the approved racemic drug; and

(ii) the application submitted under subsection (b) for such non-racemic drug—

(I) includes full reports of new clinical investigations (other than bioavailability studies)—

(aa) necessary for the approval of the application under subsections (c) and (d); and

(bb) conducted or sponsored by the applicant; and

(II) does not rely on any clinical investigations that are part of an application submitted under subsection (b) for approval of the approved racemic drug; and

(B) the application submitted under subsection (b) for such non-racemic drug is not submitted for approval of a condition of use—

(i) in a therapeutic category in which the approved racemic drug has been approved; or

(ii) for which any other enantiomer of the racemic drug has been approved.

(2) LIMITATION.—

(A) NO APPROVAL IN CERTAIN THERAPEUTIC CATEGORIES.—Until the date that is 10 years after the date of approval of a non-racemic drug described in paragraph (1) and with respect to which the applicant has made the election provided for by such paragraph, the Secretary shall not approve such non-racemic drug for any condition of use in the therapeutic category in which the racemic drug has been approved.

(B) LABELING.—If applicable, the labeling of a non-racemic drug described in paragraph (1) and with respect to which the applicant has made the election provided for by such paragraph shall include a statement that the non-racemic drug is not approved, and has not been shown to be safe and effective, for any condition of use of the racemic drug.

(3) DEFINITION.—

(A) IN GENERAL.—For purposes of this subsection, the term "therapeutic category" means a therapeutic category identified in the list developed by the United States Pharmacopeia pursuant to section 1860D–4(b)(3)(C)(ii) of the Social Security Act and as in effect on the date of the enactment of this subsection.

(B) PUBLICATION BY SECRETARY.—The Secretary shall publish the list described in subparagraph (A) and may amend such list by regulation.

(4) AVAILABILITY.—The election referred to in paragraph (1) may be made only in an application that is submitted to the Secretary after the date of the enactment of this subsection and before October 1, [2022] *2027*.

(v) ANTIBIOTIC DRUGS SUBMITTED BEFORE NOVEMBER 21, 1997.—

(1) ANTIBIOTIC DRUGS APPROVED BEFORE NOVEMBER 21, 1997.—

(A) IN GENERAL.—Notwithstanding any provision of the Food and Drug Administration Modernization Act of 1997 or any other provision of law, a sponsor of a drug that is the subject of an application described in subparagraph (B)(i) shall be eligible for, with respect to the drug, the 3-year exclusivity period referred to under clauses (iii) and (iv) of subsection (c)(3)(E) and under clauses (iii) and (iv) of subsection (j)(5)(F), subject to the requirements of such clauses, as applicable.

(B) APPLICATION; ANTIBIOTIC DRUG DESCRIBED.—

(i) APPLICATION.—An application described in this clause is an application for marketing submitted under this section after the date of the enactment of this subsection in which the drug that is the subject of the application contains an antibiotic drug described in clause (ii).

(ii) ANTIBIOTIC DRUG.—An antibiotic drug described in this clause is an antibiotic drug that was the subject of an application approved by the Secretary under section 507 of this Act (as in effect before November 21, 1997).

(2) ANTIBIOTIC DRUGS SUBMITTED BEFORE NOVEMBER 21, 1997, BUT NOT APPROVED.—

(A) IN GENERAL.—Notwithstanding any provision of the Food and Drug Administration Modernization Act of 1997 or any other provision of law, a sponsor of a drug that is the subject of an application described in subparagraph (B)(i) may elect to be eligible for, with respect to the drug—

(i)(I) the 3-year exclusivity period referred to under clauses (iii) and (iv) of subsection (c)(3)(E) and under clauses (iii) and (iv) of subsection (j)(5)(F), subject to the requirements of such clauses, as applicable; and

(II) the 5-year exclusivity period referred to under clause (ii) of subsection (c)(3)(E) and under clause (ii) of subsection (j)(5)(F), subject to the requirements of such clauses, as applicable; or

(ii) a patent term extension under section 156 of title 35, United States Code, subject to the requirements of such section.

(B) APPLICATION; ANTIBIOTIC DRUG DESCRIBED.—

(i) APPLICATION.—An application described in this clause is an application for marketing submitted under this section after the date of the enactment of this subsection in which the drug that is the subject of the application contains an antibiotic drug described in clause (ii).

(ii) ANTIBIOTIC DRUG.—An antibiotic drug described in this clause is an antibiotic drug that was the subject of 1 or more applications received by the Secretary under section 507 of this Act (as in effect before November 21, 1997), none of which was approved by the Secretary under such section.

(3) LIMITATIONS.—

(A) EXCLUSIVITIES AND EXTENSIONS.—Paragraphs (1)(A) and (2)(A) shall not be construed to entitle a drug that is the subject of an approved application described in subparagraphs (1)(B)(i) or (2)(B)(i), as applicable, to any market exclusivities or patent extensions other than those exclusivities or extensions described in paragraph (1)(A) or (2)(A).

(B) CONDITIONS OF USE.—Paragraphs (1)(A) and (2)(A)(i) shall not apply to any condition of use for which the drug referred to in subparagraph (1)(B)(i) or (2)(B)(i), as applicable, was approved before the date of the enactment of this subsection.

(4) APPLICATION OF CERTAIN PROVISIONS.—Notwithstanding section 125, or any other provision, of the Food and Drug Administration Modernization Act of 1997, or any other provision of law, and subject to the limitations in paragraphs (1), (2), and (3), the provisions of the Drug Price Competition and Patent Term Restoration Act of 1984 shall apply to any drug subject to paragraph (1) or any drug with respect to which an election is made under paragraph (2)(A).

(w) DEADLINE FOR DETERMINATION ON CERTAIN PETITIONS.—The Secretary shall issue a final, substantive determination on a petition submitted pursuant to subsection (b) of section 314.161 of title 21, Code of Federal Regulations (or any successor regulations), no later than 270 days after the date the petition is submitted.

(x) DATE OF APPROVAL IN THE CASE OF RECOMMENDED CONTROLS UNDER THE CSA.—

(1) IN GENERAL.—In the case of an application under subsection (b) with respect to a drug for which the Secretary provides notice to the sponsor that the Secretary intends to issue a scientific and medical evaluation and recommend controls under the Controlled Substances Act, approval of such application shall not take effect until the interim final rule controlling the drug is issued in accordance with section 201(j) of the Controlled Substances Act.

(2) DATE OF APPROVAL.—For purposes of this section, with respect to an application described in paragraph (1), the term "date of approval" shall mean the later of—

(A) the date an application under subsection (b) is approved under subsection (c); or

(B) the date of issuance of the interim final rule controlling the drug.

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

(1) IN GENERAL.—The sponsor of a contrast agent for which an application has been approved under this section may submit a supplement to the application seeking approval for a new use following the authorization of a premarket submission for

an applicable medical imaging device for that use with the contrast agent pursuant to section 520(p)(1).

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

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

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

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

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

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

(z) NONCLINICAL TEST DEFINED.—For purposes of this section, the term "nonclinical test" means a test conducted in vitro, in silico, or in chemico, or a nonhuman in vivo test, that occurs before or during the clinical trial phase of the investigation of the safety and effectiveness of a drug. Such test may include the following:

(1) Cell-based assays.

(2) Organ chips and microphysiological systems.

(3) Computer modeling.

(4) Other nonhuman or human biology-based test methods.

(5) Animal tests.

* * * * * * *

SEC. 505B. RESEARCH INTO PEDIATRIC USES FOR DRUGS AND BIOLOGICAL PRODUCTS.

(a) NEW DRUGS AND BIOLOGICAL PRODUCTS.—

(1) IN GENERAL.—

(A) GENERAL REQUIREMENTS.—Except with respect to an application for which subparagraph (B) applies, a person that submits, on or after the date of the enactment of the Pediatric Research Equity Act of 2007, an application (or supplement to an application) for a drug—

(i) under section 505 for a new active ingredient, new indication, new dosage form, new dosing regimen, or new route of administration; or

(ii) under section 351 of the Public Health Service Act (42 U.S.C. 262) for a new active ingredient, new indication, new dosage form, new dosing regimen, or new route of administration,

shall submit with the application the assessments described in paragraph (2).

(B) CERTAIN MOLECULARLY TARGETED CANCER INDICATIONS.—A person that submits, on or after the date that is 3 years after the date of enactment of the FDA Reau-

thorization Act of 2017, an original application for a new active ingredient under section 505 of this Act or section 351 of the Public Health Service Act, shall submit with the application reports on the investigation described in paragraph (3) if the drug or biological product that is the subject of the application is—

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

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

(C) RULE OF CONSTRUCTION.—No application that is subject to the requirements of subparagraph (B) shall be subject to the requirements of subparagraph (A), and no application (or supplement to an application) that is subject to the requirements of subparagraph (A) shall be subject to the requirements of subparagraph (B).

(2) ASSESSMENTS.—

(A) IN GENERAL.—The assessments referred to in paragraph (1)(A) shall contain data, gathered using appropriate formulations for each age group for which the assessment is required, that are adequate—

(i) to assess the safety and effectiveness of the drug or the biological product for the claimed indications in all relevant pediatric subpopulations; and

(ii) to support dosing and administration for each pediatric subpopulation for which the drug or the biological product is safe and effective.

(B) SIMILAR COURSE OF DISEASE OR SIMILAR EFFECT OF DRUG OR BIOLOGICAL PRODUCT.—

(i) IN GENERAL.—If the course of the disease and the effects of the drug are sufficiently similar in adults and pediatric patients, the Secretary may conclude that pediatric effectiveness can be extrapolated from adequate and well-controlled studies in adults, usually supplemented with other information obtained in pediatric patients, such as pharmacokinetic studies.

(ii) EXTRAPOLATION BETWEEN AGE GROUPS.—A study may not be needed in each pediatric age group if data from one age group can be extrapolated to another age group.

(iii) INFORMATION ON EXTRAPOLATION.—A brief documentation of the scientific data supporting the conclusion under clauses (i) and (ii) shall be included in any pertinent reviews for the application under section 505 of this Act or section 351 of the Public Health Service Act (42 U.S.C. 262).

(3) MOLECULARLY TARGETED PEDIATRIC CANCER INVESTIGATION.—

[(A) IN GENERAL.—With respect to a drug or biological product described in paragraph (1)(B), the investigation described in this paragraph is a molecularly targeted pediatric cancer investigation, which shall be designed to yield clinically meaningful pediatric study data, gathered using appropriate formulations for each age group for which the

study is required, regarding dosing, safety, and preliminary efficacy to inform potential pediatric labeling.]

(A) IN GENERAL.—For purposes of paragraph (1)(B), the investigation described in this paragraph is (as determined by the Secretary) a molecularly targeted pediatric cancer investigation of—

(i) the drug or biological product for which the application referred to in such paragraph is submitted; or

(ii) such drug or biological product in combination with—

(I) an active ingredient of a drug or biological product—

(aa) for which an approved application under section 505(j) under this Act or under section 351(k) of the Public Health Service Act is in effect; and

(bb) that is determined by the Secretary to be the standard of care for treating a pediatric cancer; or

(II) an active ingredient of a drug or biological product—

(aa) for which an approved application under section 505(b) of this Act or section 351(a) of the Public Health Service Act to treat an adult cancer is in effect and is held by the same person submitting the application under paragraph (1)(B); and

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

(B) ADDITIONAL REQUIREMENTS.—

(i) DESIGN OF INVESTIGATION.—A molecularly targeted pediatric cancer investigation referred to in subparagraph (A) shall be designed to yield clinically meaningful pediatric study data that is gathered using appropriate formulations for each age group for which the study is required, regarding dosing, safety, and preliminary efficacy to inform potential pediatric labeling.

(ii) LIMITATION.—An investigation described in subparagraph (A)(ii) may be required only if the drug or biological product for which the application referred to in paragraph (1)(B) contains either—

(I) a single new active ingredient; or

(II) more than one active ingredient, if an application for the combination of active ingredients has not previously been approved but each active ingredient has been previously approved to treat an adult cancer.

(iii) RESULTS OF ALREADY-COMPLETED PRECLINICAL STUDIES OF APPLICATION DRUG.—The Secretary may require that reports on an investigation required pursuant to paragraph (1)(B) include the results of all pre-

clinical studies on which the decision to conduct such investigation was based.

(iv) RULE OF CONSTRUCTION REGARDING INACTIVE INGREDIENTS.—With respect to a combination of active ingredients referred to in subparagraph (A)(ii), such subparagraph shall not be construed as addressing the use of inactive ingredients with such combination.

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

[(C)] *(D)* DEFERRALS AND WAIVERS.—Deferrals and waivers under paragraphs (4) and (5) shall apply to investigations described in this paragraph to the same extent and in the same manner as such deferrals and waivers apply with respect to [the assessments under paragraph (2)(B)] *the assessments required under paragraph (1)(A).*

(4) DEFERRAL.—

(A) IN GENERAL.—On the initiative of the Secretary or at the request of the applicant, the Secretary may defer submission of some or all assessments required under paragraph (1)(A) or reports on the investigation required under paragraph (1)(B) until a specified date after approval of the drug or issuance of the license for a biological product if—

(i) the Secretary finds that—

(I) the drug or biological product is ready for approval for use in adults before pediatric studies are complete;

(II) pediatric studies should be delayed until additional safety or effectiveness data have been collected; or

(III) there is another appropriate reason for deferral; and

(ii) the applicant submits to the Secretary—

(I) certification of the grounds for deferring the assessments or reports on the investigation;

(II) a pediatric study plan as described in subsection (e);

(III) evidence that the studies are being conducted or will be conducted with due diligence and at the earliest possible time; and

(IV) a timeline for the completion of such studies.

(B) DEFERRAL EXTENSION.—

(i) IN GENERAL.—On the initiative of the Secretary or at the request of the applicant, the Secretary may grant an extension of a deferral approved under subparagraph (A) for submission of some or all assessments required under paragraph (1)(A) or reports on the investigation required under paragraph (1)(B) if—

(I) the Secretary determines that the conditions described in subclause (II) or (III) of subparagraph (A)(i) continue to be met; and

(II) the applicant submits a new timeline under subparagraph (A)(ii)(IV) and any significant updates to the information required under subparagraph (A)(ii).

(ii) TIMING AND INFORMATION.—If the deferral extension under this subparagraph is requested by the applicant, the applicant shall submit the deferral extension request containing the information described in this subparagraph not less than 90 days prior to the date that the deferral would expire. The Secretary shall respond to such request not later than 45 days after the receipt of such letter. If the Secretary grants such an extension, the specified date shall be the extended date. The sponsor of the required assessment under paragraph (1)(A) or reports on the investigation under paragraph (1)(B) shall not be issued a letter described in subsection (d) unless the specified or extended date of submission for such required studies has passed or if the request for an extension is pending. For a deferral that has expired prior to the date of enactment of the Food and Drug Administration Safety and Innovation Act or that will expire prior to 270 days after the date of enactment of such Act, a deferral extension shall be requested by an applicant not later than 180 days after the date of enactment of such Act. The Secretary shall respond to any such request as soon as practicable, but not later than 1 year after the date of enactment of such Act. Nothing in this clause shall prevent the Secretary from updating the status of a study or studies publicly if components of such study or studies are late or delayed.

(C) ANNUAL REVIEW.—

(i) IN GENERAL.—On an annual basis following the approval of a deferral under subparagraph (A), the applicant shall submit to the Secretary the following information:

(I) Information detailing the progress made in conducting pediatric studies.

(II) If no progress has been made in conducting such studies, evidence and documentation that such studies will be conducted with due diligence and at the earliest possible time.

(III) Projected completion date for pediatric studies.

(IV) The reason or reasons why a deferral or deferral extension continues to be necessary.

(ii) PUBLIC AVAILABILITY.—Not later than 90 days after the submission to the Secretary of the information submitted through the annual review under clause (i), the Secretary shall make available to the public in an easily accessible manner, including

through the Internet Web site of the Food and Drug Administration—

(I) such information;

(II) the name of the applicant for the product subject to the assessment or investigation;

(III) the date on which the product was approved; and

(IV) the date of each deferral or deferral extension under this paragraph for the product.

(5) WAIVERS.—

(A) FULL WAIVER.—On the initiative of the Secretary or at the request of an applicant, the Secretary shall grant a full waiver, as appropriate, of the requirement to submit assessments or reports on the investigation for a drug or biological product under this subsection if the applicant certifies and the Secretary finds that—

(i) necessary studies are impossible or highly impracticable (because, for example, the number of patients is so small or the patients are geographically dispersed);

(ii) there is evidence strongly suggesting that the drug or biological product would be ineffective or unsafe in all pediatric age groups; or

(iii) the drug or biological product—

(I) does not represent a meaningful therapeutic benefit over existing therapies for pediatric patients; and

(II) is not likely to be used in a substantial number of pediatric patients.

(B) PARTIAL WAIVER.—On the initiative of the Secretary or at the request of an applicant, the Secretary shall grant a partial waiver, as appropriate, of the requirement to submit assessments or reports on the investigation for a drug or biological product under this subsection with respect to a specific pediatric age group if the applicant certifies and the Secretary finds that—

(i) necessary studies are impossible or highly impracticable (because, for example, the number of patients in that age group is so small or patients in that age group are geographically dispersed);

(ii) there is evidence strongly suggesting that the drug or biological product would be ineffective or unsafe in that age group;

(iii) the drug or biological product—

(I) does not represent a meaningful therapeutic benefit over existing therapies for pediatric patients in that age group; and

(II) is not likely to be used by a substantial number of pediatric patients in that age group; or

(iv) the applicant can demonstrate that reasonable attempts to produce a pediatric formulation necessary for that age group have failed.

(C) PEDIATRIC FORMULATION NOT POSSIBLE.—If a partial waiver is granted on the ground that it is not possible to develop a pediatric formulation, the waiver shall cover

only the pediatric groups requiring that formulation. An applicant seeking such a partial waiver shall submit to the Secretary documentation detailing why a pediatric formulation cannot be developed and, if the waiver is granted, the applicant's submission shall promptly be made available to the public in an easily accessible manner, including through posting on the Web site of the Food and Drug Administration.

(D) LABELING REQUIREMENT.—If the Secretary grants a full or partial waiver because there is evidence that a drug or biological product would be ineffective or unsafe in pediatric populations, the information shall be included in the labeling for the drug or biological product.

(b) MARKETED DRUGS AND BIOLOGICAL PRODUCTS.—

(1) IN GENERAL.—The Secretary may (by order in the form of a letter) require the sponsor or holder of an approved application for a drug under section 505 or the holder of a license for a biological product under section 351 of the Public Health Service Act to submit by a specified date the assessments described in subsection (a)(2), if the Secretary finds that—

(A)(i) the drug or biological product is used for a substantial number of pediatric patients for the labeled indications; and

(ii) adequate pediatric labeling could confer a benefit on pediatric patients;

(B) there is reason to believe that the drug or biological product would represent a meaningful therapeutic benefit over existing therapies for pediatric patients for 1 or more of the claimed indications; or

(C) the absence of adequate pediatric labeling could pose a risk to pediatric patients.

(2) WAIVERS.—

(A) FULL WAIVER.—At the request of an applicant, the Secretary shall grant a full waiver, as appropriate, of the requirement to submit assessments under this subsection if the applicant certifies and the Secretary finds that—

(i) necessary studies are impossible or highly impracticable (because, for example, the number of patients in that age group is so small or patients in that age group are geographically dispersed); or

(ii) there is evidence strongly suggesting that the drug or biological product would be ineffective or unsafe in all pediatric age groups.

(B) PARTIAL WAIVER.—At the request of an applicant, the Secretary shall grant a partial waiver, as appropriate, of the requirement to submit assessments under this subsection with respect to a specific pediatric age group if the applicant certifies and the Secretary finds that—

(i) necessary studies are impossible or highly impracticable (because, for example, the number of patients in that age group is so small or patients in that age group are geographically dispersed);

(ii) there is evidence strongly suggesting that the drug or biological product would be ineffective or unsafe in that age group;

(iii)(I) the drug or biological product—

(aa) does not represent a meaningful therapeutic benefit over existing therapies for pediatric patients in that age group; and

(bb) is not likely to be used in a substantial number of pediatric patients in that age group; and

(II) the absence of adequate labeling could not pose significant risks to pediatric patients; or

(iv) the applicant can demonstrate that reasonable attempts to produce a pediatric formulation necessary for that age group have failed.

(C) PEDIATRIC FORMULATION NOT POSSIBLE.—If a waiver is granted on the ground that it is not possible to develop a pediatric formulation, the waiver shall cover only the pediatric groups requiring that formulation. An applicant seeking either a full or partial waiver shall submit to the Secretary documentation detailing why a pediatric formulation cannot be developed and, if the waiver is granted, the applicant's submission shall promptly be made available to the public in an easily accessible manner, including through posting on the Web site of the Food and Drug Administration.

(D) LABELING REQUIREMENT.—If the Secretary grants a full or partial waiver because there is evidence that a drug or biological product would be ineffective or unsafe in pediatric populations, the information shall be included in the labeling for the drug or biological product.

(3) EFFECT OF SUBSECTION.—Nothing in this subsection alters or amends section 301(j) of this Act or section 552 of title 5 or section 1905 of title 18, United States Code.

(c) MEANINGFUL THERAPEUTIC BENEFIT.—For the purposes of paragraph (4)(A)(iii)(I) and (4)(B)(iii)(I) of subsection (a) and paragraphs (1)(B) and (2)(B)(iii)(I)(aa) of subsection (b), a drug or biological product shall be considered to represent a meaningful therapeutic benefit over existing therapies if the Secretary determines that—

(1) if approved, the drug or biological product could represent an improvement in the treatment, diagnosis, or prevention of a disease, compared with marketed products adequately labeled for that use in the relevant pediatric population; or

(2) the drug or biological product is in a class of products or for an indication for which there is a need for additional options.

(d) SUBMISSION OF ASSESSMENTS AND REPORTS ON THE INVESTIGATION.—If a person fails to submit a required assessment described in subsection (a)(2) or the investigation described in subsection (a)(3), fails to meet the applicable requirements in subsection (a)(4), or fails to submit a request for approval of a pediatric formulation described in subsection (a) or (b), in accordance with applicable provisions of subsections (a) and (b), the following shall apply:

(1) Beginning 270 days after the date of enactment of the Food and Drug Administration Safety and Innovation Act, the Secretary shall issue a non-compliance letter to such person in-

forming them of such failure to submit or meet the requirements of the applicable subsection. Such letter shall require the person to respond in writing within 45 calendar days of issuance of such letter. Such response may include the person's request for a deferral extension if applicable. Such letter and the person's written response to such letter shall be made publicly available on the Internet Web site of the Food and Drug Administration 60 calendar days after issuance, with redactions for any trade secrets and confidential commercial information. If the Secretary determines that the letter was issued in error, the requirements of this paragraph shall not apply. The Secretary shall inform the Pediatric Advisory Committee of letters issued under this paragraph and responses to such letters.

(2) The drug or biological product that is the subject of an assessment described in subsection (a)(2) or the investigation described in subsection (a)(3), applicable requirements in subsection (a)(4), or request for approval of a pediatric formulation, may be considered misbranded solely because of that failure and subject to relevant enforcement action (except that the drug or biological product shall not be subject to action under section 303), but such failure shall not be the basis for a proceeding—

(A) to withdraw approval for a drug under section 505(e); or

(B) to revoke the license for a biological product under section 351 of the Public Health Service Act.

(e) PEDIATRIC STUDY PLANS.—

(1) IN GENERAL.—An applicant subject to subsection (a) shall submit to the Secretary an initial pediatric study plan prior to the submission of the assessments described under subsection (a)(2) or the investigation described in subsection (a)(3). *The Secretary shall determine whether subparagraph (A) or (B) of subsection (a)(1) shall apply with respect to an application before the date on which the applicant is required to submit the initial pediatric study plan under paragraph (2)(A).*

(2) TIMING; CONTENT; MEETINGS.—

(A) TIMING.—An applicant shall submit the initial pediatric study plan under paragraph (1)—

(i) before the date on which the applicant submits the assessments under subsection (a)(2) or the investigation described in subsection (a)(3); and

(ii) not later than—

(I) 60 calendar days after the date of the end-of-Phase 2 meeting (as such term is used in section 312.47 of title 21, Code of Federal Regulations, or successor regulations); or

(II) such other time as may be agreed upon between the Secretary and the applicant.

Nothing in this section shall preclude the Secretary from accepting the submission of an initial pediatric study plan earlier than the date otherwise applicable under this subparagraph.

(B) CONTENT OF INITIAL PEDIATRIC STUDY PLAN.—The initial pediatric study plan shall include—

(i) an outline of the pediatric study or studies that the applicant plans to conduct (including, to the extent practicable study objectives and design, age groups, relevant endpoints, and statistical approach);

(ii) any request for a deferral, partial waiver, or waiver under this section, if applicable, along with any supporting information; and

(iii) other information specified in the regulations promulgated under paragraph (7).

(C) MEETINGS.—The Secretary—

(i) shall meet with the applicant—

(I) if requested by the applicant with respect to a drug or biological product that is intended to treat a serious or life-threatening disease or condition, to discuss preparation of the initial pediatric study plan, not later than the end-of-Phase 1 meeting (as such term is used in section 312.82(b) of title 21, Code of Federal Regulations, or successor regulations) or within 30 calendar days of receipt of such request, whichever is later;

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

(III) to discuss the bases for the deferral under subsection (a)(4) or a full or partial waiver under subsection (a)(5);

(ii) may determine that a written response to the initial pediatric study plan is sufficient to communicate comments on the initial pediatric study plan, and that no meeting under clause (i)(II) is necessary; and

(iii) if the Secretary determines that no meeting under clause (i)(II) is necessary, shall so notify the applicant and provide written comments of the Secretary as soon as practicable, but not later than 90 calendar days after the receipt of the initial pediatric study plan.

(3) AGREED INITIAL PEDIATRIC STUDY PLAN.—Not later than 90 calendar days following the meeting under paragraph (2)(C)(i)(II) or the receipt of a written response from the Secretary under paragraph (2)(C)(iii), the applicant shall document agreement on the initial pediatric study plan in a submission to the Secretary marked "Agreed Initial Pediatric Study Plan", and the Secretary shall confirm such agreement to the applicant in writing not later than 30 calendar days of receipt of such agreed initial pediatric study plan.

(4) DEFERRAL AND WAIVER.—If the agreed initial pediatric study plan contains a request from the applicant for a deferral, partial waiver, or waiver under this section, the written confirmation under paragraph (3) shall include a recommendation from the Secretary as to whether such request meets the standards under paragraphs (3) or (4) of subsection (a).

(5) AMENDMENTS TO THE AGREED INITIAL PEDIATRIC STUDY PLAN.—At the initiative of the Secretary or the applicant, the

agreed initial pediatric study plan may be amended at any time. The requirements of paragraph (2)(C) shall apply to any such proposed amendment in the same manner and to the same extent as such requirements apply to an initial pediatric study plan under paragraph (1). The requirements of paragraphs (3) and (4) shall apply to any agreement resulting from such proposed amendment in the same manner and to the same extent as such requirements apply to an agreed initial pediatric study plan.

(6) INTERNAL COMMITTEE.—The Secretary shall consult the internal committee under section 505C on the review of the initial pediatric study plan, agreed initial pediatric study plan, and any significant amendments to such plans.

(7) REQUIRED RULEMAKING.—Not later than 1 year after the date of enactment of the Food and Drug Administration Safety and Innovation Act, the Secretary shall promulgate proposed regulations and issue guidance to implement the provisions of this subsection.

(f) REVIEW OF PEDIATRIC STUDY PLANS,ASSESSMENTS, DEFERRALS, DEFERRAL EXTENSIONS, AND WAIVERS.—

(1) REVIEW.—Beginning not later than 30 days after the date of the enactment of the Pediatric Research Equity Act of 2007, the Secretary shall utilize the internal committee established under section 505C to provide consultation to reviewing divisions on initial pediatric study plans, agreed initial pediatric study plans, and any significant amendments to such plans, and assessments prior to approval of an application or supplement for which a pediatric assessment is required under this section and all deferral, deferral extension, and waiver requests granted pursuant to this section.

(2) ACTIVITY BY COMMITTEE.—The committee referred to in paragraph (1) may operate using appropriate members of such committee and need not convene all members of the committee.

(3) DOCUMENTATION OF COMMITTEE ACTION.—For each drug or biological product, the committee referred to in paragraph (1) shall document, for each activity described in paragraph (4) or (5), which members of the committee participated in such activity.

(4) REVIEW OF PEDIATRIC STUDY PLANS, ASSESSMENTS, DEFERRALS, DEFERRAL EXTENSIONS, AND WAIVERS.—Consultation on initial pediatric study plans, agreed initial pediatric study plans, and assessments by the committee referred to in paragraph (1) pursuant to this section shall occur prior to approval of an application or supplement for which a pediatric assessment is required under this section. The committee shall review all requests for deferrals, deferral extensions, and waivers from the requirement to submit a pediatric assessment granted under this section and shall provide recommendations as needed to reviewing divisions, including with respect to whether such a supplement, when submitted, shall be considered for priority review.

(5) RETROSPECTIVE REVIEW OF PEDIATRIC ASSESSMENTS, DEFERRALS, AND WAIVERS.—Not later than 1 year after the date of the enactment of the Pediatric Research Equity Act of 2007, the committee referred to in paragraph (1) shall conduct a ret-

rospective review and analysis of a representative sample of assessments submitted and deferrals and waivers approved under this section since the enactment of the Pediatric Research Equity Act of 2003. Such review shall include an analysis of the quality and consistency of pediatric information in pediatric assessments and the appropriateness of waivers and deferrals granted. Based on such review, the Secretary shall issue recommendations to the review divisions for improvements and initiate guidance to industry related to the scope of pediatric studies required under this section.

(6) TRACKING OF ASSESSMENTS AND LABELING CHANGES.—The Secretary, in consultation with the committee referred to in paragraph (1), shall track and make available to the public in an easily accessible manner, including through posting on the Web site of the Food and Drug Administration—

(A) the number of assessments conducted under this section;

(B) the specific drugs and biological products and their uses assessed under this section;

(C) the types of assessments conducted under this section, including trial design, the number of pediatric patients studied, and the number of centers and countries involved;

(D) aggregated on an annual basis—

(i) the total number of deferrals and deferral extensions requested and granted under this section and, if granted, the reasons for each such deferral or deferral extension;

(ii) the timeline for completion of the assessments;

(iii) the number of assessments completed and pending; and

(iv) the number of postmarket non-compliance letters issued pursuant to subsection (d), and the recipients of such letters;

(E) the number of waivers requested and granted under this section and, if granted, the reasons for the waivers;

(F) the number of pediatric formulations developed and the number of pediatric formulations not developed and the reasons any such formulation was not developed;

(G) the labeling changes made as a result of assessments conducted under this section;

(H) an annual summary of labeling changes made as a result of assessments conducted under this section for distribution pursuant to subsection (h)(2);

(I) an annual summary of information submitted pursuant to subsection (a)(3)(B); and

(J) the number of times the committee referred to in paragraph (1) made a recommendation to the Secretary under paragraph (4) regarding priority review, the number of times the Secretary followed or did not follow such a recommendation, and, if not followed, the reasons why such a recommendation was not followed.

(g) LABELING CHANGES.—

(1) DISPUTE RESOLUTION.—

(A) REQUEST FOR LABELING CHANGE AND FAILURE TO AGREE.—If, on or after the date of the enactment of the Pediatric Research Equity Act of 2007, the Commissioner determines that a sponsor and the Commissioner have been unable to reach agreement on appropriate changes to the labeling for the drug that is the subject of the application or supplement, not later than 180 days after the date of the submission of the application or supplement that receives a priority review or 330 days after the date of the submission of an application or supplement that receives a standard review—

(i) the Commissioner shall request that the sponsor of the application make any labeling change that the Commissioner determines to be appropriate; and

(ii) if the sponsor does not agree within 30 days after the Commissioner's request to make a labeling change requested by the Commissioner, the Commissioner shall refer the matter to the Pediatric Advisory Committee.

(B) ACTION BY THE PEDIATRIC ADVISORY COMMITTEE.—Not later than 90 days after receiving a referral under subparagraph (A)(ii), the Pediatric Advisory Committee shall—

(i) review the pediatric study reports; and

(ii) make a recommendation to the Commissioner concerning appropriate labeling changes, if any.

(C) CONSIDERATION OF RECOMMENDATIONS.—The Commissioner shall consider the recommendations of the Pediatric Advisory Committee and, if appropriate, not later than 30 days after receiving the recommendation, make a request to the sponsor of the application or supplement to make any labeling changes that the Commissioner determines to be appropriate.

(D) MISBRANDING.—If the sponsor of the application or supplement, within 30 days after receiving a request under subparagraph (C), does not agree to make a labeling change requested by the Commissioner, the Commissioner may deem the drug that is the subject of the application or supplement to be misbranded.

(E) NO EFFECT ON AUTHORITY.—Nothing in this subsection limits the authority of the United States to bring an enforcement action under this Act when a drug lacks appropriate pediatric labeling. Neither course of action (the Pediatric Advisory Committee process or an enforcement action referred to in the preceding sentence) shall preclude, delay, or serve as the basis to stay the other course of action.

(2) OTHER LABELING CHANGES.—If, on or after the date of the enactment of the Pediatric Research Equity Act of 2007, the Secretary makes a determination that a pediatric assessment conducted under this section does or does not demonstrate that the drug that is the subject of such assessment is safe and effective in pediatric populations or subpopulations, including whether such assessment results are inconclusive, the Secretary shall order the labeling of such product to include infor-

mation about the results of the assessment and a statement of the Secretary's determination.

(h) DISSEMINATION OF PEDIATRIC INFORMATION.—

(1) IN GENERAL.—Not later than 210 days after the date of submission of an application (or supplement to an application) that contains a pediatric assessment under this section, if the application (or supplement) receives a priority review, or not later than 330 days after the date of submission of an application (or supplement to an application) that contains a pediatric assessment under this section, if the application (or supplement) receives a standard review, the Secretary shall make available to the public in an easily accessible manner the medical, statistical, and clinical pharmacology reviews of such pediatric assessments, and shall post such assessments on the Web site of the Food and Drug Administration.

(2) DISSEMINATION OF INFORMATION REGARDING LABELING CHANGES.—Beginning on the date of the enactment of the Pediatric Research Equity Act of 2007, the Secretary shall require that the sponsors of the assessments that result in labeling changes that are reflected in the annual summary developed pursuant to subsection (f)(6)(H) distribute such information to physicians and other health care providers.

(3) EFFECT OF SUBSECTION.—Nothing in this subsection shall alter or amend section 301(j) of this Act or section 552 of title 5 or section 1905 of title 18, United States Code.

(i) ADVERSE EVENT REPORTING.—

(1) REPORTING IN FIRST 18-MONTH PERIOD.—Beginning on the date of the enactment of the Pediatric Research Equity Act of 2007, during the 18-month period beginning on the date a labeling change is made pursuant to subsection (g), the Secretary shall ensure that all adverse event reports that have been received for such drug (regardless of when such report was received) are referred to the Office of Pediatric Therapeutics. In considering such reports, the Director of such Office shall provide for the review of such reports by the Pediatric Advisory Committee, including obtaining any recommendations of such committee regarding whether the Secretary should take action under this Act in response to such reports.

(2) REPORTING IN SUBSEQUENT PERIODS.—Following the 18-month period described in paragraph (1), the Secretary shall, as appropriate, refer to the Office of Pediatric Therapeutics all pediatric adverse event reports for a drug for which a pediatric study was conducted under this section. In considering such reports, the Director of such Office may provide for the review of such reports by the Pediatric Advisory Committee, including obtaining any recommendation of such Committee regarding whether the Secretary should take action in response to such reports.

(3) PRESERVATION OF AUTHORITY.—Nothing in this subsection shall prohibit the Office of Pediatric Therapeutics from providing for the review of adverse event reports by the Pediatric Advisory Committee prior to the 18-month period referred to in paragraph (1), if such review is necessary to ensure safe use of a drug in a pediatric population.

(4) EFFECT.—The requirements of this subsection shall supplement, not supplant, other review of such adverse event reports by the Secretary.

(j) SCOPE OF AUTHORITY.—Nothing in this section provides to the Secretary any authority to require a pediatric assessment of any drug or biological product, or any assessment regarding other populations or uses of a drug or biological product, other than the pediatric assessments described in this section.

(k) RELATION TO ORPHAN DRUGS.—

(1) IN GENERAL; EXEMPTION FOR ORPHAN INDICATIONS.—Unless the Secretary requires otherwise by regulation and except as provided in paragraph (2), this section does not apply to any drug or biological product for an indication for which orphan designation has been granted under section 526.

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

(l) NEW ACTIVE INGREDIENT.—

(1) NON-INTERCHANGEABLE BIOSIMILAR BIOLOGICAL PRODUCT.—A biological product that is biosimilar to a reference product under section 351 of the Public Health Service Act, and that the Secretary has not determined to meet the standards described in subsection (k)(4) of such section for interchangeability with the reference product, shall be considered to have a new active ingredient under this section.

(2) INTERCHANGEABLE BIOSIMILAR BIOLOGICAL PRODUCT.—A biological product that is interchangeable with a reference product under section 351 of the Public Health Service Act shall not be considered to have a new active ingredient under this section.

(m) LIST OF PRIMARY MOLECULAR TARGETS.—

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

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

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

(2) CONSULTATION.—In establishing the lists described in paragraph (1), the Secretary shall consult the National Cancer Institute, members of the internal committee under section 505C, and the Pediatric Oncology Subcommittee of the Oncologic Drugs Advisory Committee, and shall take into account comments from the meeting under subsection (c).

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

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

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

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SEC. 505E. EXTENSION OF EXCLUSIVITY PERIOD FOR NEW QUALIFIED INFECTIOUS DISEASE PRODUCTS.

(a) EXTENSION.—If the Secretary approves an application pursuant to section 505 for a drug that has been designated as a qualified infectious disease product under subsection (d), the 4- and 5-year periods described in subsections (c)(3)(E)(ii) and (j)(5)(F)(ii) of section 505, the 3-year periods described in clauses (iii) and (iv) of subsection (c)(3)(E) and clauses (iii) and (iv) of subsection (j)(5)(F) of section 505, or the 7-year period described in section 527, as applicable, shall be extended by 5 years.

(b) RELATION TO PEDIATRIC EXCLUSIVITY.—Any extension under subsection (a) of a period shall be in addition to any extension of the period under section 505A with respect to the drug.

(c) LIMITATIONS.—Subsection (a) does not apply to the approval of—

(1) a supplement to an application under section 505(b) for any qualified infectious disease product for which an extension described in subsection (a) is in effect or has expired;

(2) a subsequent application filed with respect to a product approved under section 505 for a change that results in a new indication, route of administration, dosing schedule, dosage form, delivery system, delivery device, or strength; **[**or**]**

(3) a product that does not meet the definition of a qualified infectious disease product under subsection (g) based upon its approved uses**[**.**]***; or*

(4) an application pursuant to section 351(a) of the Public Health Service Act.

(d) DESIGNATION.—

(1) IN GENERAL.—The manufacturer or sponsor of a drug may request the Secretary to designate a drug as a qualified infectious disease product at any time before the submission of an application under section 505(b) *of this Act or section 351(a) of the Public Health Service Act* for such drug. The Secretary shall, not later than 60 days after the submission of such a request, determine whether the drug is a qualified infectious disease product.

(2) LIMITATION.—Except as provided in paragraph (3), a designation under this subsection shall not be withdrawn for any reason, including modifications to the list of qualifying pathogens under subsection (f)(2)(C).

(3) REVOCATION OF DESIGNATION.—The Secretary may revoke a designation of a drug as a qualified infectious disease product if the Secretary finds that the request for such designation contained an untrue statement of material fact.

(e) REGULATIONS.—

(1) IN GENERAL.—Not later than 2 years after the date of enactment of the Food and Drug Administration Safety and Innovation Act, the Secretary shall adopt final regulations implementing this section, including developing the list of qualifying pathogens described in subsection (f).

(2) PROCEDURE.—In promulgating a regulation implementing this section, the Secretary shall—

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

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

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

(3) RESTRICTIONS.—Notwithstanding any other provision of law, the Secretary shall promulgate regulations implementing this section only as described in paragraph (2), except that the Secretary may issue interim guidance for sponsors seeking designation under subsection (d) prior to the promulgation of such regulations.

(4) DESIGNATION PRIOR TO REGULATIONS.—The Secretary shall designate drugs as qualified infectious disease products under subsection (d) prior to the promulgation of regulations under this subsection, if such drugs meet the definition of a qualified infectious disease product described in subsection (g).

(f) QUALIFYING PATHOGEN.—

(1) DEFINITION.—In this section, the term "qualifying pathogen" means a pathogen identified and listed by the Secretary under paragraph (2) that has the potential to pose a serious threat to public health, such as—

(A) resistant gram positive pathogens, including methicillin-resistant Staphylococcus aureus, vancomycin-resistant Staphylococcus aureus, and vancomycin-resistant enterococcus;

(B) multi-drug resistant gram negative bacteria, including Acinetobacter, Klebsiella, Pseudomonas, and E. coli species;

(C) multi-drug resistant tuberculosis; and

(D) Clostridium difficile.

(2) LIST OF QUALIFYING PATHOGENS.—

(A) IN GENERAL.—The Secretary shall establish and maintain a list of qualifying pathogens, and shall make public the methodology for developing such list.

(B) CONSIDERATIONS.—In establishing and maintaining the list of pathogens described under this section, the Secretary shall—

(i) consider—

(I) the impact on the public health due to drug-resistant organisms in humans;

(II) the rate of growth of drug-resistant organisms in humans;

(III) the increase in resistance rates in humans; and

(IV) the morbidity and mortality in humans; and

(ii) consult with experts in infectious diseases and antibiotic resistance, including the Centers for Disease Control and Prevention, the Food and Drug Administration, medical professionals, and the clinical research community.

(C) REVIEW.—Every 5 years, or more often as needed, the Secretary shall review, provide modifications to, and publish the list of qualifying pathogens under subparagraph (A) and shall by regulation revise the list as necessary, in accordance with subsection (e).

[(g) QUALIFIED INFECTIOUS DISEASE PRODUCT.—The term "qualified infectious disease product" means an antibacterial or antifungal drug for human use intended to treat serious or life-threatening infections, including those caused by—

[(1) an antibacterial or antifungal resistant pathogen, including novel or emerging infectious pathogens; or

[(2) qualifying pathogens listed by the Secretary under subsection (f).]

(g) QUALIFIED INFECTIOUS DISEASE PRODUCT.—The term "qualified infectious disease product" means a drug, including an antibacterial or antifungal drug or a biological product, for human use that—

(1) acts directly on bacteria or fungi or on substances produced by such bacteria or fungi; and

(2) is intended to treat a serious or life-threatening infection, including such an infection caused by—

(A) an antibacterial or antifungal resistant pathogen, including novel or emerging infectious pathogens; or

(B) qualifying pathogens listed by the Secretary under subsection (f).

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SEC. 506. EXPEDITED APPROVAL OF DRUGS FOR SERIOUS OR LIFE-THREATENING DISEASES OR CONDITIONS.

(a) DESIGNATION OF A DRUG AS A BREAKTHROUGH THERAPY.—

(1) IN GENERAL.—The Secretary shall, at the request of the sponsor of a drug, expedite the development and review of such drug if the drug is intended, alone or in combination with 1 or more other drugs, to treat a serious or life-threatening disease or condition and preliminary clinical evidence indicates that the drug may demonstrate substantial improvement over existing therapies on 1 or more clinically significant endpoints, such as substantial treatment effects observed early in clinical development. (In this section, such a drug is referred to as a "breakthrough therapy".)

(2) REQUEST FOR DESIGNATION.—The sponsor of a drug may request the Secretary to designate the drug as a breakthrough therapy. A request for the designation may be made concurrently with, or at any time after, the submission of an application for the investigation of the drug under section 505(i) or section 351(a)(3) of the Public Health Service Act.

(3) DESIGNATION.—

(A) IN GENERAL.—Not later than 60 calendar days after the receipt of a request under paragraph (2), the Secretary shall determine whether the drug that is the subject of the

request meets the criteria described in paragraph (1). If the Secretary finds that the drug meets the criteria, the Secretary shall designate the drug as a breakthrough therapy and shall take such actions as are appropriate to expedite the development and review of the application for approval of such drug.

(B) ACTIONS.—The actions to expedite the development and review of an application under subparagraph (A) may include, as appropriate—

(i) holding meetings with the sponsor and the review team throughout the development of the drug;

(ii) providing 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;

(iii) involving senior managers and experienced review staff, as appropriate, in a collaborative, cross-disciplinary review;

(iv) assigning a cross-disciplinary project lead for the Food and Drug Administration review team to facilitate an efficient review of the development program and to serve as a scientific liaison between the review team and the sponsor; and

(v) taking steps to ensure that the design of the clinical trials is as efficient as practicable, when scientifically appropriate, such as by minimizing the number of patients exposed to a potentially less efficacious treatment.

(b) DESIGNATION OF DRUG AS FAST TRACK PRODUCT.—

(1) IN GENERAL.—The Secretary shall, at the request of the sponsor of a new drug, facilitate the development and expedite the review of such drug if it is intended, whether alone or in combination with one or more other drugs, for the treatment of a serious or life-threatening disease or condition, and it demonstrates the potential to address unmet medical needs for such a disease or condition, or if the Secretary designates the drug as a qualified infectious disease product under section 505E(d). (In this section, such a drug is referred to as a "fast track product".)

(2) REQUEST FOR DESIGNATION.—The sponsor of a new drug may request the Secretary to designate the drug as a fast track product. A request for the designation may be made concurrently with, or at any time after, submission of an application for the investigation of the drug under section 505(i) or section 351(a)(3) of the Public Health Service Act.

(3) DESIGNATION.—Within 60 calendar days after the receipt of a request under paragraph (2), the Secretary shall determine whether the drug that is the subject of the request meets the criteria described in paragraph (1). If the Secretary finds that the drug meets the criteria, the Secretary shall designate the drug as a fast track product and shall take such actions as are appropriate to expedite the development and review of the application for approval of such product.

(c) ACCELERATED APPROVAL OF A DRUG FOR A SERIOUS OR LIFE-THREATENING DISEASE OR CONDITION, INCLUDING A FAST TRACK PRODUCT.—

(1) IN GENERAL.—

(A) ACCELERATED APPROVAL.—The Secretary may approve an application for approval of a product for a serious or life-threatening disease or condition, including a fast track product, under section 505(c) or section 351(a) of the Public Health Service Act upon a determination that the product has an effect on a surrogate endpoint that is reasonably likely to predict clinical benefit, or on a clinical endpoint that can be measured earlier than irreversible morbidity or mortality, that is reasonably likely to predict an effect on irreversible morbidity or mortality or other clinical benefit, taking into account the severity, rarity, or prevalence of the condition and the availability or lack of alternative treatments. The approval described in the preceding sentence is referred to in this section as "accelerated approval".

(B) EVIDENCE.—The evidence to support that an endpoint is reasonably likely to predict clinical benefit under subparagraph (A) may include epidemiological, pathophysiological, therapeutic, pharmacologic, or other evidence developed using biomarkers, for example, or other scientific methods or tools.

[(2) LIMITATION.—Approval of a product under this subsection may be subject to 1 or both of the following requirements:

[(A) That the sponsor conduct appropriate postapproval studies to verify and describe the predicted effect on irreversible morbidity or mortality or other clinical benefit.

[(B) That the sponsor submit copies of all promotional materials related to the product during the preapproval review period and, following approval and for such period thereafter as the Secretary determines to be appropriate, at least 30 days prior to dissemination of the materials.

[(3) EXPEDITED WITHDRAWAL OF APPROVAL.—The Secretary may withdraw approval of a product approved under accelerated approval using expedited procedures (as prescribed by the Secretary in regulations which shall include an opportunity for an informal hearing) if—

[(A) the sponsor fails to conduct any required postapproval study of the drug with due diligence;

[(B) a study required to verify and describe the predicted effect on irreversible morbidity or mortality or other clinical benefit of the product fails to verify and describe such effect or benefit;

[(C) other evidence demonstrates that the product is not safe or effective under the conditions of use; or

[(D) the sponsor disseminates false or misleading promotional materials with respect to the product.]

(2) LIMITATION.—

(A) IN GENERAL.—Approval of a product under this subsection may be subject to 1 or both of the following requirements:

(i) That the sponsor conduct an appropriate postapproval study or studies (which may be augmented or supported by real world evidence) to verify and describe the predicted effect on irreversible morbidity or mortality or other clinical benefit.

(ii) That the sponsor submit copies of all promotional materials related to the product during the preapproval review period and, following approval and for such period thereafter as the Secretary determines to be appropriate, at least 30 days prior to dissemination of the materials.

(B) STUDIES NOT REQUIRED.—If the Secretary does not require that the sponsor of a product approved under accelerated approval conduct a postapproval study under this paragraph, the Secretary shall publish on the website of the Food and Drug Administration the rationale for why such study is not appropriate or necessary.

(C) POSTAPPROVAL STUDY CONDITIONS.—Not later than the time of approval of a product under accelerated approval, the Secretary shall specify the conditions for a postapproval study or studies required to be conducted under this paragraph with respect to such product, which may include enrollment targets, the study protocol, and milestones, including the target date of study completion.

(D) STUDIES BEGUN BEFORE APPROVAL.—The Secretary may require such study or studies to be underway prior to approval.

(3) EXPEDITED WITHDRAWAL OF APPROVAL.—

(A) IN GENERAL.—The Secretary may withdraw approval of a product approved under accelerated approval using expedited procedures described in subparagraph (B), if—

(i) the sponsor fails to conduct any required postapproval study of the product with due diligence, including with respect to conditions specified by the Secretary under paragraph (2)(C);

(ii) a study required to verify and describe the predicted effect on irreversible morbidity or mortality or other clinical benefit of the product fails to verify and describe such effect or benefit;

(iii) other evidence demonstrates that the product is not shown to be safe or effective under the conditions of use; or

(iv) the sponsor disseminates false or misleading promotional materials with respect to the product.

(B) EXPEDITED PROCEDURES DESCRIBED.—Expedited procedures described in this subparagraph shall consist of, prior to the withdrawal of accelerated approval—

(i) providing the sponsor with—

(I) due notice;

(II) an explanation for the proposed withdrawal;

(III) an opportunity for a meeting with the Commissioner of Food and Drugs or the Commissioner's designee; and

(IV) an opportunity for written appeal to—

(aa) the Commissioner of Food and Drugs; or

(bb) a designee of the Commissioner who has not participated in the proposed withdrawal of approval (other than a meeting pursuant to subclause (III)) and is not a subordinate of an individual (other than the Commissioner) who participated in such proposed withdrawal;

(ii) providing an opportunity for public comment on the notice proposing to withdraw approval;

(iii) the publication of a summary of the public comments received, and the Secretary's response to such comments, on the website of the Food and Drug Administration; and

(iv) convening and consulting an advisory committee on issues related to the proposed withdrawal, if requested by the sponsor and if no such advisory committee has previously advised the Secretary on such issues with respect to the withdrawal of the product prior to the sponsor's request.

(4) LABELING.—

(A) IN GENERAL.—Subject to subparagraph (B), the labeling for a product approved under accelerated approval shall include—

(i) a statement indicating that the product was approved under accelerated approval;

(ii) a statement indicating that continued approval of the product is subject to postmarketing studies to verify clinical benefit;

(iii) identification of the surrogate or intermediate endpoint or endpoints that supported approval and any known limitations of such surrogate or intermediate endpoint or endpoints in determining clinical benefit; and

(iv) a succinct description of the product and any uncertainty about anticipated clinical benefit and a discussion of available evidence with respect to such clinical benefit.

(B) APPLICABILITY.—The labeling requirements of subparagraph (A) shall apply only to products approved under accelerated approval for which the predicted effect on irreversible morbidity or mortality or other clinical benefit has not been verified.

(C) RULE OF CONSTRUCTION.—With respect to any application pending before the Secretary on the date of enactment of the Food and Drug Amendments of 2022, the Secretary shall allow any applicable changes to the product labeling required to comply with subparagraph (A) to be made by supplement after the approval of such application.

(5) REPORTING.—Not later than September 30, 2025, the Secretary shall submit to the Committee on Energy and Commerce of the House of Representatives and the Committee on Health, Education, Labor, and Pensions of the Senate a report describing circumstances in which the Secretary considered real world

evidence submitted to support postapproval studies required under this subsection that were completed after the date of enactment of the Food and Drug Amendments of 2022.

(d) REVIEW OF INCOMPLETE APPLICATIONS FOR APPROVAL OF A FAST TRACK PRODUCT.—

(1) IN GENERAL.—If the Secretary determines, after preliminary evaluation of clinical data submitted by the sponsor, that a fast track product may be effective, the Secretary shall evaluate for filing, and may commence review of portions of, an application for the approval of the product before the sponsor submits a complete application. The Secretary shall commence such review only if the applicant—

(A) provides a schedule for submission of information necessary to make the application complete; and

(B) pays any fee that may be required under section 736.

(2) EXCEPTION.—Any time period for review of human drug applications that has been agreed to by the Secretary and that has been set forth in goals identified in letters of the Secretary (relating to the use of fees collected under section 736 to expedite the drug development process and the review of human drug applications) shall not apply to an application submitted under paragraph (1) until the date on which the application is complete.

(e) CONSTRUCTION.—

(1) PURPOSE.—The amendments made by the Food and Drug Administration Safety and Innovation Act and the 21st Century Cures Act to this section are intended to encourage the Secretary to utilize innovative and flexible approaches to the assessment of products under accelerated approval for treatments for patients with serious or life-threatening diseases or conditions and unmet medical needs.

(2) CONSTRUCTION.—Nothing in this section shall be construed to alter the standards of evidence under subsection (c) or (d) of section 505 (including the substantial evidence standard in section 505(d)) of this Act or under section 351(a) of the Public Health Service Act. Such sections and standards of evidence apply to the review and approval of products under this section, including whether a product is safe and effective. Nothing in this section alters the ability of the Secretary to rely on evidence that does not come from adequate and well-controlled investigations for the purpose of determining whether an endpoint is reasonably likely to predict clinical benefit as described in subsection (b)(1)(B).

(f) AWARENESS EFFORTS.—The Secretary shall—

(1) develop and disseminate to physicians, patient organizations, pharmaceutical and biotechnology companies, and other appropriate persons a description of the provisions of this section applicable to breakthrough therapies, accelerated approval, and and fast track products; and

(2) establish a program to encourage the development of surrogate and clinical endpoints, including biomarkers, and other scientific methods and tools that can assist the Secretary in determining whether the evidence submitted in an application is reasonably likely to predict clinical benefit for serious or life-

threatening conditions for which significant unmet medical needs exist.

(g) REGENERATIVE ADVANCED THERAPY.—

(1) IN GENERAL.—The Secretary, at the request of the sponsor of a drug, shall facilitate an efficient development program for, and expedite review of, such drug if the drug qualifies as a regenerative advanced therapy under the criteria described in paragraph (2).

(2) CRITERIA.—A drug is eligible for designation as a regenerative advanced therapy under this subsection if—

(A) the drug is a regenerative medicine therapy (as defined in paragraph (8));

(B) the drug is intended to treat, modify, reverse, or cure a serious or life-threatening disease or condition; and

(C) preliminary clinical evidence indicates that the drug has the potential to address unmet medical needs for such a disease or condition.

(3) REQUEST FOR DESIGNATION.—The sponsor of a drug may request the Secretary to designate the drug as a regenerative advanced therapy concurrently with, or at any time after, submission of an application for the investigation of the drug under section 505(i) of this Act or section 351(a)(3) of the Public Health Service Act.

(4) DESIGNATION.—Not later than 60 calendar days after the receipt of a request under paragraph (3), the Secretary shall determine whether the drug that is the subject of the request meets the criteria described in paragraph (2). If the Secretary determines that the drug meets the criteria, the Secretary shall designate the drug as a regenerative advanced therapy and shall take such actions as are appropriate under paragraph (1). If the Secretary determines that a drug does not meet the criteria for such designation, the Secretary shall include with the determination a written description of the rationale for such determination.

(5) ACTIONS.—The sponsor of a regenerative advanced therapy shall be eligible for the actions to expedite development and review of such therapy under subsection (a)(3)(B), including early interactions to discuss any potential surrogate or intermediate endpoint to be used to support the accelerated approval of an application for the product under subsection (c).

(6) ACCESS TO EXPEDITED APPROVAL PATHWAYS.—An application for a regenerative advanced therapy under section 505(b)(1) of this Act or section 351(a) of the Public Health Service Act may be—

(A) eligible for priority review, as described in the Manual of Policies and Procedures of the Food and Drug Administration and goals identified in the letters described in section 101(b) of the Prescription Drug User Fee Amendments of 2012; and

(B) eligible for accelerated approval under subsection (c), as agreed upon pursuant to subsection (a)(3)(B), through, as appropriate—

(i) surrogate or intermediate endpoints reasonably likely to predict long-term clinical benefit; or

(ii) reliance upon data obtained from a meaningful number of sites, including through expansion to additional sites, as appropriate.

(7) POSTAPPROVAL REQUIREMENTS.—The sponsor of a regenerative advanced therapy that is granted accelerated approval and is subject to the postapproval requirements under subsection (c) may, as appropriate, fulfill such requirements, as the Secretary may require, through—

(A) the submission of clinical evidence, clinical studies, patient registries, or other sources of real world evidence, such as electronic health records;

(B) the collection of larger confirmatory data sets, as agreed upon pursuant to subsection (a)(3)(B); or

(C) postapproval monitoring of all patients treated with such therapy prior to approval of the therapy.

(8) DEFINITION.—For purposes of this section, the term "regenerative medicine therapy" includes cell therapy, therapeutic tissue engineering products, human cell and tissue products, and combination products using any such therapies or products, except for those regulated solely under section 361 of the Public Health Service Act and part 1271 of title 21, Code of Federal Regulations.

(h) LIMITED POPULATION PATHWAY FOR ANTIBACTERIAL AND ANTIFUNGAL DRUGS.—

(1) IN GENERAL.—The Secretary may approve an antibacterial or antifungal drug, alone or in combination with one or more other drugs, as a limited population drug pursuant to this subsection only if—

(A) the drug is intended to treat a serious or life-threatening infection in a limited population of patients with unmet needs;

(B) the standards for approval under section 505(c) and (d), or the standards for licensure under section 351 of the Public Health Service Act, as applicable, are met; and

(C) the Secretary receives a written request from the sponsor to approve the drug as a limited population drug pursuant to this subsection.

(2) BENEFIT-RISK CONSIDERATION.—The Secretary's determination of safety and effectiveness of an antibacterial or antifungal drug shall reflect the benefit-risk profile of such drug in the intended limited population, taking into account the severity, rarity, or prevalence of the infection the drug is intended to treat and the availability or lack of alternative treatment in such limited population. Such drug may be approved under this subsection notwithstanding a lack of evidence to fully establish a favorable benefit-risk profile in a population that is broader than the intended limited population.

(3) ADDITIONAL REQUIREMENTS.—A drug approved under this subsection shall be subject to the following requirements, in addition to any other applicable requirements of this Act:

(A) LABELING.—To indicate that the safety and effectiveness of a drug approved under this subsection has been demonstrated only with respect to a limited population—

(i) all labeling and advertising of an antibacterial or antifungal drug approved under this subsection shall

contain the statement "Limited Population" in a prominent manner and adjacent to, and not more prominent than—

(I) the proprietary name of such drug, if any; or

(II) if there is no proprietary name, the established name of the drug, if any, as defined in section 503(e)(3), or, in the case of a drug that is a biological product, the proper name, as defined by regulation; and

(ii) the prescribing information for the drug required by section 201.57 of title 21, Code of Federal Regulations (or any successor regulation) shall also include the following statement: "This drug is indicated for use in a limited and specific population of patients.".

(B) PROMOTIONAL MATERIAL.—The sponsor of an antibacterial or antifungal drug subject to this subsection shall submit to the Secretary copies of all promotional materials related to such drug at least 30 calendar days prior to dissemination of the materials.

(4) OTHER PROGRAMS.—A sponsor of a drug that seeks approval of a drug under this subsection may also seek designation or approval, as applicable, of such drug under other applicable sections or subsections of this Act or the Public Health Service Act.

(5) GUIDANCE.—Not later than 18 months after the date of enactment of the 21st Century Cures Act, the Secretary shall issue draft guidance describing criteria, processes, and other general considerations for demonstrating the safety and effectiveness of limited population antibacterial and antifungal drugs. The Secretary shall publish final guidance within 18 months of the close of the public comment period on such draft guidance. The Secretary may approve antibacterial and antifungal drugs under this subsection prior to issuing guidance under this paragraph.

(6) ADVICE.—The Secretary shall provide prompt advice to the sponsor of a drug for which the sponsor seeks approval under this subsection to enable the sponsor to plan a development program to obtain the necessary data for such approval, and to conduct any additional studies that would be required to gain approval of such drug for use in a broader population.

(7) TERMINATION OF LIMITATIONS.—If, after approval of a drug under this subsection, the Secretary approves a broader indication for such drug under section 505(b) or section 351(a) of the Public Health Service Act, the Secretary may remove any postmarketing conditions, including requirements with respect to labeling and review of promotional materials under paragraph (3), applicable to the approval of the drug under this subsection.

(8) RULES OF CONSTRUCTION.—Nothing in this subsection shall be construed to alter the authority of the Secretary to approve drugs pursuant to this Act or section 351 of the Public Health Service Act, including the standards of evidence and applicable conditions for approval under such Acts, the standards of approval of a drug under such Acts, or to alter the au-

thority of the Secretary to monitor drugs pursuant to such Acts.

(9) REPORTING AND ACCOUNTABILITY.—

(A) BIENNIAL REPORTING.—The Secretary shall report to Congress not less often than once every 2 years on the number of requests for approval, and the number of approvals, of an antibacterial or antifungal drug under this subsection.

(B) GAO REPORT.—Not later than December 2021, the Comptroller General of the United States shall submit to the Committee on Energy and Commerce of the House of Representatives and the Committee on Health, Education, Labor and Pensions of the Senate a report on the coordination of activities required under section 319E of the Public Health Service Act. Such report shall include a review of such activities, and the extent to which the use of the pathway established under this subsection has streamlined premarket approval for antibacterial or antifungal drugs for limited populations, if such pathway has functioned as intended, if such pathway has helped provide for safe and effective treatment for patients, if such premarket approval would be appropriate for other categories of drugs, and if the authorities under this subsection have affected antibacterial or antifungal resistance.

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SEC. 506B. REPORTS OF POSTMARKETING STUDIES.

(a) SUBMISSION.—

(1) IN GENERAL.—A sponsor of a drug that has entered into an agreement with the Secretary to conduct a postmarketing study of a drug shall submit to the Secretary, within 1 year after the approval of such drug and annually thereafter until the study is completed or terminated, a report of the progress of the study or the reasons for the failure of the sponsor to conduct the study. The report shall be submitted in such form as is prescribed by the Secretary in regulations issued by the Secretary.

(2) ACCELERATED APPROVAL.—Notwithstanding paragraph (1), a sponsor of a drug approved under accelerated approval shall submit to the Secretary a report of the progress of any study required under section 506(c), including progress toward enrollment targets, milestones, and other information as required by the Secretary, not later than 180 days after the approval of such drug and not less frequently than every 180 days thereafter, until the study is completed or terminated.

[(2)**]** *(3)* AGREEMENTS PRIOR TO EFFECTIVE DATE.—Any agreement entered into between the Secretary and a sponsor of a drug, prior to the date of enactment of the Food and Drug Administration Modernization Act of 1997, to conduct a postmarketing study of a drug shall be subject to the requirements of paragraph (1). An initial report for such an agreement shall be submitted within 6 months after the date of the issuance of the regulations under paragraph (1).

(b) CONSIDERATION OF INFORMATION AS PUBLIC INFORMATION.—Any information pertaining to a report described in subsection (a)

shall be considered to be public information to the extent that the information is necessary—

(1) to identify the sponsor; and

(2) to establish the status of a study described in subsection (a) and the reasons, if any, for any failure to carry out the study.

(c) STATUS OF STUDIES AND REPORTS.—The Secretary shall annually develop and publish in the Federal Register a report that provides information on the status of the postmarketing studies—

(1) that sponsors have entered into agreements to conduct; and

(2) for which reports have been submitted under subsection (a)(1).

(d) DISCLOSURE.—If a sponsor fails to complete an agreed upon study required by this section by its original or otherwise negotiated deadline, the Secretary shall publish a statement on the Internet site of the Food and Drug Administration stating that the study was not completed and, if the reasons for such failure to complete the study were not satisfactory to the Secretary, a statement that such reasons were not satisfactory to the Secretary.

(e) NOTIFICATION.—With respect to studies of the type required under section 506(c)(2)(A) or under section 314.510 or 601.41 of title 21, Code of Federal Regulations, as each of such sections was in effect on the day before the effective date of this subsection, the Secretary may require that a sponsor who, for reasons not satisfactory to the Secretary, fails to complete by its deadline a study under any of such sections of such type for a drug or biological product (including such a study conducted after such effective date) notify practitioners who prescribe such drug or biological product of the failure to complete such study and the questions of clinical benefit, and, where appropriate, questions of safety, that remain unanswered as a result of the failure to complete such study. Nothing in this subsection shall be construed as altering the requirements of the types of studies required under section 506(c)(2)(A) or under section 314.510 or 601.41 of title 21, Code of Federal Regulations, as so in effect, or as prohibiting the Secretary from modifying such sections of title 21 of such Code to provide for studies in addition to those of such type.

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SEC. 506C–1. ANNUAL REPORTING ON DRUG SHORTAGES.

(a) ANNUAL REPORTS TO CONGRESS.—Not later than March 31 of each calendar year, the Secretary shall submit to the Committee on Energy and Commerce of the House of Representatives and the Committee on Health, Education, Labor, and Pensions of the Senate a report, with respect to the preceding calendar year, on drug shortages that—

(1) specifies the number of manufacturers that submitted a notification to the Secretary under section 506C(a) during such calendar year;

[(2) describes the communication between the field investigators of the Food and Drug Administration and the staff of the Center for Drug Evaluation and Research's Office of Compliance and Drug Shortage Program, including the Food and

Drug Administration's procedures for enabling and ensuring such communication;]

(2)(A) describes the communication between the field investigators of the Food and Drug Administration and the staff of the Center for Drug Evaluation and Research's Office of Compliance and Drug Shortage Program, including the Food and Drug Administration's procedures for enabling and ensuring such communication;

(B) provides the number of reports described in section 704(b)(2) that were required to be sent to the appropriate offices of the Food and Drug Administration and the number of such reports that were sent; and

(C) describes the coordination and alignment activities undertaken pursuant to section 506D(g);

(3)(A) lists the major actions taken by the Secretary to prevent or mitigate the drug shortages described in paragraph (7);

(B) in the list under subparagraph (A), includes—

(i) the number of applications and supplements for which the Secretary expedited review under section 506C(g)(1) during such calendar year; and

(ii) the number of establishment inspections or reinspections that the Secretary expedited under section 506C(g)(2) during such calendar year;

(4) describes the coordination between the Food and Drug Administration and the Drug Enforcement Administration on efforts to prevent or alleviate drug shortages;

(5) identifies the number of and describes the instances in which the Food and Drug Administration exercised regulatory flexibility and discretion to prevent or alleviate a drug shortage;

(6) lists the names of manufacturers that were issued letters under section 506C(f); and

(7) specifies the number of drug shortages occurring during such calendar year, as identified by the Secretary.

(b) TREND ANALYSIS.—The Secretary is authorized to retain a third party to conduct a study, if the Secretary believes such a study would help clarify the causes, trends, or solutions related to drug shortages.

(c) DEFINITION.—In this section, the term "drug shortage" or "shortage" has the meaning given such term in section 506C.

SEC. 506D. COORDINATION; TASK FORCE AND STRATEGIC PLAN.

(a) TASK FORCE AND STRATEGIC PLAN.—

(1) IN GENERAL.—

(A) TASK FORCE.—As soon as practicable after the date of enactment of the Food and Drug Administration Safety and Innovation Act, the Secretary shall establish a task force to develop and implement a strategic plan for enhancing the Secretary's response to preventing and mitigating drug shortages.

(B) STRATEGIC PLAN.—The strategic plan described in subparagraph (A) shall include—

(i) plans for enhanced interagency and intra-agency coordination, communication, and decisionmaking;

(ii) plans for ensuring that drug shortages are considered when the Secretary initiates a regulatory ac-

tion that could precipitate a drug shortage or exacerbate an existing drug shortage;

(iii) plans for effective communication with outside stakeholders, including who the Secretary should alert about potential or actual drug shortages, how the communication should occur, and what types of information should be shared;

(iv) plans for considering the impact of drug shortages on research and clinical trials; and

(v) an examination of whether to establish a "qualified manufacturing partner program", as described in subparagraph (C).

(C) DESCRIPTION OF PROGRAM.—In conducting the examination of a "qualified manufacturing partner program" under subparagraph (B)(v), the Secretary—

(i) shall take into account that—

(I) a "qualified manufacturer", for purposes of such program, would need to have the capability and capacity to supply products determined or anticipated to be in shortage; and

(II) in examining the capability and capacity to supply products in shortage, the "qualified manufacturer" could have a site that manufactures a drug listed under section 506E or have the capacity to produce drugs in response to a shortage within a rapid timeframe; and

(ii) shall examine whether incentives are necessary to encourage the participation of "qualified manufacturers" in such a program.

(D) CONSULTATION.—In carrying out this paragraph, the task force shall ensure consultation with the appropriate offices within the Food and Drug Administration, including the Office of the Commissioner, the Center for Drug Evaluation and Research, the Office of Regulatory Affairs, and employees within the Department of Health and Human Services with expertise regarding drug shortages. The Secretary shall engage external stakeholders and experts as appropriate.

(2) TIMING.—Not later than 1 year after the date of enactment of the Food and Drug Administration Safety and Innovation Act, the task force shall—

(A) publish the strategic plan described in paragraph (1); and

(B) submit such plan to Congress.

(b) COMMUNICATION.—The Secretary shall ensure that, prior to any enforcement action or issuance of a warning letter that the Secretary determines could reasonably be anticipated to lead to a meaningful disruption in the supply in the United States of a drug described under section 506C(a), there is communication with the appropriate office of the Food and Drug Administration with expertise regarding drug shortages regarding whether the action or letter could cause, or exacerbate, a shortage of the drug.

(c) ACTION.—If the Secretary determines, after the communication described in subsection (b), that an enforcement action or a warning letter could reasonably cause or exacerbate a shortage of

a drug described under section 506C(a), then the Secretary shall evaluate the risks associated with the impact of such shortage upon patients and those risks associated with the violation involved before taking such action or issuing such letter, unless there is imminent risk of serious adverse health consequences or death to humans.

(d) REPORTING BY OTHER ENTITIES.—The Secretary shall identify or establish a mechanism by which health care providers and other third-party organizations may report to the Secretary evidence of a drug shortage.

(e) REVIEW AND CONSTRUCTION.—No determination, finding, action, or omission of the Secretary under this section shall—

(1) be subject to judicial review; or

(2) be construed to establish a defense to an enforcement action by the Secretary.

(f) SUNSET.—Subsections (a), (b), (c), and (e) shall cease to be effective on the date that is 5 years after the date of enactment of the Food and Drug Administration Safety and Innovation Act.

(g) COORDINATION.—The Secretary shall ensure timely and effective internal coordination and alignment among the field investigators of the Food and Drug Administration and the staff of the Center for Drug Evaluation and Research's Office of Compliance and Drug Shortage Program regarding—

(1) the reviews of reports shared pursuant to section 704(b)(2); and

(2) any feedback or corrective or preventive actions in response to such reports.

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SEC. 506I. PROMPT REPORTS OF MARKETING STATUS.

(a) NOTIFICATION OF WITHDRAWAL.—**[**The holder of an application approved under subsection (c) or (j) of section 505**]** *The holder of an application approved under subsection (c) or (j) of section 505 of this Act or subsection (a) or (k) of section 351 of the Public Health Service Act* shall notify the Secretary in writing 180 days prior to withdrawing the approved drug from sale, or if 180 days is not practicable as soon as practicable but not later than the date of withdrawal. The holder shall include with such notice the—

(1) National Drug Code;

(2) identity of the drug by **[**established name**]** *established name (for biological products, by proper name)* and by proprietary name, if any;

(3) new drug application number **[**or abbreviated application number**]***, abbreviated application number, or biologics license application number*;

(4) strength of the drug;

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

(6) reason for withdrawal of the drug.

(b) NOTIFICATION OF DRUG NOT AVAILABLE FOR SALE.—**[**The holder of an application approved under subsection (c) or (j)**]** *The holder of an application approved under subsection (c) or (j) of section 505 of this Act or subsection (a) or (k) of section 351 of the Public Health Service Act* shall notify the Secretary in writing within 180 calendar days of the date of approval of the drug if the drug

will not be available for sale within 180 calendar days of such date of approval. The holder shall include with such notice the—

(1) identity of the drug by [established name] *established name (for biological products, by proper name)* and by proprietary name, if any;

(2) new drug application number [or abbreviated application number], *abbreviated application number, or biologics license application number*;

(3) strength of the drug;

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

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

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

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

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

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

(c) ADDITIONAL ONE-TIME REPORT.—Within 180 days of the date of enactment of the Food and Drug Amendments of 2022, all holders of applications approved under subsection (a) or (k) of section 351 of the Public Health Service Act shall review the information in the list published under section 351(k)(9)(A) and shall submit a written notice to the Secretary—

(1) stating that all of the application holder's biological products in the list published under section 351(k)(9)(A) that are not listed as discontinued are available for sale; or

(2) including the information required pursuant to subsection (a) or (b), as applicable, for each of the application holder's biological products that are in the list published under section 351(k)(9)(A) and not listed as discontinued, but have been discontinued from sale or never have been available for sale.

(d) FAILURE TO MEET REQUIREMENTS.—If a holder of an approved application fails to submit the information required under subsection (a), (b), or (c), the Secretary may—

(1) move the application holder's drugs from the active section of the list published under section 505(j)(7)(A) to the discontinued section of the list, except that the Secretary shall remove from the list in accordance with section 505(j)(7)(C) drugs the

Secretary determines have been withdrawn from sale for reasons of safety or effectiveness; and

(2) identify the application holder's biological products as discontinued in the list published under section 351(k)(9)(A) of the Public Health Service Act, except that the Secretary shall remove from the list in accordance with section 351(k)(9)(B) of such Act biological products for which the license has been revoked or suspended for reasons of safety, purity, or potency.

(e) UPDATES.—The Secretary shall update the list published under ⟦subsection 505(j)(7)(A)⟧ *section 505(j)(7)(A)* based on the information provided under subsections (a), (b), and (c) by moving drugs that are not available for sale from the active section to the discontinued section of the list, except that drugs the Secretary determines have been withdrawn from sale for reasons of safety or effectiveness shall be removed from the list in accordance with ⟦subsection 505(j)(7)(C)⟧ *section 505(j)(7)(C). The Secretary shall update the list published under section 351(k)(9)(A) of the Public Health Service Act based on information provided under subsections (a), (b), and (c) by identifying as discontinued biological products that are not available for sale, except that biological products for which the license has been revoked or suspended for safety, purity, or potency reasons shall be removed from the list in accordance with section 351(k)(9)(B) of the Public Health Service Act.* The Secretary shall make ⟦monthly updates to the list⟧ *monthly updates to the lists referred to in the preceding sentences* based on the information provided pursuant to subsections (a) and (b), ⟦and shall update the list based on⟧ *and shall update such lists based on* the information provided under subsection (c) as soon as practicable.

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

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SEC. 506K. ADVANCED MANUFACTURING TECHNOLOGIES DESIGNATION PILOT PROGRAM.

(a) IN GENERAL.—Not later than 1 year after the date of enactment of this section, the Secretary shall initiate a pilot program under which persons may request designation of an advanced manufacturing technology as described in subsection (b).

(b) DESIGNATION PROCESS.—The Secretary shall establish a process for the designation under this section of methods of manufacturing drugs, including biological products, and active pharmaceutical ingredients of such drugs, as advanced manufacturing technologies. A method of manufacturing, or a combination of manufacturing methods, is eligible for designation as an advanced manufacturing technology if such method or combination of methods incorporates a novel technology, or uses an established technique or technology in a novel way, that will substantially improve the manufacturing process for a drug and maintain equivalent or provide superior drug quality, including by—

(1) reducing development time for a drug using the designated manufacturing method; or

(2) increasing or maintaining the supply of—

(A) a drug that is described in section 506C(a) and is intended to treat a serious or life-threatening condition; or

(B) a drug that is on the drug shortage list under section 506E.

(c) EVALUATION AND DESIGNATION OF AN ADVANCED MANUFACTURING TECHNOLOGY.—

(1) SUBMISSION.—A person who requests designation of a method of manufacturing as an advanced manufacturing technology under this section shall submit to the Secretary data or information demonstrating that the method of manufacturing meets the criteria described in subsection (b) in a particular context of use. The Secretary may facilitate the development and review of such data or information by—

(A) providing timely advice to, and interactive communication with, such person regarding the development of the method of manufacturing; and

(B) involving senior managers and experienced staff of the Food and Drug Administration, as appropriate, in a collaborative, cross-disciplinary review of the method of manufacturing, as applicable.

(2) EVALUATION AND DESIGNATION.—Not later than 180 calendar days after the receipt of a request under paragraph (1), the Secretary shall determine whether to designate such method of manufacturing as an advanced manufacturing technology, in a particular context of use, based on the data and information submitted under paragraph (1) and the criteria described in subsection (b).

(d) REVIEW OF ADVANCED MANUFACTURING TECHNOLOGIES.—If the Secretary designates a method of manufacturing as an advanced manufacturing technology, the Secretary shall—

(1) expedite the development and review of an application submitted under section 505 of this Act or section 351 of the Public Health Service Act, including supplemental applications, for drugs that are manufactured using a designated advanced manufacturing technology and could help mitigate or prevent a shortage or substantially improve manufacturing processes for a drug and maintain equivalent or provide superior drug quality, as described in subsection (b); and

(2) allow the holder of an advanced technology designation, or a person authorized by the advanced manufacturing technology designation holder, to reference or rely upon, in an application submitted under section 505 of this Act or section 351 of the Public Health Service Act, including a supplemental application, data and information about the designated advanced manufacturing technology for use in manufacturing drugs in the same context of use for which the designation was granted.

(e) IMPLEMENTATION AND EVALUATION OF ADVANCED MANUFACTURING TECHNOLOGIES PILOT.—

(1) PUBLIC MEETING.—The Secretary shall publish in the Federal Register a notice of a public meeting, to be held not later than 180 days after the date of enactment of this section, to discuss and obtain input and recommendations from relevant stakeholders regarding—

(A) the goals and scope of the pilot program, and a suitable framework, procedures, and requirements for such program; and

(B) ways in which the Food and Drug Administration will support the use of advanced manufacturing technologies and other innovative manufacturing approaches for drugs.

(2) PILOT PROGRAM GUIDANCE.—

(A) IN GENERAL.—The Secretary shall—

(i) not later than 180 days after the public meeting under paragraph (1), issue draft guidance regarding the goals and implementation of the pilot program under this section; and

(ii) not later than 2 years after the date of enactment of this section, issue final guidance regarding the implementation of such program.

(B) CONTENT.—The guidance described in subparagraph (A) shall address—

(i) the process by which a person may request a designation under subsection (b);

(ii) the data and information that a person requesting such a designation is required to submit under subsection (c), and how the Secretary intends to evaluate such submissions;

(iii) the process to expedite the development and review of applications under subsection (d); and

(iv) the criteria described in subsection (b) for eligibility for such a designation.

(3) REPORT.—Not later than 3 years after the date of enactment of this section and annually thereafter, the Secretary shall publish on the website of the Food and Drug Administration and submit to the Committee on Health, Education, Labor, and Pensions of the Senate and the Committee on Energy and Commerce of the House of Representatives a report containing a description and evaluation of the pilot program being conducted under this section, including the types of innovative manufacturing approaches supported under the program. Such report shall include the following:

(A) The number of persons that have requested designations and that have been granted designations.

(B) The number of methods of manufacturing that have been the subject of designation requests and that have been granted designations.

(C) The average number of calendar days for completion of evaluations under subsection (c)(2).

(D) An analysis of the factors in data submissions that are relevant to determinations to designate and not to designate after evaluation under subsection (c)(2).

(E) The number of applications received under section 505 of this Act or section 351 of the Public Health Service Act, including supplemental applications, that have included an advanced manufacturing technology designated under this section, and the number of such applications approved.

(f) SUNSET.—The Secretary—

(1) may not consider any requests for designation submitted under subsection (c) after October 1, 2029; and

(2) may continue all activities under this section with respect to advanced manufacturing technologies that were designated pursuant to subsection (d) prior to such date, if the Secretary determines such activities are in the interest of the public health.

* * * * * * *

SEC. 510. (a) As used in this section—

(1) the term "manufacture, preparation, propagation, compounding, or processing" shall include repackaging or otherwise changing the container, wrapper, or labeling of any drug package or device package in furtherance of the distribution of the drug or device from the original place of manufacture to the person who makes final delivery or sale to the ultimate consumer or user; and

(2) the term "name" shall include in the case of a partnership the name of each partner and, in the case of a corporation, the name of each corporate officer and director, and the State of incorporation.

(b)(1) During the period beginning on October 1 and ending on December 31 of each year, every person who owns or operates any establishment in any State engaged in the manufacture, preparation, propagation, compounding, or processing of a drug or drugs shall register with the Secretary the name of such person, places of business of such person, all such establishments, the unique facility identifier of each such establishment, and a point of contact e-mail address.

(2) During the period beginning on October 1 and ending on December 31 of each year, every person who owns or operates any establishment in any State engaged in the manufacture, preparation, propagation, compounding, or processing of a device or devices shall register with the Secretary his name, places of business, and all such establishments.

(3) The Secretary shall specify the unique facility identifier system that shall be used by registrants under paragraph (1). The requirement to include a unique facility identifier in a registration under paragraph (1) shall not apply until the date that the identifier system is specified by the Secretary under the preceding sentence.

(c) Every person upon first engaging in the manufacture, preparation, propagation, compounding, or processing of a drug or drugs or a device or devices in any establishment which he owns or operates in any State shall immediately register with the Secretary—

(1) with respect to drugs, the information described under subsection (b)(1); and

(2) with respect to devices, the information described under subsection (b)(2)..

(d) Every person duly registered in accordance with the foregoing subsections of this section shall immediately register with the Secretary any additional establishment which he owns or operates in any State and in which he begins the manufacture, preparation, propagation, compounding, or processing of a drug or drugs or a device or devices.

(e) The Secretary may assign a registration number to any person or any establishment registered in accordance with this section. The Secretary may also assign a listing number to each drug or class of drugs listed under subsection (j). Any number assigned pursuant to the preceding sentence shall be the same as that assigned pursuant to the National Drug Code. The Secretary may by regulation prescribe a uniform system for the identification of devices intended for human use and may require that persons who are required to list such devices pursuant to subsection (j) shall list such devices in accordance with such system.

(f) The Secretary shall make available for inspection, to any person so requesting, any registration filed pursuant to this section; except that any list submitted pursuant to paragraph (3) of subsection (j) and the information accompanying any list or notice filed under paragraph (1) or (2) of that subsection shall be exempt from such inspection unless the Secretary finds that such an exemption would be inconsistent with protection of the public health.

(g) The foregoing subsections of this section shall not apply to—

(1) pharmacies which maintain establishments in conformance with any applicable local laws regulating the practice of pharmacy and medicine and which are regularly engaged in dispensing prescription drugs or devices, upon prescriptions of practitioners licensed to administer such drugs or devices to patients under the care of such practitioners in the course of their professional practice, and which do not manufacture, prepare, propagate, compound, or process drugs or devices for sale other than in the regular course of their business of dispensing or selling drugs or devices at retail;

(2) practitioners licensed by law to prescribe or administer drugs or devices and who manufacture, prepare, propagate, compound, or process drugs or devices solely for use in the course of their professional practice;

(3) persons who manufacture, prepare, propagate, compound, or process drugs or devices solely for use in research, teaching, or chemical analysis and not for sale;

(4) any distributor who acts as a wholesale distributor of devices, and who does not manufacture, repackage, process, or relabel a device; or

(5) such other classes of persons as the Secretary may by regulation exempt from the application of this section upon a finding that registration by such classes of persons in accordance with this section is not necessary for the protection of the public health.

In this subsection, the term "wholesale distributor" means any person (other than the manufacturer or the initial importer) who distributes a device from the original place of manufacture to the person who makes the final delivery or sale of the device to the ultimate consumer or user.

(h) INSPECTIONS.—

(1) IN GENERAL.—Every establishment that is required to be registered with the Secretary under this section shall be subject to inspection pursuant to section 704.

(2) RISK-BASED SCHEDULE FOR DEVICES.—

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

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

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

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

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

(3) RISK-BASED SCHEDULE FOR DRUGS.—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, preparation, propagation, compounding, or processing of a drug or drugs (referred to in this subsection as "drug establishments") in accordance with a risk-based schedule established by the Secretary.

(4) RISK FACTORS.—In establishing a risk-based schedule under paragraph (2) or (3), the Secretary shall inspect establishments according to the known safety risks of such establishments, which shall be based on the following factors:

(A) The compliance history of the establishment.

(B) The record, history, and nature of recalls linked to the establishment.

(C) The inherent risk of the drug or device manufactured, prepared, propagated, compounded, or processed at the establishment.

(D) The inspection frequency and history of the establishment, including whether the establishment has been inspected pursuant to section 704 within the last 4 years.

(E) Whether the establishment has been inspected by a foreign government or an agency of a foreign government recognized under section 809.

(F) The compliance history of establishments in the country or region in which the establishment is located that are subject to regulation under this Act, including the history of violations related to products exported from such country or region that are subject to such regulation.

[(F)**]** *(G)* Any other criteria deemed necessary and appropriate by the Secretary for purposes of allocating inspection resources.

(5) EFFECT OF STATUS.—In determining the risk associated with an establishment for purposes of establishing a risk-based schedule under paragraph (3), the Secretary shall not consider whether the drugs manufactured, prepared, propagated, compounded, or processed by such establishment are drugs described in section 503(b).

(6) ANNUAL REPORT ON INSPECTIONS OF ESTABLISHMENTS.—Beginning in 2014, not later than May 1 of each year, the Sec-

retary shall make available on the Internet Web site of the Food and Drug Administration a report regarding—

(A)(i) the number of domestic and foreign establishments registered pursuant to this section in the previous calendar year; and

(ii) the number of such domestic establishments and the number of such foreign establishments that the Secretary inspected in the previous calendar year;

(B) with respect to establishments that manufacture, prepare, propagate, compound, or process an active ingredient of a drug or a finished drug product, the number of each such type of establishment; and

(C) the percentage of the budget of the Food and Drug Administration used to fund the inspections described under subparagraph (A).

(i)(1) Every person who owns or operates any establishment within any foreign country engaged in the manufacture, preparation, propagation, compounding, or processing of a drug or device that is imported or offered for import into the United States shall, through electronic means in accordance with the criteria of the Secretary—

(A) upon first engaging in any such activity, immediately submit a registration to the Secretary that includes—

(i) with respect to drugs, the name and place of business of such person, all such establishments, the unique facility identifier of each such establishment, a point of contact e-mail address, the name of the United States agent of each such establishment, the name of each importer of such drug in the United States that is known to the establishment, and the name of each person who imports or offers for import such drug to the United States for purposes of importation; and

(ii) with respect to devices, the name and place of business of the establishment, the name of the United States agent for the establishment, the name of each importer of such device in the United States that is known to the establishment, and the name of each person who imports or offers for import such device to the United States for purposes of importation; and

(B) each establishment subject to the requirements of subparagraph (A) shall thereafter register with the Secretary during the period beginning on October 1 and ending on December 31 of each year.

(2) The establishment shall also provide the information required by subsection (j).

(3) The Secretary is authorized to enter into cooperative arrangements with officials of foreign countries to ensure that adequate and effective means are available for purposes of determining, from time to time, whether drugs or devices manufactured, prepared, propagated, compounded, or processed by an establishment described in paragraph (1), if imported or offered for import into the United States, shall be refused admission on any of the grounds set forth in section 801(a).

(4) The Secretary shall specify the unique facility identifier system that shall be used by registrants under paragraph (1) with re-

spect to drugs. The requirement to include a unique facility identifier in a registration under paragraph (1) with respect to drugs shall not apply until the date that the identifier system is specified by the Secretary under the preceding sentence.

(j)(1) Every person who registers with the Secretary under subsection (b), (c), (d), or (i) shall, at the time of registration under any such subsection, file with the Secretary a list of all drugs and a list of all devices and a brief statement of the basis for believing that each device included in the list is a device rather than a drug (with each drug and device in each list listed by its established name (as defined in section 502(e)) and by any proprietary name) which are being manufactured, prepared, propagated, compounded, or processed by him for commercial distribution and which he has not included in any list of drugs or devices filed by him with the Secretary under this paragraph or paragraph (2) before such time of registration. Such list shall be prepared in such form and manner as the Secretary may prescribe and shall be accompanied by—

(A) in the case of a drug contained in the applicable list and subject to section 505 or 512, or a device intended for human use contained in the applicable list with respect to which a performance standard has been established under section 514 or which is subject to section 515, a reference to the authority for the marketing of such drug or device and a copy of all labeling for such drug or device;

(B) in the case of any other drug or device contained in an applicable list—

(i) which drug is subject to section 503(b)(1), or which device is a restricted device, a copy of all labeling for such drug or device, a representative sampling of advertisements for such drug or device, and, upon request made by the Secretary for good cause, a copy of all advertisements for a particular drug product or device, or

(ii) which drug is not subject to section 503(b)(1) or which device is not a restricted device, the label and package insert for such drug or device and a representative sampling of any other labeling for such drug or device;

(C) in the case of any drug contained in an applicable list which is described in subparagraph (B), a quantitative listing of its active ingredient or ingredients, except that with respect to a particular drug product the Secretary may require the submission of a quantitative listing of all ingredients if he finds that such submission is necessary to carry out the purposes of this Act;

(D) if the registrant filing a list has determined that a particular drug product or device contained in such list is not subject to section 505 or 512, or the particular device contained in such list is not subject to a performance standard established under section 514 or to section 515 or is not a restricted device, a brief statement of the basis upon which the registrant made such determination if the Secretary requests such a statement with respect to that particular drug product or device; and

(E) in the case of a drug contained in the applicable list, the name and place of business of each manufacturer of an excipient of the listed drug with which the person listing the drug conducts business, including all establishments used in the

production of such excipient, the unique facility identifier of each such establishment, and a point of contact e-mail address for each such excipient manufacturer.

(2) Each person who registers with the Secretary under this section shall report to the Secretary, with regard to drugs once during the month of June of each year and once during the month of December of each year, and with regard to devices once each year during the period beginning on October 1 and ending on December 31, the following information:

(A) A list of each drug or device introduced by the registrant for commercial distribution which has not been included in any list previously filed by him with the Secretary under this subparagraph or paragraph (1) of this subsection. A list under this subparagraph shall list a drug or device by its established name (as defined in section 502(e)) and by any proprietary name it may have and shall be accompanied by the other information required by paragraph (1).

(B) If since the date the registrant last made a report under this paragraph (or if he has not made a report under this paragraph, since the effective date of this subsection) he has discontinued the manufacture, preparation, propagation, compounding, or processing for commercial distribution of a drug or device included in a list filed by him under subparagraph (A) or paragraph (1); notice of such discontinuance, the date of such discontinuance, and the identity (by established name (as defined in section 502(e)) and by any proprietary name) of such drug or device.

(C) If since the date the registrant reported pursuant to subparagraph (B) a notice of discontinuance he has resumed the manufacture, preparation, propagation, compounding, or processing for commercial distribution of the drug or device with respect to which such notice of discontinuance was reported; notice of such resumption, the date of such resumption, the identity of such drug or device (by established name (as defined in section 502(e)) and by any proprietary name), and the other information required by paragraph (1), unless the registrant has previously reported such resumption to the Secretary pursuant to this subparagraph.

(D) Any material change in any information previously submitted pursuant to this paragraph or paragraph (1).

(3)(A) Each person who registers with the Secretary under this section with regard to a drug shall report annually to the Secretary on the amount of each drug listed under paragraph (1) that was manufactured, prepared, propagated, compounded, or processed by such person for commercial distribution. Such information may be required to be submitted in an electronic format as determined by the Secretary. The Secretary may require that information required to be reported under this paragraph be submitted at the time a public health emergency is declared by the Secretary under section 319 of the Public Health Service Act.

(B) By order of the Secretary, certain biological products or categories of biological products regulated under section 351 of the Public Health Service Act may be exempt from some or all of the reporting requirements under subparagraph (A), if the

Secretary determines that applying such reporting requirements to such biological products or categories of biological products is not necessary to protect the public health.

(4) The Secretary may also require each registrant under this section to submit a list of each drug product which (A) the registrant is manufacturing, preparing, propagating, compounding, or processing for commercial distribution, and (B) contains a particular ingredient. The Secretary may not require the submission of such a list unless he has made a finding that the submission of such a list is necessary to carry out the purposes of this Act.

(5) The Secretary shall require persons subject to this subsection to use, for purposes of this subsection, the unique facility identifier systems specified under subsections (b)(3) and (i)(4) with respect to drugs. Such requirement shall not apply until the date that the identifier system under subsection (b)(3) or (i)(4), as applicable, is specified by the Secretary.

(k) Each person who is required to register under this section and who proposes to begin the introduction or delivery for introduction into interstate commerce for commercial distribution of a device intended for human use shall, at least ninety days before making such introduction or delivery, report to the Secretary or person who is accredited under section 523(a) (in such form and manner as the Secretary shall by regulation prescribe)—

(1) the class in which the device is classified under section 513 or if such person determines that the device is not classified under such section, a statement of that determination and the basis for such person's determination that the device is or is not so classified, and

(2) action taken by such person to comply with requirements under section 514 or 515 which are applicable to the device.

A notification submitted under this subsection that contains clinical trial data for an applicable device clinical trial (as defined in section 402(j)(1) of the Public Health Service Act) shall be accompanied by the certification required under section 402(j)(5)(B) of such Act. Such certification shall not be considered an element of such notification.

(l)(1) A report under subsection (k) is not required for a device intended for human use that is exempted from the requirements of this subsection under subsection (m) or is within a type that has been classified into class I under section 513. The exception established in the preceding sentence does not apply to any class I device that is intended for a use which is of substantial importance in preventing impairment of human health, or to any class I device that presents a potential unreasonable risk of illness or injury.

(2) Not later than 120 calendar days after the date of enactment of the 21st Century Cures Act and at least once every 5 years thereafter, as the Secretary determines appropriate, the Secretary shall identify, through publication in the Federal Register, any type of class I device that the Secretary determines no longer requires a report under subsection (k) to provide reasonable assurance of safety and effectiveness. Upon such publication—

(A) each type of class I device so identified shall be exempt from the requirement for a report under subsection (k); and

(B) the classification regulation applicable to each such type of device shall be deemed amended to incorporate such exemption.

(m)(1) The Secretary shall—

(A) not later than 90 days after the date of enactment of the 21st Century Cures Act and at least once every 5 years thereafter, as the Secretary determines appropriate—

(i) publish in the Federal Register a notice that contains a list of each type of class II device that the Secretary determines no longer requires a report under subsection (k) to provide reasonable assurance of safety and effectiveness; and

(ii) provide for a period of not less than 60 calendar days for public comment beginning on the date of the publication of such notice; and

(B) not later than 210 calendar days after the date of enactment of the 21st Century Cures Act, publish in the Federal Register a list representing the Secretary's final determination with respect to the devices contained in the list published under subparagraph (A).

(2) Beginning on the date that is 1 calendar day after the date of publication of the final list under paragraph (1)(B), the Secretary may exempt a class II device from the requirement to submit a report under subsection (k), upon the Secretary's own initiative or a petition of an interested person, if the Secretary determines that such report is not necessary to assure the safety and effectiveness of the device. The Secretary shall publish in the Federal Register notice of the intent of the Secretary to exempt the device, or of the petition, and provide a 60-calendar-day period for public comment. Within 120 days after the issuance of the notice in the Federal Register, the Secretary shall publish an order in the Federal Register that sets forth the final determination of the Secretary regarding the exemption of the device that was the subject of the notice. If the Secretary fails to respond to a petition within 180 days of receiving it, the petition shall be deemed to be granted.

(3) Upon the publication of the final list under paragraph (1)(B)—

(A) each type of class II device so listed shall be exempt from the requirement for a report under subsection (k); and

(B) the classification regulation applicable to each such type of device shall be deemed amended to incorporate such exemption.

(n)(1) The Secretary shall review the report required in subsection (k) and make a determination under section 513(f)(1) not later than 90 days after receiving the report.

(2)(A) Not later than 18 months after the date of enactment of this paragraph, the Secretary shall submit to the Committee on Energy and Commerce of the House of Representatives and the Committee on Health, Education, Labor, and Pensions of the Senate a report regarding when a premarket notification under subsection (k) should be submitted for a modification or change to a legally marketed device. The report shall include the Secretary's interpretation of the following terms: "could significantly affect the safety or effectiveness of the device", "a significant change or modification in design, material, chemical

composition, energy source, or manufacturing process", and "major change or modification in the intended use of the device". The report also shall discuss possible processes for industry to use to determine whether a new submission under subsection (k) is required and shall analyze how to leverage existing quality system requirements to reduce premarket burden, facilitate continual device improvement, and provide reasonable assurance of safety and effectiveness of modified devices. In developing such report, the Secretary shall consider the input of interested stakeholders.

(B) The Secretary shall withdraw the Food and Drug Administration draft guidance entitled "Guidance for Industry and FDA Staff—510(k) Device Modifications: Deciding When to Submit a 510(k) for a Change to an Existing Device", dated July 27, 2011, and shall not use this draft guidance as part of, or for the basis of, any premarket review or any compliance or enforcement decisions or actions. The Secretary shall not issue—

(i) any draft guidance or proposed regulation that addresses when to submit a premarket notification submission for changes and modifications made to a manufacturer's previously cleared device before the receipt by the Committee on Energy and Commerce of the House of Representatives and the Committee on Health, Education, Labor, and Pensions of the Senate of the report required in subparagraph (A); and

(ii) any final guidance or regulation on that topic for one year after date of receipt of such report by the Committee on Energy and Commerce of the House of Representatives and the Committee on Health, Education, Labor, and Pensions of the Senate.

(C) The Food and Drug Administration guidance entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device", dated January 10, 1997, shall be in effect until the subsequent issuance of guidance or promulgation, if appropriate, of a regulation described in subparagraph (B), and the Secretary shall interpret such guidance in a manner that is consistent with the manner in which the Secretary has interpreted such guidance since 1997.

(o)(1) With respect to reprocessed single-use devices for which reports are required under subsection (k):

(A) The Secretary shall identify such devices or types of devices for which reports under such subsection must, in order to ensure that the device is substantially equivalent to a predicate device, include validation data, the types of which shall be specified by the Secretary, regarding cleaning and sterilization, and functional performance demonstrating that the single-use device will remain substantially equivalent to its predicate device after the maximum number of times the device is reprocessed as intended by the person submitting the premarket notification. Within six months after enactment of this subsection, the Secretary shall publish in the Federal Register a list of the types so identified, and shall revise the list as appropriate. Reports under subsection (k) for devices or types of de-

vices within a type included on the list are, upon publication of the list, required to include such validation data.

(B) In the case of each report under subsection (k) that was submitted to the Secretary before the publication of the initial list under subparagraph (A), or any revision thereof, and was for a device or type of device included on such list, the person who submitted the report under subsection (k) shall submit validation data as described in subparagraph (A) to the Secretary not later than nine months after the publication of the list. During such nine-month period, the Secretary may not take any action under this Act against such device solely on the basis that the validation data for the device have not been submitted to the Secretary. After the submission of the validation data to the Secretary, the Secretary may not determine that the device is misbranded under section 502(o) or adulterated under section 501(f)(1)(B), or take action against the device under section 301(p) for failure to provide any information required by subsection (k) until (i) the review is terminated by withdrawal of the submission of the report under subsection (k); (ii) the Secretary finds the data to be acceptable and issues a letter; or (iii) the Secretary determines that the device is not substantially equivalent to a predicate device. Upon a determination that a device is not substantially equivalent to a predicate device, or if such submission is withdrawn, the device can no longer be legally marketed.

(C) In the case of a report under subsection (k) for a device identified under subparagraph (A) that is of a type for which the Secretary has not previously received a report under such subsection, the Secretary may, in advance of revising the list under subparagraph (A) to include such type, require that the report include the validation data specified in subparagraph (A).

(D) Section 502(o) applies with respect to the failure of a report under subsection (k) to include validation data required under subparagraph (A).

(2) With respect to critical or semi-critical reprocessed single-use devices that, under subsection (l) or (m), are exempt from the requirement of submitting reports under subsection (k):

(A) The Secretary shall identify such devices or types of devices for which such exemptions should be terminated in order to provide a reasonable assurance of the safety and effectiveness of the devices. The Secretary shall publish in the Federal Register a list of the devices or types of devices so identified, and shall revise the list as appropriate. The exemption for each device or type included on the list is terminated upon the publication of the list. For each report under subsection (k) submitted pursuant to this subparagraph the Secretary shall require the validation data described in paragraph (1)(A).

(B) For each device or type of device included on the list under subparagraph (A), a report under subsection (k) shall be submitted to the Secretary not later than 15 months after the publication of the initial list, or a revision of the list, whichever terminates the exemption for the device. During such 15-month period, the Secretary may not take any action under this Act against such device solely on the basis that such re-

port has not been submitted to the Secretary. After the submission of the report to the Secretary the Secretary may not determine that the device is misbranded under section 502(o) or adulterated under section 501(f)(1)(B), or take action against the device under section 301(p) for failure to provide any information required by subsection (k) until (i) the review is terminated by withdrawal of the submission; (ii) the Secretary determines by order that the device is substantially equivalent to a predicate device; or (iii) the Secretary determines by order that the device is not substantially equivalent to a predicate device. Upon a determination that a device is not substantially equivalent to a predicate device, the device can no longer be legally marketed.

(C) In the case of semi-critical devices, the initial list under subparagraph (A) shall be published not later than 18 months after the effective date of this subsection. In the case of critical devices, the initial list under such subparagraph shall be published not later than six months after such effective date.

(D) Section 502(o) applies with respect to the failure to submit a report under subsection (k) that is required pursuant to subparagraph (A), including a failure of the report to include validation data required in such subparagraph.

(E) The termination under subparagraph (A) of an exemption under subsection (l) or (m) for a critical or semi-critical reprocessed single-use device does not terminate the exemption under subsection (l) or (m) for the original device.

(p) ELECTRONIC REGISTRATION AND LISTING.—

(1) IN GENERAL.—Registrations and listings under this section (including the submission of updated information) shall be submitted to the Secretary by electronic means unless the Secretary grants a request for waiver of such requirement because use of electronic means is not reasonable for the person requesting such waiver.

(2) ELECTRONIC DATABASE.—Not later than 2 years after the Secretary specifies a unique facility identifier system under subsections (b) and (i), the Secretary shall maintain an electronic database, which shall not be subject to inspection under subsection (f), populated with the information submitted as described under paragraph (1) that—

(A) enables personnel of the Food and Drug Administration to search the database by any field of information submitted in a registration described under paragraph (1), or combination of such fields; and

(B) uses the unique facility identifier system to link with other relevant databases within the Food and Drug Administration, including the database for submission of information under section 801(r).

(3) RISK-BASED INFORMATION AND COORDINATION.—The Secretary shall ensure the accuracy and coordination of relevant Food and Drug Administration databases in order to identify and inform risk-based inspections under section 510(h).

(q) REUSABLE MEDICAL DEVICES.—

(1) IN GENERAL.—Not later than 180 days after the date of enactment of the 21st Century Cures Act, the Secretary shall

identify and publish a list of reusable device types for which reports under subsection (k) are required to include—

(A) instructions for use, which have been validated in a manner specified by the Secretary; and

(B) validation data, the types of which shall be specified by the Secretary;

regarding cleaning, disinfection, and sterilization, and for which a substantial equivalence determination may be based.

(2) REVISION OF LIST.—The Secretary shall revise the list under paragraph (2), as the Secretary determines appropriate, with notice in the Federal Register.

(3) CONTENT OF REPORTS.—Reports under subsection (k) that are submitted after the publication of the list described in paragraph (1), for devices or types of devices included on such list, shall include such instructions for use and validation data.

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CLASSIFICATION OF DEVICES INTENDED FOR HUMAN USE

Device Classes

SEC. 513. (a)(1) There are established the following classes of devices intended for human use:

(A) CLASS I, GENERAL CONTROLS.—

(i) A device for which the controls authorized by or under section 501, 502, 510, 516, 518, 519, or 520 or any combination of such sections are sufficient to provide reasonable assurance of the safety and effectiveness of the device.

(ii) A device for which insufficient information exists to determine that the controls referred to in clause (i) are sufficient to provide reasonable assurance of the safety and effectiveness of the device or to establish special controls to provide such assurance, but because it—

(I) is not purported or represented to be for a use in supporting or sustaining human life or for a use which is of substantial importance in preventing impairment of human health, and

(II) does not present a potential unreasonable risk of illness or injury,

is to be regulated by the controls referred to in clause (i).

(B) CLASS II, SPECIAL CONTROLS.—A device which cannot be classified as a class I device because the general controls by themselves are insufficient to provide reasonable assurance of the safety and effectiveness of the device, and for which there is sufficient information to establish special controls to provide such assurance, including the promulgation of performance standards, postmarket surveillance, patient registries, development and dissemination of guidelines (including guidelines for the submission of clinical data in premarket notification submissions in accordance with section 510(k)), recommendations, and other appropriate actions as the Secretary deems necessary to provide such assurance. For a device that is purported or represented to be for a use in supporting or sustaining human life, the Secretary shall examine and identify

the special controls, if any, that are necessary to provide adequate assurance of safety and effectiveness and describe how such controls provide such assurance.

(C) CLASS III, PREMARKET APPROVAL.—A device which because—

(i) it (I) cannot be classified as a class I device because insufficient information exists to determine that the application of general controls are sufficient to provide reasonable assurance of the safety and effectiveness of the device, and (II) cannot be classified as a class II device because insufficient information exists to determine that the special controls described in subparagraph (B) would provide reasonable assurance of its safety and effectiveness, and

(ii)(I) is purported or represented to be for a use in supporting or sustaining human life or for a use which is of substantial importance in preventing impairment of human health, or

(II) presents a potential unreasonable risk of illness or injury,

is to be subject, in accordance with section 515, to premarket approval to provide reasonable assurance of its safety and effectiveness.

If there is not sufficient information to establish a performance standard for a device to provide reasonable assurance of its safety and effectiveness, the Secretary may conduct such activities as may be necessary to develop or obtain such information.

(2) For purposes of this section and sections 514 and 515, the safety and effectiveness of a device are to be determined—

(A) with respect to the persons for whose use the device is represented or intended,

(B) with respect to the conditions of use prescribed, recommended, or suggested in the labeling of the device, and

(C) weighing any probable benefit to health from the use of the device against any probable risk of injury or illness from such use.

(3)(A) Except as authorized by subparagraph (B), the effectiveness of a device is, for purposes of this section and sections 514 and 515, to be determined, in accordance with regulations promulgated by the Secretary, on the basis of well-controlled investigations, including 1 or more clinical investigations where appropriate, by experts qualified by training and experience to evaluate the effectiveness of the device, from which investigations it can fairly and responsibly be concluded by qualified experts that the device will have the effect it purports or is represented to have under the conditions of use prescribed, recommended, or suggested in the labeling of the device.

(B) If the Secretary determines that there exists valid scientific evidence (other than evidence derived from investigations described in subparagraph (A))—

(i) which is sufficient to determine the effectiveness of a device, and

(ii) from which it can fairly and responsibly be concluded by qualified experts that the device will have the effect it purports or is represented to have under the conditions of use pre-

scribed, recommended, or suggested in the labeling of the device,

then, for purposes of this section and sections 514 and 515, the Secretary may authorize the effectiveness of the device to be determined on the basis of such evidence.

(C) In making a determination of a reasonable assurance of the effectiveness of a device for which an application under section 515 has been submitted, the Secretary shall consider whether the extent of data that otherwise would be required for approval of the application with respect to effectiveness can be reduced through reliance on postmarket controls.

(D)(i) The Secretary, upon the written request of any person intending to submit an application under section 515, shall meet with such person to determine the type of valid scientific evidence (within the meaning of subparagraphs (A) and (B)) that will be necessary to demonstrate for purposes of approval of an application the effectiveness of a device for the conditions of use proposed by such person. The written request shall include a detailed description of the device, a detailed description of the proposed conditions of use of the device, a proposed plan for determining whether there is a reasonable assurance of effectiveness, and, if available, information regarding the expected performance from the device. Within 30 days after such meeting, the Secretary shall specify in writing the type of valid scientific evidence that will provide a reasonable assurance that a device is effective under the conditions of use proposed by such person.

(ii) Any clinical data, including one or more well-controlled investigations, specified in writing by the Secretary for demonstrating a reasonable assurance of device effectiveness shall be specified as result of a determination by the Secretary that such data are necessary to establish device effectiveness. The Secretary shall consider, in consultation with the applicant, the least burdensome appropriate means of evaluating device effectiveness that would have a reasonable likelihood of resulting in approval.

(iii) For purposes of clause (ii), the term "necessary" means the minimum required information that would support a determination by the Secretary that an application provides reasonable assurance of the effectiveness of the device.

(iv) Nothing in this subparagraph shall alter the criteria for evaluating an application for premarket approval of a device.

(v) The determination of the Secretary with respect to the specification of valid scientific evidence under clauses (i) and (ii) shall be binding upon the Secretary, unless such determination by the Secretary could be contrary to the public health.

Classification; Classification Panels

(b)(1) For purposes of—

(A) determining which devices intended for human use should be subject to the requirements of general controls, performance standards, or premarket approval, and

(B) providing notice to the manufacturers and importers of such devices to enable them to prepare for the application of such requirements to devices manufactured or imported by them,

the Secretary shall classify all such devices (other than devices classified by subsection (f)) into the classes established by subsection (a). For the purpose of securing recommendations with respect to the classification of devices, the Secretary shall establish panels of experts or use panels of experts established before the date of the enactment of this section, or both. Section 14 of the Federal Advisory Committee Act shall not apply to the duration of a panel established under this paragraph.

(2) The Secretary shall appoint to each panel established under paragraph (1) persons who are qualified by training and experience to evaluate the safety and effectiveness of the devices to be referred to the panel and who, to the extent feasible, possess skill in the use of, or experience in the development, manufacture, or utilization of, such devices. The Secretary shall make appointments to each panel so that each panel shall consist of members with adequately diversified expertise in such fields as clinical and administrative medicine, engineering, biological and physical sciences, and other related professions. In addition, each panel shall include as nonvoting members a representative of consumer interests and a representative of interests of the device manufacturing industry. Scientific, trade, and consumer organizations shall be afforded an opportunity to nominate individuals for appointment to the panels. No individual who is in the regular full-time employ of the United States and engaged in the administration of this Act may be a member of any panel. The Secretary shall designate one of the members of each panel to serve as chairman thereof.

(3) Panel members (other than officers or employees of the United States), while attending meetings or conferences of a panel or otherwise engaged in its business, shall be entitled to receive compensation at rates to be fixed by the Secretary, but not at rates exceeding the daily equivalent of the rate in effect for grade GS–18 of the General Schedule, for each day so engaged, including traveltime; and while so serving away from their homes or regular places of business each member may be allowed travel expenses (including per diem in lieu of subsistence) as authorized by section 5703 of title 5, United States Code, for persons in the Government service employed intermittently.

(4) The Secretary shall furnish each panel with adequate clerical and other necessary assistance.

(5)(A) Classification panels covering each type of device shall be scheduled to meet at such times as may be appropriate for the Secretary to meet applicable statutory deadlines.

(B) When a device is specifically the subject of review by a classification panel, the Secretary shall—

(i) ensure that adequate expertise is represented on the classification panel to assess—

(I) the disease or condition which the device is intended to cure, treat, mitigate, prevent, or diagnose; and

(II) the technology of the device; and

(ii) provide an opportunity for the person whose device is specifically the subject of panel review to provide recommendations on the expertise needed among the voting members of the panel.

(C) For purposes of subparagraph (B)(i), the term "adequate expertise" means that the membership of the classification panel includes—

(i) two or more voting members, with a specialty or other expertise clinically relevant to the device under review; and

(ii) at least one voting member who is knowledgeable about the technology of the device.

(D) The Secretary shall provide an annual opportunity for patients, representatives of patients, and sponsors of medical devices that may be specifically the subject of a review by a classification panel to provide recommendations for individuals with appropriate expertise to fill voting member positions on classification panels.

(6)(A) Any person whose device is specifically the subject of review by a classification panel shall have—

(i) the same access to data and information submitted to a classification panel (except for data and information that are not available for public disclosure under section 552 of title 5, United States Code) as the Secretary;

(ii) the opportunity to submit, for review by a classification panel, information that is based on the data or information provided in the application submitted under section 515 by the person, which information shall be submitted to the Secretary for prompt transmittal to the classification panel; and

(iii) the same opportunity as the Secretary to participate in meetings of the panel, including, subject to the discretion of the panel chairperson, by designating a representative who will be provided a time during the panel meeting to address the panel for the purpose of correcting misstatements of fact or providing clarifying information, and permitting the person or representative to call on experts within the person's organization to address such specific issues in the time provided.

(B)(i) Any meeting of a classification panel with respect to the review of a device shall—

(I) provide adequate time for initial presentations by the person whose device is specifically the subject of such review and by the Secretary; and

(II) encourage free and open participation by all interested persons.

(ii) Following the initial presentations described in clause (i), the panel may—

(I) pose questions to a designated representative described in subparagraph (A)(iii); and

(II) consider the responses to such questions in the panel's review of the device.

(7) After receiving from a classification panel the conclusions and recommendations of the panel on a matter that the panel has reviewed, the Secretary shall review the conclusions and recommendations, shall make a final decision on the matter in accordance with section 515(d)(2), and shall notify the affected persons of the decision in writing and, if the decision differs from the conclusions and recommendations of the panel, shall include the reasons for the difference.

(8) A classification panel under this subsection shall not be subject to the annual chartering and annual report requirements of the Federal Advisory Committee Act.

Classification Panel Organization and Operation

(c)(1) The Secretary shall organize the panels according to the various fields of clinical medicine and fundamental sciences in which devices intended for human use are used. The Secretary shall refer a device to be classified under this section to an appropriate panel established or authorized to be used under subsection (b) for its review and for its recommendation respecting the classification of the device. The Secretary shall by regulation prescribe the procedure to be followed by the panels in making their reviews and recommendations. In making their reviews of devices, the panels, to the maximum extent practicable, shall provide an opportunity for interested persons to submit data and views on the classification of the devices.

(2)(A) Upon completion of a panel's review of a device referred to it under paragraph (1), the panel shall, subject to subparagraphs (B) and (C), submit to the Secretary its recommendation for the classification of the device. Any such recommendation shall (i) contain (I) a summary of the reasons for the recommendation, (II) a summary of the data upon which the recommendation is based, and (III) an identification of the risks to health (if any) presented by the device with respect to which the recommendation is made, and (ii) to the extent practicable, include a recommendation for the assignment of a priority for the application of the requirements of section 514 or 515 to a device recommended to be classified in class II or class III.

(B) A recommendation of a panel for the classification of a device in class I shall include a recommendation as to whether the device should be exempted from the requirements of section 510, 519, or 520(f).

(C) In the case of a device which has been referred under paragraph (1) to a panel, and which—

(i) is intended to be implanted in the human body or is purported or represented to be for a use in supporting or sustaining human life, and

(ii)(I) has been introduced or delivered for introduction into interstate commerce for commercial distribution before the date of enactment of this section, or

(II) is within a type of device which was so introduced or delivered before such date and is substantially equivalent to another device within that type,

such panel shall recommend to the Secretary that the device be classified in class III unless the panel determines that classification of the device in such class is not necessary to provide reasonable assurance of its safety and effectiveness. If a panel does not recommend that such a device be classified in class III, it shall in its recommendation to the Secretary for the classification of the device set forth the reasons for not recommending classification of the device in such class.

(3) The panels shall submit to the Secretary within one year of the date funds are first appropriated for the implementation of this section their recommendations respecting all devices of a type introduced or delivered for introduction into interstate commerce for commercial distribution before the date of the enactment of this section.

Classification

(d)(1) Upon receipt of a recommendation from a panel respecting a device, the Secretary shall publish in the Federal Register the panel's recommendation and a proposed regulation classifying such device and shall provide interested persons an opportunity to submit comments on such recommendation and the proposed regulation. After reviewing such comments, the Secretary shall, subject to paragraph (2), by regulation classify such device.

(2)(A) A regulation under paragraph (1) classifying a device in class I shall prescribe which, if any, of the requirements of section 510, 519 or 520(f) shall not apply to the device. A regulation which makes a requirement of section 510, 519, or 520(f) inapplicable to a device shall be accompanied by a statement of the reasons of the Secretary for making such requirement inapplicable.

(B) A device described in subsection (c)(2)(C) shall be classified in class III unless the Secretary determines that classification of the device in such class is not necessary to provide reasonable assurance of its safety and effectiveness. A proposed regulation under paragraph (1) classifying such a device in a class other than class III shall be accompanied by a full statement of the reasons of the Secretary (and supporting documentation and data) for not classifying such device in such class and an identification of the risks to health (if any) presented by such device.

(3) In the case of devices classified in class II and devices classified under this subsection in class III and described in section 515(b)(1) the Secretary may establish priorities which, in his discretion, shall be used in applying sections 514 and 515, as appropriate, to such devices.

Classification Changes

(e)(1)(A)(i) Based on new information respecting a device, the Secretary may, upon the initiative of the Secretary or upon petition of an interested person, change the classification of such device, and revoke, on account of the change in classification, any regulation or requirement in effect under section 514 or 515 with respect to such device, by administrative order published in the Federal Register following publication of a proposed reclassification order in the Federal Register, a meeting of a device classification panel described in subsection (b), and consideration of comments to a public docket, notwithstanding subchapter II of chapter 5 of title 5, United States Code. The proposed reclassification order published in the Federal Register shall set forth the proposed reclassification, and a substantive summary of the valid scientific evidence concerning the proposed reclassification, including—

(I) the public health benefit of the use of the device, and the nature and, if known, incidence of the risk of the device;

(II) in the case of a reclassification from class II to class III, why general controls pursuant to subsection (a)(1)(A) and special controls pursuant to subsection (a)(1)(B) together are not sufficient to provide a reasonable assurance of safety and effectiveness for such device; and

(III) in the case of reclassification from class III to class II, why general controls pursuant to subsection (a)(1)(A) and special controls pursuant to subsection (a)(1)(B) together are suffi-

cient to provide a reasonable assurance of safety and effectiveness for such device.

(ii) An order under this subsection changing the classification of a device from class III to class II may provide that such classification shall not take effect until the effective date of a performance standard established under section 514 for such device.

(B) Authority to issue such administrative order shall not be delegated below the Director of the Center for Devices and Radiological Health, acting in consultation with the Commissioner.

(2) By an order issued under paragraph (1), the Secretary may change the classification of a device from class III—

(A) to class II if the Secretary determines that special controls would provide reasonable assurance of the safety and effectiveness of the device and that general controls would not provide reasonable assurance of the safety and effectiveness of the device, or

(B) to class I if the Secretary determines that general controls would provide reasonable assurance of the safety and effectiveness of the device.

Initial Classification and Reclassification of Certain Devices

(f)(1) Any device intended for human use which was not introduced or delivered for introduction into interstate commerce for commercial distribution before the date of the enactment of this section is classified in class III unless—

(A) the device—

(i) is within a type of device (I) which was introduced or delivered for introduction into interstate commerce for commercial distribution before such date and which is to be classified pursuant to subsection (b), or (II) which was not so introduced or delivered before such date and has been classified in class I or II, and

(ii) is substantially equivalent to another device within such type;

(B) the Secretary in response to a petition submitted under paragraph (3) has classified such device in class I or II; or

(C) the device is classified pursuant to a request submitted under paragraph (2).

A device classified in class III under this paragraph shall be classified in that class until the effective date of an order of the Secretary under paragraph (2) or (3) classifying the device in class I or II.

(2)(A)(i) Any person who submits a report under section 510(k) for a type of device that has not been previously classified under this Act, and that is classified into class III under paragraph (1), may request, after receiving written notice of such a classification, the Secretary to classify the device.

(ii) In lieu of submitting a report under section 510(k) and submitting a request for classification under clause (i) for a device, if a person determines there is no legally marketed device upon which to base a determination of substantial equivalence (as defined in subsection (i)), a person may submit a request under this clause for the Secretary to classify the device.

(iii) Upon receipt of a request under clause (i) or (ii), the Secretary shall classify the device subject to the request under the cri-

teria set forth in subparagraphs (A) through (C) of subsection (a)(1) within 120 days.

(iv) Notwithstanding clause (iii), the Secretary may decline to undertake a classification request submitted under clause (ii) if the Secretary identifies a legally marketed device that could provide a reasonable basis for review of substantial equivalence under paragraph (1), or when the Secretary determines that the device submitted is not of low to moderate risk or that general controls would be inadequate to control the risks and special controls to mitigate the risks cannot be developed.

(v) The person submitting the request for classification under this subparagraph may recommend to the Secretary a classification for the device and shall, if recommending classification in class II, include in the request an initial draft proposal for applicable special controls, as described in subsection (a)(1)(B), that are necessary, in conjunction with general controls, to provide reasonable assurance of safety and effectiveness and a description of how the special controls provide such assurance. Any such request shall describe the device and provide detailed information and reasons for the recommended classification.

(B)(i) The Secretary shall by written order classify the device involved. Such classification shall be the initial classification of the device for purposes of paragraph (1) and any device classified under this paragraph shall be a predicate device for determining substantial equivalence under paragraph (1).

(ii) A device that remains in class III under this subparagraph shall be deemed to be adulterated within the meaning of section 501(f)(1)(B) until approved under section 515 or exempted from such approval under section 520(g).

(C) Within 30 days after the issuance of an order classifying a device under this paragraph, the Secretary shall publish a notice in the Federal Register announcing such classification.

(3)(A) The Secretary may initiate the reclassification of a device classified into class III under paragraph (1) of this subsection or the manufacturer or importer of a device classified under paragraph (1) may petition the Secretary (in such form and manner as he shall prescribe) for the issuance of an order classifying the device in class I or class II. Within thirty days of the filing of such a petition, the Secretary shall notify the petitioner of any deficiencies in the petition which prevent the Secretary from making a decision on the petition.

(B)(i) Upon determining that a petition does not contain any deficiency which prevents the Secretary from making a decision on the petition, the Secretary may for good cause shown refer the petition to an appropriate panel established or authorized to be used under subsection (b). A panel to which such a petition has been referred shall not later than ninety days after the referral of the petition make a recommendation to the Secretary respecting approval or denial of the petition. Any such recommendation shall contain (I) a summary of the reasons for the recommendation, (II) a summary of the data upon which the recommendation is based, and (III) an identification of the risks to health (if any) presented by the device with respect to which the petition was filed. In the case of a petition for a device which is intended to be implanted in the human body or which is purported or represented to be for a use in sup-

porting or sustaining human life, the panel shall recommend that the petition be denied unless the panel determines that the classification in class III of the device is not necessary to provide reasonable assurance of its safety and effectiveness. If the panel recommends that such petition be approved, it shall in its recommendation to the Secretary set forth its reasons for such recommendation.

(ii) The requirements of paragraphs (1) and (2) of subsection (c) (relating to opportunities for submission of data and views and recommendations respecting priorities and exemptions from sections 510, 519, and 520(f)) shall apply with respect to consideration by panels of petitions submitted under subparagraph (A).

(C)(i) Within ninety days from the date the Secretary receives the recommendation of a panel respecting a petition (but not later than 210 days after the filing of such petition) the Secretary shall by order deny or approve the petition. If the Secretary approves the petition, the Secretary shall order the classification of the device into class I or class II in accordance with the criteria prescribed by subsection (a)(1)(A) or (a)(1)(B). In the case of a petition for a device which is intended to be implanted in the human body or which is purported or represented to be for a use in supporting or sustaining human life, the Secretary shall deny the petition unless the Secretary determines that the classification in class III of the device is not necessary to provide reasonable assurance of its safety and effectiveness. An order approving such petition shall be accompanied by a full statement of the reasons of the Secretary (and supporting documentation and data) for approving the petition and an identification of the risks to health (if any) presented by the device to which such order applies.

(ii) The requirements of paragraphs (1) and (2)(A) of subsection (d) (relating to publication of recommendations, opportunity for submission of comments, and exemption from sections 510, 519, and 520(f)) shall apply with respect to action by the Secretary on petitions submitted under subparagraph (A).

(4) If a manufacturer reports to the Secretary under section 510(k) that a device is substantially equivalent to another device—

(A) which the Secretary has classified as a class III device under subsection (b),

(B) which was introduced or delivered for introduction into interstate commerce for commercial distribution before December 1, 1990, and

(C) for which no final regulation requiring premarket approval has been promulgated under section 515(b),

the manufacturer shall certify to the Secretary that the manufacturer has conducted a reasonable search of all information known or otherwise available to the manufacturer respecting such other device and has included in the report under section 510(k) a summary of and a citation to all adverse safety and effectiveness data respecting such other device and respecting the device for which the section 510(k) report is being made and which has not been submitted to the Secretary under section 519. The Secretary may require the manufacturer to submit the adverse safety and effectiveness data described in the report.

(5) The Secretary may not withhold a determination of the initial classification of a device under paragraph (1) because of a failure

to comply with any provision of this Act unrelated to a substantial equivalence decision, including a finding that the facility in which the device is manufactured is not in compliance with good manufacturing requirements as set forth in regulations of the Secretary under section 520(f) (other than a finding that there is a substantial likelihood that the failure to comply with such regulations will potentially present a serious risk to human health).

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

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

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

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

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

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

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

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

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

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

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

(iii) The Secretary shall respond to a request made under clause (ii) not later than 85 calendar days after receiving such request by issuing a written order classifying the accessory or denying the request. If the Secretary does not agree with the recommendation for classification submitted by the manufacturer or importer, the response shall include a detailed description and justification for such determination. Within 30 calendar days after granting such a request, the Secretary shall publish a notice in the Federal Register announcing such response.

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

Information

(g) Within sixty days of the receipt of a written request of any person for information respecting the class in which a device has been classified or the requirements applicable to a device under this Act, the Secretary shall provide such person a written statement of the classification (if any) of such device and the requirements of this Act applicable to the device.

Definitions

(h) For purposes of this section and sections 501, 510, 514, 515, 516, 519, and 520—

(1) a reference to "general controls" is a reference to the controls authorized by or under sections 501, 502, 510, 516, 518, 519, and 520,

(2) a reference to "class I,""class II," or "class III" is a reference to a class of medical devices described in subparagraph (A), (B), or (C) of subsection (a)(1), and

(3) a reference to a "panel under section 513" is a reference to a panel established or authorized to be used under this section.

Substantial Equivalence

(i)(1)(A) For purposes of determinations of substantial equivalence under subsection (f) and section 520(l), the term "substantially equivalent" or "substantial equivalence" means, with respect to a device being compared to a predicate device, that the device has the same intended use as the predicate device and that the Secretary by order has found that the device—

(i) has the same technological characteristics as the predicate device, or

(ii)(I) has different technological characteristics and the information submitted that the device is substantially equivalent to the predicate device contains information, including appropriate clinical or scientific data if deemed necessary by the Secretary or a person accredited under section 523, that demonstrates that the device is as safe and effective as a legally marketed device, and (II) does not raise different questions of safety and effectiveness than the predicate device.

(B) For purposes of subparagraph (A), the term "different technological characteristics" means, with respect to a device being compared to a predicate device, that there is a significant change in the materials, design, energy source, or other features of the device from those of the predicate device.

(C) To facilitate reviews of reports submitted to the Secretary under section 510(k), the Secretary shall consider the extent to which reliance on postmarket controls may expedite the classification of devices under subsection (f)(1) of this section.

(D)(i) Whenever the Secretary requests information to demonstrate that devices with differing technological characteristics are substantially equivalent, the Secretary shall only request information that is necessary to making substantial equivalence determinations. In making such request, the Secretary shall consider the least burdensome means of demonstrating substantial equivalence and request information accordingly.

(ii) For purposes of clause (i), the term "necessary" means the minimum required information that would support a determination of substantial equivalence between a new device and a predicate device.

(iii) Nothing in this subparagraph shall alter the standard for determining substantial equivalence between a new device and a predicate device.

(E)(i) Any determination by the Secretary of the intended use of a device shall be based upon the proposed labeling submitted in a report for the device under section 510(k). However, when determining that a device can be found substantially equivalent to a legally marketed device, the director of the organizational unit responsible for regulating devices (in this subparagraph referred to as the "Director") may require a statement in labeling that provides appropriate information regarding a use of the device not identified in the proposed labeling if, after providing an opportunity for consultation with the person who submitted such report, the Director determines and states in writing—

(I) that there is a reasonable likelihood that the device will be used for an intended use not identified in the proposed labeling for the device; and

(II) that such use could cause harm.

(ii) Such determination shall—

(I) be provided to the person who submitted the report within 10 days from the date of the notification of the Director's concerns regarding the proposed labeling;

(II) specify the limitations on the use of the device not included in the proposed labeling; and

(III) find the device substantially equivalent if the requirements of subparagraph (A) are met and if the labeling for such device conforms to the limitations specified in subclause (II).

(iii) The responsibilities of the Director under this subparagraph may not be delegated.

(F) Not later than 270 days after the date of the enactment of the Food and Drug Administration Modernization Act of 1997, the Secretary shall issue guidance specifying the general principles that the Secretary will consider in determining when a specific intended use of a device is not reasonably included within a general use of such device for purposes of a determination of substantial equivalence under subsection (f) or section 520(l).

(2) A device may not be found to be substantially equivalent to a predicate device that has been removed from the market at the initiative of the Secretary or that has been determined to be misbranded or adulterated by a judicial order.

(3)(A) As part of a submission under section 510(k) respecting a device, the person required to file a premarket notification under such section shall provide an adequate summary of any information respecting safety and effectiveness or state that such information will be made available upon request by any person.

(B) Any summary under subparagraph (A) respecting a device shall contain detailed information regarding data concerning adverse health effects and shall be made available to the public by the Secretary within 30 days of the issuance of a determination that such device is substantially equivalent to another device.

(j) TRAINING AND OVERSIGHT OF LEAST BURDENSOME REQUIREMENTS.—

(1) The Secretary shall—

(A) ensure that each employee of the Food and Drug Administration who is involved in the review of premarket submissions, including supervisors, receives training regarding the meaning and implementation of the least bur-

densome requirements under subsections (a)(3)(D) and (i)(1)(D) of this section and section 515(c)(5); and

(B) periodically assess the implementation of the least burdensome requirements, including the employee training under subparagraph (A), to ensure that the least burdensome requirements are fully and consistently applied.

(2) Not later than 18 months after the date of enactment of the 21st Century Cures Act, the ombudsman for any organizational unit of the Food and Drug Administration responsible for the premarket review of devices shall—

(A) conduct an audit of the training described in paragraph (1)(A), including the effectiveness of such training in implementing the least burdensome requirements;

(B) include in such audit interviews of persons who are representatives of the device industry regarding their experiences in the device premarket review process, including with respect to the application of least burdensome concepts to premarket review and decisionmaking;

(C) include in such audit a list of the measurement tools the Secretary uses to assess the implementation of the least burdensome requirements, including under paragraph (1)(B) and section 517A(a)(3), and may also provide feedback on the effectiveness of such tools in the implementation of the least burdensome requirements;

(D) summarize the findings of such audit in a final audit report; and

(E) within 30 calendar days of completion of such final audit report, make such final audit report available—

(i) to the Committee on Health, Education, Labor, and Pensions of the Senate and the Committee on Energy and Commerce of the House of Representatives; and

(ii) on the Internet website of the Food and Drug Administration.

(k) For a device authorized for emergency use under section 564 for which, in accordance with section 564(m), the Secretary has deemed a laboratory examination or procedure associated with such device to be in the category of examinations and procedures described in section 353(d)(3) of the Public Health Service Act, the sponsor of such device may, when submitting a request for classification under section 513(f)(2), submit a single submission containing—

(1) the information needed for such a request; and

(2) sufficient information to enable the Secretary to determine whether such laboratory examination or procedure satisfies the criteria to be categorized under section 353(d)(3) of the Public Health Service Act.

PERFORMANCE STANDARDS

Provisions of Standards

SEC. 514. (a)(1) The special controls required by section 513(a)(1)(B) shall include performance standards for a class II device if the Secretary determines that a performance standard is necessary to provide reasonable assurance of the safety and effec-

tiveness of the device. A class III device may also be considered a class II device for purposes of establishing a standard for the device under subsection (b) if the device has been reclassified as a class II device under an administrative order under section 513(e) (or a regulation promulgated under such section prior to the date of enactment of the Food and Drug Administration Safety and Innovation Act) but such order (or regulation) provides that the reclassification is not to take effect until the effective date of such a standard for the device.

(2) A performance standard established under subsection (b) for a device—

(A) shall include provisions to provide reasonable assurance of its safe and effective performance;

(B) shall, where necessary to provide reasonable assurance of its safe and effective performance, include—

(i) provisions respecting the construction, components, ingredients, and properties of the device and its compatibility with power systems and connections to such systems,

(ii) provisions for the testing (on a sample basis or, if necessary, on an individual basis) of the device or, if it is determined that no other more practicable means are available to the Secretary to assure the conformity of the device to the standard, provisions for the testing (on a sample basis or, if necessary, on an individual basis) by the Secretary or by another person at the direction of the Secretary,

(iii) provisions for the measurement of the performance characteristics of the device,

(iv) provisions requiring that the results of each or of certain of the tests of the device required to be made under clause (ii) show that the device is in conformity with the portions of the standard for which the test or tests were required, and

(v) a provision requiring that the sale and distribution of the device be restricted but only to the extent that the sale and distribution of a device may be restricted under a regulation under section 520(e); and

(C) shall, where appropriate, require the use and prescribe the form and content of labeling for the proper installation, maintenance, operation, and use of the device.

(3) The Secretary shall provide for periodic evaluation of performance standards established under subsection (b) to determine if such standards should be changed to reflect new medical, scientific, or other technological data.

(4) In carrying out his duties under this subsection and subsection (b), the Secretary shall, to the maximum extent practicable—

(A) use personnel, facilities, and other technical support available in other Federal agencies,

(B) consult with other Federal agencies concerned with standard-setting and other nationally or internationally recognized standard-setting entities, and

(C) invite appropriate participation, through joint or other conferences, workshops, or other means, by informed persons

representative of scientific, professional, industry, or consumer organizations who in his judgment can make a significant contribution.

Establishment of a Standard

(b)(1)(A) The Secretary shall publish in the Federal Register a notice of proposed rulemaking for the establishment, amendment, or revocation of any performance standard for a device.

(B) A notice of proposed rulemaking for the establishment or amendment of a performance standard for a device shall—

(i) set forth a finding with supporting justification that the performance standard is appropriate and necessary to provide reasonable assurance of the safety and effectiveness of the device,

(ii) set forth proposed findings with respect to the risk of illness or injury that the performance standard is intended to reduce or eliminate,

(iii) invite interested persons to submit to the Secretary, within 30 days of the publication of the notice, requests for changes in the classification of the device pursuant to section 513(e) based on new information relevant to the classification, and

(iv) invite interested persons to submit an existing performance standard for the device, including a draft or proposed performance standard, for consideration by the Secretary.

(C) A notice of proposed rulemaking for the revocation of a performance standard shall set forth a finding with supporting justification that the performance standard is no longer necessary to provide reasonable assurance of the safety and effectiveness of a device.

(D) The Secretary shall provide for a comment period of not less than 60 days.

(2) If, after publication of a notice in accordance with paragraph (1), the Secretary receives a request for a change in the classification of the device, the Secretary shall, within 60 days of the publication of the notice, after consultation with the appropriate panel under section 513, either deny the request or give notice of an intent to initiate such change under section 513(e).

(3)(A) After the expiration of the period for comment on a notice of proposed rulemaking published under paragraph (1) respecting a performance standard and after consideration of such comments and any report from an advisory committee under paragraph (5), the Secretary shall (i) promulgate a regulation establishing a performance standard and publish in the Federal Register findings on the matters referred to in paragraph (1), or (ii) publish a notice terminating the proceeding for the development of the standard together with the reasons for such termination. If a notice of termination is published, the Secretary shall (unless such notice is issued because the device is a banned device under section 516) initiate a proceeding under section 513(e) to reclassify the device subject to the proceeding terminated by such notice.

(B) A regulation establishing a performance standard shall set forth the date or dates upon which the standard shall take effect, but no such regulation may take effect before one year after the date of its publication unless (i) the Secretary determines that an

earlier effective date is necessary for the protection of the public health and safety, or (ii) such standard has been established for a device which, effective upon the effective date of the standard, has been reclassified from class III to class II. Such date or dates shall be established so as to minimize, consistent with the public health and safety, economic loss to, and disruption or dislocation of, domestic and international trade.

(4)(A) The Secretary, upon his own initiative or upon petition of an interested person may by regulation, promulgated in accordance with the requirements of paragraphs (1), (2), and (3)(B) of this subsection, amend or revoke a performance standard.

(B) The Secretary may declare a proposed amendment of a performance standard to be effective on and after its publication in the Federal Register and until the effective date of any final action taken on such amendment if he determines that making it so effective is in the public interest. A proposed amendment of a performance standard made so effective under the preceding sentence may not prohibit, during the period in which it is so effective, the introduction or delivery for introduction into interstate commerce of a device which conforms to such standard without the change or changes provided by such proposed amendment.

(5)(A) The Secretary—

(i) may on his own initiative refer a proposed regulation for the establishment, amendment, or revocation of a performance standard, or

(ii) shall, upon the request of an interested person which demonstrates good cause for referral and which is made before the expiration of the period for submission of comments on such proposed regulation refer such proposed regulation,

to an advisory committee of experts, established pursuant to subparagraph (B) for a report and recommendation with respect to any matter involved in the proposed regulation which requires the exercise of scientific judgment. If a proposed regulation is referred under this subparagraph to an advisory committee, the Secretary shall provide the advisory committee with the data and information on which such proposed regulation is based. The advisory committee shall, within sixty days of the referral of a proposed regulation and after independent study of the data and information furnished to it by the Secretary and other data and information before it, submit to the Secretary a report and recommendation respecting such regulation, together with all underlying data and information and a statement of the reason or basis for the recommendation. A copy of such report and recommendation shall be made public by the Secretary.

(B) The Secretary shall establish advisory committees (which may not be panels under section 513) to receive referrals under subparagraph (A). The Secretary shall appoint as members of any such advisory committee persons qualified in the subject matter to be referred to the committee and of appropriately diversified professional background, except that the Secretary may not appoint to such a committee any individual who is in the regular full-time employ of the United States and engaged in the administration of this Act. Each such committee shall include as nonvoting members a representative of consumer interests and a representative of interests of the device manufacturing industry. Members of an advisory

committee who are not officers or employees of the United States, while attending conferences or meetings of their committee or otherwise serving at the request of the Secretary, shall be entitled to receive compensation at rates to be fixed by the Secretary, which rates may not exceed the daily equivalent of the rate in effect for grade GS–18 of the General Schedule, for each day (including traveltime) they are so engaged; and while so serving away from their homes or regular places of business each member may be allowed travel expenses, including per diem in lieu of subsistence, as authorized by section 5703 of title 5 of the United States Code for persons in the Government service employed intermittently. The Secretary shall designate one of the members of each advisory committee to serve as chairman thereof. The Secretary shall furnish each advisory committee with clerical and other assistance, and shall by regulation prescribe the procedures to be followed by each such committee in acting on referrals made under subparagraph (A).

Recognition of a Standard

(c)(1)(A) In addition to establishing a performance standard under this section, the Secretary shall, by publication in the Federal Register (or, with respect to a susceptibility test interpretive criteria standard under section 511A, by posting on the Interpretive Criteria Website in accordance with such section), recognize all or part of an appropriate standard established by a nationally or internationally recognized standard development organization for which a person may submit a declaration of conformity in order to meet a premarket submission requirement or other requirement under this Act to which such standard is applicable.

(B) If a person elects to use a standard recognized by the Secretary under subparagraph (A) to meet the requirements described in such subparagraph, the person shall provide a declaration of conformity to the Secretary that certifies that the device is in conformity with such standard. A person may elect to use data, or information, other than data required by a standard recognized under subparagraph (A) to meet any requirement regarding devices under this Act.

(C)(i) Any person may submit a request for recognition under subparagraph (A) of all or part of an appropriate standard established by a nationally or internationally recognized standard organization.

(ii) Not later than 60 calendar days after the Secretary receives such a request, the Secretary shall—

(I) make a determination to recognize all, part, or none of the standard that is the subject of the request; and

(II) issue to the person who submitted such request a response in writing that states the Secretary's rationale for that determination, including the scientific, technical, regulatory, or other basis for such determination.

(iii) The Secretary shall make a response issued under clause (ii)(II) publicly available, in such a manner as the Secretary determines appropriate.

(iv) The Secretary shall take such actions as may be necessary to implement all or part of a standard recognized under clause (ii)(I), in accordance with subparagraph (A).

(D) The Secretary shall make publicly available, in such manner as the Secretary determines appropriate, the rationale for recognition under subparagraph (A) of all, part, or none of a standard, including the scientific, technical, regulatory, or other basis for the decision regarding such recognition.

(2) The Secretary may withdraw such recognition of a standard through publication of a notice in the Federal Register if the Secretary determines that the standard is no longer appropriate for meeting a requirement regarding devices under this Act.

(3)(A) Subject to subparagraph (B), the Secretary shall accept a declaration of conformity that a device is in conformity with a standard recognized under paragraph (1) unless the Secretary finds—

(i) that the data or information submitted to support such declaration does not demonstrate that the device is in conformity with the standard identified in the declaration of conformity; or

(ii) that the standard identified in the declaration of conformity is not applicable to the particular device under review.

(B) The Secretary may request, at any time, the data or information relied on by the person to make a declaration of conformity with respect to a standard recognized under paragraph (1).

(C) A person making a declaration of conformity with respect to a standard recognized under paragraph (1) shall maintain the data and information demonstrating conformity of the device to the standard for a period of two years after the date of the classification or approval of the device by the Secretary or a period equal to the expected design life of the device, whichever is longer.

(4) The Secretary shall provide to all employees of the Food and Drug Administration who review premarket submissions for devices periodic training on the concept and use of recognized standards for purposes of meeting a premarket submission requirement or other applicable requirement under this Act, including standards relevant to an employee's area of device review.

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

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

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

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

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

[(A) review determinations by testing laboratories accredited pursuant to this subsection, including by conducting periodic audits of such determinations or processes of accredited bodies or testing laboratories and, following such review, taking additional measures under this Act,

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

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

[(3) IMPLEMENTATION AND REPORTING.—

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

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

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

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

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

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

[(4) SUNSET.—As of October 1, 2022—

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

[(B) the Secretary—

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

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

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

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

(d) ACCREDITATION SCHEME FOR CONFORMITY ASSESSMENT.—

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

(A) testing laboratories meeting criteria specified in guidance by the Secretary may be accredited by accreditation bodies meeting criteria specified in guidance by the Secretary, to conduct testing to support the assessment of the conformity of a device to certain standards recognized under this section; and

(B) subject to paragraph (2), results from tests conducted to support the assessment of conformity of devices as described in subparagraph (A) conducted by testing laboratories accredited pursuant to this subsection shall be accepted by the Secretary for purposes of demonstrating such conformity unless the Secretary finds that certain results of such tests should not be so accepted.

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

(A) review the results of tests conducted by testing laboratories accredited pursuant to this subsection, including by conducting periodic audits of such results or of the processes of accredited bodies or testing laboratories;

(B) following such review, take additional measures under this Act, as the Secretary determines appropriate, such as—

(i) suspension or withdrawal of accreditation of a testing laboratory or recognition of an accreditation body under paragraph (1)(A); or

(ii) requesting additional information with respect to a device; and

(C) if the Secretary becomes aware of information materially bearing on the safety or effectiveness of a device for which an assessment of conformity was supported by testing conducted by a testing laboratory accredited under this subsection, take such additional measures under this Act, as the Secretary determines appropriate, such as—

(i) suspension or withdrawal of accreditation of a testing laboratory or recognition of an accreditation body under paragraph (1)(A); or

(ii) requesting additional information with regard to such device.

(3) IMPLEMENTATION AND REPORTING.—

(A) PILOT PROGRAM TRANSITION.—After September 30, 2023, the pilot program previously initiated under this subsection, as in effect prior to the date of enactment of the Medical Device User Fee Amendments of 2022, shall be considered to be completed, and the Secretary may continue operating a program consistent with this subsection.

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

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BANNED DEVICES

General Rule

SEC. 516. (a) Whenever the Secretary finds, on the basis of all available data and information, that—

(1) a device intended for human use presents substantial deception or an unreasonable and substantial risk of illness or injury *for one or more intended use*; and

(2) in the case of substantial deception or an unreasonable and substantial risk of illness or injury which the Secretary determined could be corrected or eliminated by labeling or change in labeling and with respect to which the Secretary provided written notice to the manufacturer specifying the deception or risk of illness or injury, the labeling or change in labeling to correct the deception or eliminate or reduce such risk, and the period within which such labeling or change in labeling was to be done, such labeling or change in labeling was not done within such period;

he may initiate a proceeding to promulgate a regulation to make such device a banned device *for any such intended use or uses. A device that is banned for one or more intended uses is not a legally marketed device under section 1006 when intended for such use or uses*.

Special Effective Date

(b) The Secretary may declare a proposed regulation under subsection (a) to be effective upon its publication in the Federal Register and until the effective date of any final action taken respecting such regulation if (1) he determines, on the basis of all available data and information, that the deception or risk of illness or injury associated with the use of the device which is subject to the regulation presents an unreasonable, direct, and substantial danger to the health of individuals, and (2) before the date of the publication of such regulation, the Secretary notifies the manufacturer of such device that such regulation is to be made so effective. If the Secretary makes a proposed regulation so effective, he shall, as expeditiously as possible, give interested persons prompt notice of his action under this subsection, provide reasonable opportunity for an informal hearing on the proposed regulation, and either affirm, modify, or revoke such proposed regulation.

(c) SPECIFIC DEVICE BANNED.—Electrical stimulation devices that apply a noxious electrical stimulus to a person's skin intended to reduce or cease self-injurious behavior or aggressive behavior are deemed to be banned devices, as described in subsection (a).

(d) REVERSAL BY REGULATION.—Devices banned under this section are banned devices unless or until the Secretary promulgates a regulation to make such devices or use of such devices no longer banned based on a finding that such devices or use of such devices does not present substantial deception or an unreasonable and substantial risk of illness or injury, or that such risk can be corrected or eliminated by labeling.

* * * * * * *

GENERAL PROVISIONS RESPECTING CONTROL OF DEVICES INTENDED FOR HUMAN USE

General Rule

SEC. 520. (a) Any requirement authorized by or under section 501, 502, 510, or 519 applicable to a device intended for human use shall apply to such device until the applicability of the requirement to the device has been changed by action taken under section 513, 514, or 515 or under subsection (g) of this section, and any requirement established by or under section 501, 502, 510, or 519 which is inconsistent with a requirement imposed on such device under section 514 or 515 or under subsection (g) of this section shall not apply to such device.

(b) CUSTOM DEVICES.—

(1) IN GENERAL.—The requirements of sections 514 and 515 shall not apply to a device that—

(A) is created or modified in order to comply with the order of an individual physician or dentist (or any other specially qualified person designated under regulations promulgated by the Secretary after an opportunity for an oral hearing);

(B) in order to comply with an order described in subparagraph (A), necessarily deviates from an otherwise applicable performance standard under section 514 or requirement under section 515;

(C) is not generally available in the United States in finished form through labeling or advertising by the manufacturer, importer, or distributor for commercial distribution;

(D) is designed to treat a unique pathology or physiological condition that no other device is domestically available to treat;

(E)(i) is intended to meet the special needs of such physician or dentist (or other specially qualified person so designated) in the course of the professional practice of such physician or dentist (or other specially qualified person so designated); or

(ii) is intended for use by an individual patient named in such order of such physician or dentist (or other specially qualified person so designated);

(F) is assembled from components or manufactured and finished on a case-by-case basis to accommodate the unique needs of individuals described in clause (i) or (ii) of subparagraph (E); and

(G) may have common, standardized design characteristics, chemical and material compositions, and manufacturing processes as commercially distributed devices.

(2) LIMITATIONS.—Paragraph (1) shall apply to a device only if—

(A) such device is for the purpose of treating a sufficiently rare condition, such that conducting clinical investigations on such device would be impractical;

(B) production of such device under paragraph (1) is limited to no more than 5 units per year of a particular device type, provided that such replication otherwise complies with this section; and

(C) the manufacturer of such device notifies the Secretary on an annual basis, in a manner prescribed by the Secretary, of the manufacture of such device.

(3) GUIDANCE.—Not later than 2 years after the date of enactment of this section, the Secretary shall issue final guidance on replication of multiple devices described in paragraph (2)(B).

Trade Secrets

(c) Any information reported to or otherwise obtained by the Secretary or his representative under section 513, 514, 515, 516, 518, 519, or 704 or under subsection (f) or (g) of this section which is exempt from disclosure pursuant to subsection (a) of section 552 of title 5, United States Code, by reason of subsection (b)(4) of such section shall be considered confidential and shall not be disclosed and may not be used by the Secretary as the basis for the reclassification of a device from class III to class II or class I or as the basis for the establishment or amendment of a performance standard under section 514 for a device reclassified from class III to class II, except (1) in accordance with subsection (h), and (2) that such information may be disclosed to other officers or employees concerned with carrying out this Act or when relevant in any proceeding under this Act (other than section 513 or 514 thereof).

Notices and Findings

(d) Each notice of proposed rulemaking under section 513, 514, 515, 516, 518, or 519, or under this section, any other notice which is published in the Federal Register with respect to any other action taken under any such section and which states the reasons for such action, and each publication of findings required to be made in connection with rulemaking under any such section shall set forth—

(1) the manner in which interested persons may examine data and other information on which the notice or findings is based, and

(2) the period within which interested persons may present their comments on the notice or findings (including the need therefor) orally or in writing, which period shall be at least sixty days but may not exceed ninety days unless the time is extended by the Secretary by a notice published in the Federal Register stating good cause therefor.

Restricted Devices

(e)(1) The Secretary may by regulation require that a device be restricted to sale, distribution, or use—

(A) only upon the written or oral authorization of a practitioner licensed by law to administer or use such device, or

(B) upon such other conditions as the Secretary may prescribe in such regulation,

if, because of its potentiality for harmful effect or the collateral measures necessary to its use, the Secretary determines that there cannot otherwise be reasonable assurance of its safety and effectiveness. No condition prescribed under subparagraph (B) may restrict the use of a device to persons with specific training or experi-

ence in its use or to persons for use in certain facilities unless the Secretary determines that such a restriction is required for the safe and effective use of the device. No such condition may exclude a person from using a device solely because the person does not have the training or experience to make him eligible for certification by a certifying board recognized by the American Board of Medical Specialties or has not been certified by such a Board. A device subject to a regulation under this subsection is a restricted device.

(2) The label of a restricted device shall bear such appropriate statements of the restrictions required by a regulation under paragraph (1) as the Secretary may in such regulation prescribe.

Good Manufacturing Practice Requirements

(f)(1)(A) The Secretary may, in accordance with subparagraph (B), prescribe regulations requiring that the methods used in, and the facilities and controls used for, the manufacture, pre-production design validation (including a process to assess the performance of a device but not including an evaluation of the safety or effectiveness of a device), packing, storage, and installation of a device conform to current good manufacturing practice, as prescribed in such regulations, to assure that the device will be safe and effective and otherwise in compliance with this Act.

(B) Before the Secretary may promulgate any regulation under subparagraph (A) he shall—

(i) afford the advisory committee established under paragraph (3) an opportunity to submit recommendations to him with respect to the regulation proposed to be promulgated;

(ii) afford opportunity for an oral hearing; and

(iii) ensure that such regulation conforms, to the extent practicable, with internationally recognized standards defining quality systems, or parts of the standards, for medical devices.

The Secretary shall provide the advisory committee a reasonable time to make its recommendation with respect to proposed regulations under subparagraph (A).

(2)(A) Any person subject to any requirement prescribed by regulations under paragraph (1) may petition the Secretary for an exemption or variance from such requirement. Such a petition shall be submitted to the Secretary in such form and manner as he shall prescribe and shall—

(i) in the case of a petition for an exemption from a requirement, set forth the basis for the petitioner's determination that compliance with the requirement is not required to assure that the device will be safe and effective and otherwise in compliance with this Act,

(ii) in the case of a petition for a variance from a requirement, set forth the methods proposed to be used in, and the facilities and controls proposed to be used for, the manufacture, packing, storage, and installation of the device in lieu of the methods, facilities, and controls prescribed by the requirement, and

(iii) contain such other information as the Secretary shall prescribe.

(B) The Secretary may refer to the advisory committee established under paragraph (3) any petition submitted under subparagraph (A). The advisory committee shall report its recommenda-

tions to the Secretary with respect to a petition referred to it within sixty days of the date of the petition's referral. Within sixty days after—

(i) the date the petition was submitted to the Secretary under subparagraph (A), or

(ii) if the petition was referred to an advisory committee, the expiration of the sixty-day period beginning on the date the petition was referred to the advisory committee,

whichever occurs later, the Secretary shall by order either deny the petition or approve it.

(C) The Secretary may approve—

(i) a petition for an exemption for a device from a requirement if he determines that compliance with such requirement is not required to assure that the device will be safe and effective and otherwise in compliance with this Act, and

(ii) a petition for a variance for a device from a requirement if he determines that the methods to be used in, and the facilities and controls to be used for, the manufacture, packing, storage, and installation of the device in lieu of the methods, controls, and facilities prescribed by the requirement are sufficient to assure that the device will be safe and effective and otherwise in compliance with this Act.

An order of the Secretary approving a petition for a variance shall prescribe such conditions respecting the methods used in, and the facilities and controls used for, the manufacture, packing, storage, and installation of the device to be granted the variance under the petition as may be necessary to assure that the device will be safe and effective and otherwise in compliance with this Act.

(D) After the issuance of an order under subparagraph (B) respecting a petition, the petitioner shall have an opportunity for an informal hearing on such order.

(3) The Secretary shall establish an advisory committee for the purpose of advising and making recommendations to him with respect to regulations proposed to be promulgated under paragraph (1)(A) and the approval or disapproval of petitions submitted under paragraph (2). The advisory committee shall be composed of nine members as follows:

(A) Three of the members shall be appointed from persons who are officers or employees of any State or local government or of the Federal Government.

(B) Two of the members shall be appointed from persons who are representative of interests of the device manufacturing industry; two of the members shall be appointed from persons who are representative of the interests of physicians and other health professionals; and two of the members shall be representative of the interests of the general public.

Members of the advisory committee who are not officers or employees of the United States, while attending conferences or meetings of the committee or otherwise engaged in its business, shall be entitled to receive compensation at rates to be fixed by the Secretary, which rates may not exceed the daily equivalent of the rate in effect for grade GS–18 of the General Schedule, for each day (including traveltime) they are so engaged; and while so serving away from their homes or regular places of business each member may be allowed travel expenses, including per diem in lieu of subsist-

ence, as authorized by section 5703 of title 5 of the United States Code for persons in the Government service employed intermittently. The Secretary shall designate one of the members of the advisory committee to serve as its chairman. The Secretary shall furnish the advisory committee with clerical and other assistance. Section 14 of the Federal Advisory Committee Act shall not apply with respect to the duration of the advisory committee established under this paragraph.

Exemption for Devices for Investigational Use

(g)(1) It is the purpose of this subsection to encourage to the extent consistent with the protection of the public health and safety and with ethical standards, the discovery and development of useful devices intended for human use and to that end to maintain optimum freedom for scientific investigators in their pursuit of that purpose.

(2)(A) The Secretary shall, within the one hundred and twenty-day period beginning on the date of the enactment of this section, by regulation prescribe procedures and conditions under which devices intended for human use may upon application be granted an exemption from the requirements of section 502, 510, 514, 515, 516, 519, or 721 or subsection (e) or (f) of this section or from any combination of such requirements to permit the investigational use of such devices by experts qualified by scientific training and experience to investigate the safety and effectiveness of such devices.

(B) The conditions prescribed pursuant to subparagraph (A) shall include the following:

(i) A requirement that an application be submitted to the Secretary before an exemption may be granted and that the application be submitted in such form and manner as the Secretary shall specify.

(ii) A requirement that the person applying for an exemption for a device assure the establishment and maintenance of such records, and the making of such reports to the Secretary of safety or effectiveness data obtained as a result of the investigational use of the device during the exemption, as the Secretary determines will enable him to assure compliance with such conditions, review the progress of the investigation, and evaluate the safety and effectiveness of the device.

(iii) Such other requirements as the Secretary may determine to be necessary for the protection of the public health and safety.

(C) Procedures and conditions prescribed pursuant to subparagraph (A) for an exemption may appropriately vary depending on (i) the scope and duration of clinical testing to be conducted under such exemption, (ii) the number of human subjects that are to be involved in such testing, (iii) the need to permit changes to be made in the device subject to the exemption during testing conducted in accordance with a clinical testing plan required under paragraph (3)(A), and (iv) whether the clinical testing of such device is for the purpose of developing data to obtain approval for the commercial distribution of such device.

(3) Procedures and conditions prescribed pursuant to paragraph (2)(A) shall require, as a condition to the exemption of any device

to be the subject of testing involving human subjects, that the person applying for the exemption—

(A) submit a plan for any proposed clinical testing of the device and a report of prior investigations of the device (including, where appropriate, tests on animals) adequate to justify the proposed clinical testing—

(i) to the institutional review committee established in accordance with regulations of the Secretary to supervise clinical testing of devices in the facilities where the proposed clinical testing is to be conducted, or

(ii) to the Secretary, if—

(I) no such committee exists, or

(II) the Secretary finds that the process of review by such committee is inadequate (whether or not the plan for such testing has been approved by such committee),

for review for adequacy to justify the commencement of such testing; and, unless the plan and report are submitted to the Secretary, submit to the Secretary a summary of the plan and a report of prior investigations of the device (including, where appropriate, tests on animals);

(B) promptly notify the Secretary (under such circumstances and in such manner as the Secretary prescribes) of approval by an institutional review committee of any clinical testing plan submitted to it in accordance with subparagraph (A);

(C) in the case of a device to be distributed to investigators for testing, obtain signed agreements from each of such investigators that any testing of the device involving human subjects will be under such investigator's supervision and in accordance with subparagraph (D) and submit such agreements to the Secretary; and

(D) assure that informed consent will be obtained from each human subject (or his representative) of proposed clinical testing involving such device, except where, subject to such conditions as the Secretary may prescribe—

(i) the proposed clinical testing poses no more than minimal risk to the human subject and includes appropriate safeguards to protect the rights, safety, and welfare of the human subject; or

(ii) the investigator conducting or supervising the proposed clinical testing of the device determines in writing that there exists a life threatening situation involving the human subject of such testing which necessitates the use of such device and it is not feasible to obtain informed consent from the subject and there is not sufficient time to obtain such consent from his representative.

The determination required by subparagraph (D)(ii) shall be concurred in by a licensed physician who is not involved in the testing of the human subject with respect to which such determination is made unless immediate use of the device is required to save the life of the human subject of such testing and there is not sufficient time to obtain such concurrence.

(4)(A) An application, submitted in accordance with the procedures prescribed by regulations under paragraph (2), for an exemption for a device (other than an exemption from section 516) shall

be deemed approved on the thirtieth day after the submission of the application to the Secretary unless on or before such day the Secretary by order disapproves the application and notifies the applicant of the disapproval of the application.

(B) The Secretary may disapprove an application only if he finds that the investigation with respect to which the application is submitted does not conform to procedures and conditions prescribed under regulations under paragraph (2). Such a notification shall contain the order of disapproval and a complete statement of the reasons for the Secretary's disapproval of the application and afford the applicant opportunity for an informal hearing on the disapproval order.

(C) Consistent with paragraph (1), the Secretary shall not disapprove an application under this subsection because the Secretary determines that—

(i) the investigation may not support a substantial equivalence or de novo classification determination or approval of the device;

(ii) the investigation may not meet a requirement, including a data requirement, relating to the approval or clearance of a device; or

(iii) an additional or different investigation may be necessary to support clearance or approval of the device.

(5) The Secretary may by order withdraw an exemption granted under this subsection for a device if the Secretary determines that the conditions applicable to the device under this subsection for such exemption are not met. Such an order may be issued only after opportunity for an informal hearing, except that such an order may be issued before the provision of an opportunity for an informal hearing if the Secretary determines that the continuation of testing under the exemption with respect to which the order is to be issued will result in an unreasonable risk to the public health.

(6)(A) Not later than 1 year after the date of the enactment of the Food and Drug Administration Modernization Act of 1997, the Secretary shall by regulation establish, with respect to a device for which an exemption under this subsection is in effect, procedures and conditions that, without requiring an additional approval of an application for an exemption or the approval of a supplement to such an application, permit—

(i) developmental changes in the device (including manufacturing changes) that do not constitute a significant change in design or in basic principles of operation and that are made in response to information gathered during the course of an investigation; and

(ii) changes or modifications to clinical protocols that do not affect—

(I) the validity of data or information resulting from the completion of an approved protocol, or the relationship of likely patient risk to benefit relied upon to approve a protocol;

(II) the scientific soundness of an investigational plan submitted under paragraph (3)(A); or

(III) the rights, safety, or welfare of the human subjects involved in the investigation.

(B) Regulations under subparagraph (A) shall provide that a change or modification described in such subparagraph may be made if—

(i) the sponsor of the investigation determines, on the basis of credible information (as defined by the Secretary) that the applicable conditions under subparagraph (A) are met; and

(ii) the sponsor submits to the Secretary, not later than 5 days after making the change or modification, a notice of the change or modification.

(7)(A) In the case of a person intending to investigate the safety or effectiveness of a class III device or any implantable device, the Secretary shall ensure that the person has an opportunity, prior to submitting an application to the Secretary or to an institutional review committee, to submit to the Secretary, for review, an investigational plan (including a clinical protocol). If the applicant submits a written request for a meeting with the Secretary regarding such review, the Secretary shall, not later than 30 days after receiving the request, meet with the applicant for the purpose of reaching agreement regarding the investigational plan (including a clinical protocol). The written request shall include a detailed description of the device, a detailed description of the proposed conditions of use of the device, a proposed plan (including a clinical protocol) for determining whether there is a reasonable assurance of effectiveness, and, if available, information regarding the expected performance from the device.

(B) Any agreement regarding the parameters of an investigational plan (including a clinical protocol) that is reached between the Secretary and a sponsor or applicant shall be reduced to writing and made part of the administrative record by the Secretary. Any such agreement shall not be changed, except—

(i) with the written agreement of the sponsor or applicant; or

(ii) pursuant to a decision, made in accordance with subparagraph (C) by the director of the office in which the device involved is reviewed, that a substantial scientific issue essential to determining the safety or effectiveness of the device involved has been identified.

(C) A decision under subparagraph (B)(ii) by the director shall be in writing, and may be made only after the Secretary has provided to the sponsor or applicant an opportunity for a meeting at which the director and the sponsor or applicant are present and at which the director documents the scientific issue involved.

(8)(A) At any time, the Secretary may prohibit the sponsor of an investigation from conducting the investigation (referred to in this paragraph as a "clinical hold") if the Secretary makes a determination described in subparagraph (B). The Secretary shall specify the basis for the clinical hold, including the specific information available to the Secretary which served as the basis for such clinical hold, and confirm such determination in writing.

(B) For purposes of subparagraph (A), a determination described in this subparagraph with respect to a clinical hold is a determination that—

(i) the device involved represents an unreasonable risk to the safety of the persons who are the subjects of the clinical investigation, taking into account the qualifications of the clinical

investigators, information about the device, the design of the clinical investigation, the condition for which the device is to be investigated, and the health status of the subjects involved; or

(ii) the clinical hold should be issued for such other reasons as the Secretary may by regulation establish.

(C) Any written request to the Secretary from the sponsor of an investigation that a clinical hold be removed shall receive a decision, in writing and specifying the reasons therefor, within 30 days after receipt of such request. Any such request shall include sufficient information to support the removal of such clinical hold.

(9)(A)(i) In order for a device in a clinical study for which submission of an application for an investigational device exemption is required to be exempt under this subsection, the sponsor of such study shall submit to the Secretary in such application a diversity action plan in the form and manner specified in the guidance required by section 524B.

(ii) In order for a device in a clinical study for which submission of an application for an investigational device exemption is not required, except for a device being studied as described in section 812.2(c) of title 21, Code of Federal Regulations (or successor regulations), to be exempt under this subsection, the sponsor of such study shall develop and implement a diversity action plan. Such diversity action plan shall be submitted to the Secretary in any premarket notification under section 510(k), request for classification under section 513(f)(2), or application for premarket approval under section 515 for such device.

(B) A diversity action plan under clause (i) or (ii) of subparagraph (A) shall include—

(i) the sponsor's goals for enrollment in the clinical study;

(ii) the sponsor's rationale for such goals; and

(iii) an explanation of how the sponsor intends to meet such goals.

(C) The Secretary may waive the requirement in subparagraph (A) or (B) if the Secretary determines that a waiver is necessary based on what is known about the prevalence of the disease in terms of the patient population that may use the device.

(D) No diversity action plan shall be required for a submission described in section 561.

Release of Safety and Effectiveness Information

(h)(1) The Secretary shall promulgate regulations under which a detailed summary of information respecting the safety and effectiveness of a device which information was submitted to the Secretary and which was the basis for—

(A) an order under section 515(d)(1)(A) approving an application for premarket approval for the device or denying approval of such an application or an order under section 515(e) withdrawing approval of such an application for the device,

(B) an order under section 515(f)(6)(A) revoking an approved protocol for the device, an order under section 515(f)(6)(B) declaring a protocol for the device completed or not completed, or an order under section 515(f)(7) revoking the approval of the device, or

(C) an order approving an application under subsection (g) for an exemption for the device from section 516 or an order disapproving, or withdrawing approval of, an application for an exemption under such subsection for the device,

shall be made available to the public upon issuance of the order. Summaries of information made available pursuant to this paragraph respecting a device shall include information respecting any adverse effects on health of the device.

(2) The Secretary shall promulgate regulations under which each advisory committee established under section 515(g)(2)(B) shall make available to the public a detailed summary of information respecting the safety and effectiveness of a device which information was submitted to the advisory committee and which was the basis for its recommendation to the Secretary made pursuant to section 515(g)(2)(A). A summary of information upon which such a recommendation is based shall be made available pursuant to this paragraph only after the issuance of the order with respect to which the recommendation was made and each summary shall include information respecting any adverse effect on health of the device subject to such order.

(3) Except as provided in paragraph (4), any information respecting a device which is made available pursuant to paragraph (1) or (2) of this subsection (A) may not be used to establish the safety or effectiveness of another device for purposes of this Act by any person other than the person who submitted the information so made available, and (B) shall be made available subject to subsection (c) of this section.

(4)(A) Subject to subparagraph (C), any information contained in an application for premarket approval filed with the Secretary pursuant to section 515(c) (including information from clinical and preclinical tests or studies that demonstrate the safety and effectiveness of a device, but excluding descriptions of methods of manufacture and product composition and other trade secrets) shall be available, 6 years after the application has been approved by the Secretary, for use by the Secretary in—

(i) approving another device;

(ii) determining whether a product development protocol has been completed, under section 515 for another device;

(iii) establishing a performance standard or special control under this Act; or

(iv) classifying or reclassifying another device under section 513 and subsection (l)(2).

(B) The publicly available detailed summaries of information respecting the safety and effectiveness of devices required by paragraph (1)(A) shall be available for use by the Secretary as the evidentiary basis for the agency actions described in subparagraph (A).

(C) No information contained in an application for premarket approval filed with the Secretary pursuant to section 515(c) may be used to approve or clear any application submitted under section 515 or 510(k) or to classify a product under section 513(f)(2) for a combination product containing as a constituent part an approved drug (as defined in section 503(g)(5)(B)) unless—

(i) the application includes the certification or statement referenced in section 503(g)(5)(A);

(ii) the applicant provides notice as described in section 503(g)(5)(A); and

(iii) the Secretary's approval of such application is subject to the provisions in section 503(g)(5)(C).

Proceedings of Advisory Panels and Committees

(i) Each panel under section 513 and each advisory committee established under section 514(b)(5)(B) or 515(g) or under subsection (f) of this section shall make and maintain a transcript of any proceeding of the panel or committee. Each such panel and committee shall delete from any transcript made pursuant to this subsection information which under subsection (c) of this section is to be considered confidential.

Traceability Requirements

(j) Except as provided in section 519(e), no regulation under this Act may impose on a type or class of device requirements for the traceability of such type or class of device unless such requirements are necessary to assure the protection of the public health.

Research and Development

(k) The Secretary may enter into contracts for research, testing, and demonstrations respecting devices and may obtain devices for research, testing, and demonstration purposes without regard to sections 3648 and 3709 of the Revised Statutes (31 U.S.C. 529, 41 U.S.C. 5).

Transitional Provisions for Devices Considered as New Drugs

(l)(1) Any device intended for human use—

(A) for which on the date of enactment of the Medical Device Amendments of 1976 (hereinafter in this subsection referred to as the "enactment date") an approval of an application submitted under section 505(b) was in effect;

(B) for which such an application was filed on or before the enactment date and with respect to which application no order of approval or refusing to approve had been issued on such date under subsection (c) or (d) of such section;

(C) for which on the enactment date an exemption under subsection (i) of such section was in effect;

(D) which is within a type of device described in subparagraph (A), (B), or (C) and is substantially equivalent to another device within that type;

(E) which the Secretary in a notice published in the Federal Register before the enactment date has declared to be a new drug subject to section 505; or

(F) with respect to which on the enactment date an action is pending in a United States court under section 302, 303, or 304 for an alleged violation of a provision of section 301 which enforces a requirement of section 505 or for an alleged violation of section 505(a),

is classified in class III unless the Secretary in response to a petition submitted under paragraph (2) has classified such device in class I or II.

(2) The Secretary may initiate the reclassification of a device classified into class III under paragraph (1) of this subsection or the manufacturer or importer of a device classified under paragraph (1) may petition the Secretary (in such form and manner as he shall prescribe) for the issuance of an order classifying the device in class I or class II. Within thirty days of the filing of such a petition, the Secretary shall notify the petitioner of any deficiencies in the petition which prevent the Secretary from making a decision on the petition. Except as provided in paragraph (3)(D)(ii), within one hundred and eighty days after the filing of a petition under this paragraph, the Secretary shall, after consultation with the appropriate panel under section 513, by order either deny the petition or order the classification, in accordance with the criteria prescribed by section 513(a)(1)(A) or 513(a)(1)(B), of the device in class I or class II.

(3)(A) In the case of a device which is described in paragraph (1)(A) and which is in class III—

(i) such device shall on the enactment date be considered a device with an approved application under section 515, and

(ii) the requirements applicable to such device before the enactment date under section 505 shall continue to apply to such device until changed by the Secretary as authorized by this Act.

(B) In the case of a device which is described in paragraph (1)(B) and which is in class III, an application for such device shall be considered as having been filed under section 515 on the enactment date. The period in which the Secretary shall act on such application in accordance with section 515(d)(1) shall be one hundred and eighty days from the enactment date (or such greater period as the Secretary and the applicant may agree upon after the Secretary has made the finding required by section 515(d)(1)(B)(i)) less the number of days in the period beginning on the date an application for such device was filed under section 505 and ending on the enactment date. After the expiration of such period such device is required, unless exempt under subsection (g), to have in effect an approved application under section 515.

(C) A device which is described in paragraph (1)(C) and which is in class III shall be considered a new drug until the expiration of the ninety-day period beginning on the date of the promulgation of regulations under subsection (g) of this section. After the expiration of such period such device is required, unless exempt under subsection (g), to have in effect an approved application under section 515.

(D)(i) Except as provided in clauses (ii) and (iii), a device which is described in subparagraph (D), (E), or (F) of paragraph (1) and which is in class III is required, unless exempt under subsection (g) of this section, to have on and after sixty days after the enactment date in effect an approved application under section 515.

(ii) If—

(I) a petition is filed under paragraph (2) for a device described in subparagraph (D), (E), or (F) of paragraph (1), or

(II) an application for premarket approval is filed under section 515 for such a device,

within the sixty-day period beginning on the enactment date (or within such greater period as the Secretary, after making the find-

ing required under section 515(d)(1)(B), and the petitioner or applicant may agree upon), the Secretary shall act on such petition or application in accordance with paragraph (2) or section 515 except that the period within which the Secretary must act on the petition or application shall be within the one hundred and twenty-day period beginning on the date the petition or application is filed. If such a petition or application is filed within such sixty-day (or greater) period, clause (i) of this subparagraph shall not apply to such device before the expiration of such one hundred and twenty-day period, or if such petition is denied or such application is denied approval, before the date of such denial, whichever occurs first.

(iii) In the case of a device which is described in subparagraph (E) of paragraph (1), which the Secretary in a notice published in the Federal Register after March 31, 1976, declared to be a new drug subject to section 505, and which is in class III—

(I) the device shall, after eighteen months after the enactment date, have in effect an approved application under section 515 unless exempt under subsection (g) of this section, and

(II) the Secretary may, during the period beginning one hundred and eighty days after the enactment date and ending eighteen months after such date, restrict the use of the device to investigational use by experts qualified by scientific training and experience to investigate the safety and effectiveness of such device, and to investigational use in accordance with the requirements applicable under regulations under subsection (g) of this section to investigational use of devices granted an exemption under such subsection.

If the requirements under subsection (g) of this section are made applicable to the investigational use of such a device, they shall be made applicable in such a manner that the device shall be made reasonably available to physicians meeting appropriate qualifications prescribed by the Secretary.

(5)(A) Before December 1, 1991, the Secretary shall by order require manufacturers of devices described in paragraph (1), which are subject to revision of classification under subparagraph (B), to submit to the Secretary a summary of and citation to any information known or otherwise available to the manufacturers respecting the devices, including adverse safety or effectiveness information which has not been submitted under section 519. The Secretary may require a manufacturer to submit the adverse safety or effectiveness data for which a summary and citation were submitted, if such data are available to the manufacturer.

(B) Except as provided in subparagraph (C), after the issuance of an order under subparagraph (A) but before December 1, 1992, the Secretary shall publish a regulation in the Federal Register for each device which is classified in class III under paragraph (1) revising the classification of the device so that the device is classified into class I or class II, unless the regulation requires the device to remain in class III. In determining whether to revise the classification of a device or to require a device to remain in class III, the Secretary shall apply the criteria set forth in section 513(a). Before the publication of a regulation requiring a device to remain in class III or revising its classification, the Secretary shall publish a proposed regulation respecting the classification of a device under this

subparagraph and provide an opportunity for the submission of comments on any such regulation. No regulation under this subparagraph requiring a device to remain in class III or revising its classification may take effect before the expiration of 90 days from the date of the publication in the Federal Register of the proposed regulation.

(C) The Secretary may by notice published in the Federal Register extend the period prescribed by subparagraph (B) for a device for an additional period not to exceed 1 year.

Humanitarian Device Exemption

(m)(1) To the extent consistent with the protection of the public health and safety and with ethical standards, it is the purpose of this subsection to encourage the discovery and use of devices intended to benefit patients in the treatment and diagnosis of diseases or conditions that affect not more than 8,000 individuals in the United States.

(2) The Secretary may grant a request for an exemption from the effectiveness requirements of sections 514 and 515 for a device for which the Secretary finds that—

(A) the device is designed to treat or diagnose a disease or condition that affects not more than 8,000 individuals in the United States,

(B) the device would not be available to a person with a disease or condition referred to in subparagraph (A) unless the Secretary grants such an exemption and there is no comparable device, other than under this exemption, available to treat or diagnose such disease or condition, and

(C) the device will not expose patients to an unreasonable or significant risk of illness or injury and the probable benefit to health from the use of the device outweighs the risk of injury or illness from its use, taking into account the probable risks and benefits of currently available devic or alternative forms of treatment.

The request shall be in the form of an application submitted to the Secretary and such application shall include the certification required under section 402(j)(5)(B) of the Public Health Service Act (which shall not be considered an element of such application). Not later than 75 days after the date of the receipt of the application, the Secretary shall issue an order approving or denying the application.

(3) Except as provided in paragraph (6), no person granted an exemption under paragraph (2) with respect to a device may sell the device for an amount that exceeds the costs of research and development, fabrication, and distribution of the device.

(4) Devices granted an exemption under paragraph (2) may only be used—

(A) in facilities in which clinical testing of devices is supervised by an institutional review committee established in accordance with the regulations of the Secretary; and

(B) if, before the use of a device, an institutional review committee or an appropriate local committee approves the use in the treatment or diagnosis of a disease or condition referred to in paragraph (2)(A), unless a physician determines in an emergency situation that approval from an institutional review com-

mittee or an appropriate local committee can not be obtained in time to prevent serious harm or death to a patient.

In a case described in subparagraph (B) in which a physician uses a device without an approval from an institutional review committee or an appropriate local committee, the physician shall, after the use of the device, notify the chairperson of the institutional review committee or an appropriate local committee of such use. Such notification shall include the identification of the patient involved, the date on which the device was used, and the reason for the use.

(5) The Secretary may require a person granted an exemption under paragraph (2) to demonstrate continued compliance with the requirements of this subsection if the Secretary believes such demonstration to be necessary to protect the public health, if the Secretary has reason to believe that the requirements of paragraph (6) are no longer met, or if the Secretary has reason to believe that the criteria for the exemption are no longer met. If the person granted an exemption under paragraph (2) fails to demonstrate continued compliance with the requirements of this subsection, the Secretary may suspend or withdraw the exemption from the effectiveness requirements of sections 514 and 515 for a humanitarian device only after providing notice and an opportunity for an informal hearing.

(6)(A) Except as provided in subparagraph (D), the prohibition in paragraph (3) shall not apply with respect to a person granted an exemption under paragraph (2) if each of the following conditions apply:

(i) The device with respect to which the exemption is granted—

(I) is intended for the treatment or diagnosis of a disease or condition that occurs in pediatric patients or in a pediatric subpopulation, and such device is labeled for use in pediatric patients or in a pediatric subpopulation in which the disease or condition occurs; or

(II) is intended for the treatment or diagnosis of a disease or condition that does not occur in pediatric patients or that occurs in pediatric patients in such numbers that the development of the device for such patients is impossible, highly impracticable, or unsafe.

(ii) During any calendar year, the number of such devices distributed during that year under each exemption granted under this subsection does not exceed the annual distribution number for such device. In this paragraph, the term "annual distribution number" means the number of such devices reasonably needed to treat, diagnose, or cure a population of 8,000 individuals in the United States. The Secretary shall determine the annual distribution number when the Secretary grants such exemption.

(iii) Such person immediately notifies the Secretary if the number of such devices distributed during any calendar year exceeds the annual distribution number referred to in clause (ii).

(iv) The request for such exemption is submitted on or before October 1, ⟦2022⟧ *2027*.

(B) The Secretary may inspect the records relating to the number of devices distributed during any calendar year of a person granted

an exemption under paragraph (2) for which the prohibition in paragraph (3) does not apply.

(C) A person may petition the Secretary to modify the annual distribution number determined by the Secretary under subparagraph (A)(ii) with respect to a device if additional information arises, and the Secretary may modify such annual distribution number.

(D) If a person notifies the Secretary, or the Secretary determines through an inspection under subparagraph (B), that the number of devices distributed during any calendar year exceeds the annual distribution number, as required under subparagraph (A)(iii), and modified under subparagraph (C), if applicable, then the prohibition in paragraph (3) shall apply with respect to such person for such device for any sales of such device after such notification.

(E)(i) In this subsection, the term "pediatric patients" means patients who are 21 years of age or younger at the time of the diagnosis or treatment.

(ii) In this subsection, the term "pediatric subpopulation" means 1 of the following populations:

(I) Neonates.

(II) Infants.

(III) Children.

(IV) Adolescents.

(7) The Secretary shall refer any report of an adverse event regarding a device described in paragraph (6)(A)(i)(I) for which the prohibition under paragraph (3) does not apply pursuant to paragraph (6)(A) that the Secretary receives to the Office of Pediatric Therapeutics, established under section 6 of the Best Pharmaceuticals for Children Act (Public Law 107–109). In considering the report, the Director of the Office of Pediatric Therapeutics, in consultation with experts in the Center for Devices and Radiological Health, shall provide for periodic review of the report by the Pediatric Advisory Committee, including obtaining any recommendations of such committee regarding whether the Secretary should take action under this Act in response to the report.

(8) The Secretary, acting through the Office of Pediatric Therapeutics and the Center for Devices and Radiological Health, shall provide for an annual review by the Pediatric Advisory Committee of all devices described in paragraph (6)(A)(i)(I) to ensure that the exemption under paragraph (2) remains appropriate for the pediatric populations for which it is granted.

Regulation of Contact Lens as Devices

(n)(1) All contact lenses shall be deemed to be devices under section 201(h).

(2) Paragraph (1) shall not be construed as bearing on or being relevant to the question of whether any product other than a contact lens is a device as defined by section 201(h) or a drug as defined by section 201(g).

(o) REGULATION OF MEDICAL AND CERTAIN DECISIONS SUPPORT SOFTWARE.—

(1) The term device, as defined in section 201(h), shall not include a software function that is intended—

(A) for administrative support of a health care facility, including the processing and maintenance of financial records, claims or billing information, appointment schedules, business analytics, information about patient populations, admissions, practice and inventory management, analysis of historical claims data to predict future utilization or cost-effectiveness, determination of health benefit eligibility, population health management, and laboratory workflow;

(B) for maintaining or encouraging a healthy lifestyle and is unrelated to the diagnosis, cure, mitigation, prevention, or treatment of a disease or condition;

(C) to serve as electronic patient records, including patient-provided information, to the extent that such records are intended to transfer, store, convert formats, or display the equivalent of a paper medical chart, so long as—

(i) such records were created, stored, transferred, or reviewed by health care professionals, or by individuals working under supervision of such professionals;

(ii) such records are part of health information technology that is certified under section 3001(c)(5) of the Public Health Service Act; and

(iii) such function is not intended to interpret or analyze patient records, including medical image data, for the purpose of the diagnosis, cure, mitigation, prevention, or treatment of a disease or condition;

(D) for transferring, storing, converting formats, or displaying clinical laboratory test or other device data and results, findings by a health care professional with respect to such data and results, general information about such findings, and general background information about such laboratory test or other device, unless such function is intended to interpret or analyze clinical laboratory test or other device data, results, and findings; or

(E) unless the function is intended to acquire, process, or analyze a medical image or a signal from an in vitro diagnostic device or a pattern or signal from a signal acquisition system, for the purpose of—

(i) displaying, analyzing, or printing medical information about a patient or other medical information (such as peer-reviewed clinical studies and clinical practice guidelines);

(ii) supporting or providing recommendations to a health care professional about prevention, diagnosis, or treatment of a disease or condition; and

(iii) enabling such health care professional to independently review the basis for such recommendations that such software presents so that it is not the intent that such health care professional rely primarily on any of such recommendations to make a clinical diagnosis or treatment decision regarding an individual patient.

(2) In the case of a product with multiple functions that contains—

(A) at least one software function that meets the criteria under paragraph (1) or that otherwise does not meet the definition of device under section 201(h); and

(B) at least one function that does not meet the criteria under paragraph (1) and that otherwise meets the definition of a device under section 201(h),

the Secretary shall not regulate the software function of such product described in subparagraph (A) as a device. Notwithstanding the preceding sentence, when assessing the safety and effectiveness of the device function or functions of such product described in subparagraph (B), the Secretary may assess the impact that the software function or functions described in subparagraph (A) have on such device function or functions.

(3)(A) Notwithstanding paragraph (1), a software function described in subparagraph (C), (D), or (E) of paragraph (1) shall not be excluded from the definition of device under section 201(h) if—

(i) the Secretary makes a finding that use of such software function would be reasonably likely to have serious adverse health consequences; and

(ii) the software function has been identified in a final order issued by the Secretary under subparagraph (B).

(B) Subparagraph (A) shall apply only if the Secretary—

(i) publishes a notification and proposed order in the Federal Register;

(ii) includes in such notification the Secretary's finding, including the rationale and identification of the evidence on which such finding was based, as described in subparagraph (A)(i); and

(iii) provides for a period of not less than 30 calendar days for public comment before issuing a final order or withdrawing such proposed order.

(C) In making a finding under subparagraph (A)(i) with respect to a software function, the Secretary shall consider—

(i) the likelihood and severity of patient harm if the software function were to not perform as intended;

(ii) the extent to which the software function is intended to support the clinical judgment of a health care professional;

(iii) whether there is a reasonable opportunity for a health care professional to review the basis of the information or treatment recommendation provided by the software function; and

(iv) the intended user and user environment, such as whether a health care professional will use a software function of a type described in subparagraph (E) of paragraph (1).

(4) Nothing in this subsection shall be construed as limiting the authority of the Secretary to—

(A) exercise enforcement discretion as to any device subject to regulation under this Act;

(B) regulate software used in the manufacture and transfusion of blood and blood components to assist in the prevention of disease in humans; or

(C) regulate software as a device under this Act if such software meets the criteria under section 513(a)(1)(C).

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

(1) IN GENERAL.—The Secretary may, subject to the succeeding provisions of this subsection, approve an application (or a supplement to such an application) submitted under section 515 with respect to an applicable medical imaging device, or, in the case of an applicable medical imaging device for which a notification is submitted under section 510(k), may make a substantial equivalence determination with respect to an applicable medical imaging device, or may grant a request submitted under section 513(f)(2) for an applicable medical imaging device, if such application, notification, or request involves the use of a contrast agent that is not—

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

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

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

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

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

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

(B) review information and data provided to the Secretary by the sponsor of a contrast agent in an application submitted under section 505 of this Act or section 351 of the Public Health Service Act, so long as the sponsor of such contrast agent has provided to the sponsor of the ap-

plicable medical imaging device that is the subject of such review a right of reference and the application is submitted in accordance with this subsection.

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

(4) DEFINITIONS.—For purposes of this subsection—

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

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

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

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

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

(1) DEFINITION.—

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

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

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

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

(iv) may—

(I) use wireless technology; or

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

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

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

(2) REGULATION.—An over-the-counter hearing aid shall be subject to the regulations promulgated in accordance with section 709(b) of the FDA Reauthorization Act of 2017 and shall be exempt from sections 801.420 and 801.421 of title 21, Code of Federal Regulations (or any successor regulations).

* * * * * * *

SEC. 523. ACCREDITED PERSONS.

(a) IN GENERAL.—

(1) REVIEW AND CLASSIFICATION OF DEVICES.—Not later than 1 year after the date of the enactment of the Food and Drug Administration Modernization Act of 1997, the Secretary shall, subject to paragraph (3), accredit persons for the purpose of reviewing reports submitted under section 510(k) and making recommendations to the Secretary regarding the initial classification of devices under section 513(f)(1).

(2) REQUIREMENTS REGARDING REVIEW.—

(A) IN GENERAL.—In making a recommendation to the Secretary under paragraph (1), an accredited person shall notify the Secretary in writing of the reasons for the recommendation.

(B) TIME PERIOD FOR REVIEW.—Not later than 30 days after the date on which the Secretary is notified under subparagraph (A) by an accredited person with respect to a recommendation of an initial classification of a device, the Secretary shall make a determination with respect to the initial classification.

(C) SPECIAL RULE.—The Secretary may change the initial classification under section 513(f)(1) that is recommended under paragraph (1) by an accredited person, and in such case shall provide to such person, and the person who submitted the report under section 510(k) for the device, a statement explaining in detail the reasons for the change.

(3) CERTAIN DEVICES.—

(A) IN GENERAL.—An accredited person may not be used to perform a review of—

(i) a class III device;

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

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

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

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

(i) issue draft guidance on the factors the Secretary will use in determining whether a class I or class II

device type, or subset of such device types, is eligible for review by an accredited person, including—

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

(II) whether the device type, or subset of such device type, is permanently implantable, life sustaining, or life supporting, and whether there is a detailed public health justification for permitting the review by an accredited person of such device type or subset;

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

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

(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.

(b) ACCREDITATION.—

(1) PROGRAMS.—The Secretary shall provide for such accreditation through programs administered by the Food and Drug Administration, other government agencies, or by other qualified nongovernment organizations.

(2) ACCREDITATION.—

(A) IN GENERAL.—Not later than 180 days after the date of the enactment of the Food and Drug Administration Modernization Act of 1997, the Secretary shall establish and publish in the Federal Register criteria to accredit or deny accreditation to persons who request to perform the duties specified in subsection (a). The Secretary shall respond to a request for accreditation within 60 days of the receipt of the request. The accreditation of such person shall specify the particular activities under subsection (a) for which such person is accredited.

(B) WITHDRAWAL OF ACCREDITATION.—The Secretary may suspend or withdraw accreditation of any person accredited under this paragraph, after providing notice and an opportunity for an informal hearing, when such person is substantially not in compliance with the requirements of this section or poses a threat to public health or fails to act in a manner that is consistent with the purposes of this section.

(C) PERFORMANCE AUDITING.—To ensure that persons accredited under this section will continue to meet the standards of accreditation, the Secretary shall—

(i) make onsite visits on a periodic basis to each accredited person to audit the performance of such person; and

(ii) take such additional measures as the Secretary determines to be appropriate.

(D) PERIODIC REACCREDITATION.—

(i) PERIOD.—Subject to suspension or withdrawal under subparagraph (B), any accreditation under this section shall be valid for a period of 3 years after its issuance.

(ii) RESPONSE TO REACCREDITATION REQUEST.—Upon the submission of a request by an accredited person for reaccreditation under this section, the Secretary shall approve or deny such request not later than 60 days after receipt of the request.

(iii) CRITERIA.—Not later than 120 days after the date of the enactment of this subparagraph, the Secretary shall establish and publish in the Federal Register criteria to reaccredit or deny reaccreditation to persons under this section. The reaccreditation of persons under this section shall specify the particular activities under subsection (a), and the devices, for which such persons are reaccredited.

(3) QUALIFICATIONS.—An accredited person shall, at a minimum, meet the following requirements:

(A) Such person may not be an employee of the Federal Government.

(B) Such person shall be an independent organization which is not owned or controlled by a manufacturer, supplier, or vendor of devices and which has no organizational, material, or financial affiliation with such a manufacturer, supplier, or vendor.

(C) Such person shall be a legally constituted entity permitted to conduct the activities for which it seeks accreditation.

(D) Such person shall not engage in the design, manufacture, promotion, or sale of devices.

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

(F) 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—

(i) certify that reported information accurately reflects data reviewed;

(ii) limit work to that for which competence and capacity are available;

(iii) treat information received, records, reports, and recommendations as proprietary information;

(iv) promptly respond and attempt to resolve complaints regarding its activities for which it is accredited; and

(v) protect against the use, in carrying out subsection (a) with respect to a device, of any officer or

employee of the person who has a financial conflict of interest regarding the device, and annually make available to the public disclosures of the extent to which the person, and the officers and employees of the person, have maintained compliance with requirements under this clause relating to financial conflicts of interest.

(4) SELECTION OF ACCREDITED PERSONS.—The Secretary shall provide each person who chooses to use an accredited person to receive a section 510(k) report a panel of at least two or more accredited persons from which the regulated person may select one for a specific regulatory function.

(5) COMPENSATION OF ACCREDITED PERSONS.—Compensation for an accredited person shall be determined by agreement between the accredited person and the person who engages the services of the accredited person, and shall be paid by the person who engages such services.

(c) DURATION.—The authority provided by this section terminates October 1, [2022] *2027*.

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SEC. 524A. PRIORITY REVIEW FOR QUALIFIED INFECTIOUS DISEASE PRODUCTS.

(a) IN GENERAL.—If the Secretary designates a drug under section 505E(d) as a qualified infectious disease product, then the Secretary shall give priority review to the first application submitted for approval for such drug under section 505(b) *of this Act or section 351(a) of the Public Health Service Act that requires clinical data (other than bioavailability studies) to demonstrate safety or effectiveness*.

(b) CONSTRUCTION.—Nothing in this section shall prohibit the Secretary from giving priority review to a human drug application or efficacy supplement submitted for approval under section 505(b) that otherwise meets the criteria for the Secretary to grant priority review.

SEC. 524B. GUIDANCE ON DIVERSITY ACTION PLANS FOR CLINICAL STUDIES.

(a) IN GENERAL.—The Secretary shall issue guidance relating to—

(1) the format and content of the diversity action plans required by sections 505(i)(5) and 520(g)(9) pertaining to the sponsor's goals for clinical study enrollment, disaggregated by age group, sex, race, geographic location, socioeconomic status, and ethnicity, including with respect to—

(A) the rationale for the sponsor's enrollment goals, which may include—

(i) the estimated prevalence or incidence in the United States of the disease or condition for which the drug or device is being developed or investigated, if such estimated prevalence or incidence is known or can be determined based on available data;

(ii) what is known about the disease or condition for which the drug or device is being developed or investigated;

(iii) any relevant pharmacokinetic or pharmacogenomic data;

(iv) what is known about the patient population for such disease or condition, including, to the extent data is available—

(I) demographic information, including age group, sex, race, geographic location, socioeconomic status, and ethnicity;

(II) non-demographic factors, including comorbidities affecting the patient population; and

(III) potential barriers to enrolling diverse participants, such as patient population size, geographic location, and socioeconomic status; and

(v) any other data or information relevant to selecting appropriate enrollment goals, disaggregated by demographic subgroup, such as the inclusion of pregnant and lactating women;

(B) an explanation for how the sponsor intends to meet such goals, including demographic-specific outreach and enrollment strategies, study-site selection, clinical study inclusion and exclusion practices, and any diversity training for study personnel; and

(C) procedures for the public posting of key information from the diversity action plan that would be useful to patients and providers on the sponsor's website, as appropriate; and

(2) how sponsors should include in regular reports to the Secretary—

(A) the sponsor's progress in meeting the goals referred to in paragraph (1)(A); and

(B) if the sponsor does not expect to meet such goals—

(i) any updates needed to be made to a diversity action plan referred to in paragraph (1) to help meet such goals; and

(ii) the sponsor's reasons for why the sponsor does not expect to meet such goals.

(b) ISSUANCE.—The Secretary shall—

(1) not later than 12 months after the date of enactment of this section, issue new draft guidance or update existing draft guidance described in subsection (a); and

(2) not later than 9 months after closing the comment period on such draft guidance, finalize such guidance.

SEC. 524C. ENSURING CYBERSECURITY OF DEVICES.

(a) IN GENERAL.—For purposes of ensuring cybersecurity throughout the lifecycle of a cyber device, any person who submits a premarket submission for the cyber device shall include such information as the Secretary may require to ensure that the cyber device meets such cybersecurity requirements as the Secretary determines to be appropriate to demonstrate a reasonable assurance of safety and effectiveness, including at a minimum the cybersecurity requirements under subsection (b).

(b) CYBERSECURITY REQUIREMENTS.—At a minimum, the manufacturer of a cyber device shall meet the following cybersecurity requirements:

(1) The manufacturer shall have a plan to appropriately monitor, identify, and address in a reasonable time postmarket cy-

bersecurity vulnerabilities and exploits, including coordinated vulnerability disclosure and procedures.

(2) The manufacturer shall design, develop, and maintain processes and procedures to ensure the device and related systems are cybersecure, and shall make available updates and patches to the cyber device and related systems throughout the lifecycle of the cyber device to address—

(A) on a reasonably justified regular cycle, known unacceptable vulnerabilities; and

(B) as soon as possible out of cycle, critical vulnerabilities that could cause uncontrolled risks.

(3) The manufacturer shall provide in the labeling of the cyber device a software bill of materials, including commercial, open-source, and off-the-shelf software components.

(4) The manufacturer shall comply with such other requirements as the Secretary may require to demonstrate reasonable assurance of the safety and effectiveness of the device for purposes of cybersecurity, which the Secretary may require by an order published in the Federal Register.

(c) SUBSTANTIAL EQUIVALENCE.—In making a determination of substantial equivalence under section 513(i) for a cyber device, the Secretary may—

(1) find that cybersecurity information for the cyber device described in the relevant premarket submission in the cyber device's use environment is inadequate; and

(2) issue a nonsubstantial equivalence determination based on this finding.

(d) DEFINITION.—In this section:

(1) CYBER DEVICE.—The term "cyber device" means a device that—

(A) includes software, including software as or in a device;

(B) has the ability to connect to the internet; or

(C) contains any such technological characteristics that could be vulnerable to cybersecurity threats.

(2) LIFECYCLE OF THE CYBER DEVICE.—The term "lifecycle of the cyber device" includes the postmarket lifecycle of the cyber device.

(3) PREMARKET SUBMISSION.—The term "premarket submission" means any submission under section 510(k), 513, 515(c), 515(f), or 520(m).

(e) EXEMPTION.—The Secretary may identify devices or types of devices that are exempt from meeting the cybersecurity requirements established by this section and regulations promulgated pursuant to this section. The Secretary shall publish in the Federal Register, and update, as appropriate, a list of the devices and types of devices so identified by the Secretary.

SUBCHAPTER B—DRUGS FOR RARE DISEASES OR CONDITIONS

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PROTECTION FOR DRUGS FOR RARE DISEASES OR CONDITIONS

SEC. 527. (a) Except as provided in subsection (b), if the Secretary—

(1) approves an application filed pursuant to section 505, or

(2) issues a license under section 351 of the Public Health Service Act

for a drug designated under section 526 for a rare disease or condition, the Secretary may not approve another application under section 505 or issue another license under section 351 of the Public Health Service Act for the same drug for the [same disease or condition] *same approved indication or use within such rare disease or condition* for a person who is not the holder of such approved application or of such license until the expiration of seven years from the date of the approval of the approved application or the issuance of the license. Section 505(c)(2) does not apply to the refusal to approve an application under the preceding sentence.

(b) During the 7-year period described in subsection (a) for an approved application under section 505 or license under section 351 of the Public Health Service Act, the Secretary may approve an application or issue a license for a drug that is otherwise the same, as determined by the Secretary, as the already approved drug for the [same rare disease or condition] *same indication or use for which the Secretary has approved or licensed such drug* if—

(1) the Secretary finds, after providing the holder of exclusive approval or licensure notice and opportunity for the submission of views, that during such period the holder of the exclusive approval or licensure cannot ensure the availability of sufficient quantities of the drug to meet the needs of persons [with the disease or condition for which the drug was designated] *for whom the drug is indicated*; or

(2) the holder provides the Secretary in writing the consent of such holder for the approval of other applications or the issuance of other licenses before the expiration of such seven-year period.

(c) CONDITION OF CLINICAL SUPERIORITY.—

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

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

(3) APPLICABILITY.—This subsection applies to any drug designated under section 526 for which an application was approved under section 505 of this Act or licensed under section 351 of the Public Health Service Act after the date of enactment of the FDA Reauthorization Act of 2017, regardless of the date on which such drug was designated under section 526.

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

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

(1) upon the designation of any drug under section 526, shall notify the sponsor of such drug in writing of the basis for the designation, including, as applicable, any plausible hypothesis offered by the sponsor and relied upon by the Secretary that the drug is clinically superior to a previously approved drug; and

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

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SUBCHAPTER E—GENERAL PROVISIONS RELATING TO DRUGS AND DEVICES

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SEC. 566. CRITICAL PATH PUBLIC-PRIVATE PARTNERSHIPS.

(a) ESTABLISHMENT.—The Secretary, acting through the Commissioner of Food and Drugs, may enter into collaborative agreements, to be known as Critical Path Public-Private Partnerships, with one or more eligible entities to implement the Critical Path Initiative of the Food and Drug Administration by developing innovative, collaborative projects in research, education, and outreach for the purpose of fostering medical product innovation, enabling the acceleration of medical product development, manufacturing, and translational therapeutics, and enhancing medical product safety.

(b) ELIGIBLE ENTITY.—In this section, the term "eligible entity" means an entity that meets each of the following:

(1) The entity is—

(A) an institution of higher education (as such term is defined in section 101 of the Higher Education Act of 1965) or a consortium of such institutions; or

(B) an organization described in section 501(c)(3) of the Internal Revenue Code of 1986 and exempt from tax under section 501(a) of such Code.

(2) The entity has experienced personnel and clinical and other technical expertise in the biomedical sciences, which may include graduate training programs in areas relevant to priorities of the Critical Path Initiative.

(3) The entity demonstrates to the Secretary's satisfaction that the entity is capable of—

(A) developing and critically evaluating tools, methods, and processes—

(i) to increase efficiency, predictability, and productivity of medical product development; and

(ii) to more accurately identify the benefits and risks of new and existing medical products;

(B) establishing partnerships, consortia, and collaborations with health care practitioners and other providers of health care goods or services; pharmacists; pharmacy benefit managers and purchasers; health maintenance organizations and other managed health care organizations; health care insurers; government agencies; patients and consumers; manufacturers of prescription drugs, biological products, diagnostic technologies, and devices; and academic scientists; and

(C) securing funding for the projects of a Critical Path Public-Private Partnership from Federal and nonfederal governmental sources, foundations, and private individuals.

(c) FUNDING.—The Secretary may not enter into a collaborative agreement under subsection (a) unless the eligible entity involved provides an assurance that the entity will not accept funding for a Critical Path Public-Private Partnership project from any organization that manufactures or distributes products regulated by the Food and Drug Administration unless the entity provides assurances in its agreement with the Food and Drug Administration that the results of the Critical Path Public-Private Partnership project will not be influenced by any source of funding.

(d) ANNUAL REPORT.—Not later than 18 months after the date of the enactment of this section, and annually thereafter, the Secretary, in collaboration with the parties to each Critical Path Public-Private Partnership, shall submit a report to the Committee on Health, Education, Labor, and Pensions of the Senate and the Committee on Energy and Commerce of the House of Representatives—

(1) reviewing the operations and activities of the Partnerships in the previous year; and

(2) addressing such other issues relating to this section as the Secretary determines to be appropriate.

(e) DEFINITION.—In this section, the term "medical product" includes a drug, a biological product as defined in section 351 of the Public Health Service Act, a device, and any combination of such products.

(f) AUTHORIZATION OF APPROPRIATIONS.—To carry out this section, there is authorized to be appropriated **[**$6,000,000 for each of fiscal years 2018 through 2022**]** *$10,000,000 for each of fiscal years 2023 through 2027*.

SEC. 566A. EMERGING TECHNOLOGY PROGRAM.

(a) PROGRAM ESTABLISHMENT.—

(1) IN GENERAL.—The Secretary shall establish a program to support the adoption of, and improve the development of, innovative approaches to drug product design and manufacturing.

(2) ACTIONS.—In carrying out the program under paragraph (1), the Secretary may—

(A) facilitate and increase communication between public and private entities, consortia, and individuals with respect to innovative drug product design and manufacturing;

(B) solicit information regarding, and conduct or support research on, innovative approaches to drug product design and manufacturing;

(C) convene meetings with representatives of industry, academia, other Federal agencies, international agencies, and other interested persons, as appropriate;

(D) convene working groups to support drug product design and manufacturing research and development;

(E) support education and training for regulatory staff and scientists related to innovative approaches to drug product design and manufacturing;

(F) advance regulatory science related to the development and review of innovative approaches to drug product design and manufacturing;

(G) convene or participate in working groups to support the harmonization of international regulatory requirements related to innovative approaches to drug product design and manufacturing; and

(H) award grants or contracts to carry out or support the program under paragraph (1).

(3) GRANTS AND CONTRACTS.—To seek a grant or contract under this section, an entity shall submit an application—

(A) in such form and manner as the Secretary may require; and

(B) containing such information as the Secretary may require, including a description of—

(i) how the entity will conduct the activities to be supported through the grant or contract; and

(ii) how such activities will further research and development related to, or adoption of, innovative approaches to drug product design and manufacturing.

(b) GUIDANCE.—The Secretary shall—

(1) issue or update guidance to help facilitate the adoption of, and advance the development of, innovative approaches to drug product design and manufacturing; and

(2) include in such guidance descriptions of—

(A) any regulatory requirements related to the development or review of technologies related to innovative approaches to drug product design and manufacturing, including updates and improvements to such technologies after product approval; and

(B) data that can be used to demonstrate the identity, safety, purity, and potency of drugs manufactured using such technologies.

(c) REPORT TO CONGRESS.—Not later than 4 years after the date of enactment of this section, the Secretary shall submit to the Committee on Energy and Commerce of the House of Representatives and the Committee on Health, Education, Labor, and Pensions of the Senate a report containing—

(1) an annual accounting of the allocation of funds made available to carry out this section;

(2) a description of how Food and Drug Administration staff were utilized to carry out this section and, as applicable, any challenges or limitations related to staffing;

(3) the number of public meetings held or participated in by the Food and Drug Administration pursuant to this section, including meetings convened as part of a working group described in subparagraph (D) or (G) of subsection (a)(2), and the topics of each such meeting; and

(4) the number of drug products approved or licensed, after the date of enactment of this section, using an innovative approach to drug product design and manufacturing.

(d) AUTHORIZATION OF APPROPRIATIONS.—To carry out this section, there is authorized to be appropriated $20,000,000 for each fiscal year 2023 through 2027.

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SEC. 569. CONSULTATION WITH EXTERNAL EXPERTS ON RARE DISEASES, TARGETED THERAPIES, AND GENETIC TARGETING OF TREATMENTS.

(a) IN GENERAL.—For the purpose of promoting the efficiency of and informing the review by the Food and Drug Administration of new drugs and biological products for rare diseases and drugs and biological products that are genetically targeted, the following shall apply:

(1) CONSULTATION WITH STAKEHOLDERS.—Consistent with sections X.C and IX.E.4 of the PDUFA Reauthorization Performance Goals and Procedures Fiscal Years 2013 through 2017, as referenced in the letters described in section 101(b) of the Prescription Drug User Fee Amendments of 2012, the Secretary shall ensure that opportunities exist, at a time the Secretary determines appropriate, for consultations with stakeholders on the topics described in subsection (b).

(2) CONSULTATION WITH EXTERNAL EXPERTS.—

(A) IN GENERAL.—The Secretary shall develop and maintain a list of external experts who, because of their special expertise, are qualified to provide advice on rare disease issues, including topics described in subsection (b). The Secretary may, when appropriate to address a specific regulatory question, consult such external experts on issues related to the review of new drugs and biological products for rare diseases and drugs and biological products that are genetically targeted, including the topics described in subsection (b), when such consultation is necessary because the Secretary lacks the specific scientific, medical, or technical expertise necessary for the performance of the Secretary's regulatory responsibilities and the necessary expertise can be provided by the external experts.

(B) EXTERNAL EXPERTS.—For purposes of subparagraph (A), external experts are individuals who possess scientific or medical training that the Secretary lacks with respect to one or more rare diseases.

(C) SMALL POPULATION STUDIES.—The external experts on the list maintained pursuant to subparagraph (A) may include experts on the science of small population studies.

(b) TOPICS FOR CONSULTATION.—Topics for consultation pursuant to this section may include—

(1) rare diseases;

(2) the severity of rare diseases;

(3) the unmet medical need associated with rare diseases;

(4) the willingness and ability of individuals with a rare disease to participate in clinical trials;

(5) an assessment of the benefits and risks of therapies to treat rare diseases;

(6) the general design of clinical trials for rare disease populations and subpopulations; and

(7) the demographics and the clinical description of patient populations.

(c) CLASSIFICATION AS SPECIAL GOVERNMENT EMPLOYEES.—The external experts who are consulted under this section may be considered special government employees, as defined under section 202 of title 18, United States Code.

(d) PROTECTION OF CONFIDENTIAL INFORMATION AND TRADE SECRETS.—

(1) RULE OF CONSTRUCTION.—Nothing in this section shall be construed to alter the protections offered by laws, regulations, and policies governing disclosure of confidential commercial or trade secret information, and any other information exempt from disclosure pursuant to section 552(b) of title 5, United States Code, as such provisions would be applied to consultation with individuals and organizations prior to the date of enactment of this section.

(2) CONSENT REQUIRED FOR DISCLOSURE.—The Secretary shall not disclose confidential commercial or trade secret information to an expert consulted under this section without the written consent of the sponsor unless the expert is a special government employee (as defined under section 202 of title 18, United States Code) or the disclosure is otherwise authorized by law.

(e) OTHER CONSULTATION.—Nothing in this section shall be construed to limit the ability of the Secretary to consult with individuals and organizations as authorized prior to the date of enactment of this section.

(f) NO RIGHT OR OBLIGATION.—

(1) NO RIGHT TO CONSULTATION.—Nothing in this section shall be construed to create a legal right for a consultation on any matter or require the Secretary to meet with any particular expert or stakeholder.

(2) NO ALTERING OF GOALS.—Nothing in this section shall be construed to alter agreed upon goals and procedures identified in the letters described in section 101(b) of the Prescription Drug User Fee Amendments of 2012.

(3) NO CHANGE TO NUMBER OF REVIEW CYCLES.—Nothing in this section is intended to increase the number of review cycles as in effect before the date of enactment of this section.

(g) NO DELAY IN PRODUCT REVIEW.—

(1) IN GENERAL.—Prior to a consultation with an external expert, as described in this section, relating to an investigational new drug application under section 505(i), a new drug application under section 505(b), or a biologics license application under section 351 of the Public Health Service Act, the Director of the Center for Drug Evaluation and Research or the Director of the Center for Biologics Evaluation and Research (or appropriate Division Director), as appropriate, shall determine that—

(A) such consultation will—

(i) facilitate the Secretary's ability to complete the Secretary's review; and

(ii) address outstanding deficiencies in the application; or

(B) the sponsor authorized such consultation.

(2) LIMITATION.—The requirements of this subsection shall apply only in instances where the consultation is undertaken solely under the authority of this section. The requirements of this subsection shall not apply to any consultation initiated under any other authority.

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CHAPTER VII—GENERAL AUTHORITY

SUBCHAPTER A—GENERAL ADMINISTRATIVE PROVISIONS

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SEC. 703. RECORDS.

(a) IN GENERAL.—For the purpose of enforcing the provisions of this Act, carriers engaged in interstate commerce, and persons receiving food, drugs, devices, tobacco products, or cosmetics in interstate commerce or holding such articles so received, shall, upon the request of an officer or employee duly designated by the Secretary, permit such officer or employee, at reasonable times, to have access to and to copy all records showing the movement in interstate commerce of any food, drug, device, tobacco product, or cosmetic, or the holding thereof during or after such movement, and the quantity, shipper, and consignee thereof; and it shall be unlawful for any such carrier or person to fail to permit such access to and copying of any such record so requested when such request is accompanied by a statement in writing specifying the nature or kind of food, drug, device, tobacco product, or cosmetic to which such request relates, except that evidence obtained under this section, or any evidence which is directly or indirectly derived from such evidence, shall not be used in a criminal prosecution of the person from whom obtained, and except that carriers shall not be subject to the other provisions of this Act by reason of their receipt, carriage, holding, or delivery of food, drugs, devices, tobacco products, or cosmetics in the usual course of business as carriers, except as provided in subsection (b).

(b) FOOD TRANSPORTATION RECORDS.—A shipper, carrier by motor vehicle or rail vehicle, receiver, or other person subject to section 416 shall, on request of an officer or employee designated by the Secretary, permit the officer or employee, at reasonable times, to have access to and to copy all records that the Secretary requires to be kept under section 416(c)(1)(E).

(c) APPLICABILITY.—The limitations on the Secretary's use of evidence obtained under this section, or any evidence which is directly or indirectly derived from such evidence, in a criminal prosecution of the person from whom such evidence was obtained shall not apply to evidence, including records or other information, obtained under authorities other than this section, unless such limitations are specifically incorporated by reference in such other authorities.

FACTORY INSPECTION

SEC. 704. (a)(1) For purposes of enforcement of this Act, officers or employees duly designated by the Secretary, upon presenting appropriate credentials and a written notice to the owner, operator, or agent in charge, are authorized (A) to enter, at reasonable times, any factory, warehouse, or establishment in which food, drugs, devices, tobacco products, or cosmetics are manufactured, processed, packed, or held, for introduction into interstate commerce or after such introduction, or to enter any vehicle, being used to transport or hold such food, drugs, devices, tobacco products, or cosmetics in interstate commerce; and (B) to inspect, at reasonable times and within reasonable limits and in a reasonable manner, such factory, warehouse, establishment, or vehicle and all pertinent equipment, finished and unfinished materials, containers, and labeling therein. In the case of any person (excluding farms and restaurants) who manufactures, processes, packs, transports, distributes, holds, or imports foods, the inspection shall extend to all records and other information described in section 414, when the standard for records inspection under paragraph (1) or (2) of section 414(a) applies, subject to the limitations established in section 414(d). In the case of any factory, warehouse, establishment, or consulting laboratory in which prescription drugs, nonprescription drugs intended for human use, [restricted devices] *devices*, or tobacco products are manufactured, processed, packed, or held, inspection shall extend to all things therein (including records, files, papers, processes, controls, and facilities) bearing on whether prescription drugs, nonprescription drugs intended for human use, [restricted devices] *devices*, or tobacco products which are adulterated or misbranded within the meaning of this Act, or which may not be manufactured, introduced into interstate commerce, or sold, or offered for sale by reason of any provision of this Act, have been or are being manufactured, processed, packed, transported, or held in any such place, or otherwise bearing on violation of this Act. No inspection authorized by the preceding sentence or by paragraph (3) shall extend to financial data, sales data other than shipment data, pricing data, personnel data (other than data as to qualifications of technical and professional personnel performing functions subject to this Act), and research data (other than data relating to new drugs, antibiotic drugs, devices, and tobacco products and subject to reporting and inspection under regulations lawfully issued pursuant to section 505 (i) or (k), section 519, section 520(g), or chapter IX and data relating to other drugs, devices, or tobacco products which in the case of a new drug would be subject to reporting or inspection under lawful regulations issued pursuant to section 505(j)). A separate notice shall be given for each such inspection, but a notice shall not be required for each entry made during the period covered by the inspection. Each such inspection shall be commenced and completed with reasonable promptness.

(2) The provisions of the third sentence of paragraph (1) shall not apply to—

(A) pharmacies which maintain establishments in conformance with any applicable local laws regulating the practice of pharmacy and medicine and which are regularly engaged in dispensing prescription drugs or devices, upon prescriptions of

practitioners licensed to administer such drugs or devices to patients under the care of such practitioners in the course of their professional practice, and which do not, either through a subsidiary or otherwise, manufacture, prepare, propagate, compound, or process drugs or devices for sale other than in the regular course of their business of dispensing or selling drugs or devices at retail;

(B) practitioners licensed by law to prescribe or administer drugs, or prescribe or use devices, as the case may be, and who manufacture, prepare, propagate, compound, or process drugs, or manufacture or process devices solely for use in the course of their professional practice;

(C) persons who manufacture, prepare, propagate, compound, or process drugs, or manufacture or process devices solely for use in research, teaching, or chemical analysis and not for sale;

(D) such other classes of persons as the Secretary may by regulation exempt from the application of this section upon a finding that inspection as applied to such classes of persons in accordance with this section is not necessary for the protection of the public health.

(3) An officer or employee making an inspection under paragraph (1) for purposes of enforcing the requirements of section 412 applicable to infant formulas shall be permitted, at all reasonable times, to have access to and to copy and verify any records—

(A) bearing on whether the infant formula manufactured or held in the facility inspected meets the requirements of section 412, or

(B) required to be maintained under section 412.

(4)(A) Any records or other information that the Secretary may inspect under this section from a person that owns or operates ⟦an establishment that is engaged in the manufacture, preparation, propagation, compounding, or processing of a drug⟧ *an establishment that is engaged in the manufacture, preparation, propagation, compounding, or processing of a drug or device, or that is subject to inspection under paragraph (5)(C),* shall, upon the request of the Secretary, be provided to the Secretary by such person, in advance of or in lieu of an inspection, within a reasonable timeframe, within reasonable limits, and in a reasonable manner, and in either electronic or physical form, at the expense of such person. The Secretary's request shall include a sufficient description of the records requested *and a rationale for requesting such records or other information in advance of, or in lieu of, an inspection*.

(B) Upon receipt of the records requested under subparagraph (A), the Secretary shall provide to the person confirmation of receipt.

(C) The Secretary may rely on any records or other information that the Secretary may inspect under this section to satisfy requirements that may pertain to a preapproval or risk-based surveillance inspection, or to resolve deficiencies identified during such inspections, if applicable and appropriate.

⟦(C)⟧ *(D)* Nothing in this paragraph supplants the authority of the Secretary to conduct inspections otherwise permitted under this Act in order to ensure compliance with this Act.

(5) BIORESEARCH MONITORING INSPECTIONS.—

(A) IN GENERAL.—The Secretary may, to ensure the accuracy and reliability of studies and records or other information described in subparagraph (B) and to assess compliance with applicable requirements under this Act or the Public Health Service Act, enter sites and facilities specified in subparagraph (C) in order to inspect such records or other information.

(B) INFORMATION SUBJECT TO INSPECTION.—An inspection under this paragraph shall extend to all records and other information related to the studies and submissions described in subparagraph (E), including records and information related to the conduct, results, and analyses of, and the protection of human and animal trial participants participating in, such studies.

(C) SITES AND FACILITIES SUBJECT TO INSPECTION.—

(i) SITES AND FACILITIES DESCRIBED.—The sites and facilities subject to inspection by the Secretary under this paragraph are those owned or operated by a person described in clause (ii) and which are (or were) utilized by such person in connection with—

(I) developing an application or other submission to the Secretary under this Act or the Public Health Service Act related to marketing authorization for a product described in paragraph (1);

(II) preparing, conducting, or analyzing the results of a study described in subparagraph (E); or

(III) holding any records or other information described in subparagraph (B).

(ii) PERSONS DESCRIBED.—A person described in this clause is—

(I) the sponsor of an application or submission specified in subparagraph (E);

(II) a person engaged in any activity described in clause (i) on behalf of such a sponsor, through a contract, grant, or other business arrangement with such sponsor;

(III) an institutional review board, or other individual or entity, engaged by contract, grant, or other business arrangement with a nonsponsor in preparing, collecting, or analyzing records or other information described in subparagraph (B); or

(IV) any person not otherwise described in this clause that conducts, or has conducted, a study described in subparagraph (E) yielding records or other information described in subparagraph (B).

(D) CONDITIONS OF INSPECTION.—

(i) ACCESS TO INFORMATION SUBJECT TO INSPECTION.—Subject to clause (ii), an entity that owns or operates any site or facility subject to inspection under this paragraph shall provide the Secretary with access to records and other information described in subparagraph (B) that is held by or under the control of such entity, including—

(I) permitting the Secretary to record or copy such information for purposes of this paragraph;

(II) providing the Secretary with access to any electronic information system utilized by such entity to hold, process, analyze, or transfer any records or other information described in subparagraph (B); and

(III) permitting the Secretary to inspect the facilities, equipment, written procedures, processes, and conditions through which records or other information described in subparagraph (B) is or was generated, held, processed, analyzed, or transferred.

(ii) NO EFFECT ON APPLICABILITY OF PROVISIONS FOR PROTECTION OF PROPRIETARY INFORMATION OR TRADE SECRETS.—Nothing in clause (i) shall negate, supersede, or otherwise affect the applicability of provisions, under this or any other Act, preventing or limiting the disclosure of confidential commercial information or other information considered proprietary or trade secret.

(iii) REASONABLENESS OF INSPECTIONS.—An inspection under this paragraph shall be conducted at reasonable times and within reasonable limits and in a reasonable manner.

(E) STUDIES AND SUBMISSIONS DESCRIBED.—The studies and submissions described in this subparagraph are each of the following:

(i) Clinical and nonclinical studies submitted to the Secretary in support of, or otherwise related to, applications and other submissions to the Secretary under this Act or the Public Health Service Act for marketing authorization of a product described in paragraph (1).

(ii) Postmarket safety activities conducted under this Act or the Public Health Service Act.

(iii) Any other clinical investigation of—

(I) a drug subject to section 505 or 512 of this Act or section 351 of the Public Health Service Act; or

(II) a device subject to section 520(g).

(iv) Any other submissions made under this Act or the Public Health Service Act with respect to which the Secretary determines an inspection under this paragraph is warranted in the interest of public health.

(F) CLARIFICATION.—This paragraph clarifies the authority of the Secretary to conduct inspections of the type described in this paragraph and shall not be construed as a basis for inferring that, prior to the date of enactment of this paragraph, the Secretary lacked the authority to conduct such inspections, including under this Act or the Public Health Service Act.

(b)(1) Upon completion of any such inspection of a factory, warehouse, consulting laboratory, or other establishment, and prior to leaving the premises, the officer or employee making the inspection shall give to the owner, operator, or agent in charge a report in writing setting forth any conditions or practices observed by him which, in his judgment, indicate that any food, drug, device, to-

bacco product, or cosmetic in such establishment (A) consists in whole or in part of any filthy, putrid, or decomposed substance, or (B) has been prepared, packed, or held under insanitary conditions whereby it may have become contaminated with filth, or whereby it may have been rendered injurious to health. A copy of such report shall be sent promptly to the Secretary.

(2) In carrying out this subsection with respect to any establishment manufacturing a drug approved under subsection (c) or (j) of section 505 for which a notification has been submitted in accordance with section 506C is, or has been in the last 5 years, listed on the drug shortage list under section 506E, or that is described in section 505(j)(11)(A), a copy of the report shall be sent promptly to the appropriate offices of the Food and Drug Administration with expertise regarding drug shortages.

(c) If the officer or employee making any such inspection of a factory, warehouse, or other establishment has obtained any sample in the course of the inspection, upon completion of the inspection and prior to leaving the premises he shall give to the owner, operator, or agent in charge a receipt describing the samples obtained.

(d) Whenever in the course of any such inspection of a factory or other establishment where food is manufactured, processed, or packed, the officer or employee making the inspection obtains a sample of any such food, and an analysis is made of such sample for the purpose of ascertaining whether such food consists in whole or in part of any filthy, putrid, or decomposed substance, or is otherwise unfit for food, a copy of the results of such analysis shall be furnished promptly to the owner, operator, or agent in charge.

(e) Every person required under section 519 or 520(g) to maintain records and every person who is in charge or custody of such records shall, upon request of an officer or employee designated by the Secretary, permit such officer or employee at all reasonable times to have access to, and to copy and verify, such records.

(f)(1) An accredited person described in paragraph (3) shall maintain records documenting the training qualifications of the person and the employees of the person, the procedures used by the person for handling confidential information, the compensation arrangements made by the person, and the procedures used by the person to identify and avoid conflicts of interest. Upon the request of an officer or employee designated by the Secretary, the person shall permit the officer or employee, at all reasonable times, to have access to, to copy, and to verify, the records.

(2) Within 15 days after the receipt of a written request from the Secretary to an accredited person described in paragraph (3) for copies of records described in paragraph (1), the person shall produce the copies of the records at the place designated by the Secretary.

(3) For purposes of paragraphs (1) and (2), an accredited person described in this paragraph is a person who—

(A) is accredited under subsection (g); or

(B) is accredited under section 523.

(g)(1) The Secretary shall, subject to the provisions of this subsection, accredit persons for the purpose of conducting inspections of establishments that manufacture, prepare, propagate, compound, or process class II or class III devices, which inspections are required under section 510(h) or are inspections of such establish-

ments required to register under section 510(i). The owner or operator of such an establishment that is eligible under paragraph (6) may, from the list published under paragraph (4), select an accredited person to conduct such inspections.

(2) The Secretary shall publish in the Federal Register criteria to accredit or deny accreditation to persons who request to perform the duties specified in paragraph (1). Thereafter, the Secretary shall inform those requesting accreditation, within 60 days after the receipt of such request, whether the request for accreditation is adequate for review, and the Secretary shall promptly act on the request for accreditation. Any resulting accreditation shall state that such person is accredited to conduct inspections at device establishments identified in paragraph (1). The accreditation of such person shall specify the particular activities under this subsection for which such person is accredited.

(3) An accredited person shall, at a minimum, meet the following requirements:

(A) Such person may not be an employee of the Federal Government.

(B) Such person shall be an independent organization which is not owned or controlled by a manufacturer, supplier, or vendor of articles regulated under this Act and which has no organizational, material, or financial affiliation (including a consultative affiliation) with such a manufacturer, supplier, or vendor.

(C) Such person shall be a legally constituted entity permitted to conduct the activities for which it seeks accreditation.

(D) Such person shall not engage in the design, manufacture, promotion, or sale of articles regulated under this Act.

(E) The operations of such person shall be in accordance with generally accepted professional and ethical business practices, and such person shall agree in writing that at a minimum the person will—

(i) certify that reported information accurately reflects data reviewed, inspection observations made, other matters that relate to or may influence compliance with this Act, and recommendations made during an inspection or at an inspection's closing meeting;

(ii) limit work to that for which competence and capacity are available;

(iii) treat information received, records, reports, and recommendations as confidential commercial or financial information or trade secret information, except such information may be made available to the Secretary;

(iv) promptly respond and attempt to resolve complaints regarding its activities for which it is accredited; and

(v) protect against the use, in carrying out paragraph (1), of any officer or employee of the accredited person who has a financial conflict of interest regarding any product regulated under this Act, and annually make available to the public disclosures of the extent to which the accredited person, and the officers and employees of the person, have maintained compliance with requirements under this clause relating to financial conflicts of interest.

(F) Such person shall notify the Secretary of any withdrawal, suspension, restriction, or expiration of certificate of conformance with the quality systems standard referred to in paragraph (7) for any device establishment that such person inspects under this subsection not later than 30 days after such withdrawal, suspension, restriction, or expiration.

(G) Such person may conduct audits to establish conformance with the quality systems standard referred to in paragraph (7).

(4) The Secretary shall publish on the Internet site of the Food and Drug Administration a list of persons who are accredited under paragraph (2). Such list shall be updated to ensure that the identity of each accredited person, and the particular activities for which the person is accredited, is known to the public. The updating of such list shall be no later than one month after the accreditation of a person under this subsection or the suspension or withdrawal of accreditation, or the modification of the particular activities for which the person is accredited.

(5)(A) To ensure that persons accredited under this subsection continue to meet the standards of accreditation, the Secretary shall (i) audit the performance of such persons on a periodic basis through the review of inspection reports and inspections by persons designated by the Secretary to evaluate the compliance status of a device establishment and the performance of accredited persons, and (ii) take such additional measures as the Secretary determines to be appropriate.

(B) The Secretary may withdraw accreditation of any person accredited under paragraph (2), after providing notice and an opportunity for an informal hearing, when such person is substantially not in compliance with the standards of accreditation, poses a threat to public health, fails to act in a manner that is consistent with the purposes of this subsection, or where the Secretary determines that there is a financial conflict of interest in the relationship between the accredited person and the owner or operator of a device establishment that the accredited person has inspected under this subsection. The Secretary may suspend the accreditation of such person during the pendency of the process under the preceding sentence.

(6)(A) Subject to subparagraphs (B) and (C), a device establishment is eligible for inspection by persons accredited under paragraph (2) if the following conditions are met:

(i) The Secretary classified the results of the most recent inspection of the establishment as "no action indicated" or "voluntary action indicated".

(ii) With respect to inspections of the establishment to be conducted by an accredited person, the owner or operator of the establishment submits to the Secretary a notice that—

(I) provides the date of the last inspection of the establishment by the Secretary and the classification of that inspection;

(II) states the intention of the owner or operator to use an accredited person to conduct inspections of the establishment;

(III) identifies the particular accredited person the owner or operator intends to select to conduct such inspections; and

(IV) includes a certification that, with respect to the devices that are manufactured, prepared, propagated, compounded, or processed in the establishment—

(aa) at least 1 of such devices is marketed in the United States; and

(bb) at least 1 of such devices is marketed, or is intended to be marketed, in 1 or more foreign countries, 1 of which countries certifies, accredits, or otherwise recognizes the person accredited under paragraph (2) and identified under subclause (III) as a person authorized to conduct inspections of device establishments.

(B)(i) Except with respect to the requirement of subparagraph (A)(i), a device establishment is deemed to have clearance to participate in the program and to use the accredited person identified in the notice under subparagraph (A)(ii) for inspections of the establishment unless the Secretary, not later than 30 days after receiving such notice, issues a response that—

(I) denies clearance to participate as provided under subparagraph (C); or

(II) makes a request under clause (ii).

(ii) The Secretary may request from the owner or operator of a device establishment in response to the notice under subparagraph (A)(ii) with respect to the establishment, or from the particular accredited person identified in such notice—

(I) compliance data for the establishment in accordance with clause (iii)(I); or

(II) information concerning the relationship between the owner or operator of the establishment and the accredited person identified in such notice in accordance with clause (iii)(II).

The owner or operator of the establishment, or such accredited person, as the case may be, shall respond to such a request not later than 60 days after receiving such request.

(iii)(I) The compliance data to be submitted by the owner or operator of a device establishment in response to a request under clause (ii)(I) are data describing whether the quality controls of the establishment have been sufficient for ensuring consistent compliance with current good manufacturing practice within the meaning of section 501(h) and with other applicable provisions of this Act. Such data shall include complete reports of inspectional findings regarding good manufacturing practice or other quality control audits that, during the preceding 2-year period, were conducted at the establishment by persons other than the owner or operator of the establishment, together with all other compliance data the Secretary deems necessary. Data under the preceding sentence shall demonstrate to the Secretary whether the establishment has facilitated consistent compliance by promptly correcting any compliance problems identified in such inspections.

(II) A request to an accredited person under clause (ii)(II) may not seek any information that is not required to be maintained by such person in records under subsection (f)(1).

(iv) A device establishment is deemed to have clearance to participate in the program and to use the accredited person identified in the notice under subparagraph (A)(ii) for inspections of the establishment unless the Secretary, not later than 60 days after receiving the information requested under clause (ii), issues a response that denies clearance to participate as provided under subparagraph (C).

(C)(i) The Secretary may deny clearance to a device establishment if the Secretary has evidence that the certification under subparagraph (A)(ii)(IV) is untrue and the Secretary provides to the owner or operator of the establishment a statement summarizing such evidence.

(ii) The Secretary may deny clearance to a device establishment if the Secretary determines that the establishment has failed to demonstrate consistent compliance for purposes of subparagraph (B)(iii)(I) and the Secretary provides to the owner or operator of the establishment a statement of the reasons for such determination.

(iii)(I) The Secretary may reject the selection of the accredited person identified in the notice under subparagraph (A)(ii) if the Secretary provides to the owner or operator of the establishment a statement of the reasons for such rejection. Reasons for the rejection may include that the establishment or the accredited person, as the case may be, has failed to fully respond to the request, or that the Secretary has concerns regarding the relationship between the establishment and such accredited person.

(II) If the Secretary rejects the selection of an accredited person by the owner or operator of a device establishment, the owner or operator may make an additional selection of an accredited person by submitting to the Secretary a notice that identifies the additional selection. Clauses (i) and (ii) of subparagraph (B), and subclause (I) of this clause, apply to the selection of an accredited person through a notice under the preceding sentence in the same manner and to the same extent as such provisions apply to a selection of an accredited person through a notice under subparagraph (A)(ii).

(iv) In the case of a device establishment that is denied clearance under clause (i) or (ii) or with respect to which the selection of the accredited person is rejected under clause (iii), the Secretary shall designate a person to review the statement of reasons, or statement summarizing such evidence, as the case may be, of the Secretary under such clause if, during the 30-day period beginning on the date on which the owner or operator of the establishment receives such statement, the owner or operator requests the review. The review shall commence not later than 30 days after the owner or operator requests the review, unless the Secretary and the owner or operator otherwise agree.

(7)(A) Persons accredited under paragraph (2) to conduct inspections shall record in writing their inspection observations and shall present the observations to the device establishment's designated representative and describe each observation. Additionally, such accredited person shall prepare an inspection report in a form and manner designated by the Secretary to conduct inspections, taking into consideration the goals of international harmonization of quality systems standards. Any official classification of the inspection shall be determined by the Secretary.

(B) At a minimum, an inspection report under subparagraph (A) shall identify the persons responsible for good manufacturing practice compliance at the inspected device establishment, the dates of the inspection, the scope of the inspection, and shall describe in detail each observation identified by the accredited person, identify other matters that relate to or may influence compliance with this Act, and describe any recommendations during the inspection or at the inspection's closing meeting.

(C) An inspection report under subparagraph (A) shall be sent to the Secretary and to the designated representative of the inspected device establishment at the same time, but under no circumstances later than three weeks after the last day of the inspection. The report to the Secretary shall be accompanied by all written inspection observations previously provided to the designated representative of the establishment.

(D) Any statement or representation made by an employee or agent of a device establishment to a person accredited under paragraph (2) to conduct inspections shall be subject to section 1001 of title 18, United States Code.

(E) If at any time during an inspection by an accredited person the accredited person discovers a condition that could cause or contribute to an unreasonable risk to the public health, the accredited person shall immediately notify the Secretary of the identification of the device establishment subject to inspection and such condition.

(F) For the purpose of setting risk-based inspectional priorities, the Secretary shall accept voluntary submissions of reports of audits assessing conformance with appropriate quality systems standards set by the International Organization for Standardization (ISO) and identified by the Secretary in public notice. If the owner or operator of an establishment elects to submit audit reports under this subparagraph, the owner or operator shall submit all such audit reports with respect to the establishment during the preceding 2-year periods.

(8) Compensation for an accredited person shall be determined by agreement between the accredited person and the person who engages the services of the accredited person, and shall be paid by the person who engages such services.

(9) Nothing in this subsection affects the authority of the Secretary to inspect any device establishment pursuant to this Act.

(10)(A) For fiscal year 2005 and each subsequent fiscal year, no device establishment may be inspected during the fiscal year involved by a person accredited under paragraph (2) if—

(i) of the amounts appropriated for salaries and expenses of the Food and Drug Administration for the preceding fiscal year (referred to in this subparagraph as the "first prior fiscal year"), the amount obligated by the Secretary for inspections of device establishments by the Secretary was less than the adjusted base amount applicable to such first prior fiscal year; and

(ii) of the amounts appropriated for salaries and expenses of the Food and Drug Administration for the fiscal year preceding the first prior fiscal year (referred to in this subparagraph as the "second prior fiscal year"), the amount obligated by the Secretary for inspections of device establishments by the Sec-

retary was less than the adjusted base amount applicable to such second prior fiscal year.

(B)(i) Subject to clause (ii), the Comptroller General of the United States shall determine the amount that was obligated by the Secretary for fiscal year 2002 for compliance activities of the Food and Drug Administration with respect to devices (referred to in this subparagraph as the "compliance budget"), and of such amount, the amount that was obligated for inspections by the Secretary of device establishments (referred to in this subparagraph as the "inspection budget").

(ii) For purposes of determinations under clause (i), the Comptroller General shall not include in the compliance budget or the inspection budget any amounts obligated for inspections of device establishments conducted as part of the process of reviewing applications under section 515.

(iii) Not later than March 31, 2003, the Comptroller General shall complete the determinations required in this subparagraph and submit to the Secretary and the Congress a report describing the findings made through such determinations.

(C) For purposes of this paragraph:

(i) The term "base amount" means the inspection budget determined under subparagraph (B) for fiscal year 2002.

(ii) The term "adjusted base amount", in the case of applicability to fiscal year 2003, means an amount equal to the base amount increased by 5 percent.

(iii) The term "adjusted base amount", with respect to applicability to fiscal year 2004 or any subsequent fiscal year, means the adjusted base amount applicable to the preceding year increased by 5 percent.

(11) The authority provided by this subsection terminates on October 1, ⟦2022⟧ *2027*.

(12) No later than four years after the enactment of this subsection the Comptroller General shall report to the Committee on Energy and Commerce of the House of Representatives and the Committee on Health, Education, Labor and Pensions of the Senate—

(A) the number of inspections conducted by accredited persons pursuant to this subsection and the number of inspections conducted by Federal employees pursuant to section 510(h) and of device establishments required to register under section 510(i);

(B) the number of persons who sought accreditation under this subsection, as well as the number of persons who were accredited under this subsection;

(C) the reasons why persons who sought accreditation, but were denied accreditation, were denied;

(D) the number of audits conducted by the Secretary of accredited persons, the quality of inspections conducted by accredited persons, whether accredited persons are meeting their obligations under this Act, and whether the number of audits conducted is sufficient to permit these assessments;

(E) whether this subsection is achieving the goal of ensuring more information about device establishment compliance is being presented to the Secretary, and whether that information is of a quality consistent with information obtained by the Sec-

retary pursuant to inspections conducted by Federal employees;

(F) whether this subsection is advancing efforts to allow device establishments to rely upon third-party inspections for purposes of compliance with the laws of foreign governments; and

(G) whether the Congress should continue, modify, or terminate the program under this subsection.

(13) The Secretary shall include in the annual report required under section 1003(g) the names of all accredited persons and the particular activities under this subsection for which each such person is accredited and the name of each accredited person whose accreditation has been withdrawn during the year.

(14) Notwithstanding any provision of this subsection, this subsection does not have any legal effect on any agreement described in section 803(b) between the Secretary and a foreign country.

(15)(A) Notwithstanding any other provision of this subsection, the Secretary may recognize auditing organizations that are recognized by organizations established by governments to facilitate international harmonization for purposes of conducting inspections of—

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

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

(B) Nothing in this paragraph affects—

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

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

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

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

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

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

(D) regular communications during the inspection with the owner, operator, or agent in charge of the establishment re-

garding inspection status, which may be recorded by either party with advance notice and mutual consent.

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

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

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

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

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

* * * * * * *

SEC. 714A. HIRING AUTHORITY FOR SCIENTIFIC, TECHNICAL, AND PROFESSIONAL PERSONNEL.

(a) IN GENERAL.—The Secretary may, notwithstanding title 5, United States Code, governing appointments in the competitive service, appoint outstanding and qualified candidates to scientific, technical, or professional positions that support the development, review, and regulation of [medical products] *products regulated by the Food and Drug Administration*. Such positions shall be within the competitive service.

(b) COMPENSATION.—

(1) IN GENERAL.—Notwithstanding any other provision of law, including any requirement with respect to General Schedule pay rates under subchapter III of chapter 53 of title 5, United States Code, and consistent with the requirements of paragraph (2), the Commissioner of Food and Drugs may determine and set—

(A) the annual rate of pay of any individual appointed under subsection (a); and

(B) for purposes of retaining qualified employees, the annual rate of pay for any qualified scientific, technical, or professional personnel appointed to a position described in subsection (a) before the date of enactment of the 21st Century Cures Act.

(2) LIMITATION.—The annual rate of pay established pursuant to paragraph (1) may not exceed the amount of annual compensation (excluding expenses) specified in section 102 of title 3, United States Code.

(3) PUBLIC AVAILABILITY.—The annual rate of pay provided to an individual in accordance with this section shall be publicly available information.

(c) RULE OF CONSTRUCTION.—The authorities under this section shall not be construed to affect the authority provided under section 714.

[(d) REPORT ON WORKFORCE PLANNING.—

[(1) IN GENERAL.—Not later than 18 months after the date of enactment of the 21st Century Cures Act, the Secretary shall submit a report on workforce planning to the Committee on Health, Education, Labor, and Pensions of the Senate and the Committee on Energy and Commerce of the House of Representatives that examines the extent to which the Food and Drug Administration has a critical need for qualified individuals for scientific, technical, or professional positions, including—

[(A) an analysis of the workforce needs at the Food and Drug Administration and the Secretary's strategic plan for addressing such needs, including through use of the authority under this section; and

[(B) a recruitment and retention plan for hiring qualified scientific, technical, and professional candidates, which may include the use of—

[(i) recruitment through nongovernmental recruitment or placement agencies;

[(ii) recruitment through academic institutions;

[(iii) recruitment or hiring bonuses, if applicable;

[(iv) recruitment using targeted direct hiring authorities; and

[(v) retention of qualified scientific, technical, and professional employees using the authority under this section, or other applicable authorities of the Secretary.

[(2) RECOMMENDATIONS.—The report under paragraph (1) may include the recommendations of the Commissioner of Food and Drugs that would help the Food and Drug Administration to better recruit and retain qualified individuals for scientific, technical, or professional positions at the agency.]

(d) AGENCY-WIDE STRATEGIC WORKFORCE PLAN.—

(1) IN GENERAL.—Not later than 1 year after the date of enactment of the Food and Drug Amendments of 2022, the Commissioner of Food and Drugs shall develop and begin implementation of an agency-wide strategic workforce plan at the Food and Drug Administration, which shall include—

(A) agency-wide human capital goals and strategies;

(B) performance measures, benchmarks, or other elements to facilitate the monitoring and evaluation of the progress made toward such goals and the effectiveness of such strategies; and

(C) a process for updating such plan based on timely and relevant information on an ongoing basis.

(2) REPORT TO CONGRESS.—Not later than 18 months after the date of enactment of the Food and Drug Amendments of 2022, the Secretary shall submit to the Committee on Energy and Commerce of the House of Representatives and the Committee on Health, Education, Labor, and Pensions of the Senate a report describing the plan under paragraph (1) and the status of its implementation.

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SUBCHAPTER C—FEES

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PART 2—FEES RELATING TO DRUGS

SEC. 735. DEFINITIONS.

For purposes of this part:

(1) The term "human drug application" means an application for—

(A) approval of a new drug submitted under section 505(b), or

(B) licensure of a biological product under subsection (a) of section 351 of the Public Health Service Act.

Such term does not include a supplement to such an application, does not include an application with respect to whole blood or a blood component for transfusion, does not include an application with respect to a bovine blood product for topical application licensed before September 1, 1992, [an allergenic extract product, or] *does not include an application with respect to an allergenic extract product licensed before October 1, 2022, does not include an application with respect to a standardized allergenic extract product submitted pursuant to a notification to the applicant from the Secretary regarding the existence of a potency test that measures the allergenic activity of an allergenic extract product licensed by the applicant before October 1, 2022, does not include an application with respect to* an in vitro diagnostic biologic product licensed under section 351 of the Public Health Service Act, does not include an application with respect to a large volume parenteral drug product approved before September 1, 1992, does not include an application for a licensure of a biological product for further manufacturing use only, and does not include an application or supplement submitted by a State or Federal Government entity for a drug that is not distributed commercially. Such term does include an application for licensure, as described in subparagraph (B), of a large volume biological product intended for single dose injection for intravenous use or infusion.

(2) The term "supplement" means a request to the Secretary to approve a change in a human drug application which has been approved.

[(3) The term] *(3)(A) The term* "prescription drug product" means a specific strength or potency of a drug in final dosage form—

[(A)] *(i)* for which a human drug application has been approved,

[(B)] *(ii)* which may be dispensed only under prescription pursuant to section 503(b), and

[(C)] *(iii)* which is on the list of products described in section 505(j)(7)(A) (not including the discontinued section of such list) or is on a list created and maintained by the Secretary of products approved under human drug applications under section 351 of the Public Health Service Act (not including the discontinued section of such list).

[Such term does not include whole blood]

(B) Such term does not include whole blood or a blood component for transfusion, does not include a bovine blood product for topical application licensed before September 1, 1992, [an allergenic extract product,] *an allergenic extract product licensed before October 1, 2022, a standardized allergenic extract product submitted pursuant to a notification to the applicant from the Secretary regarding the existence of a potency test that measures the allergenic activity of an allergenic extract product licensed by the applicant before October 1, 2022,* or an in vitro diagnostic biologic product licensed under section 351 of the Public Health Service Act. Such term does not include a biological product that is licensed for further manufacturing use only, and does not include a drug that is not distributed commercially and is the subject of an application or supplement submitted by a State or Federal Government entity. Such term does include a large volume biological product intended for single dose injection for intravenous use or infusion.

(C)(i) If a written request to place a product in the discontinued section of either of the lists referenced in subparagraph (A)(iii) is submitted to the Secretary on behalf of an applicant, and the request identifies the date the product is withdrawn from sale, then for purposes of assessing the prescription drug program fee under section 736(a)(2), the Secretary shall consider such product to have been included in the discontinued section on the later of—

(I) the date such request was received; or

(II) if the product will be withdrawn from sale on a future date, such future date when the product is withdrawn from sale.

(ii) For purposes of this subparagraph, a product shall be considered withdrawn from sale once the applicant has ceased its own distribution of the product, whether or not the applicant has ordered recall of all previously distributed lots of the product, except that a routine, temporary interruption in supply shall not render a product withdrawn from sale.

(4) The term "final dosage form" means, with respect to a prescription drug product, a finished dosage form which is approved for administration to a patient without substantial further manufacturing (such as capsules, tablets, or lyophilized products before reconstitution).

(5) The term "prescription drug establishment" means a foreign or domestic place of business which is at one general physical location consisting of one or more buildings all of which are within five miles of each other and at which one or more prescription drug products are manufactured in final dosage form. For purposes of this paragraph, the term "manufactured" does not include packaging.

(6) The term "process for the review of human drug applications" means the following activities of the Secretary with respect to the review of human drug applications and supplements:

(A) The activities necessary for the review of human drug applications and supplements.

(B) The issuance of action letters which approve human drug applications or which set forth in detail the specific deficiencies in such applications and, where appropriate, the actions necessary to place such applications in condition for approval.

(C) The inspection of prescription drug establishments and other facilities undertaken as part of the Secretary's review of pending human drug applications and supplements.

(D) Activities necessary for the review of applications for licensure of establishments subject to section 351 of the Public Health Service Act and for the release of lots of biologics under such section.

(E) Monitoring of research conducted in connection with the review of human drug applications.

(F) Postmarket safety activities with respect to drugs approved under human drug applications or supplements, including the following activities:

(i) Collecting, developing, and reviewing safety information on approved drugs, including adverse event reports.

(ii) Developing and using improved adverse-event data-collection systems, including information technology systems.

(iii) Developing and using improved analytical tools to assess potential safety problems, including access to external data bases.

(iv) Implementing and enforcing section 505(o) (relating to postapproval studies and clinical trials and labeling changes) and section 505(p) (relating to risk evaluation and mitigation strategies).

(v) Carrying out section 505(k)(5) (relating to adverse event reports and postmarket safety activities).

(7) The term "costs of resources allocated for the process for the review of human drug applications" means the expenses in connection with the process for the review of human drug applications for—

(A) officers and employees of the Food and Drug Administration, contractors of the Food and Drug Administration, advisory committees, and costs related to such officers, employees, and committees and to contracts with such contractors,

(B) management of information, and the acquisition, maintenance, and repair of computer resources,

(C) leasing, maintenance, renovation, and repair of facilities and acquisition, maintenance, and repair of fixtures, furniture, scientific equipment, and other necessary materials and supplies, and

(D) collecting fees under section 736 and accounting for resources allocated for the review of human drug applications and supplements.

(8) The term "adjustment factor" applicable to a fiscal year is the Consumer Price Index for all urban consumers (all items; United States city average) for October of the preceding fiscal year divided by such Index for October 1996.

(9) The term "person" includes an affiliate thereof.

(10) The term "active", with respect to a commercial investigational new drug application, means such an application to which information was submitted during the relevant period.

(11) The term "affiliate" means a business entity that has a relationship with a second business entity if, directly or indirectly—

(A) one business entity controls, or has the power to control, the other business entity; or

(B) a third party controls, or has power to control, both of the business entities.

(12) The term "skin-test diagnostic product"—

(A) means a product—

(i) for prick, scratch, intradermal, or subcutaneous administration;

(ii) expected to produce a limited, local reaction at the site of administration (if positive), rather than a systemic effect;

(iii) not intended to be a preventive or therapeutic intervention; and

(iv) intended to detect an immediate- or delayed-type skin hypersensitivity reaction to aid in the diagnosis of—

(I) an allergy to an antimicrobial agent;

(II) an allergy that is not to an antimicrobial agent, if the diagnostic product was authorized for marketing prior to October 1, 2022; or

(III) infection with fungal or mycobacterial pathogens; and

(B) includes positive and negative controls required to interpret the results of a product described in subparagraph (A).

SEC. 736. AUTHORITY TO ASSESS AND USE DRUG FEES.

(a) TYPES OF FEES.—Beginning in ⟦fiscal year 2018⟧ *fiscal year 2023*, the Secretary shall assess and collect fees in accordance with this section as follows:

(1) HUMAN DRUG APPLICATION FEE.—

(A) IN GENERAL.—Each person that submits, on or after September 1, 1992, a human drug application shall be subject to a fee as follows:

(i) A fee established under subsection ⟦(c)(5)⟧ *(c)(6)* for a human drug application for which clinical data (other than bioavailability or bioequivalence studies) with respect to safety or effectiveness are required for approval.

(ii) A fee established under subsection ⟦(c)(5)⟧ *(c)(6)* 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. Such fee shall be half of the amount of the fee established under clause (i).

(B) PAYMENT.—The fee required by subparagraph (A) shall be due upon submission of the application.

(C) EXCEPTION FOR PREVIOUSLY FILED APPLICATION.—If a human drug application was submitted by a person that

paid the fee for such application, was accepted for filing, and was not approved or was withdrawn *prior to approval* (without a waiver), the submission of a human drug application for the same product by the same person (or the person's licensee, assignee, or successor) shall not be subject to a fee under subparagraph (A).

(D) REFUND OF FEE IF APPLICATION REFUSED FOR FILING OR WITHDRAWN BEFORE FILING.—The Secretary shall refund 75 percent of the fee paid under subparagraph (B) for any application which is refused for filing or withdrawn without a waiver before filing.

(E) FEES FOR APPLICATIONS PREVIOUSLY REFUSED FOR FILING OR WITHDRAWN BEFORE FILING.—A human drug application that was submitted but was refused for filing, or was withdrawn before being accepted or refused for filing, shall be subject to the full fee under subparagraph (A) upon being resubmitted or filed over protest, unless the fee is waived or reduced under subsection (d).

(F) EXCEPTION FOR DESIGNATED ORPHAN DRUG.—A human drug application for a prescription drug product that has been designated as a drug for a rare disease or condition pursuant to section 526 shall not be subject to a fee under subparagraph (A), unless the human drug application includes an indication for other than a rare disease or condition.

(G) REFUND OF FEE IF APPLICATION WITHDRAWN.—If an application is withdrawn after the application was filed, the Secretary may refund the fee or a portion of the fee if no substantial work was performed on the application after the application was filed. The Secretary shall have the sole discretion to refund a fee or a portion of the fee under this subparagraph. A determination by the Secretary concerning a refund under this paragraph shall not be reviewable.

(H) EXCEPTION FOR SKIN-TEST DIAGNOSTIC PRODUCTS.—A human drug application for a skin-test diagnostic product shall not be subject to a fee under subparagraph (A).

(2) PRESCRIPTION DRUG PROGRAM FEE.—

(A) IN GENERAL.—**[**Except as provided in subparagraphs (B) and (C)**]**

(i) FEE.—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)**]** *subsection (c)(6)* for each prescription drug product that is identified in such a human drug application approved as of October 1 of such fiscal year. Such fee shall be due on the later of the first business day on or after October 1 of each fiscal year or the first business day after the enactment of an appropriations Act providing for the collection and obligation of fees for such fiscal year under

this section. Such fee shall be paid only once for each product for a fiscal year in which the fee is payable.

(ii) SPECIAL RULE.—If a drug product that is identified in a human drug application approved as of October 1 of a fiscal year is not a prescription drug product as of that date because the drug product is in the discontinued section of a list referenced in section 735(3)(A)(iii), and on any subsequent day during such fiscal year the drug product is a prescription drug product, then except as provided in subparagraphs (B) and (C), each person who is named as the applicant in a human drug application with respect to such product, and who, after September 1, 1992, had pending before the Secretary a human drug application or supplement with respect to such product, shall pay the annual prescription drug program fee established for a fiscal year under subsection (c)(6) for such prescription drug product. Such fee shall be due on the last business day of such fiscal year and shall be paid only once for each such product for a fiscal year in which the fee is payable.

[(B) EXCEPTION FOR CERTAIN PRESCRIPTION DRUG PRODUCTS.—A prescription drug program fee shall not be assessed for a prescription drug product under subparagraph (A) if such product is—

[(i) identified on the list compiled under section 505(j)(7) with a potency described in terms of per 100 mL;

[(ii) the same product as another product that—

[(I) was approved under an application filed under section 505(b) or 505(j); and

[(II) is not in the list of discontinued products compiled under section 505(j)(7);

[(iii) the same product as another product that was approved under an abbreviated application filed under section 507 (as in effect on the day before the date of enactment of the Food and Drug Administration Modernization Act of 1997); or

[(iv) the same product as another product that was approved under an abbreviated new drug application pursuant to regulations in effect prior to the implementation of the Drug Price Competition and Patent Term Restoration Act of 1984.]

(B) EXCEPTION FOR CERTAIN PRESCRIPTION DRUG PRODUCTS.—A prescription drug program fee shall not be assessed for a prescription drug product under subparagraph (A) if such product is—

(i) a large volume parenteral product (a sterile aqueous drug product packaged in a single-dose container with a volume greater than or equal to 100 mL, not including powders for reconstitution or pharmacy bulk packages) identified on the list compiled under section 505(j)(7);

(ii) pharmaceutically equivalent (as defined in section 314.3 of title 21, Code of Federal Regulations (or

any successor regulation)) to another product on the list of products compiled under section 505(j)(7) (not including the discontinued section of such list); or

(iii) a skin-test diagnostic product.

(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.

(b) FEE REVENUE AMOUNTS.—

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

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

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

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

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

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

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

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

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

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

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

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

(1) IN GENERAL.—For each of the fiscal years 2023 through 2027, 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 strategic hiring and retention adjustment for the fiscal year (as determined under subsection (c)(2));

(D) the dollar amount equal to the capacity planning adjustment for the fiscal year (as determined under subsection (c)(3));

(E) the dollar amount equal to the operating reserve adjustment for the fiscal year, if applicable (as determined under subsection (c)(4));

(F) the dollar amount equal to the additional direct cost adjustment for the fiscal year (as determined under subsection (c)(5)); and

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

(i) $65,773,693 for fiscal year 2023.
(ii) $25,097,671 for fiscal year 2024.
(iii) $14,154,169 for fiscal year 2025.
(iv) $4,864,860 for fiscal year 2026.
(v) $1,314,620 for fiscal year 2027.

(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).**]**

(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 2023, $1,151,522,958; and

(B) for fiscal years 2024 through 2027, 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)(4) or (c)(5).

(c) ADJUSTMENTS; ANNUAL FEE SETTING.—

(1) INFLATION ADJUSTMENT.—

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

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

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

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

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

(ii) the average annual percent change that occurred in the Consumer Price Index for urban consumers (**[**Washington-Baltimore, DC–MD–VA–WV**]** *Washington-Arlington-Alexandria, DC–VA–MD–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) STRATEGIC HIRING AND RETENTION ADJUSTMENT.—For each fiscal year, after the annual base revenue established in subsection (b)(1)(A) is adjusted for inflation in accordance with paragraph (1), the Secretary shall further increase the fee revenue and fees by the following amounts:

(A) For fiscal year 2023, $9,000,000.

(B) For each of fiscal years 2024 through 2027, $4,000,000.

[(2) CAPACITY PLANNING ADJUSTMENT.—

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

[(B) INTERIM METHODOLOGY.—

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

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

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

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

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

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

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

[(C) CAPACITY PLANNING METHODOLOGY.—

[(i) DEVELOPMENT; EVALUATION AND REPORT.—The Secretary shall obtain, through a contract with an

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

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

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

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

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

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

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

(3) CAPACITY PLANNING ADJUSTMENT.—

(A) IN GENERAL.—For each fiscal year, after the annual base revenue established in subsection (b)(1)(A) is adjusted in accordance with paragraphs (1) and (2), 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) METHODOLOGY.—For purposes of this paragraph, the Secretary shall employ the capacity planning methodology utilized by the Secretary in setting fees for fiscal year 2021, as described in the notice titled "Prescription Drug User Fee Rates for Fiscal Year 2021" published in the Federal Register on August 3, 2020 (85 Fed. Reg. 46651). The workload categories used in applying such methodology in forecasting shall include only the activities described in that notice and, as feasible, additional activities that are also directly related to the direct review of applications and supplements, including additional formal meeting types, the direct review of postmarketing commitments and requirements, the direct review of risk evaluation and mitigation strategies, and the direct review of annual reports for approved prescription drug products. Subject to the exceptions

in the preceding sentence, the Secretary shall not include as workload categories in applying such methodology in forecasting any non-core review activities, including those activities that the Secretary referenced for potential future use in such notice but did not utilize in setting fees for fiscal year 2021.

(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)(1)(A) (the annual base revenue for the fiscal year), (b)(1)(B) (the dollar amount of the inflation adjustment for the fiscal year), and (b)(1)(C) (the dollar amount of the strategic hiring and retention adjustment for the fiscal year).

(D) PUBLICATION IN FEDERAL REGISTER.—The Secretary shall publish in the Federal Register notice under paragraph (6) of the fee revenue and fees resulting from the adjustment and the methodologies under this paragraph.

[(3)**]** *(4)* 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.**]**

(A) INCREASE.—For fiscal year 2023 and subsequent fiscal years, the Secretary shall, in addition to adjustments under paragraphs (1), (2), and (3), further increase the fee revenue and fees if such an adjustment is necessary to provide for operating reserves of carryover user fees for the process for the review of human drug applications for each fiscal year in at least the following amounts:

(i) For fiscal year 2023, at least 8 weeks of operating reserves.

(ii) For fiscal year 2024, at least 9 weeks of operating reserves.

(iii) For fiscal year 2025 and subsequent fiscal years, at least 10 weeks of operating reserves.

(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)**]** *paragraph (6)* 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) ADDITIONAL DIRECT COST ADJUSTMENT.—

(A) INCREASE.—The Secretary shall, in addition to adjustments under paragraphs (1), (2), (3), and (4), further increase the fee revenue and fees—

(i) for fiscal year 2023, by $44,386,150; and

(ii) for each of fiscal years 2024 through 2027, by the amount set forth in clauses (i) through (iv) of subparagraph (B), as applicable, multiplied by the Consumer Price Index for urban consumers (Washington-Arlington-Alexandria, DC–VA–MD–WV; Not Seasonally Adjusted; All Items; Annual Index) for the most recent year of available data, divided by such Index for 2021.

(B) APPLICABLE AMOUNTS.—The amounts referred to in subparagraph (A)(ii) are the following:

(i) For fiscal year 2024, $60,967,993.

(ii) For fiscal year 2025, $35,799,314.

(iii) For fiscal year 2026, $35,799, 314.

(iv) For fiscal year 2027, $35,799,314.

[(5)] *(6)* ANNUAL FEE SETTING.—The Secretary shall, not later than 60 days before the start of each fiscal year that begins after [September 30, 2017] *September 30, 2022*—

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

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

[(6)] *(7)* 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.—

(1) IN GENERAL.—The Secretary shall grant to a person who is named as the applicant in a human drug application a waiver from or a reduction of one or more fees assessed to that person under subsection (a) where the Secretary finds that—

(A) such waiver or reduction is necessary to protect the public health,

(B) the assessment of the fee would present a significant barrier to innovation because of limited resources available to such person or other circumstances, or

(C) the applicant involved is a small business submitting its first human drug application to the Secretary for review.

(2) CONSIDERATIONS.—In determining whether to grant a waiver or reduction of a fee under paragraph (1), the Secretary shall consider only the circumstances and assets of the applicant involved and any affiliate of the applicant.

(3) RULES RELATING TO SMALL BUSINESSES.—

(A) DEFINITION.—In paragraph (1)(C), the term "small business" means an entity that has fewer than 500 employees, including employees of affiliates, and that does not have a drug product that has been approved under a human drug application and introduced or delivered for introduction into interstate commerce.

(B) WAIVER OF APPLICATION FEE.—The Secretary shall waive under paragraph (1)(C) the application fee for the first human drug application that a small business or its affiliate submits to the Secretary for review. After a small business or its affiliate is granted such a waiver, the small business or its affiliate shall pay application fees for all subsequent human drug applications submitted to the Secretary for review in the same manner as an entity that does not qualify as a small business.

(e) EFFECT OF FAILURE TO PAY FEES.—A human drug application or supplement submitted by a person subject to fees under subsection (a) shall be considered incomplete and shall not be accepted for filing by the Secretary until all such fees owed by such person have been paid.

(f) LIMITATIONS.—

(1) IN GENERAL.—Fees under subsection (a) shall be refunded for a fiscal year beginning after fiscal year 1997 unless appropriations for salaries and expenses of the Food and Drug Administration for such fiscal year (excluding the amount of fees appropriated for such fiscal year) are equal to or greater than the amount of appropriations for the salaries and expenses of the Food and Drug Administration for the fiscal year 1997 (excluding the amount of fees appropriated for such fiscal year) multiplied by the adjustment factor applicable to the fiscal year involved.

(2) AUTHORITY.—If the Secretary does not assess fees under subsection (a) during any portion of a fiscal year because of paragraph (1) and if at a later date in such fiscal year the Secretary may assess such fees, the Secretary may assess and collect such fees, without any modification in the rate, for human drug applications and prescription drug program fees at any time in such fiscal year notwithstanding the provisions of subsection (a) relating to the date fees are to be paid.

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

(g) CREDITING AND AVAILABILITY OF FEES.—

(1) IN GENERAL.—Subject to paragraph (2)(C), fees authorized under subsection (a) shall be collected and available for obligation only to the extent and in the amount provided in advance in appropriations Acts. Such fees are authorized to remain available until expended. Such sums as may be necessary may be transferred from the Food and Drug Administration salaries and expenses appropriation account without fiscal year

limitation to such appropriation account for salaries and expenses with such fiscal year limitation. The sums transferred shall be available solely for the process for the review of human drug applications.

(2) COLLECTIONS AND APPROPRIATION ACTS.—

(A) IN GENERAL.—The fees authorized by this section—

(i) subject to subparagraph (C), shall be collected and available in each fiscal year in an amount not to exceed the amount specified in appropriation Acts, or otherwise made available for obligation, for such fiscal year, and

(ii) shall be available to defray increases in the costs of the resources allocated for the process for the review of human drug applications (including increases in such costs for an additional number of full-time equivalent positions in the Department of Health and Human Services to be engaged in such process) over such costs, excluding costs paid from fees collected under this section, for fiscal year 1997 multiplied by the adjustment factor.

(B) COMPLIANCE.—The Secretary shall be considered to have met the requirements of subparagraph (A)(ii) in any fiscal year if the costs funded by appropriations and allocated for the process for the review of human drug applications—

(i) are not more than 3 percent below the level specified in subparagraph (A)(ii); or

(ii)(I) are more than 3 percent below the level specified in subparagraph (A)(ii), and fees assessed for the fiscal year following the subsequent fiscal year are decreased by the amount in excess of 3 percent by which such costs fell below the level specified in such subparagraph; and

(II) such costs are not more than 5 percent below the level specified in such subparagraph.

(C) PROVISION FOR EARLY PAYMENTS.—Payment of fees authorized under this section for a fiscal year, prior to the due date for such fees, may be accepted by the Secretary in accordance with authority provided in advance in a prior year appropriations Act.

(3) AUTHORIZATION OF APPROPRIATIONS.—For each of the [fiscal years 2018 through 2022] *fiscal years 2023 through 2027*, there is authorized to be appropriated for fees under this section an amount equal to the total revenue amount determined under subsection (b) for the fiscal year, as adjusted or otherwise affected under subsection (c).

(h) COLLECTION OF UNPAID FEES.—In any case where the Secretary does not receive payment of a fee assessed under subsection (a) within 30 days after it is due, such fee shall be treated as a claim of the United States Government subject to subchapter II of chapter 37 of title 31, United States Code.

[(i) WRITTEN REQUESTS FOR WAIVERS, REDUCTIONS, AND REFUNDS.—To qualify for consideration for a waiver or reduction under subsection (d), or for a refund of any fee collected in accordance with subsection (a), a person shall submit to the Secretary a

written request for such waiver, reduction, or refund not later than 180 days after such fee is due.]

(i) WRITTEN REQUESTS FOR WAIVERS, REDUCTIONS, EXEMPTIONS, AND RETURNS; DISPUTES CONCERNING FEES.—To qualify for consideration for a waiver or reduction under subsection (d), an exemption under subsection (k), or the return of any fee paid under this section, including if the fee is claimed to have been paid in error, a person shall—

(1) not later than 180 days after such fee is due, submit to the Secretary a written request justifying such waiver, reduction, exemption, or return; and

(2) include in the request any legal authorities under which the request is made.

(j) CONSTRUCTION.—This section may not be construed to require that the number of full-time equivalent positions in the Department of Health and Human Services, for officers, employers, and advisory committees not engaged in the process of the review of human drug applications, be reduced to offset the number of officers, employees, and advisory committees so engaged.

(k) ORPHAN DRUGS.—

(1) EXEMPTION.—A drug designated under section 526 for a rare disease or condition and approved under section 505 or under section 351 of the Public Health Service Act shall be exempt from prescription drug program fees under this section, if the drug meets all of the following conditions:

(A) The drug meets the public health requirements contained in this Act as such requirements are applied to requests for waivers for prescription drug program fees.

(B) The drug is owned or licensed and is marketed by a company that had less than $50,000,000 in gross worldwide revenue [during the previous year] *as determined under paragraph (2).*

[(2) EVIDENCE OF QUALIFICATION.—An exemption under paragraph (1) applies with respect to a drug only if the applicant involved submits a certification that its gross annual revenues did not exceed $50,000,000 for the preceding 12 months before the exemption was requested.]

(2) EVIDENCE OF QUALIFICATION.—An exemption under paragraph (1) applies with respect to a drug only if the applicant involved submits a certification that the applicant's gross annual revenues did not exceed $50,000,000 for the last calendar year ending prior to the fiscal year for which the exemption is requested. Such certification shall be supported by—

(A) tax returns submitted to the United States Internal Revenue Service; or

(B) as necessary, other appropriate financial information.

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SEC. 736B. REAUTHORIZATION; REPORTING REQUIREMENTS.

(a) PERFORMANCE REPORT.—

(1) IN GENERAL.—[Beginning with fiscal year 2018, not] *Not* later than 120 days after the end of each fiscal year for which fees are collected under this part, the Secretary shall prepare and submit to the Committee on Energy and Commerce of the House of Representatives and the Committee on Health, Edu-

cation, Labor, and Pensions of the Senate a report concerning—

(A) the progress of the Food and Drug Administration in achieving the goals identified in the letters described in section 101(b) of the ⟦Prescription Drug User Fee Amendments of 2017⟧ *Prescription Drug User Fee Amendments of 2022* during such fiscal year and the future plans of the Food and Drug Administration for meeting the goals, including the status of the independent assessment described in such letters; and

(B) the progress of the Center for Drug Evaluation and Research and the Center for Biologics Evaluation and Research in achieving the goals, and future plans for meeting the goals, including, for each review division—

(i) the number of original standard new drug applications and biologics license applications filed per fiscal year for each review division;

(ii) the number of original priority new drug applications and biologics license applications filed per fiscal year for each review division;

(iii) the number of standard efficacy supplements filed per fiscal year for each review division;

(iv) the number of priority efficacy supplements filed per fiscal year for each review division;

(v) the number of applications filed for review under accelerated approval per fiscal year for each review division;

(vi) the number of applications filed for review as fast track products per fiscal year for each review division;

(vii) the number of applications filed for orphan-designated products per fiscal year for each review division; and

(viii) the number of breakthrough designations for a fiscal year for each review division.

(2) INCLUSION.—The report under this subsection for a fiscal year shall include information on all previous cohorts for which the Secretary has not given a complete response on all human drug applications and supplements in the cohort.

(3) REAL TIME REPORTING.—

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

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

(i) The number and titles of draft and final guidance on topics related to the process for the review of

human drug applications, and whether such guidances were issued as required by statute or pursuant to a commitment under the letters described in section 101(b) of the ⟦Prescription Drug User Fee Amendments of 2017⟧ *Prescription Drug User Fee Amendments of 2022*.

(ii) The number and titles of public meetings held on topics related to the process for the review of human drug applications, and whether such meetings were required by statute or pursuant to a commitment under the letters described in section 101(b) of the ⟦Prescription Drug User Fee Amendments of 2017⟧ *Prescription Drug User Fee Amendments of 2022*.

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

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

(v) For fiscal years 2023 and 2024, of the meeting requests from sponsors for which the Secretary has determined that a face-to-face meeting is appropriate, the number of face-to-face meetings requested by sponsors to be conducted in person (in such manner as the Secretary shall prescribe on the internet website of the Food and Drug Administration), and the number of such in-person meetings granted by the Secretary.

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

(A) data, analysis, and discussion of the changes in the number of full-time equivalents hired as agreed upon in the letters described in section 101(b) of the ⟦Prescription Drug User Fee Amendments of 2017⟧ *Prescription Drug User Fee Amendments of 2022* and the number of full time equivalents funded by budget authority at the Food and Drug Administration by each division within the Center for Drug Evaluation and Research, the Center for Biologics Evaluation and Research, the Office of Regulatory Affairs, and the Office of the Commissioner;

(B) data, analysis, and discussion of the changes in the fee revenue amounts and costs for the process for the review of human drugs, including identifying drivers of such changes; and

(C) for each of the Center for Drug Evaluation and Research, the Center for Biologics Evaluation and Research, the Office of Regulatory Affairs, and the Office of the Commissioner, the number of employees for whom time reporting is required and the number of employees for whom time reporting is not required.

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

(A) The difference between the aggregate number of human drug applications filed and the aggregate number of approvals, accounting for—

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

(ii) the aggregate number of applications for each fiscal year that did not meet the goals identified in the letters described in section 101(b) of the [Prescription Drug User Fee Amendments of 2017] *Prescription Drug User Fee Amendments of 2022* for the applicable fiscal year.

(B) Relevant data to determine whether the Center for Drug Evaluation and Research and the Center for Biologics Evaluation and Research have met performance enhancement goals identified in the letters described in section 101(b) of the [Prescription Drug User Fee Amendments of 2017] *Prescription Drug User Fee Amendments of 2022* for the applicable fiscal year.

(C) The most common causes and trends of external or other circumstances affecting the ability of the Center for Drug Evaluation and Research, the Center for Biologics Evaluation and Research, Office of Regulatory Affairs, and the Food and Drug Administration to meet the review time and performance enhancement goals identified in the letters described in section 101(b) of the [Prescription Drug User Fee Amendments of 2017] *Prescription Drug User Fee Amendments of 2022*.

(b) FISCAL REPORT.—[Beginning with fiscal year 2018, not] *Not* later than 120 days after the end of each fiscal year for which fees are collected under this part, the Secretary shall prepare and submit to the Committee on Energy and Commerce of the House of Representatives and the Committee on Health, Education, Labor, and Pensions of the Senate a report on the implementation of the authority for such fees during such fiscal year and the use, by the Food and Drug Administration, of the fees collected for such fiscal year.

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

(1) GOALS MET.—For each fiscal year, if the Secretary determines, based on the analysis under subsection (a)(5), that each of the goals identified in the letters described in section 101(b) of the [Prescription Drug User Fee Amendments of 2017] *Prescription Drug User Fee Amendments of 2022* for the applicable fiscal year have been met, the corrective action report shall include recommendations on ways in which the Secretary can improve and streamline the human drug application review process.

(2) GOALS MISSED.—For any of the goals identified in the letters described in section 101(b) of the [Prescription Drug User Fee Amendments of 2017] *Prescription Drug User Fee Amendments of 2022* for the applicable fiscal year that the Secretary

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

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

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

(d) ENHANCED COMMUNICATION.—

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

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

(e) PUBLIC AVAILABILITY.—The Secretary shall make the reports required under subsections (a) and (b) available to the public on the Internet Web site of the Food and Drug Administration.

(f) REAUTHORIZATION.—

(1) CONSULTATION.—In developing recommendations to present to the Congress with respect to the goals, and plans for meeting the goals, for the process for the review of human drug applications for the first 5 fiscal years after ⟦fiscal year 2022⟧ *fiscal year 2027*, and for the reauthorization of this part for such fiscal years, the Secretary shall consult with—

(A) the Committee on Energy and Commerce of the House of Representatives;

(B) the Committee on Health, Education, Labor, and Pensions of the Senate;

(C) scientific and academic experts;

(D) health care professionals;

(E) representatives of patient and consumer advocacy groups; and

(F) the regulated industry.

(2) PRIOR PUBLIC INPUT.—Prior to beginning negotiations with the regulated industry on the reauthorization of this part, the Secretary shall—

(A) publish a notice in the Federal Register requesting public input on the reauthorization;

(B) hold a public meeting at which the public may present its views on the reauthorization, including specific suggestions for changes to the goals referred to in subsection (a);

(C) provide a period of 30 days after the public meeting to obtain written comments from the public suggesting changes to this part; and

(D) publish the comments on the Food and Drug Administration's Internet Web site.

(3) PERIODIC CONSULTATION.—Not less frequently than once every month during negotiations with the regulated industry, the Secretary shall hold discussions with representatives of patient and consumer advocacy groups to continue discussions of their views on the reauthorization and their suggestions for changes to this part as expressed under paragraph (2).

(4) PUBLIC REVIEW OF RECOMMENDATIONS.—After negotiations with the regulated industry, the Secretary shall—

(A) present the recommendations developed under paragraph (1) to the Congressional committees specified in such paragraph;

(B) publish such recommendations in the Federal Register;

(C) provide for a period of 30 days for the public to provide written comments on such recommendations;

(D) hold a meeting at which the public may present its views on such recommendations; and

(E) after consideration of such public views and comments, revise such recommendations as necessary.

(5) TRANSMITTAL OF RECOMMENDATIONS.—Not later than [January 15, 2022] *January 15, 2027*, the Secretary shall transmit to the Congress the revised recommendations under paragraph (4), a summary of the views and comments received under such paragraph, and any changes made to the recommendations in response to such views and comments.

(6) MINUTES OF NEGOTIATION MEETINGS.—

(A) PUBLIC AVAILABILITY.—Before presenting the recommendations developed under paragraphs (1) through (5) to the Congress, the Secretary shall make publicly available, on the public Web site of the Food and Drug Administration, minutes of all negotiation meetings conducted under this subsection between the Food and Drug Administration and the regulated industry.

(B) CONTENT.—The minutes described under subparagraph (A) shall summarize any substantive proposal made by any party to the negotiations as well as significant controversies or differences of opinion during the negotiations and their resolution.

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PART 3—FEES RELATING TO DEVICES

SEC. 737. DEFINITIONS.

For purposes of this part:

(1) The term "premarket application" means—

(A) an application for approval of a device submitted under section 515(c) or section 351 of the Public Health Service Act; or

(B) a product development protocol described in section 515(f).

Such term does not include a supplement, a premarket report, or a premarket notification submission.

(2) The term "premarket report" means a report submitted under section 515(c)(2).

(3) The term "premarket notification submission" means a report submitted under section 510(k).

(4)(A) The term "supplement", with respect to a panel-track supplement, a 180-day supplement, a real-time supplement, or an efficacy supplement, means a request to the Secretary to approve a change in a device for which—

(i) an application or report has been approved under section 515(d), or an application has been approved under section 351 of the Public Health Service Act; or

(ii) a notice of completion has become effective under section 515(f).

(B) The term "panel-track supplement" means a supplement to an approved premarket application or premarket report under section 515 that requests a significant change in design or performance of the device, or a new indication for use of the device, and for which substantial clinical data are necessary to provide a reasonable assurance of safety and effectiveness.

(C) The term "180-day supplement" means a supplement to an approved premarket application or premarket report under section 515 that is not a panel-track supplement and requests a significant change in components, materials, design, specification, software, color additives, or labeling.

(D) The term "real-time supplement" means a supplement to an approved premarket application or premarket report under section 515 that requests a minor change to the device, such as a minor change to the design of the device, software, sterilization, or labeling, and for which the applicant has requested and the agency has granted a meeting or similar forum to jointly review and determine the status of the supplement.

(E) The term "efficacy supplement" means a supplement to an approved premarket application under section 351 of the Public Health Service Act that requires substantive clinical data.

(5) The term "30-day notice" means a notice under section 515(d)(5) that is limited to a request to make modifications to manufacturing procedures or methods of manufacture affecting the safety and effectiveness of the device.

(6) The term "request for classification information" means a request made under section 513(g) for information respecting the class in which a device has been classified or the requirements applicable to a device.

(7) The term "annual fee", for periodic reporting concerning a class III device, means the annual fee associated with periodic reports required by a premarket application approval order.

(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.

(9) The term "process for the review of device applications" means the following activities of the Secretary with respect to the review of premarket applications, premarket reports, supplements, [and premarket notification submissions] *premarket notification submissions, and de novo classification requests*:

(A) The activities necessary for the review of premarket applications, premarket reports, supplements, and premarket notification submissions.

(B) The issuance of action letters that allow the marketing of devices or which set forth in detail the specific deficiencies in such applications, reports, supplements, or submissions and, where appropriate, the actions necessary to place them in condition for approval.

(C) The inspection of manufacturing establishments and other facilities undertaken as part of the Secretary's review of pending premarket applications, premarket reports, and supplements.

(D) Monitoring of research conducted in connection with the review of such applications, reports, supplements, [and submissions] *submissions, and requests*.

(E) Review of device applications subject to section 351 of the Public Health Service Act for an investigational new drug application under section 505(i) or for an investigational device exemption under section 520(g) and activities conducted in anticipation of the submission of such applications under section 505(i) or 520(g).

(F) The development of guidance, policy documents, or regulations to improve the process for the review of premarket applications, premarket reports, supplements, [and premarket notification submissions] *premarket notification submissions, and de novo classification requests*.

(G) The development of voluntary test methods, consensus standards, or mandatory performance standards under section 514 in connection with the review of such applications, reports, supplements, [or submissions] *submissions, or requests* and related activities.

(H) The provision of technical assistance to device manufacturers in connection with the submission of such applications, reports, supplements, [or submissions] *submissions, or requests*.

(I) Any activity undertaken under section 513 or 515(i) in connection with the initial classification or reclassification of a device or under section 515(b) in connection with any requirement for approval of a device.

(J) Evaluation of postmarket studies required as a condition of an approval of a premarket application or premarket report under section 515 or a premarket application under section 351 of the Public Health Service Act.

(K) Compiling, developing, and reviewing information on relevant devices to identify safety and effectiveness issues for devices subject to premarket applications, premarket reports, supplements, [or premarket notification submis-

sions] *premarket notification submissions, or de novo classification requests*.

(10) The term "costs of resources allocated for the process for the review of device applications" means the expenses in connection with the process for the review of device applications for—

(A) officers and employees of the Food and Drug Administration, contractors of the Food and Drug Administration, advisory committees, and costs related to such officers, employees, and committees and to contracts with such contractors;

(B) management of information, and the acquisition, maintenance, and repair of computer resources;

(C) leasing, maintenance, renovation, and repair of facilities and acquisition, maintenance, and repair of fixtures, furniture, scientific equipment, and other necessary materials and supplies; and

(D) collecting fees and accounting for resources allocated for the review of premarket applications, premarket reports, supplements, submissions, and de novo classification requests.

(11) The term "adjustment factor" applicable to a fiscal year is the Consumer Price Index for all urban consumers (all items; United States city average) for October of the preceding fiscal year divided by such Index for October [2016] *2021*.

(12) The term "person" includes an affiliate thereof.

(13) The term "affiliate" means a business entity that has a relationship with a second business entity (whether domestic or international) if, directly or indirectly—

(A) one business entity controls, or has the power to control, the other business entity; or

(B) a third party controls, or has power to control, both of the business entities.

(14) The term "establishment subject to a registration fee" means an establishment that is registered (or is required to register) with the Secretary under section 510 because such establishment is engaged in the manufacture, preparation, propagation, compounding, or processing of a device.

SEC. 738. AUTHORITY TO ASSESS AND USE DEVICE FEES.

(a) TYPES OF FEES.—

(1) IN GENERAL.—Beginning in [fiscal year 2018] *fiscal year 2023*, the Secretary shall assess and collect fees in accordance with this section.

(2) PREMARKET APPLICATION, PREMARKET REPORT, SUPPLEMENT, AND SUBMISSION FEE, AND ANNUAL FEE FOR PERIODIC REPORTING CONCERNING A CLASS III DEVICE.—

(A) IN GENERAL.—Except as provided in subparagraph (B) and subsections (d) and (e) each person who submits any of the following, on or after [October 1, 2017] *October 1, 2022*, shall be subject to a fee established under subsection (c) for the fiscal year involved in accordance with the following:

(i) A premarket application.

(ii) For a premarket report, a fee equal to the fee that applies under clause (i).

(iii) For a panel track supplement, a fee equal to [75 percent] *80 percent* of the fee that applies under clause (i).

(iv) For a 180-day supplement, a fee equal to 15 percent of the fee that applies under clause (i).

(v) For a real-time supplement, a fee equal to 7 percent of the fee that applies under clause (i).

(vi) For a 30-day notice, a fee equal to 1.6 percent of the fee that applies under clause (i).

(vii) For an efficacy supplement, a fee equal to the fee that applies under clause (i).

(viii) For a premarket notification submission, a fee equal to [3.4 percent] *4.5 percent* of the fee that applies under clause (i).

(ix) For a request for classification information, a fee equal to 1.35 percent of the fee that applies under clause (i).

(x) For periodic reporting concerning a class III device, an annual fee equal to 3.5 percent of the fee that applies under clause (i).

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

(B) EXCEPTIONS.—

(i) HUMANITARIAN DEVICE EXEMPTION.—An application under section 520(m) is not subject to any fee under subparagraph (A).

(ii) FURTHER MANUFACTURING USE.—No fee shall be required under subparagraph (A) for the submission of a premarket application under section 351 of the Public Health Service Act for a product licensed for further manufacturing use only.

(iii) STATE OR FEDERAL GOVERNMENT SPONSORS.—No fee shall be required under subparagraph (A) for a premarket application, premarket report, supplement, [or premarket notification submission] *premarket notification submission, or de novo classification request* submitted by a State or Federal Government entity unless the device involved is to be distributed commercially.

(iv) PREMARKET NOTIFICATIONS BY THIRD PARTIES.—No fee shall be required under subparagraph (A) for a premarket notification submission reviewed by an accredited person pursuant to section 523.

(v) PEDIATRIC CONDITIONS OF USE.—

(I) IN GENERAL.—No fee shall be required under subparagraph (A) for a premarket application, premarket report, premarket notification submission, or de novo classification request if the proposed conditions of use for the device involved are solely for a pediatric population. No fee shall be required under such subparagraph for a supplement if the sole purpose of the supplement is to propose conditions of use for a pediatric population.

(II) SUBSEQUENT PROPOSAL OF ADULT CONDITIONS OF USE.—In the case of a person who submits a premarket application or premarket report for which, under subclause (I), a fee under subparagraph (A) is not required, any supplement to such application that proposes conditions of use for any adult population is subject to the fee that applies under such subparagraph for a premarket application.

(C) PAYMENT.—The fee required by subparagraph (A) shall be due upon submission of the premarket application, premarket report, supplement, premarket notification submission, 30-day notice, request for classification information, [or periodic reporting concerning a class III device] *periodic reporting concerning a class III device, or de novo classification request*. Applicants submitting portions of applications pursuant to section 515(c)(4) shall pay such fees upon submission of the first portion of such applications.

(D) REFUNDS.—

(i) APPLICATION REFUSED FOR FILING.—The Secretary shall refund 75 percent of the fee paid under subparagraph (A) for any application, report, or supplement that is refused for filing.

(ii) APPLICATION WITHDRAWN BEFORE FILING.—The Secretary shall refund 75 percent of the fee paid under subparagraph (A) for any application, report, or supplement that is withdrawn prior to the filing decision of the Secretary.

(iii) APPLICATION WITHDRAWN BEFORE FIRST ACTION.—After receipt of a request for a refund of the fee paid under subparagraph (A) for a premarket application, premarket report, or supplement that is withdrawn after filing but before a first action, the Secretary may return some or all of the fee. The amount of refund, if any, shall be based on the level of effort already expended on the review of such application, report, or supplement.

(iv) MODULAR APPLICATIONS WITHDRAWN BEFORE FIRST ACTION.—The Secretary shall refund 75 percent of the application fee paid for an application submitted under section 515(c)(4) that is withdrawn before a second portion is submitted and before a first action on the first portion.

(v) LATER WITHDRAWN MODULAR APPLICATIONS.—If an application submitted under section 515(c)(4) is withdrawn after a second or subsequent portion is submitted but before any first action, the Secretary may return a portion of the fee. The amount of refund, if any, shall be based on the level of effort already expended on the review of the portions submitted.

(vi) SOLE DISCRETION TO REFUND.—The Secretary shall have sole discretion to refund a fee or portion of the fee under clause (iii) or (v). A determination by the Secretary concerning a refund under clause (iii) or (v) shall not be reviewable.

(3) ANNUAL ESTABLISHMENT REGISTRATION FEE.—

(A) IN GENERAL.—Except as provided in subparagraph (B), each establishment subject to a registration fee shall be subject to a fee for each initial or annual registration under section 510 beginning with its registration for fiscal year 2008.

(B) EXCEPTION.—No fee shall be required under subparagraph (A) for an establishment operated by a State or Federal governmental entity or an Indian tribe (as defined in the Indian Self Determination and Educational Assistance Act), unless a device manufactured by the establishment is to be distributed commercially.

(C) PAYMENT.—The fee required under subparagraph (A) shall be due once each fiscal year, upon the later of—

(i) the initial or annual registration (as applicable) of the establishment under section 510; 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 year under this section.

(b) FEE AMOUNTS.—

(1) IN GENERAL.—Subject to subsections (c), (d), (e), and (h), for each of fiscal years [2018 through 2022] *2023 through 2027*, 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]

(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 2023*	*Fiscal Year 2024*	*Fiscal Year 2025*	*Fiscal Year 2026*	*Fiscal Year 2027*
Premarket Application	*$425,000*	*$435,000*	*$445,000*	*$455,000*	*$470,000*
Establishment Registration	*$6,250*	*$6,875*	*$7,100*	*$7,575*	*$8,465*

[(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.]

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

(A) $312,606,000 for fiscal year 2023.

(B) $335,750,000 for fiscal year 2024.

(C) $350,746,400 for fiscal year 2025.

(D) $366,486,300 for fiscal year 2026.

(E) $418,343,000 for fiscal year 2027.

(c) ANNUAL FEE SETTING; ADJUSTMENTS.—

(1) IN GENERAL.—The Secretary shall, 60 days before the start of each fiscal year after September 30, [2017] *2022*, establish fees under subsection (a), based on amounts specified under subsection (b) and the adjustments provided under this subsection, and publish such fees, and the rationale for any adjustments to such fees, in the Federal Register.

(2) INFLATION ADJUSTMENTS.—

(A) ADJUSTMENT TO TOTAL REVENUE AMOUNTS.—For fiscal year [2018] *2023* and each subsequent fiscal year, the Secretary shall adjust the total revenue amount specified in subsection (b)(3) for such fiscal year by multiplying such amount by the applicable inflation adjustment under subparagraph (B) for such year.

(B) APPLICABLE INFLATION ADJUSTMENT.—The applicable inflation adjustment for [fiscal year 2018] *fiscal year 2023* 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] *fiscal year 2022*.

(C) BASE INFLATION ADJUSTMENT.—

(i) IN GENERAL.—Subject to further adjustment under clause (ii), the base inflation adjustment for a fiscal year is the sum of one plus—

(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 0.60; and

(II) the average annual percent change that occurred in the Consumer Price Index for urban consumers ([Washington-Baltimore, DC–MD–VA–WV] *Washington-Arlington-Alexandria, DC–VA–MD–WV*; Not Seasonally Adjusted; All items; Annual Index) for the first 3 years of the preceding 4 years of available data multiplied by 0.40.

(ii) LIMITATIONS.—For purposes of subparagraph (B), if the base inflation adjustment for a fiscal year under clause (i)—

(I) is less than 1, such adjustment shall be considered to be equal to 1; or

(II) is greater than 1.04, such adjustment shall be considered to be equal to 1.04.

(D) ADJUSTMENT TO BASE FEE AMOUNTS.—For each of [fiscal years 2018 through 2022] *fiscal years 2023 through 2027*, 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).

(3) VOLUME-BASED ADJUSTMENTS TO ESTABLISHMENT REGISTRATION BASE FEES.—For each of fiscal years [2018 through 2022] *2023 through 2027*, after the base fee amounts specified in subsection (b)(2) are adjusted under paragraph (2)(D), the base establishment registration fee amounts specified in such subsection shall be increased, as the Secretary estimates is necessary in order for total fee collections for such fiscal year to generate the total revenue amounts, as adjusted under paragraph (2).

(4) PERFORMANCE IMPROVEMENT ADJUSTMENT.—

(A) IN GENERAL.—For each of fiscal years 2025 through 2027, after the adjustments under paragraphs (2) and (3), the base establishment registration fee amounts for such fiscal year shall be increased to reflect changes in the resource needs of the Secretary due to improved review performance goals for the process for the review of device applications identified in the letters described in section 201(b) of the Medical Device User Fee Amendments of 2022, as the Secretary determines necessary to achieve an increase in total fee collections for such fiscal year equal to the following amounts:

(i) For fiscal year 2025, the product of—

(I) the amount determined under subparagraph (B)(i)(I); and

(II) the applicable inflation adjustment under paragraph (2)(B) for such fiscal year.

(ii) For fiscal year 2026, the product of—

(I) the sum of the amounts determined under subparagraphs (B)(i)(II), (B)(ii)(I), and (B)(iii)(I); and

(II) the applicable inflation adjustment under paragraph (2)(B) for such fiscal year.

(iii) For fiscal year 2027, the product of—

(I) the sum of the amounts determined under subparagraphs (B)(i)(III), (B)(ii)(II), and (B)(iii)(II); and

(II) the applicable inflation adjustment under paragraph (2)(B) for such fiscal year.

(B) AMOUNTS.—

(i) PRE-SUBMISSION AMOUNT.—For purposes of subparagraph (A), with respect to the pre-submission writ-

ten feedback goal, the amounts determined under this subparagraph are as follows:

(I) For fiscal year 2025, $15,396,600 if such goal for fiscal year 2023 is met.

(II) For fiscal year 2026:

(aa) $15,396,600 if such goal for fiscal year 2023 is met and such goal for fiscal year 2024 is not met.

(bb) $36,792,200 if such goal for fiscal year 2024 is met.

(III) For fiscal year 2027:

(aa) $15,396,600 if such goal for fiscal year 2023 is met and such goal for each of fiscal years 2024 and 2025 is not met.

(bb) $36,792,200 if such goal for fiscal year 2024 is met and such goal for fiscal year 2025 is not met.

(cc) $40,572,600 if such goal for fiscal year 2025 is met.

(ii) DE NOVO CLASSIFICATION AMOUNT.—For purposes of subparagraph (A), with respect to the de novo decision goal, the amounts determined under this subparagraph are as follows:

(I) For fiscal year 2026, $6,323,500 if such goal for fiscal year 2023 is met.

(II) For fiscal year 2027:

(aa) $6,323,500 if such goal for fiscal year 2023 is met and such goal for fiscal year 2024 is not met.

(bb) $11,765,400 if such goal for fiscal year 2024 is met.

(iii) PREMARKET NOTIFICATION AND PREMARKET APPROVAL AMOUNT.—For purposes of subparagraph (A), with respect to the 510(k) decision goal, 510(k) shared outcome total time to decision goal, PMA decision goal, and PMA shared outcome total time to decision goal, the amounts determined under this subparagraph are as follows:

(I) For fiscal year 2026, $1,020,000 if the four goals for fiscal year 2023 are met.

(II) For fiscal year 2027:

(aa) $1,020,000 if the four goals for fiscal year 2023 are met and one or more of the four goals for fiscal year 2024 are not met.

(bb) $3,906,000 if the four goals for fiscal year 2024 are met.

(C) PERFORMANCE CALCULATION.—For purposes of this paragraph, performance of the goals listed in subparagraph (D) shall be determined as specified in the letters described in section 201(b) of the Medical Device User Fee Amendments of 2022 and based on data available as of the following dates:

(i) The performance of the pre-submission written feedback goal shall be based on data available as of—

(I) for fiscal year 2023, March 31, 2024;

(II) for fiscal year 2024, March 31, 2025; and

(III) for fiscal year 2025, March 31, 2026.

(ii) The performance of the de novo decision goal, 510(k) decision goal, 510(k) shared outcome total time to decision goal, PMA decision goal, and PMA shared outcome total time to decision goal shall be based on data available as of—

(I) for fiscal year 2023, March 31, 2025; and

(II) for fiscal year 2024, March 31, 2026.

(D) GOALS DEFINED.—For purposes of this paragraph, the terms "pre-submission written feedback goal", "de novo decision goal", "510(k) decision goal", "510(k) shared outcome total time to decision goal", "PMA decision goal", and "PMA shared outcome total time to decision goal" refer to the goals identified by the same names in the letters described in section 201(b) of the Medical Device User Fee Amendments of 2022.

(5) HIRING ADJUSTMENT.—

(A) IN GENERAL.—For each of fiscal years 2025 through 2027, after the adjustments under paragraphs (2), (3), and (4), if applicable, if the number of hires to support the process for the review of device applications falls below the thresholds specified in subparagraph (B) for the applicable fiscal years, the base establishment registration fee amounts shall be decreased as the Secretary determines necessary to achieve a reduction in total fee collections equal to the hiring adjustment amount under subparagraph (C).

(B) THRESHOLDS.—The thresholds specified in this subparagraph are as follows:

(i) For fiscal year 2025, the threshold is 123 hires for fiscal year 2023.

(ii) For fiscal year 2026, the threshold is 38 hires for fiscal year 2024.

(iii) For fiscal year 2027, the threshold is—

(I) 22 hires for fiscal year 2025 if the base establishment registration fees are not increased by the amount determined under paragraph (4)(A)(i); or

(II) 75 hires for fiscal year 2025 if such fees are so increased.

(C) HIRING ADJUSTMENT AMOUNT.—The hiring adjustment amount for fiscal year 2025 and each subsequent fiscal year is the product of—

(i) the number of hires by which the hiring goal specified in subparagraph (D) for the fiscal year before the prior fiscal year was not met;

(ii) $72,877; and

(iii) the applicable inflation adjustment under paragraph (2)(B) for the fiscal year for which the hiring goal was not met.

(D) HIRING GOALS.—The hiring goals for each of fiscal years 2023 through 2025 are as follows:

(i) For fiscal year 2023, 144 hires.

(ii) For fiscal year 2024, 42 hires.

(iii) For fiscal year 2025:

(I) 24 hires if the base establishment registration fees are not increased by the amount determined under paragraph (4)(A)(i).

(II) 83 hires if the base establishment registration fees are increased by the amount determined under paragraph (4)(A)(i).

(E) NUMBER OF HIRES.—For purposes of this paragraph, the number of hires shall be determined by the Secretary as set forth in the letters described in section 201(b) of the Medical Device User Fee Amendments of 2022.

(6) OPERATING RESERVE ADJUSTMENT.—

(A) IN GENERAL.—For each of fiscal years 2023 through 2027, after the adjustments under paragraphs (2), (3), (4), and (5), if applicable, if the Secretary has operating reserves of carryover user fees for the process for the review of device applications in excess of the designated amount in subparagraph (B), the Secretary shall decrease the base establishment registration fee amounts to provide for not more than such designated amount of operating reserves.

(B) DESIGNATED AMOUNT.—Subject to subparagraph (C), for each fiscal year, the designated amount in this subparagraph is equal to the sum of—

(i) 13 weeks of operating reserves of carryover user fees; and

(ii) 1 month of operating reserves maintained pursuant to paragraph (8).

(C) EXCLUDED AMOUNT.—For the period of fiscal years 2023 through 2026, a total amount equal to $118,000,000 shall not be considered part of the designated amount under subparagraph (B) and shall not be subject to the decrease under subparagraph (A).

[(4)**]** *(7)* 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 device applications.

[(5)**]** *(8)* SUPPLEMENT.—

(A) IN GENERAL.—The Secretary may use unobligated carryover balances from fees collected in previous fiscal years to ensure that sufficient fee revenues are available in that fiscal year, so long as the Secretary maintains unobligated carryover balances of not less than 1 month of operating reserves for the first month of the next fiscal year.

(B) NOTICE TO CONGRESS.—Not later than 14 days before the Secretary anticipates the use of funds described in subparagraph (A), the Secretary shall provide notice to the Committee on Health, Education, Labor, and Pensions and the Committee on Appropriations of the Senate and the Committee on Energy and Commerce and the Committee on Appropriations of the House of Representatives.

(d) SMALL BUSINESSES; FEE WAIVER AND FEE REDUCTION REGARDING PREMARKET APPROVAL FEES.—

(1) IN GENERAL.—The Secretary shall grant a waiver of the fee required under subsection (a) for one premarket application, or one premarket report, where the Secretary finds that

the applicant involved is a small business submitting its first premarket application to the Secretary, or its first premarket report, respectively, for review. For the purposes of this paragraph, the term "small business" means an entity that reported $30,000,000 or less of gross receipts or sales in its most recent Federal income tax return for a taxable year, including such returns of all of its affiliates. In addition, for subsequent premarket applications, premarket reports, and supplements where the Secretary finds that the applicant involved is a small business, the fees specified in clauses (i) through (vii) and clauses (ix), (x), and (xi) of subsection (a)(2)(A) may be paid at a reduced rate in accordance with paragraph (2)(C).

(2) RULES RELATING TO PREMARKET APPROVAL FEES.—

(A) DEFINITION.—For purposes of this paragraph, the term "small business" means an entity that reported $100,000,000 or less of gross receipts or sales in its most recent Federal income tax return for a taxable year, including such returns of all of its affiliates.

(B) EVIDENCE OF QUALIFICATION.—

(i) IN GENERAL.—An applicant shall pay the higher fees established by the Secretary each year unless the applicant submits evidence that it qualifies for a waiver of the fee or the lower fee rate.

(ii) FIRMS SUBMITTING TAX RETURNS TO THE UNITED STATES INTERNAL REVENUE SERVICE.—The applicant shall support its claim that it meets the definition under subparagraph (A) by submission of a copy of its most recent Federal income tax return for a taxable year, and a copy of such returns of its affiliates, which show an amount of gross sales or receipts that is less than the maximum established in subparagraph (A). The applicant, and each of such affiliates, shall certify that the information provided is a true and accurate copy of the actual tax forms they submitted to the Internal Revenue Service. If no tax forms are submitted for any affiliate, the applicant shall certify that the applicant has no affiliates.

(iii) FIRMS NOT SUBMITTING TAX RETURNS TO THE UNITED STATES INTERNAL REVENUE SERVICE.—In the case of an applicant that has not previously submitted a Federal income tax return, the applicant and each of its affiliates shall demonstrate that it meets the definition under subparagraph (A) by submission of a signed certification, in such form as the Secretary may direct through a notice published in the Federal Register, that the applicant or affiliate meets the criteria for a small business and a certification, in English, from the national taxing authority, *if extant,* of the country in which the applicant or, if applicable, affiliate is headquartered. The certification from such taxing authority shall bear the official seal of such taxing authority and shall provide the applicant's or affiliate's gross receipts or sales for the most recent year in both the local currency of such country and in United States dollars, the exchange rate used in converting

such local currency to dollars, and the dates during which these receipts or sales were collected. The applicant shall also submit a statement signed by the head of the applicant's firm or by its chief financial officer that the applicant has submitted certifications for all of its affiliates, or that the applicant has no affiliates.

(C) REDUCED FEES.—Where the Secretary finds that the applicant involved meets the definition under subparagraph (A), the fees established under subsection (c)(1) may be paid at a reduced rate of—

(i) 25 percent of the fee established under such subsection for a premarket application, a premarket report, a supplement, periodic reporting concerning a class III device, or a de novo classification request; and

(ii) 50 percent of the fee established under such subsection for a 30-day notice or a request for classification information.

(D) REQUEST FOR FEE WAIVER OR REDUCTION.—An applicant seeking a fee waiver or reduction under this subsection shall submit supporting information to the Secretary at least 60 days before the fee is required pursuant to subsection (a). The decision of the Secretary regarding whether an entity qualifies for such a waiver or reduction is not reviewable.

(e) SMALL BUSINESSES; FEE REDUCTION REGARDING PREMARKET NOTIFICATION SUBMISSIONS.—

(1) IN GENERAL.—For fiscal year 2008 and each subsequent fiscal year, where the Secretary finds that the applicant involved is a small business, the fee specified in subsection (a)(2)(A)(viii) may be paid at a reduced rate in accordance with paragraph (2)(C).

(2) RULES RELATING TO PREMARKET NOTIFICATION SUBMISSIONS.—

(A) DEFINITION.—For purposes of this subsection, the term "small business" means an entity that reported $100,000,000 or less of gross receipts or sales in its most recent Federal income tax return for a taxable year, including such returns of all of its affiliates.

(B) EVIDENCE OF QUALIFICATION.—

(i) IN GENERAL.—An applicant shall pay the higher fees established by the Secretary each year unless the applicant submits evidence that it qualifies for the lower fee rate.

(ii) FIRMS SUBMITTING TAX RETURNS TO THE UNITED STATES INTERNAL REVENUE SERVICE.—The applicant shall support its claim that it meets the definition under subparagraph (A) by submission of a copy of its most recent Federal income tax return for a taxable year, and a copy of such returns of its affiliates, which show an amount of gross sales or receipts that is less than the maximum established in subparagraph (A). The applicant, and each of such affiliates, shall certify that the information provided is a true and accurate copy of the actual tax forms they submitted to the Internal Revenue Service. If no tax forms are submitted

for any affiliate, the applicant shall certify that the applicant has no affiliates.

(iii) FIRMS NOT SUBMITTING TAX RETURNS TO THE UNITED STATES INTERNAL REVENUE SERVICE.—In the case of an applicant that has not previously submitted a Federal income tax return, the applicant and each of its affiliates shall demonstrate that it meets the definition under subparagraph (A) by submission of a signed certification, in such form as the Secretary may direct through a notice published in the Federal Register, that the applicant or affiliate meets the criteria for a small business and a certification, in English, from the national taxing authority, *if extant,* of the country in which the applicant or, if applicable, affiliate is headquartered. The certification from such taxing authority shall bear the official seal of such taxing authority and shall provide the applicant's or affiliate's gross receipts or sales for the most recent year in both the local currency of such country and in United States dollars, the exchange rate used in converting such local currency to dollars, and the dates during which these receipts or sales were collected. The applicant shall also submit a statement signed by the head of the applicant's firm or by its chief financial officer that the applicant has submitted certifications for all of its affiliates, or that the applicant has no affiliates.

(C) REDUCED FEES.—For fiscal year 2008 and each subsequent fiscal year, where the Secretary finds that the applicant involved meets the definition under subparagraph (A), the fee for a premarket notification submission may be paid at 25 percent of the fee that applies under subsection (a)(2)(A)(viii), and as established under subsection (c)(1).

(D) REQUEST FOR REDUCTION.—An applicant seeking a fee reduction under this subsection shall submit supporting information to the Secretary at least 60 days before the fee is required pursuant to subsection (a). The decision of the Secretary regarding whether an entity qualifies for such a reduction is not reviewable.

(f) EFFECT OF FAILURE TO PAY FEES.—

(1) NO ACCEPTANCE OF SUBMISSIONS.—A premarket application, premarket report, supplement, premarket notification submission, 30-day notice, request for classification information, periodic reporting concerning a class III device, or de novo classification request submitted by a person subject to fees under subsections (a)(2) and (a)(3) shall be considered incomplete and shall not be accepted by the Secretary until all such fees owed by such person have been paid.

(2) NO REGISTRATION.—Registration information submitted under section 510 by an establishment subject to a registration fee shall be considered incomplete and shall not be accepted by the Secretary until the registration fee under subsection (a)(3) owed for the establishment has been paid. Until the fee is paid and the registration is complete, the establishment is deemed to have failed to register in accordance with section 510.

(g) CONDITIONS.—

(1) PERFORMANCE GOALS; TERMINATION OF PROGRAM.—With respect to the amount that, under the salaries and expenses account of the Food and Drug Administration, is appropriated for a fiscal year for devices and radiological products, fees may not be assessed under subsection (a) for the fiscal year, and the Secretary is not expected to meet any performance goals identified for the fiscal year, if—

(A) the amount so appropriated for the fiscal year, excluding the amount of fees appropriated for the fiscal year, is more than 1 percent less than **[**$320,825,000**]** *$398,566,000* multiplied by the adjustment factor applicable to such fiscal year; or

(B) fees were not assessed under subsection (a) for the previous fiscal year.

(2) AUTHORITY.—If the Secretary does not assess fees under subsection (a) during any portion of a fiscal year because of paragraph (1) and if at a later date in such fiscal year the Secretary may assess such fees, the Secretary may assess and collect such fees, without any modification in the rate for premarket applications, supplements, premarket reports, premarket notification submissions, 30-day notices, requests for classification information, periodic reporting concerning a class III device, *de novo classification requests,* and establishment registrations at any time in such fiscal year, notwithstanding the provisions of subsection (a) relating to the date fees are to be paid.

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

(h) CREDITING AND AVAILABILITY OF FEES.—

(1) IN GENERAL.—Subject to paragraph (2)(C), fees authorized under subsection (a) shall be collected and available for obligation only to the extent and in the amount provided in advance in appropriation Acts. Such fees are authorized to be appropriated to remain available until expended. Such sums as may be necessary may be transferred from the Food and Drug Administration salaries and expenses appropriation account without fiscal year limitation to such appropriation account for salaries and expenses with such fiscal year limitation. The sums transferred shall be available solely for the process for the review of device applications.

(2) COLLECTIONS AND APPROPRIATION ACTS.—

(A) IN GENERAL.—The fees authorized by this section—

(i) subject to subparagraph (C), shall be collected and available in each fiscal year in an amount not to exceed the amount specified in appropriation Acts, or otherwise made available for obligation, for such fiscal year, and

(ii) shall be available to defray increases in the costs of the resources allocated for the process for the review of device applications (including increases in such costs for an additional number of full-time equivalent positions in the Department of Health and Human Services to be engaged in such process) over such costs, excluding costs paid from fees collected under

this section, for fiscal year 2009 multiplied by the adjustment factor.

(B) COMPLIANCE.—

(i) IN GENERAL.—The Secretary shall be considered to have met the requirements of subparagraph (A)(ii) in any fiscal year if the costs funded by appropriations and allocated for the process for the review of device applications—

(I) are not more than 3 percent below the level specified in subparagraph (A)(ii); or

(II)(aa) are more than 3 percent below the level specified in subparagraph (A)(ii), and fees assessed for a subsequent fiscal year are decreased by the amount in excess of 3 percent by which such costs fell below the level specified in such subparagraph; and

(bb) such costs are not more than 5 percent below the level specified in such subparagraph.

(ii) MORE THAN 5 PERCENT.—To the extent such costs are more than 5 percent below the specified level in subparagraph (A)(ii), fees may not be collected under this section for that fiscal year.

(C) PROVISION FOR EARLY PAYMENTS.—Payment of fees authorized under this section for a fiscal year, prior to the due date for such fees, may be accepted by the Secretary in accordance with authority provided in advance in a prior year appropriations Act.

[(3) AUTHORIZATIONS OF APPROPRIATIONS.—For each of the fiscal years 2018 through 2022, there is authorized to be appropriated for fees under this section an amount equal to the total revenue amount specified under subsection (b)(3) for the fiscal year, as adjusted under subsection (c).]

(3) AUTHORIZATION OF APPROPRIATIONS.—

(A) IN GENERAL.—For each of fiscal years 2023 through 2027, there is authorized to be appropriated for fees under this section an amount equal to the revenue amount determined under subparagraph (B), less the amount of reductions determined under subparagraph (C).

(B) REVENUE AMOUNT.—For purposes of this paragraph, the revenue amount for each fiscal year is the sum of—

(i) the total revenue amount under subsection (b)(3) for the fiscal year, as adjusted under paragraphs (2) and (3) of subsection (c); and

(ii) the performance improvement adjustment amount for the fiscal year under subsection (c)(4), if applicable.

(C) REDUCTIONS.—For purposes of this paragraph, the amount of reductions for each fiscal year is the sum of—

(i) the hiring adjustment amount for the fiscal year under subsection (c)(5), if applicable; and

(ii) the operating reserve adjustment amount for the fiscal year under subsection (c)(6), if applicable.

(i) COLLECTION OF UNPAID FEES.—In any case where the Secretary does not receive payment of a fee assessed under subsection (a) within 30 days after it is due, such fee shall be treated as a

claim of the United States Government subject to subchapter II of chapter 37 of title 31, United States Code.

(j) WRITTEN REQUESTS FOR REFUNDS.—To qualify for consideration for a refund under subsection (a)(2)(D), a person shall submit to the Secretary a written request for such refund not later than 180 days after such fee is due.

(k) CONSTRUCTION.—This section may not be construed to require that the number of full-time equivalent positions in the Department of Health and Human Services, for officers, employees, and advisory committees not engaged in the process of the review of device applications, be reduced to offset the number of officers, employees, and advisory committees so engaged.

SEC. 738A. REAUTHORIZATION; REPORTING REQUIREMENTS.

(a) REPORTS.—

(1) PERFORMANCE REPORT.—

(A) IN GENERAL.—

(i) GENERAL REQUIREMENTS.—Beginning with ⟦fiscal year 2018⟧ *fiscal year 2023*, for each fiscal year for which fees are collected under this part, the Secretary shall prepare and submit to the Committee on Health, Education, Labor, and Pensions of the Senate and the Committee on Energy and Commerce of the House of Representatives annual reports concerning the progress of the Food and Drug Administration in achieving the goals identified in the letters described in section 201(b) of the ⟦Medical Device User Fee Amendments of 2017⟧ *Medical Device User Fee Amendments of 2022* during such fiscal year and the future plans of the Food and Drug Administration for meeting the goals.

(ii) ADDITIONAL INFORMATION.—Beginning with ⟦fiscal year 2018⟧ *fiscal year 2023*, the annual report under this subparagraph shall include the progress of the Center for Devices and Radiological Health in achieving the goals, and future plans for meeting the goals, including—

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

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

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

(iii) REAL TIME REPORTING.—

(I) IN GENERAL.—Not later than 30 calendar days after the end of the second quarter of ⟦fiscal year 2018⟧ *fiscal year 2023*, and not later than 30 calendar days after the end of each quarter of each fiscal year thereafter, the Secretary shall post the data described in subclause (II) on the internet website of the Food and Drug Administration for such quarter

and on a cumulative basis for such fiscal year, and may remove duplicative data from the annual report under this subparagraph.

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

(aa) The number and titles of draft and final guidance on topics related to the process for the review of devices, and whether such guidances were issued as required by statute or pursuant to the letters described in section 201(b) of the ⟦Medical Device User Fee Amendments of 2017⟧ *Medical Device User Fee Amendments of 2022*; and

(bb) The number and titles of public meetings held on topics related to the process for the review of devices, and if such meetings were required by statute or pursuant to a commitment under the letters described in section 201(b) of the ⟦Medical Device User Fee Amendments of 2017⟧ *Medical Device User Fee Amendments of 2022*.

(iv) RATIONALE FOR MDUFA PROGRAM CHANGES.—Beginning with ⟦fiscal year 2020⟧ *fiscal year 2023*, the Secretary shall include in the annual report under paragraph (1)—

(I) data, analysis, and discussion of the changes in the number of full-time equivalents hired as agreed upon in the letters described in section 201(b) of the ⟦Medical Device User Fee Amendments of 2017⟧ *Medical Device User Fee Amendments of 2022* and the number of full time equivalents funded by budget authority at the Food and Drug Administration by each division within the Center for Devices and Radiological Health, the Center for Biologics Evaluation and Research, the Office of Regulatory Affairs, and the Office of the Commissioner;

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

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

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

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

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

(bb) the aggregate number of applications for each fiscal year that did not meet the goals as identified by the letters described in section 201(b) of the [Medical Device User Fee Amendments of 2017] *Medical Device User Fee Amendments of 2022* for the applicable fiscal year.

(II) Relevant data to determine whether the Center for Devices and Radiological Health has met performance enhancement goals identified by the letters described in section 201(b) of the [Medical Device User Fee Amendments of 2017] *Medical Device User Fee Amendments of 2022* for the applicable fiscal year.

(III) The most common causes and trends for external or other circumstances affecting the ability of the Center for Devices and Radiological Health, the Office of Regulatory Affairs, or the Food and Drug Administration to meet review time and performance enhancement goals identified by the letters described in section 201(b) of the [Medical Device User Fee Amendments of 2017] *Medical Device User Fee Amendments of 2022*.

(B) PUBLICATION.—With regard to information to be reported by the Food and Drug Administration to industry on a quarterly and annual basis pursuant to the letters described in section 201(b) of the [Medical Device User Fee Amendments of 2017] *Medical Device User Fee Amendments of 2022*, the Secretary shall make such information publicly available on the Internet Web site of the Food and Drug Administration not later than 60 days after the end of each quarter or 120 days after the end of each fiscal year, respectively, to which such information applies. This information shall include the status of the independent assessment identified in the letters described in such section 201(b).

(C) UPDATES.—The Secretary shall include in each report under subparagraph (A) information on all previous

cohorts for which the Secretary has not given a complete response on all device premarket applications and reports, supplements, and premarket notifications in the cohort.

(2) CORRECTIVE ACTION REPORT.—Beginning with ⟦fiscal year 2018⟧ *fiscal year 2023*, for each fiscal year for which fees are collected under this part, the Secretary shall prepare and submit a corrective action report to the Committee on Energy and Commerce and the Committee on Appropriations of the House of Representatives and the Committee on Health, Education, Labor, and Pensions and the Committee on Appropriations of the Senate. The report shall include the following information, as applicable:

(A) GOALS MET.—For each fiscal year, if the Secretary determines, based on the analysis under paragraph (1)(A)(iv), that each of the goals identified by the letters described in section 201(b) of the ⟦Medical Device User Fee Amendments of 2017⟧ *Medical Device User Fee Amendments of 2022* for the applicable fiscal year have been met, the corrective action report shall include recommendations on ways in which the Secretary can improve and streamline the medical device application review process.

(B) GOALS MISSED.—For each of the goals identified by the letters described in section 201(b) of the ⟦Medical Device User Fee Amendments of 2017⟧ *Medical Device User Fee Amendments of 2022* for the applicable fiscal year that the Secretary determines to not have been met, the corrective action report shall include—

(i) a justification for such determination;

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

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

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

(3) ENHANCED COMMUNICATION.—

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

(B) PARTICIPATION IN CONGRESSIONAL HEARING.—Each fiscal year, as applicable and requested, representatives

from the Food and Drug Administration shall participate in a public hearing before the Committee on Health, Education, Labor, and Pensions of the Senate and the Committee on Energy and Commerce of the House of Representatives, to report on the contents described in the reports under this section. Such hearing shall occur not later than 120 days after the end of each fiscal year for which fees are collected under this part.

(4) FISCAL REPORT.—For fiscal years [2018 through 2022] *2023 through 2027*, not later than 120 days after the end of each fiscal year during which fees are collected under this part, the Secretary shall prepare and submit to the Committee on Health, Education, Labor, and Pensions of the Senate and the Committee on Energy and Commerce of the House of Representatives, a report on the implementation of the authority for such fees during such fiscal year and the use, by the Food and Drug Administration, of the fees collected during such fiscal year for which the report is made.

(5) PUBLIC AVAILABILITY.—The Secretary shall make the reports required under paragraphs (1) and (2) available to the public on the Internet Web site of the Food and Drug Administration.

(b) REAUTHORIZATION.—

(1) CONSULTATION.—In developing recommendations to present to Congress with respect to the goals, and plans for meeting the goals, for the process for the review of device applications for the first 5 fiscal years after fiscal year [2022] *2027*, and for the reauthorization of this part for such fiscal years, the Secretary shall consult with—

(A) the Committee on Energy and Commerce of the House of Representatives;

(B) the Committee on Health, Education, Labor, and Pensions of the Senate;

(C) scientific and academic experts;

(D) health care professionals;

(E) representatives of patient and consumer advocacy groups; and

(F) the regulated industry.

(2) PRIOR PUBLIC INPUT.—Prior to beginning negotiations with the regulated industry on the reauthorization of this part, the Secretary shall—

(A) publish a notice in the Federal Register requesting public input on the reauthorization;

(B) hold a public meeting at which the public may present its views on the reauthorization, including specific suggestions for changes to the goals referred to in subsection (a)(1);

(C) provide a period of 30 days after the public meeting to obtain written comments from the public suggesting changes to this part; and

(D) publish the comments on the Food and Drug Administration's Internet Web site.

(3) PERIODIC CONSULTATION.—Not less frequently than once every month during negotiations with the regulated industry, the Secretary shall hold discussions with representatives of pa-

tient and consumer advocacy groups to continue discussions of their views on the reauthorization and their suggestions for changes to this part as expressed under paragraph (2).

(4) PUBLIC REVIEW OF RECOMMENDATIONS.—After negotiations with the regulated industry, the Secretary shall—

(A) present the recommendations developed under paragraph (1) to the Congressional committees specified in such paragraph;

(B) publish such recommendations in the Federal Register;

(C) provide for a period of 30 days for the public to provide written comments on such recommendations;

(D) hold a meeting at which the public may present its views on such recommendations; and

(E) after consideration of such public views and comments, revise such recommendations as necessary.

(5) TRANSMITTAL OF RECOMMENDATIONS.—Not later than January 15, [2022] *2027*, the Secretary shall transmit to Congress the revised recommendations under paragraph (4), a summary of the views and comments received under such paragraph, and any changes made to the recommendations in response to such views and comments.

(6) MINUTES OF NEGOTIATION MEETINGS.—

(A) PUBLIC AVAILABILITY.—Before presenting the recommendations developed under paragraphs (1) through (5) to the Congress, the Secretary shall make publicly available, on the public Web site of the Food and Drug Administration, minutes of all negotiation meetings conducted under this subsection between the Food and Drug Administration and the regulated industry.

(B) CONTENT.—The minutes described under subparagraph (A) shall summarize any substantive proposal made by any party to the negotiations as well as significant controversies or differences of opinion during the negotiations and their resolution.

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PART 7—FEES RELATING TO GENERIC DRUGS

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SEC. 744B. AUTHORITY TO ASSESS AND USE HUMAN GENERIC DRUG FEES.

(a) TYPES OF FEES.—Beginning in [fiscal year 2018] *fiscal year 2023*, the Secretary shall assess and collect fees in accordance with this section as follows:

(1) ONE-TIME BACKLOG FEE FOR ABBREVIATED NEW DRUG APPLICATIONS PENDING ON OCTOBER 1, 2012.—

(A) IN GENERAL.—Each person that owns an abbreviated new drug application that is pending on October 1, 2012, and that has not received a tentative approval prior to that date, shall be subject to a fee for each such application, as calculated under subparagraph (B).

(B) METHOD OF FEE AMOUNT CALCULATION.—The amount of each one-time backlog fee shall be calculated by dividing

$50,000,000 by the total number of abbreviated new drug applications pending on October 1, 2012, that have not received a tentative approval as of that date.

(C) NOTICE.—Not later than October 31, 2012, the Secretary shall publish in the Federal Register a notice announcing the amount of the fee required by subparagraph (A).

(D) FEE DUE DATE.—The fee required by subparagraph (A) shall be due no later than 30 calendar days after the date of the publication of the notice specified in subparagraph (C).

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

(2) DRUG MASTER FILE FEE.—

(A) IN GENERAL.—Each person that owns a Type II active pharmaceutical ingredient drug master file that is referenced on or after October 1, 2012, in a generic drug submission by any initial letter of authorization shall be subject to a drug master file fee.

(B) ONE-TIME PAYMENT.—If a person has paid a drug master file fee for a Type II active pharmaceutical ingredient drug master file, the person shall not be required to pay a subsequent drug master file fee when that Type II active pharmaceutical ingredient drug master file is subsequently referenced in generic drug submissions.

(C) NOTICE.—Not later than 60 days before the start of each of fiscal years ⟦2018 through 2022⟧ *2023 through 2027*, the Secretary shall publish in the Federal Register the amount of the drug master file fee established by this paragraph for such fiscal year.

(D) AVAILABILITY FOR REFERENCE.—

(i) IN GENERAL.—Subject to subsection (g)(2)(C), for a generic drug submission to reference a Type II active pharmaceutical ingredient drug master file, the drug master file must be deemed available for reference by the Secretary.

(ii) CONDITIONS.—A drug master file shall be deemed available for reference by the Secretary if—

(I) the person that owns a Type II active pharmaceutical ingredient drug master file has paid the fee required under subparagraph (A) within 20 calendar days after the applicable due date under subparagraph (E); and

(II) the drug master file has not failed an initial completeness assessment by the Secretary, in accordance with criteria to be published by the Secretary.

(iii) LIST.—The Secretary shall make publicly available on the Internet Web site of the Food and Drug Administration a list of the drug master file numbers that correspond to drug master files that have successfully undergone an initial completeness assessment, in accordance with criteria to be published by the Secretary, and are available for reference.

(E) FEE DUE DATE.—

(i) IN GENERAL.—Subject to clause (ii), a drug master file fee shall be due on the earlier of—

(I) the date on which the first generic drug submission is submitted that references the associated Type II active pharmaceutical ingredient drug master file; or

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

(ii) LIMITATION.—No fee shall be due under subparagraph (A) for a fiscal year until the later of—

(I) 30 calendar days after publication of the notice provided for in subparagraph (C); or

(II) 30 calendar days after the date of enactment of an appropriations Act providing for the collection and obligation of fees for such year under this section.

(3) ABBREVIATED NEW DRUG APPLICATION FILING FEE.—

(A) IN GENERAL.—Each applicant that submits, on or after October 1, 2012, an abbreviated new drug application shall be subject to a fee for each such submission in the amount established under subsection (d).

(B) NOTICE.—Not later than 60 days before the start of each of fiscal years ⟦2018 through 2022⟧ *2023 through 2027*, 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) REFUND OF FEE IF ABBREVIATED NEW DRUG APPLICATION IS NOT CONSIDERED TO HAVE BEEN RECEIVED, IS WITHDRAWN PRIOR TO BEING RECEIVED, OR IS NO LONGER RECEIVED.—

(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) FEE FOR AN APPLICATION THE SECRETARY CONSIDERS NOT TO HAVE BEEN RECEIVED, OR THAT HAS BEEN WITH-

DRAWN.—An abbreviated new drug application that was submitted on or after October 1, 2012, and that the Secretary considers not to have been received, or that has been withdrawn, shall, upon resubmission of the application or a subsequent new submission following the applicant's withdrawal of the application, be subject to a full fee under subparagraph (A).

(F) ADDITIONAL FEE FOR ACTIVE PHARMACEUTICAL INGREDIENT INFORMATION NOT INCLUDED BY REFERENCE TO TYPE II ACTIVE PHARMACEUTICAL INGREDIENT DRUG MASTER FILE.—An applicant that submits a generic drug submission on or after October 1, 2017, shall pay a fee, in the amount determined under subsection (d)(2), in addition to the fee required under subparagraph (A), if—

(i) such submission contains information concerning the manufacture of an active pharmaceutical ingredient at a facility by means other than reference by a letter of authorization to a Type II active pharmaceutical drug master file; and

(ii) a fee in the amount equal to the drug master file fee established in paragraph (2) has not been previously paid with respect to such information.

(4) GENERIC DRUG FACILITY FEE AND ACTIVE PHARMACEUTICAL INGREDIENT FACILITY FEE.—

(A) IN GENERAL.—Facilities identifiedin at least one generic drug submission that is approved to produce a finished dosage form of a human generic drug or an active pharmaceutical ingredient contained in a human generic drug shall be subject to fees as follows:

(i) GENERIC DRUG FACILITY.—Each person that owns a facility which is identified in at least one generic drug submission that is approved to produce one or more finished dosage forms of a human generic drug shall be assessed an annual fee for each such facility.

(ii) ACTIVE PHARMACEUTICAL INGREDIENT FACILITY.—Each person that owns a facility which 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 generic drug submission, shall be assessed an annual fee for each such facility.

(iii) FACILITIES PRODUCING BOTH ACTIVE PHARMACEUTICAL INGREDIENTS AND FINISHED DOSAGE FORMS.—Each person that owns a facility identified, or intended to be identified, in at least one generic drug submission that is pending or approved to produce both one or more finished dosage forms subject to clause (i) and one or more active pharmaceutical ingredients subject to clause (ii) shall be subject only to the fee attributable to the manufacture of the finished dosage forms for that facility.

(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] *2023 through 2027*, 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.

(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] *2023 through 2027*, 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.

(6) DATE OF SUBMISSION.—For purposes of this Act, a generic drug submission or Type II pharmaceutical master file is deemed to be "submitted" to the Food and Drug Administration—

(A) if it is submitted via a Food and Drug Administration electronic gateway, on the day when transmission to that electronic gateway is completed, except that a submission or master file that arrives on a weekend, Federal holiday, or day when the Food and Drug Administration office that will review that submission is not otherwise open for business shall be deemed to be submitted on the next day when that office is open for business; or

(B) if it is submitted in physical media form, on the day it arrives at the appropriate designated document room of the Food and Drug Administration.

(b) FEE REVENUE AMOUNTS.—

(1) IN GENERAL.—

(A) FISCAL YEAR [2018] *2023*.—For fiscal year [2018] *2023*, fees under subsection (a) shall be established to generate a total estimated revenue amount under such subsection of [$493,600,000] *$582,500,000*.

[(B) FISCAL YEARS 2019 THROUGH 2022.—For each of the fiscal years 2019 through 2022, fees under paragraphs (2) through (5) of subsection (a) shall be established to generate a total estimated revenue amount under such subsection that is equal to $493,600,000, as adjusted pursuant to subsection (c).]

(B) FISCAL YEARS 2024 THROUGH 2027.—

(i) IN GENERAL.—For each of the fiscal years 2024 through 2027, fees under paragraphs (2) through (5) of subsection (a) shall be established to generate a total estimated revenue amount under such subsection that is equal to the base revenue amount for the fiscal year under clause (ii), as adjusted pursuant to subsection (c).

(ii) BASE REVENUE AMOUNT.—The base revenue amount for a fiscal year referred to in clause (i) is equal to the total revenue amount established under this paragraph for the previous fiscal year, not including any adjustments made for such previous fiscal year under subsection (c)(3).

(2) TYPES OF FEES.—In establishing fees under paragraph (1) to generate the revenue amounts specified in such paragraph for a fiscal year, such fees shall be derived from the fees under paragraphs (2) through (5) of subsection (a) as follows:

(A) Five percent shall be derived from fees under subsection (a)(2) (relating to drug master files).

(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] *twenty-four percent* 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) [Seven percent] *Six percent* shall be derived from fees under subsection (a)(4)(A)(ii) (relating to active pharmaceutical ingredient facilities). 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, including its territories and possessions.

(E)(i) [Thirty-five percent] *Thirty-six 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.—

(1) INFLATION ADJUSTMENT.—For fiscal year [2019] *2024* and subsequent fiscal years, the revenues established in subsection (b) shall be adjusted by the Secretary by notice, published in the Federal Register, for a fiscal year, [to equal the product of the total revenues established in such notice for the prior fiscal year multiplied] *to equal the base revenue amount for the fiscal year (as specified in subsection (b)(1)(B)) multiplied* by an amount equal to the sum of—

(A) one;

(B) 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 human generic drug activities for the first 3 years of the preceding 4 fiscal years; and

(C) the average annual percent change that occurred in the Consumer Price Index for urban consumers ([Washington-Baltimore, DC–MD–VA–WV] *Washington-Arlington-Alexandria, DC–VA–MD–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 human generic drug activities for the first 3 years of the preceding 4 fiscal years.

[(2) FINAL YEAR ADJUSTMENT.—For fiscal year 2022, the Secretary may, in addition to adjustments under paragraph (1), further increase the fee revenues and fees established in sub-

section (b) if such an adjustment is necessary to provide for not more than 3 months of operating reserves of carryover user fees for human generic drug activities for the first 3 months of fiscal year 2023. If such an adjustment is necessary, the rationale for the amount of the increase shall be contained in the annual notice establishing fee revenues and fees for fiscal year 2022. If the Secretary has carryover balances for such activities in excess of 3 months of such operating reserves, the adjustment under this subparagraph shall not be made.]

(2) CAPACITY PLANNING ADJUSTMENT.—

(A) IN GENERAL.—Beginning with fiscal year 2024, 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, in accordance with this paragraph, to reflect changes in the resource capacity needs of the Secretary for human generic drug activities.

(B) CAPACITY PLANNING METHODOLOGY.—The Secretary shall establish a capacity planning methodology for purposes of this paragraph, which shall—

(i) be derived from the methodology and recommendations made in the report titled "Independent Evaluation of the GDUFA Resource Capacity Planning Adjustment Methodology: Evaluation and Recommendations" announced in the Federal Register on August 3, 2020;

(ii) incorporate approaches and attributes determined appropriate by the Secretary, including approaches and attributes made in such report, except that in incorporating such approaches and attributes the workload categories used in forecasting resources shall only be the workload categories specified in section VIII.B.2.e. of the letters described in section 301(b) of the Generic Drug User Fee Amendments of 2022; and

(iii) be effective beginning with fiscal year 2024.

(C) LIMITATIONS.—

(i) IN GENERAL.—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 subsection (b)(1)(B)(ii) (the base revenue amount for the fiscal year) and paragraph (1) (the dollar amount of the inflation adjustment for the fiscal year).

(ii) PERCENTAGE LIMITATION.—An adjustment under this paragraph shall not exceed three percent of the sum described in clause (i) for the fiscal year, except that such limitation shall be four percent if—

(I) for purposes of a fiscal year 2024 adjustment, the Secretary determines that during the period from April 1, 2021, through March 31, 2023—

(aa) the total number of abbreviated new drug applications submitted was greater than or equal to 2,000; or

(bb) thirty-five percent or more of abbreviated new drug applications submitted re-

lated to complex products (as that term is defined in section XI of the letters described in section 301(b) of the Generic Drug User Fee Amendments of 2022);

(II) for purposes of a fiscal year 2025 adjustment, the Secretary determines that during the period from April 1, 2022, through March 31, 2024—

(aa) the total number of abbreviated new drug applications submitted was greater than or equal to 2,300; or

(bb) thirty-five percent or more of abbreviated new drug applications submitted related to complex products (as so defined);

(III) for purposes of a fiscal year 2026 adjustment, the Secretary determines that during the period from April 1, 2023, through March 31, 2025—

(aa) the total number of abbreviated new drug applications submitted was greater than or equal to 2,300; or

(bb) thirty-five percent or more of abbreviated new drug applications submitted related to complex products (as so defined); and

(IV) for purposes of a fiscal year 2027 adjustment, the Secretary determines that during the period from April 1, 2024, through March 31, 2026—

(aa) the total number of abbreviated new drug applications submitted was greater than or equal to 2,300; or

(bb) thirty-five percent or more of abbreviated new drug applications submitted related to complex products (as so defined).

(D) PUBLICATION IN FEDERAL REGISTER.—The Secretary shall publish in the Federal Register notice referred to in subsection (a) the fee revenue and fees resulting from the adjustment and the methodology under this paragraph.

(3) OPERATING RESERVE ADJUSTMENT.—

(A) IN GENERAL.—For fiscal year 2024 and each subsequent fiscal year, the Secretary may, in addition to adjustments under paragraphs (1) and (2), further increase the fee revenue and fees under this section for such fiscal year if such an adjustment is necessary to provide operating reserves of carryover user fees for human generic drug activities for not more than the number of weeks specified in subparagraph (B) with respect to that fiscal year.

(B) NUMBER OF WEEKS.—The number of weeks specified in this subparagraph is—

(i) 8 weeks for fiscal year 2024;

(ii) 9 weeks for fiscal year 2025; and

(iii) 10 weeks for each of fiscal year 2026 and 2027.

(C) DECREASE.—If the Secretary has carryover balances for human generic drug activities in excess of 12 weeks of the operating reserves referred to in subparagraph (A), the Secretary shall decrease the fee revenue and fees referred to in such subparagraph to provide for not more than 12 weeks of such operating reserves.

(D) RATIONALE FOR ADJUSTMENT.—If an adjustment under this paragraph 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 subsection (a) publishing the fee revenue and fees for the fiscal year involved.

(d) ANNUAL FEE SETTING.—

(1) FISCAL YEARS ⟦2018 THROUGH 2022⟧ *2023 THROUGH 2027*.—Not ⟦more than 60 days before the first day of each of fiscal years 2018 through 2022⟧ *later than 60 days before the first day of each of fiscal years 2023 through 2027*, 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) FEE FOR ACTIVE PHARMACEUTICAL INGREDIENT INFORMATION NOT INCLUDED BY REFERENCE TO TYPE II ACTIVE PHARMACEUTICAL INGREDIENT DRUG MASTER FILE.—In establishing the fee under paragraph (1), the amount of the fee under subsection (a)(3)(F) shall be determined by multiplying—

(A) the sum of—

(i) the total number of such active pharmaceutical ingredients in such submission; and

(ii) for each such ingredient that is manufactured at more than one such facility, the total number of such additional facilities; and

(B) the amount equal to the drug master file fee established in subsection (a)(2) for such submission.

(e) LIMITATIONS.—

(1) IN GENERAL.—The total amount of fees charged, as adjusted under subsection (c), for a fiscal year may not exceed the total costs for such fiscal year for the resources allocated for human generic drug activities.

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

(f) IDENTIFICATION OF FACILITIES.—

(1) REQUIRED SUBMISSION OF FACILITY IDENTIFICATION.—Each person that owns a facility described in subsection (a)(4)(A) or a site or organization required to be identified by paragraph (3) shall submit to the Secretary the information required under this subsection each year. Such information shall, for each fiscal year, be submitted, updated, or reconfirmed on or before June 1 of the previous fiscal year.

(2) INFORMATION REQUIRED TO BE SUBMITTED.—At a minimum, the submission required by paragraph (1) shall include for each such facility—

(A) identification of a facility identified in an approved or pending generic drug submission;

(B) whether the facility manufactures active pharmaceutical ingredients or finished dosage forms, or both;

(C) whether or not the facility is located within the United States and its territories and possessions;

(D) whether the facility manufactures positron emission tomography drugs solely, or in addition to other drugs;

(E) whether the facility manufactures drugs that are not generic drugs; and

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

(3) CERTAIN SITES AND ORGANIZATIONS.—

(A) IN GENERAL.—Any person that owns or operates a site or organization described in subparagraph (B) shall submit to the Secretary information concerning the ownership, name, and address of the site or organization.

(B) SITES AND ORGANIZATIONS.—A site or organization is described in this subparagraph if it is identified in a generic drug submission and is—

(i) a site in which a bioanalytical study is conducted;

(ii) a clinical research organization;

(iii) a contract analytical testing site; or

(iv) a contract repackager site.

(C) NOTICE.—The Secretary may, by notice published in the Federal Register, specify the means and format for submission of the information under subparagraph (A) and may specify, as necessary for purposes of this section, any additional information to be submitted.

(D) INSPECTION AUTHORITY.—The Secretary's inspection authority under section 704(a)(1) shall extend to all such sites and organizations.

(g) EFFECT OF FAILURE TO PAY FEES.—

(1) GENERIC DRUG BACKLOG FEE.—Failure to pay the fee under subsection (a)(1) shall result in the Secretary placing the person that owns the abbreviated new drug application subject to that fee on a publicly available arrears list, such that no new abbreviated new drug applications or supplement submitted on or after October 1, 2012, from that person, or any affiliate of that person, will be received within the meaning of section 505(j)(5)(A) until such outstanding fee is paid. This paragraph shall cease to be effective on October 1, 2022.

(2) DRUG MASTER FILE FEE.—

(A) Failure to pay the fee under subsection (a)(2) within 20 calendar days after the applicable due date under subparagraph (E) of such subsection (as described in subsection (a)(2)(D)(ii)(I)) shall result in the Type II active pharmaceutical ingredient drug master file not being deemed available for reference.

(B)(i) Any generic drug submission submitted on or after October 1, 2012, that references, by a letter of authorization, a Type II active pharmaceutical ingredient drug master file that has not been deemed available for reference shall not be received within the meaning of section 505(j)(5)(A) unless the condition specified in clause (ii) is met.

(ii) The condition specified in this clause is that the fee established under subsection (a)(2) has been paid within 20 calendar days of the Secretary providing the notification to the sponsor of the abbreviated new drug application or supplement of the failure of the owner of the Type II active pharmaceutical ingredient drug master file to pay the drug master file fee as specified in subparagraph (C).

(C)(i) If an abbreviated new drug application or supplement to an abbreviated new drug application references a Type II active pharmaceutical ingredient drug master file for which a fee under subsection (a)(2)(A) has not been paid by the applicable date under subsection (a)(2)(E), the Secretary shall notify the sponsor of the abbreviated new drug application or supplement of the failure of the owner of the Type II active pharmaceutical ingredient drug master file to pay the applicable fee.

(ii) If such fee is not paid within 20 calendar days of the Secretary providing the notification, the abbreviated new drug application or supplement to an abbreviated new drug application shall not be received within the meaning of section 505(j)(5)(A).

(3) ABBREVIATED NEW DRUG APPLICATION FEE [AND PRIOR APPROVAL SUPPLEMENT FEE].—Failure to pay a fee under subparagraph (A) or (F) of subsection (a)(3) within 20 calendar days of the applicable due date under subparagraph (C) of such subsection shall result in the abbreviated new drug application or the prior approval supplement to an abbreviated new drug application not being received within the meaning of section 505(j)(5)(A) until such outstanding fee is paid.

(4) GENERIC DRUG FACILITY FEE AND ACTIVE PHARMACEUTICAL INGREDIENT FACILITY FEE.—

(A) IN GENERAL.—Failure to pay the fee under subsection (a)(4) within 20 calendar days of the due date as specified in subparagraph (D) of such subsection shall result in the following:

(i) The Secretary shall place the facility on a publicly available arrears list, such that no new abbreviated new drug application or supplement submitted on or after October 1, 2012, from the person that is responsible for paying such fee, or any affiliate of that person, will be received within the meaning of section 505(j)(5)(A).

(ii) Any new generic drug submission submitted on or after October 1, 2012, that references such a facility shall not be received, within the meaning of section 505(j)(5)(A) if the outstanding facility fee is not paid within 20 calendar days of the Secretary providing the notification to the sponsor of the failure of the owner of the facility to pay the facility fee under subsection (a)(4)(C).

(iii) All drugs or active pharmaceutical ingredients manufactured in such a facility or containing an ingredient manufactured in such a facility shall be deemed misbranded under section 502(aa).

(B) APPLICATION OF PENALTIES.—The penalties under this paragraph shall apply until the fee established by subsection (a)(4) is paid or the facility is removed from all generic drug submissions that refer to the facility.

(C) NONRECEIVAL FOR NONPAYMENT.—

(i) NOTICE.—If an abbreviated new drug application or supplement to an abbreviated new drug application submitted on or after October 1, 2012, references a fa-

cility for which a facility fee has not been paid by the applicable date under subsection (a)(4)(C), the Secretary shall notify the sponsor of the generic drug submission of the failure of the owner of the facility to pay the facility fee.

(ii) NONRECEIVAL.—If the facility fee is not paid within 20 calendar days of the Secretary providing the notification under clause (i), the abbreviated new drug application or supplement to an abbreviated new drug application shall not be received within the meaning of section 505(j)(5)(A).

(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.

(h) LIMITATIONS.—

(1) IN GENERAL.—Fees under subsection (a) shall be refunded for a fiscal year beginning after fiscal year 2012, unless appropriations for salaries and expenses of the Food and Drug Administration for such fiscal year (excluding the amount of fees appropriated for such fiscal year) are equal to or greater than the amount of appropriations for the salaries and expenses of the Food and Drug Administration for fiscal year 2009 (excluding the amount of fees appropriated for such fiscal year) multiplied by the adjustment factor (as defined in section 744A) applicable to the fiscal year involved.

(2) AUTHORITY.—If the Secretary does not assess fees under subsection (a) during any portion of a fiscal year and if at a later date in such fiscal year the Secretary may assess such fees, the Secretary may assess and collect such fees, without any modification in the rate, at any time in such fiscal year notwithstanding the provisions of subsection (a) relating to the date fees are to be paid.

(i) CREDITING AND AVAILABILITY OF FEES.—

(1) IN GENERAL.—Fees authorized under subsection (a) shall be collected and available for obligation only to the extent and in the amount provided in advance in appropriations Acts, subject to paragraph (2). Such fees are authorized to remain available until expended. Such sums as may be necessary may be transferred from the Food and Drug Administration salaries

and expenses appropriation account without fiscal year limitation to such appropriation account for salaries and expenses with such fiscal year limitation. The sums transferred shall be available solely for human generic drug activities.

(2) COLLECTIONS AND APPROPRIATION ACTS.—

(A) IN GENERAL.—The fees authorized by this section—

(i) subject to subparagraph (C), shall be collected and available in each fiscal year in an amount not to exceed the amount specified in appropriation Acts, or otherwise made available for obligation for such fiscal year; and

(ii) shall be available for a fiscal year beginning after fiscal year 2012 to defray the costs of human generic drug activities (including such costs for an additional number of full-time equivalent positions in the Department of Health and Human Services to be engaged in such activities), only if the Secretary allocates for such purpose an amount for such fiscal year (excluding amounts from fees collected under this section) no less than $97,000,000 multiplied by the adjustment factor defined in section 744A(3) applicable to the fiscal year involved.

(B) COMPLIANCE.—The Secretary shall be considered to have met the requirements of subparagraph (A)(ii) in any fiscal year if the costs funded by appropriations and allocated for human generic activities are not more than 10 percent below the level specified in such subparagraph.

(C) PROVISION FOR EARLY PAYMENTS.—Payment of fees authorized under this section for a fiscal year, prior to the due date for such fees, may be accepted by the Secretary in accordance with authority provided in advance in a prior year appropriations Act.

(3) AUTHORIZATION OF APPROPRIATIONS.—For each of the ⟦fiscal years 2018 through 2022⟧ *fiscal years 2023 through 2027*, there is authorized to be appropriated for fees under this section an amount equivalent to the total revenue amount determined under subsection (b) for the fiscal year, as adjusted under subsection (c), if applicable, or as otherwise affected under paragraph (2) of this subsection.

(j) COLLECTION OF UNPAID FEES.—In any case where the Secretary does not receive payment of a fee assessed under subsection (a) within 30 calendar days after it is due, such fee shall be treated as a claim of the United States Government subject to subchapter II of chapter 37 of title 31, United States Code.

(k) CONSTRUCTION.—This section may not be construed to require that the number of full-time equivalent positions in the Department of Health and Human Services, for officers, employees, and advisory committees not engaged in human generic drug activities, be reduced to offset the number of officers, employees, and advisory committees so engaged.

(l) POSITRON EMISSION TOMOGRAPHY DRUGS.—

(1) EXEMPTION FROM FEES.—Submission of an application for a positron emission tomography drug or active pharmaceutical ingredient for a positron emission tomography drug shall not require the payment of any fee under this section. Facilities

that solely produce positron emission tomography drugs shall not be required to pay a facility fee as established in subsection (a)(4).

(2) IDENTIFICATION REQUIREMENT.—Facilities that produce positron emission tomography drugs or active pharmaceutical ingredients of such drugs are required to be identified pursuant to subsection (f).

(m) DISPUTES CONCERNING FEES.—To qualify for the return of a fee claimed to have been paid in error under this section, a person shall submit to the Secretary a written request justifying such return within 180 calendar days after such fee was paid.

(n) SUBSTANTIALLY COMPLETE APPLICATIONS.—An abbreviated new drug application that is not considered to be received within the meaning of section 505(j)(5)(A) because of failure to pay an applicable fee under this provision within the time period specified in subsection (g) shall be deemed not to have been "substantially complete" on the date of its submission within the meaning of section 505(j)(5)(B)(iv)(II)(cc). An abbreviated new drug application that is not substantially complete on the date of its submission solely because of failure to pay an applicable fee under the preceding sentence shall be deemed substantially complete and received within the meaning of section 505(j)(5)(A) as of the date such applicable fee is received.

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

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

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

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

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

SEC. 744C. REAUTHORIZATION; REPORTING REQUIREMENTS.

(a) PERFORMANCE REPORT.—

(1) GENERAL REQUIREMENTS.—[Beginning with fiscal year 2018, not] *Not* later than 120 days after the end of each fiscal year for which fees are collected under this part, the Secretary shall prepare and submit to the Committee on Energy and Commerce of the House of Representatives and the Committee on Health, Education, Labor, and Pensions of the Senate a report concerning the progress of the Food and Drug Administration in achieving the goals identified in the letters described in section 301(b) of the [Generic Drug User Fee Amendments of 2017] *Generic Drug User Fee Amendments of 2022* during such fiscal year and the future plans of the Food and Drug Administration for meeting the goals.

(2) REAL TIME REPORTING.—

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

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

(i) The number and titles of draft and final guidance on topics related to human generic drug activities and whether such guidances were issued as required by statute or pursuant to a commitment under the letters described in section 301(b) of the [Generic Drug User Fee Amendments of 2017] *Generic Drug User Fee Amendments of 2022*.

(ii) The number and titles of public meetings held on topics related to human generic drug activities and whether such meetings were required by statute or pursuant to a commitment under the letters described in section 301(b) of the [Generic Drug User Fee Amendments of 2017] *Generic Drug User Fee Amendments of 2022*.

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

(A) data, analysis, and discussion of the changes in the number of full-time equivalents hired as agreed upon in the letters described in section 301(b) of the [Generic Drug User Fee Amendments of 2017] *Generic Drug User Fee Amendments of 2022* and the number of full time equivalents funded by budget authority at the Food and Drug Administration by each division within the Center for Drug Evaluation and Research, the Center for Biologics Evaluation and Research, the Office of Regulatory Affairs, and the Office of the Commissioner;

(B) data, analysis, and discussion of the changes in the fee revenue amounts and costs for human generic drug activities, including identifying drivers of such changes; and

(C) for each of the Center for Drug Evaluation and Research, the Center for Biologics Evaluation and Research, the Office of Regulatory Affairs, and the Office of the Commissioner, the number of employees for whom time reporting is required and the number of employees for whom time reporting is not required.

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

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

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

(ii) the aggregate number of applications for each fiscal year that did not meet the goals identified by the letters described in section 301(b) of the ⟦Generic Drug User Fee Amendments of 2017⟧ *Generic Drug User Fee Amendments of 2022* for the applicable fiscal year.

(B) Relevant data to determine whether the Food and Drug Administration has met the performance enhancement goals identified by the letters described in section 301(b) of the ⟦Generic Drug User Fee Amendments of 2017⟧ *Generic Drug User Fee Amendments of 2022* for the applicable fiscal year.

(C) The most common causes and trends for external or other circumstances that affected the ability of the Secretary to meet review time and performance enhancement goals identified by the letters described in section 301(b) of the ⟦Generic Drug User Fee Amendments of 2017⟧ *Generic Drug User Fee Amendments of 2022*.

(b) FISCAL REPORT.—⟦Beginning with fiscal year 2018, not⟧ *Not* later than 120 days after the end of each fiscal year for which fees are collected under this part, the Secretary shall prepare and submit to the Committee on Energy and Commerce of the House of Representatives and the Committee on Health, Education, Labor, and Pensions of the Senate a report on the implementation of the authority for such fees during such fiscal year and the use, by the Food and Drug Administration, of the fees collected for such fiscal year.

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

(1) GOALS MET.—For each fiscal year, if the Secretary determines, based on the analysis under subsection (a)(4), that each of the goals identified by the letters described in section 301(b) of the ⟦Generic Drug User Fee Amendments of 2017⟧ *Generic Drug User Fee Amendments of 2022* for the applicable fiscal year have been met, the corrective action report shall include recommendations on ways in which the Secretary can improve and streamline the abbreviated new drug application review process.

(2) GOALS MISSED.—For each of the goals identified by the letters described in section 301(b) of the ⟦Generic Drug User Fee Amendments of 2017⟧ *Generic Drug User Fee Amendments of 2022* for the applicable fiscal year that the Secretary determines to not have been met, the corrective action report shall include—

(A) a detailed justification for such determination and a description, as applicable, of the types of circumstances

and trends under which abbreviated new drug applications missed the review goal times but were approved during the first cycle review, or review goals were missed; and

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

(d) ENHANCED COMMUNICATION.—

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

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

(e) PUBLIC AVAILABILITY.—The Secretary shall make the reports required under subsections (a) and (b) available to the public on the Internet Web site of the Food and Drug Administration.

(f) REAUTHORIZATION.—

(1) CONSULTATION.—In developing recommendations to present to the Congress with respect to the goals, and plans for meeting the goals, for human generic drug activities for the first 5 fiscal years after ⟦fiscal year 2022⟧ *fiscal year 2027*, and for the reauthorization of this part for such fiscal years, the Secretary shall consult with—

(A) the Committee on Energy and Commerce of the House of Representatives;

(B) the Committee on Health, Education, Labor, and Pensions of the Senate;

(C) scientific and academic experts;

(D) health care professionals;

(E) representatives of patient and consumer advocacy groups; and

(F) the generic drug industry.

(2) PRIOR PUBLIC INPUT.—Prior to beginning negotiations with the generic drug industry on the reauthorization of this part, the Secretary shall—

(A) publish a notice in the Federal Register requesting public input on the reauthorization;

(B) hold a public meeting at which the public may present its views on the reauthorization, including specific suggestions for changes to the goals referred to in subsection (a);

(C) provide a period of 30 days after the public meeting to obtain written comments from the public suggesting changes to this part; and

(D) publish the comments on the Food and Drug Administration's Internet Web site.

(3) PERIODIC CONSULTATION.—Not less frequently than once every month during negotiations with the generic drug industry, the Secretary shall hold discussions with representatives of patient and consumer advocacy groups to continue discussions of their views on the reauthorization and their suggestions for changes to this part as expressed under paragraph (2).

(4) PUBLIC REVIEW OF RECOMMENDATIONS.—After negotiations with the generic drug industry, the Secretary shall—

(A) present the recommendations developed under paragraph (1) to the congressional committees specified in such paragraph;

(B) publish such recommendations in the Federal Register;

(C) provide for a period of 30 days for the public to provide written comments on such recommendations;

(D) hold a meeting at which the public may present its views on such recommendations; and

(E) after consideration of such public views and comments, revise such recommendations as necessary.

(5) TRANSMITTAL OF RECOMMENDATIONS.—Not later than [January 15, 2022] *January 15, 2027*, the Secretary shall transmit to the Congress the revised recommendations under paragraph (4), a summary of the views and comments received under such paragraph, and any changes made to the recommendations in response to such views and comments.

(6) MINUTES OF NEGOTIATION MEETINGS.—

(A) PUBLIC AVAILABILITY.—Before presenting the recommendations developed under paragraphs (1) through (5) to the Congress, the Secretary shall make publicly available, on the Internet Web site of the Food and Drug Administration, minutes of all negotiation meetings conducted under this subsection between the Food and Drug Administration and the generic drug industry.

(B) CONTENT.—The minutes described under subparagraph (A) shall summarize any substantive proposal made by any party to the negotiations as well as significant controversies or differences of opinion during the negotiations and their resolution.

PART 8—FEES RELATING TO BIOSIMILAR BIOLOGICAL PRODUCTS

SEC. 744G. DEFINITIONS.

For purposes of this part:

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

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

(2) The term "affiliate" means a business entity that has a relationship with a second business entity if, directly or indirectly—

(A) one business entity controls, or has the power to control, the other business entity; or

(B) a third party controls, or has power to control, both of the business entities.

(3) The term "biosimilar biological product"means a specific strength of a biological product in final dosage form for which a biosimilar biological product application has been approved.

(4)(A) Subject to subparagraph (B), the term "biosimilar biological product application" means an application for licensure of a biological product under section 351(k) of the Public Health Service Act.

(B) Such term does not include—

(i) a supplement to such an application;

(ii) an application filed under section 351(k) of the Public Health Service Act that cites as the reference product a bovine blood product for topical application licensed before September 1, 1992, or a large volume parenteral drug product approved before such date;

(iii) an application filed under section 351(k) of the Public Health Service Act with respect to—

(I) whole blood or a blood component for transfusion;

[(II) an allergenic extract product;**]**

[(III)**]** *(II)* an in vitro diagnostic biological product; or

[(IV)**]** *(III)* a biological product for further manufacturing use only; or

(iv) an application for licensure under section 351(k) of the Public Health Service Act that is submitted by a State or Federal Government entity for a product that is not distributed commercially.

(5) The term "biosimilar biological product development meeting" means any meeting, other than a biosimilar initial advisory meeting, regarding the content of a development program, including a proposed design for, or data from, a study intended to support a biosimilar biological product application.

(6) The term "biosimilar biological product development program" means the program under this part for expediting the process for the review of submissions in connection with biosimilar biological product development.

(7)(A) The term "biosimilar biological product establishment" means a foreign or domestic place of business—

(i) that is at one general physical location consisting of one or more buildings, all of which are within 5 miles of each other; and

(ii) at which one or more biosimilar biological products are manufactured in final dosage form.

(B) For purposes of subparagraph (A)(ii), the term "manufactured" does not include packaging.

(8) The term "biosimilar initial advisory meeting"—

(A) means a meeting, if requested, that is limited to—

(i) a general discussion regarding whether licensure under section 351(k) of the Public Health Service Act may be feasible for a particular product; and

(ii) if so, general advice on the expected content of the development program; and

(B) does not include any meeting that involves substantive review of summary data or full study reports.

(9) The term "costs of resources allocated for the process for the review of biosimilar biological product applications" means the expenses in connection with the process for the review of biosimilar biological product applications for—

(A) officers and employees of the Food and Drug Administration, contractors of the Food and Drug Administration, advisory committees, and costs related to such officers employees and committees and to contracts with such contractors;

(B) management of information, and the acquisition, maintenance, and repair of computer resources;

(C) leasing, maintenance, renovation, and repair of facilities and acquisition, maintenance, and repair of fixtures, furniture, scientific equipment, and other necessary materials and supplies; and

(D) collecting fees under section 744H and accounting for resources allocated for the review of submissions in connection with biosimilar biological product development, biosimilar biological product applications, and supplements.

(10) The term "final dosage form" means, with respect to a biosimilar biological product, a finished dosage form which is approved for administration to a patient without substantial further manufacturing (such as lyophilized products before reconstitution).

(11) The term "financial hold"—

(A) means an order issued by the Secretary to prohibit the sponsor of a clinical investigation from continuing the investigation if the Secretary determines that the investigation is intended to support a biosimilar biological product application and the sponsor has failed to pay any fee for the product required under subparagraph (A), (B), or (D) of section 744H(a)(1); and

(B) does not mean that any of the bases for a "clinical hold" under section 505(i)(3) have been determined by the Secretary to exist concerning the investigation.

(12) The term "person" includes an affiliate of such person.

(13) The term "process for the review of biosimilar biological product applications" means the following activities of the Secretary with respect to the review of submissions in connection with biosimilar biological product development, biosimilar biological product applications, and supplements:

(A) The activities necessary for the review of submissions in connection with biosimilar biological product de-

velopment, biosimilar biological product applications, and supplements.

(B) Actions related to submissions in connection with biosimilar biological product development, the issuance of action letters which approve biosimilar biological product applications or which set forth in detail the specific deficiencies in such applications, and where appropriate, the actions necessary to place such applications in condition for approval.

(C) The inspection of biosimilar biological product establishments and other facilities undertaken as part of the Secretary's review of pending biosimilar biological product applications and supplements.

(D) Activities necessary for the release of lots of biosimilar biological products under section 351(k) of the Public Health Service Act.

(E) Monitoring of research conducted in connection with the review of biosimilar biological product applications.

(F) Postmarket safety activities with respect to biologics approved under biosimilar biological product applications or supplements, including the following activities:

(i) Collecting, developing, and reviewing safety information on biosimilar biological products, including adverse-event reports.

(ii) Developing and using improved adverse-event data-collection systems, including information technology systems.

(iii) Developing and using improved analytical tools to assess potential safety problems, including access to external data bases.

(iv) Implementing and enforcing section 505(o) (relating to postapproval studies and clinical trials and labeling changes) and section 505(p) (relating to risk evaluation and mitigation strategies).

(v) Carrying out section 505(k)(5) (relating to adverse-event reports and postmarket safety activities).

(14) The term "supplement" means a request to the Secretary to approve a change in a biosimilar biological product application which has been approved, including a supplement requesting that the Secretary determine that the biosimilar biological product meets the standards for interchangeability described in section 351(k)(4) of the Public Health Service Act.

SEC. 744H. AUTHORITY TO ASSESS AND USE BIOSIMILAR BIOLOGICAL PRODUCT FEES.

(a) TYPES OF FEES.—Beginning in [fiscal year 2018] *fiscal year 2023*, the Secretary shall assess and collect fees in accordance with this section as follows:

(1) BIOSIMILAR BIOLOGICAL PRODUCT DEVELOPMENT PROGRAM FEES.—

(A) INITIAL BIOSIMILAR BIOLOGICAL PRODUCT DEVELOPMENT FEE.—

(i) IN GENERAL.—Each person that submits to the Secretary a meeting request described under clause (ii) or a clinical protocol for an investigational new drug protocol described under clause (iii) shall pay for

the product named in the meeting request or the investigational new drug application the initial biosimilar biological product development fee established under subsection (c)(5).

(ii) MEETING REQUEST.—The meeting request described in this clause is a request for a biosimilar biological product development meeting for a product.

(iii) CLINICAL PROTOCOL FOR IND.—A clinical protocol for an investigational new drug protocol described in this clause is a clinical protocol consistent with the provisions of section 505(i), including any regulations promulgated under section 505(i), (referred to in this section as "investigational new drug application") describing an investigation that the Secretary determines is intended to support a biosimilar biological product application for a product.

(iv) DUE DATE.—The initial biosimilar biological product development fee shall be due by the earlier of the following:

(I) Not later than [5 days] *7 days* after the Secretary grants a request for a biosimilar biological product development meeting.

(II) The date of submission of an investigational new drug application describing an investigation that the Secretary determines is intended to support a biosimilar biological product application.

(v) TRANSITION RULE.—Each person that has submitted an investigational new drug application prior to the date of enactment of the Biosimilar User Fee Act of 2012 shall pay the initial biosimilar biological product development fee by the earlier of the following:

(I) Not later than 60 days after the date of the enactment of the Biosimilar User Fee Act of 2012, if the Secretary determines that the investigational new drug application describes an investigation that is intended to support a biosimilar biological product application.

(II) Not later than [5 days] *7 days* after the Secretary grants a request for a biosimilar biological product development meeting.

(B) ANNUAL BIOSIMILAR BIOLOGICAL PRODUCT DEVELOPMENT FEE.—

(i) IN GENERAL.—A person that pays an initial biosimilar biological product development fee for a product shall pay for such product, beginning in the fiscal year following the fiscal year in which the initial biosimilar biological product development fee was paid, an annual fee established under subsection (c)(5)for the biosimilar biological product development program (referred to in this section as "annual biosimilar biological product development fee")*, except where such product (including, where applicable, ownership of the relevant investigational new drug application) is transferred to a licensee, assignee, or successor of such per-*

son, and written notice of such transfer is provided to the Secretary, in which case such licensee, assignee, or successor shall pay the annual biosimilar biological product development fee.

(ii) DUE DATE.—The annual biosimilar biological product development fee for each fiscal year will 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.

(iii) EXCEPTION.—The annual biosimilar biological product development fee for each fiscal year will be due on the date specified in clause (ii), unless the person has—

(I) submitted a marketing application for the biological product that was accepted for filing; [or]

(II) discontinued participation in the biosimilar biological product development program for the product under subparagraph (C)[.]*; or*

(III) been administratively removed from the biosimilar biological product development program for the product under subparagraph (E)(v).

(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] *is subsequently accepted for filing*, the person may request a refund equal to the annual biosimilar biological product development fee paid by the person for the product for such fiscal year. To qualify for consideration for a refund under this clause, a person shall submit to the Secretary a written request for such refund not later than 180 days after the marketing application is accepted for filing.

(C) DISCONTINUATION OF FEE OBLIGATION.—A person may discontinue participation in the biosimilar biological product development program for a product, effective October 1 of a fiscal year, by, not later than August 1 of the preceding fiscal year—

(i) if no investigational new drug application concerning the product has been submitted, submitting to the Secretary a written declaration that the person has no present intention of further developing the product as a biosimilar biological product; or

(ii) if an investigational new drug application concerning the product has been submitted, withdrawing the investigational new drug application in accordance with part 312 of title 21, Code of Federal Regulations (or any successor regulations).

[(D) REACTIVATION FEE.—

[(i) IN GENERAL.—A person that has discontinued participation in the biosimilar biological product devel-

opment program for a product under subparagraph (C) shall, if the person seeks to resume participation in such program, pay a fee (referred to in this section as "reactivation fee") by the earlier of the following:

[(I) Not later than 5 days after the Secretary grants a request by such person for a biosimilar biological product development meeting for the product (after the date on which such participation was discontinued).

[(II) Upon the date of submission (after the date on which such participation was discontinued) by such person of an investigational new drug application describing an investigation that the Secretary determines is intended to support a biosimilar biological product application for that product.

[(ii) APPLICATION OF ANNUAL FEE.—A person that pays a reactivation fee for a product shall pay for such product, beginning in the next fiscal year, the annual biosimilar biological product development fee under subparagraph (B).]

(D) REACTIVATION FEE.—

(i) IN GENERAL.—A person that has discontinued participation in the biosimilar biological product development program for a product under subparagraph (C), or who has been administratively removed from the biosimilar biological product development program for a product under subparagraph (E)(v), shall, if the person seeks to resume participation in such program, pay all annual biosimilar biological product development fees previously assessed for such product and still owed and a fee (referred to in this section as "reactivation fee") by the earlier of the following:

(I) Not later than 7 days after the Secretary grants a request by such person for a biosimilar biological product development meeting for the product (after the date on which such participation was discontinued or the date of administrative removal, as applicable).

(II) Upon the date of submission (after the date on which such participation was discontinued or the date of administrative removal, as applicable) by such person of an investigational new drug application describing an investigation that the Secretary determines is intended to support a biosimilar biological product application for that product.

(ii) APPLICATION OF ANNUAL FEE.—A person that pays a reactivation fee for a product shall pay for such product, beginning in the next fiscal year, the annual biosimilar biological product development fee under subparagraph (B), except where such product (including, where applicable, ownership of the relevant investigational new drug application) is transferred to a licensee, assignee, or successor of such person, and writ-

ten notice of such transfer is provided to the Secretary, in which case such licensee, assignee, or successor shall pay the annual biosimilar biological product development fee.

(E) EFFECT OF FAILURE TO PAY FEES.—

(i) NO BIOSIMILAR BIOLOGICAL PRODUCT DEVELOPMENT MEETINGS.—If a person has failed to pay an initial or annual biosimilar biological product development fee as required under subparagraph (A) or (B), or a reactivation fee as required under subparagraph (D), the Secretary shall not provide a biosimilar biological product development meeting relating to the product for which fees are owed.

(ii) NO RECEIPT OF INVESTIGATIONAL NEW DRUG APPLICATIONS.—Except in extraordinary circumstances, the Secretary shall not consider an investigational new drug application to have been received under section 505(i)(2) if—

(I) the Secretary determines that the investigation is intended to support a biosimilar biological product application; and

(II) the sponsor has failed to pay an initial or annual biosimilar biological product development fee for the product as required under subparagraph (A) or (B), or a reactivation fee as required under subparagraph (D).

(iii) FINANCIAL HOLD.—Notwithstanding section 505(i)(2), except in extraordinary circumstances, the Secretary shall prohibit the sponsor of a clinical investigation from continuing the investigation if—

(I) the Secretary determines that the investigation is intended to support a biosimilar biological product application; and

(II) the sponsor has failed to pay an initial or annual biosimilar biological product development fee for the product as required under subparagraph (A) or (B), or a reactivation fee for the product as required under subparagraph (D).

(iv) NO ACCEPTANCE OF BIOSIMILAR BIOLOGICAL PRODUCT APPLICATIONS OR SUPPLEMENTS.—If a person has failed to pay an initial or annual biosimilar biological product development fee as required under subparagraph (A) or (B), or a reactivation fee as required under subparagraph (D), any biosimilar biological product application or supplement submitted by that person shall be considered incomplete and shall not be accepted for filing by the Secretary until all such fees owed by such person have been paid.

(v) ADMINISTRATIVE REMOVAL FROM THE BIOSIMILAR BIOLOGICAL PRODUCT DEVELOPMENT PROGRAM.—If a person has failed to pay an annual biosimilar biological product development fee for a product as required under subparagraph (B) for a period of two consecutive fiscal years, the Secretary may administratively remove such person from the biosimilar biological product de-

velopment program for the product. At least 30 days prior to administratively removing a person from the biosimilar biological product development program for a product under this clause, the Secretary shall provide written notice to such person of the intended administrative removal.

(F) LIMITS REGARDING FEES.—

(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).

(ii) NO WAIVERS, EXEMPTIONS, OR REDUCTIONS.—The Secretary shall not grant a waiver, exemption, or reduction of any initial or annual biosimilar biological product development fee due or payable under subparagraph (A) or (B), or any reactivation fee due or payable under subparagraph (D).

(2) BIOSIMILAR BIOLOGICAL PRODUCT APPLICATION FEE.—

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

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

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

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

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

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

(C) PAYMENT DUE DATE.—Any fee required by subparagraph (A) shall be due upon submission of the application for which such fee applies.

(D) EXCEPTION FOR PREVIOUSLY FILED APPLICATION.—If a biosimilar biological product application was submitted by a person that paid the fee for such application, was accepted for filing, and was not approved or was withdrawn *prior to approval* (without a waiver), the submission of a bio-

similar biological product application for the same product by the same person (or the person's licensee, assignee, or successor) shall not be subject to a fee under subparagraph (A).

(E) REFUND OF APPLICATION FEE IF APPLICATION REFUSED FOR FILING OR WITHDRAWN BEFORE FILING.—The Secretary shall refund 75 percent of the fee paid under this paragraph for any application which is refused for filing or withdrawn without a waiver before filing.

(F) FEES FOR APPLICATIONS PREVIOUSLY REFUSED FOR FILING OR WITHDRAWN BEFORE FILING.—A biosimilar biological product application that was submitted but was refused for filing, or was withdrawn before being accepted or refused for filing, shall be subject to the full fee under subparagraph (A) upon being resubmitted or filed over protest, unless the fee is waived under subsection (d).

(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) may be dispensed only under prescription pursuant to section 503(b); and

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

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

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

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

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

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

(E) MOVEMENT TO DISCONTINUED LIST.—

(i) DATE OF INCLUSION.—If a written request to place a product on the list referenced in subparagraph (A) of discontinued biosimilar biological products is submitted to the Secretary on behalf of an applicant, and the request identifies the date the product is withdrawn from sale, then for purposes of assessing the biosimilar biological product program fee, the Secretary shall con-

sider such product to have been included on such list on the later of—

(I) the date such request was received; or

(II) if the product will be withdrawn from sale on a future date, such future date when the product is withdrawn from sale.

(ii) TREATMENT AS WITHDRAWN FROM SALE.—For purposes of clause (i), a product shall be considered withdrawn from sale once the applicant has ceased its own distribution of the product, whether or not the applicant has ordered recall of all previously distributed lots of the product, except that a routine, temporary interruption in supply shall not render a product withdrawn from sale.

(iii) SPECIAL RULE.—If a biosimilar biological product that is identified in a biosimilar biological product application approved as of October 1 of a fiscal year appears, as of October 1 of such fiscal year, on the list referenced in subparagraph (A) of discontinued biosimilar biological products, and on any subsequent day during such fiscal year the biosimilar biological product does not appear on such list, then except as provided in subparagraph (D), each person who is named as the applicant in a biosimilar biological product application with respect to such product shall pay the annual biosimilar biological product program fee established for a fiscal year under subsection (c)(5) for such biosimilar biological product. Notwithstanding subparagraph (B), such fee shall be due on the last business day of such fiscal year and shall be paid only once for each such product for each fiscal year.

⟦(4) BIOSIMILAR BIOLOGICAL PRODUCT FEE.—

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

⟦(B) DUE DATE.—The biosimilar biological product 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 fee shall be paid only once for each product for each fiscal year.⟧

(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)).]

(1) IN GENERAL.—For each of the fiscal years 2023 through 2027, 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 (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 strategic hiring and retention adjustment (as determined under subsection (c)(2));

(D) the dollar amount equal to the capacity planning adjustment for the fiscal year (as determined under subsection (c)(3));

(E) the dollar amount equal to the operating reserve adjustment for the fiscal year, if applicable (as determined under subsection (c)(4));

(F) for fiscal year 2023 an additional amount of $4,428,886; and

(G) for fiscal year 2024 an additional amount of $320,569.

[(3)] *(2)* ALLOCATION OF REVENUE AMOUNT AMONG FEES[; LIMITATIONS ON FEE AMOUNTS].—

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

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

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

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

[(B) LIMITATIONS ON FEE AMOUNTS.—Until the first fiscal year for which the capacity planning adjustment under subsection (c)(2) is effective, the amount of any fee under subsection (a) for a fiscal year after fiscal year 2018 shall not exceed 125 percent of the amount of such fee for fiscal year 2018.]

[(C)] *(B)* 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)] *(C)* 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).]

(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 2023, $43,376,922; and

(B) for fiscal years 2024 through 2027, the dollar amount of the total revenue amount established under paragraph (1) for the previous fiscal year, excluding any adjustments to such revenue amount under subsection (c)(4).

(c) ADJUSTMENTS; ANNUAL FEE SETTING.—

(1) INFLATION ADJUSTMENT.—

(A) IN GENERAL.—For purposes of [subsection (b)(2)(B)] *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)] *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 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] *Washington-Arlington-Alexandria, DC–VA–MD–WV*; Not Seasonally Adjusted; All items; Annual Index) for the first 3 years of the preceding 4 years of available data multiplied by the proportion of all costs other than personnel compensation and benefits costs to total costs of the process for the review of biosimilar biological product applications (as defined in section 744G(13)) for the first 3 years of the preceding 4 fiscal years.

[(2) CAPACITY PLANNING ADJUSTMENT.—

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

[(B) CAPACITY PLANNING METHODOLOGY.—

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

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

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

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

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

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

[(3) OPERATING RESERVE ADJUSTMENT.—

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

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

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

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

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

[(4) FISCAL YEAR 2018 ADJUSTMENT.—

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

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

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

(2) STRATEGIC HIRING AND RETENTION ADJUSTMENT.—For each fiscal year, after the annual base revenue under subsection (b)(1)(A) is adjusted for inflation in accordance with paragraph (1), the Secretary shall further increase the fee revenue and fees by $150,000.

(3) CAPACITY PLANNING ADJUSTMENT.—

(A) IN GENERAL.—For each fiscal year, the Secretary shall, in addition to the adjustments under paragraphs (1) and (2), further adjust 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) METHODOLOGY.—For purposes of this paragraph, the Secretary shall employ the capacity planning methodology utilized by the Secretary in setting fees for fiscal year 2021, as described in the notice titled "Biosimilar User Fee Rates for Fiscal Year 2021" published in the Federal Register on August 4, 2020 (85 Fed. Reg. 47220). The workload categories used in applying such methodology in forecasting shall include only the activities described in that notice and, as feasible, additional activities that are also directly related to the direct review of biosimilar biological product applications and supplements, including additional formal meeting types, the direct review of postmarketing commitments and requirements, the direct review of risk evaluation and mitigation strategies, and the direct review of annual reports for approved biosimilar biological products.

Subject to the exceptions in the preceding sentence, the Secretary shall not include as workload categories in applying such methodology in forecasting any non-core review activities, including those activities that the Secretary referenced for potential future use in such notice but did not utilize in setting fees for fiscal year 2021.

(C) LIMITATIONS.—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), (b)(1)(B) (the dollar amount of the inflation adjustment for the fiscal year), and (b)(1)(C) (the dollar amount of the strategic hiring and retention adjustment).

(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.

(4) OPERATING RESERVE ADJUSTMENT.—

(A) INCREASE.—For fiscal year 2023 and subsequent fiscal years, the Secretary shall, in addition to adjustments under paragraphs (1), (2), and (3), further increase the fee revenue and fees if such an adjustment is necessary to provide for at least 10 weeks of operating reserves of carryover user fees for the process for the review of biosimilar biological product applications.

(B) DECREASE.—

(i) FISCAL YEAR 2023.—For fiscal year 2023, if the Secretary has carryover balances for such process in excess of 33 weeks of such operating reserves, the Secretary shall decrease such fee revenue and fees to provide for not more than 33 weeks of such operating reserves.

(ii) FISCAL YEAR 2024.—For fiscal year 2024, if the Secretary has carryover balances for such process in excess of 27 weeks of such operating reserves, the Secretary shall decrease such fee revenue and fees to provide for not more than 27 weeks of such operating reserves.

(iii) FISCAL YEAR 2025 AND SUBSEQUENT FISCAL YEARS.—For fiscal year 2025 and subsequent fiscal years, if the Secretary has carryover balances for such process in excess of 21 weeks of such operating reserves, the Secretary shall decrease such fee revenue and fees to provide for not more than 21 weeks of such operating reserves.

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

(5) ANNUAL FEE SETTING.—For fiscal year **[**2018**]** *2023* 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.—

(1) WAIVER OF APPLICATION FEE.—The Secretary shall grant to a person who is named in a biosimilar biological product application a waiver from the application fee assessed to that person under subsection (a)(2)(A) for the first biosimilar biological product application that a small business or its affiliate submits to the Secretary for review. After a small business or its affiliate is granted such a waiver, the small business or its affiliate shall pay application fees for all subsequent biosimilar biological product applications submitted to the Secretary for review in the same manner as an entity that is not a small business.

(2) CONSIDERATIONS.—In determining whether to grant a waiver of a fee under paragraph (1), the Secretary shall consider only the circumstances and assets of the applicant involved and any affiliate of the applicant.

(3) SMALL BUSINESS DEFINED.—In this subsection, the term "small business" means an entity that has fewer than 500 employees, including employees of affiliates, and does not have a drug product that has been approved under a human drug application (as defined in section 735) or a biosimilar biological product application (as defined in section 744G(4)) and introduced or delivered for introduction into interstate commerce.

(e) EFFECT OF FAILURE TO PAY FEES.—A biosimilar biological product application or supplement submitted by a person subject to fees under subsection (a) shall be considered incomplete and shall not be accepted for filing by the Secretary until all such fees owed by such person have been paid.

(f) CREDITING AND AVAILABILITY OF FEES.—

(1) IN GENERAL.—Subject to paragraph (2), fees authorized under subsection (a) shall be collected and available for obligation only to the extent and in the amount provided in advance in appropriations Acts. Such fees are authorized to remain available until expended. Such sums as may be necessary may be transferred from the Food and Drug Administration salaries and expenses appropriation account without fiscal year limitation to such appropriation account for salaries and expenses with such fiscal year limitation. The sums transferred shall be available solely for the process for the review of biosimilar biological product applications.

(2) COLLECTIONS AND APPROPRIATION ACTS.—

(A) IN GENERAL.—Subject to subparagraphs (C) and (D), the fees authorized by this section shall be collected and available in each fiscal year in an amount not to exceed the amount specified in appropriation Acts, or otherwise made available for obligation for such fiscal year.

(B) USE OF FEES AND LIMITATIONS.—

(i) IN GENERAL.—The fees authorized by this section shall be available for a fiscal year beginning after fiscal year 2012 to defray the costs of the process for the review of biosimilar biological product applications (including such costs for an additional number of full-time equivalent positions in the Department of Health and Human Services to be engaged in such process), only if the Secretary allocates for such purpose an amount for such fiscal year (excluding amounts from fees collected under this section) no less than $20,000,000, multiplied by the adjustment factor applicable to the fiscal year involved.

(ii) LEASING AND NECESSARY EQUIPMENT.—Beginning on October 1, 2023, the authorities under section 744G(9)(C) shall include only leasing and necessary scientific equipment.

(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.

(D) PROVISION FOR EARLY PAYMENTS.—Payment of fees authorized under this section for a fiscal year, prior to the due date for such fees, may be accepted by the Secretary in accordance with authority provided in advance in a prior year appropriations Act.

(3) AUTHORIZATION OF APPROPRIATIONS.—For each of fiscal years ⟦2018 through 2022⟧ *2023 through 2027*, there is authorized to be appropriated for fees under this section an amount equivalent to the total amount of fees assessed for such fiscal year under this section.

(g) COLLECTION OF UNPAID FEES.—In any case where the Secretary does not receive payment of a fee assessed under subsection (a) within 30 days after it is due, such fee shall be treated as a claim of the United States Government subject to subchapter II of chapter 37 of title 31, United States Code.

⟦(h) WRITTEN REQUESTS FOR WAIVERS AND REFUNDS.—To qualify for consideration for a waiver under subsection (d), or for a refund of any fee collected in accordance with subsection (a)(2)(A), a person shall submit to the Secretary a written request for such waiver or refund not later than 180 days after such fee is due.⟧

(h) WRITTEN REQUESTS FOR WAIVERS AND RETURNS; DISPUTES CONCERNING FEES.—To qualify for consideration for a waiver under subsection (d), or for the return of any fee paid under this section, including if the fee is claimed to have been paid in error, a person shall submit to the Secretary a written request justifying such waiver or return and, except as otherwise specified in this section, such written request shall be submitted to the Secretary not later than 180 days after such fee is due. A request submitted under

this paragraph shall include any legal authorities under which the request is made.

(i) CONSTRUCTION.—This section may not be construed to require that the number of full-time equivalent positions in the Department of Health and Human Services, for officers, employers, and advisory committees not engaged in the process of the review of biosimilar biological product applications, be reduced to offset the number of officers, employees, and advisory committees so engaged.

SEC. 744I. REAUTHORIZATION; REPORTING REQUIREMENTS.

(a) PERFORMANCE REPORT.—

(1) GENERAL REQUIREMENTS.—[Beginning with fiscal year 2018, not] *Not* later than 120 days after the end of each fiscal year for which fees are collected under this part, the Secretary shall prepare and submit to the Committee on Energy and Commerce of the House of Representatives and the Committee on Health, Education, Labor, and Pensions of the Senate a report concerning the progress of the Food and Drug Administration in achieving the goals identified in the letters described in section 401(b) of the [Biosimilar User Fee Amendments of 2017] *Biosimilar User Fee Amendments of 2022* during such fiscal year and the future plans of the Food and Drug Administration for meeting such goals. The report for a fiscal year shall include information on all previous cohorts for which the Secretary has not given a complete response on all biosimilar biological product applications and supplements in the cohort.

(2) ADDITIONAL INFORMATION.—[Beginning with fiscal year 2018, the] *The* report under this subsection shall include the progress of the Food and Drug Administration in achieving the goals, and future plans for meeting the goals, including—

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

(B) the number of original biosimilar biological product applications filed per fiscal year, and the number of approvals issued by the agency for such applications; and

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

(3) REAL TIME REPORTING.—

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

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

(i) The number and titles of draft and final guidance on topics related to the process for the review of biosimilars, and whether such guidances were required by statute or pursuant to a commitment under the letters described in section 401(b) of the ⟦Biosimilar User Fee Amendments of 2017⟧ *Biosimilar User Fee Amendments of 2022*.

(ii) The number and titles of public meetings held on topics related to the process for the review of biosimilars, and whether such meetings were required by statute or pursuant to a commitment under the letters described in section 401(b) of the ⟦Biosimilar User Fee Amendments of 2017⟧ *Biosimilar User Fee Amendments of 2022*.

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

(A) data, analysis, and discussion of the changes in the number of full-time equivalents hired as agreed upon in the letters described in section 401(b) of the ⟦Biosimilar User Fee Amendments of 2017⟧ *Biosimilar User Fee Amendments of 2022* and the number of full time equivalents funded by budget authority at the Food and Drug Administration by each division within the Center for Drug Evaluation and Research, the Center for Biologics Evaluation and Research, the Office of Regulatory Affairs, and the Office of the Commissioner;

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

(C) for each of the Center for Drug Evaluation and Research, the Center for Biologics Evaluation and Research, the Office of Regulatory Affairs, and the Office of the Commissioner, the number of employees for whom time reporting is required and the number of employees for whom time reporting is not required.

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

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

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

(ii) the aggregate number of applications for each fiscal year that did not meet the goals identified by the letters described in section 401(b) of the ⟦Biosimilar User Fee Amendments of 2017⟧ *Biosimilar User Fee Amendments of 2022* for the applicable fiscal year.

(B) Relevant data to determine whether the Center for Drug Evaluation and Research and the Center for Biologics Evaluation and Research have met the performance

enhancement goals identified by the letters described in section 401(b) of the [Biosimilar User Fee Amendments of 2017] *Biosimilar User Fee Amendments of 2022* for the applicable fiscal year.

(C) The most common causes and trends for external or other circumstances affecting the ability of the Secretary to meet review time and performance enhancement goals identified by the letters described in section 401(b) of the Biosimilar User Fee Amendments of 2017.

(b) FISCAL REPORT.—[Not later than 120 days after the end of fiscal year 2018 and each subsequent fiscal year for which fees are collected under this part] *Not later than 120 days after the end of each fiscal year for which fees are collected under this part*, the Secretary shall prepare and submit to the Committee on Energy and Commerce of the House of Representatives and the Committee on Health, Education, Labor, and Pensions of the Senate a report on the implementation of the authority for such fees during such fiscal year and the use, by the Food and Drug Administration, of the fees collected for such fiscal year.

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

(1) GOALS MET.—For each fiscal year, if the Secretary determines, based on the analysis under subsection (a)(5), that each of the goals identified by the letters described in section 401(b) of the [Biosimilar User Fee Amendments of 2017] *Biosimilar User Fee Amendments of 2022* for the applicable fiscal year have been met, the corrective action report shall include recommendations on ways in which the Secretary can improve and streamline the biosimilar biological product application review process.

(2) GOALS MISSED.—For each of the goals identified by the letters described in section 401(b) of the [Biosimilar User Fee Amendments of 2017] *Biosimilar User Fee Amendments of 2022* for the applicable fiscal year that the Secretary determines to not have been met, the corrective action report shall include—

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

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

(d) ENHANCED COMMUNICATION.—

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

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

(e) PUBLIC AVAILABILITY.—The Secretary shall make the reports required under subsections (a) and (b) available to the public on the Internet Web site of the Food and Drug Administration.

(f) REAUTHORIZATION.—

(1) CONSULTATION.—In developing recommendations to present to the Congress with respect to the goals described in subsection (a), and plans for meeting the goals, for the process for the review of biosimilar biological product applications for the first 5 fiscal years after ⟦fiscal year 2022⟧ *fiscal year 2027*, and for the reauthorization of this part for such fiscal years, the Secretary shall consult with—

(A) the Committee on Energy and Commerce of the House of Representatives;

(B) the Committee on Health, Education, Labor, and Pensions of the Senate;

(C) scientific and academic experts;

(D) health care professionals;

(E) representatives of patient and consumer advocacy groups; and

(F) the regulated industry.

(2) PUBLIC REVIEW OF RECOMMENDATIONS.—After negotiations with the regulated industry, the Secretary shall—

(A) present the recommendations developed under paragraph (1) to the congressional committees specified in such paragraph;

(B) publish such recommendations in the Federal Register;

(C) provide for a period of 30 days for the public to provide written comments on such recommendations;

(D) hold a meeting at which the public may present its views on such recommendations; and

(E) after consideration of such public views and comments, revise such recommendations as necessary.

(3) TRANSMITTAL OF RECOMMENDATIONS.—Not later than ⟦January 15, 2022⟧ *January 15, 2027*, the Secretary shall transmit to the Congress the revised recommendations under paragraph (2), a summary of the views and comments received

under such paragraph, and any changes made to the recommendations in response to such views and comments.

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CHAPTER VIII—IMPORTS AND EXPORTS

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SEC. 809. RECOGNITION OF FOREIGN GOVERNMENT INSPECTIONS.

(a) INSPECTION.—The Secretary—

(1) may enter into arrangements and agreements with a foreign government or an agency of a foreign government to recognize the inspection of foreign establishments registered under section 510(i) in order to facilitate *preapproval or* risk-based inspections in accordance with the schedule established in paragraph (2) or (3) of section 510(h);

(2) may enter into arrangements and agreements with a foreign government or an agency of a foreign government under this section only with a foreign government or an agency of a foreign government that the Secretary has determined as having the capability of conducting inspections that meet the applicable requirements of this Act; and

(3) shall perform such reviews and audits of drug safety programs, systems, and standards of a foreign government or agency for the foreign government as the Secretary deems necessary to determine that the foreign government or agency of the foreign government is capable of conducting inspections that meet the applicable requirements of this Act.

(b) RESULTS OF INSPECTION.—The results of inspections performed by a foreign government or an agency of a foreign government under this section may be used as—

(1) evidence of compliance with section 501(a)(2)(B) or section 801(r); and

(2) for any other purposes as determined appropriate by the Secretary.

(c) PERIODIC REVIEW.—

(1) IN GENERAL.—Beginning not later than 1 year after the date of the enactment of the Food and Drug Amendments of 2022, the Secretary shall periodically assess whether additional arrangements and agreements with a foreign government or an agency of a foreign government, as allowed under this section, are appropriate.

(2) REPORTS TO CONGRESS.—Beginning not later than 4 years after the date of the enactment of the Food and Drug Amendments of 2022, and every 4 years thereafter, the Secretary shall submit to the Committee on Energy and Commerce of the House of Representatives and the Committee on Health, Education, Labor, and Pensions of the Senate a report describing the findings and conclusions of each review conducted under paragraph (1).

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FDA REAUTHORIZATION ACT OF 2017

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TITLE I—FEES RELATING TO DRUGS

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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.

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TITLE II—FEES RELATING TO DEVICES

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SEC. 210. SUNSET DATES.

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

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

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

TITLE III—FEES RELATING TO GENERIC DRUGS

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SEC. 305. SUNSET DATES.

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

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

(c) PREVIOUS SUNSET PROVISION.—

(1) IN GENERAL.—Effective October 1, 2017, section 304 of the Food and Drug Administration Safety and Innovation Act (Public Law 112-144) is repealed.

(2) CONFORMING AMENDMENT.—The Food and Drug Administration Safety and Innovation Act (Public Law 112-144) is amended in the table of contents in section 2 by striking the item relating to section 304.

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TITLE IV—FEES RELATING TO BIOSIMILAR BIOLOGICAL PRODUCTS

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SEC. 405. SUNSET DATES.

[(a) AUTHORIZATION.—Sections 744G and 744H of the Federal Food, Drug, and Cosmetic Act shall cease to be effective October 1, 2022.

[(b) REPORTING REQUIREMENTS.—Section 744I of the Federal Food, Drug, and Cosmetic Act shall cease to be effective January 31, 2023.]

(c) PREVIOUS SUNSET PROVISION.—

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

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

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TITLE VIII—IMPROVING GENERIC DRUG ACCESS

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

Not later than 180 calendar days after the date of enactment of this Act, and quarterly thereafter until October 1, [2022] *2027*, the Secretary of Health and Human Services shall post on the internet website of the Food and Drug Administration a report that provides, with respect to the months covered by the report—

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

(A) awaiting action by the applicant;

(B) awaiting action by the Secretary; and

(C) approved by the Secretary;

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

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

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

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

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TITLE IX—ADDITIONAL PROVISIONS

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[SEC. 902. ANNUAL REPORT ON INSPECTIONS.

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

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

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

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

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

SEC. 902. ANNUAL REPORT ON INSPECTIONS.

Not later than 120 days after the end of each fiscal year, the Secretary of Health and Human Services shall post on the public website of the Food and Drug Administration information related to inspections of facilities necessary for approval of a drug under subsection (c) or (j) of section 505 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355), approval of a device under section 515 of such Act (21 U.S.C. 360e), or clearance of a device under section 510(k) of such Act (21 U.S.C. 360(k)) that were conducted during the previous fiscal year. Such information shall include the following:

(1) The median time following a request from staff of the Food and Drug Administration reviewing an application or report to the beginning of the inspection, including—

(A) the median time for drugs described in section 505(j)(11)(A)(i) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(j)(11)(A)(i));

(B) the median time for drugs described in section 506C(a) of such Act (21 U.S.C. 356c(a)) only; and

(C) the median time for drugs on the drug shortage list in effect under section 506E of such Act (21 U.S.C. 356e).

(2) The median time from the issuance of a report pursuant to section 704(b) of such Act (21 U.S.C. 374(b)) to the sending of a warning letter, issuance of an import alert, or holding of a regulatory meeting for inspections for which the Secretary concluded that regulatory or enforcement action was indicated, including the median time for each category of drugs listed in subparagraphs (A) through (C) of paragraph (1).

(3) The median time from the sending of a warning letter, issuance of an import alert, or holding of a regulatory meeting to resolution of the actions indicated to address the conditions or practices observed during an inspection.

(4) The number of facilities that failed to implement adequate corrective or preventive actions following a report pursuant to such section 704(b), resulting in a withhold recommendation, including the number of such times for each category of drugs listed in subparagraphs (A) through (C) of paragraph (1).

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PUBLIC HEALTH SERVICE ACT

TITLE IV—NATIONAL RESEARCH INSTITUTES

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PART B—GENERAL PROVISIONS RESPECTING NATIONAL RESEARCH INSTITUTES

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SEC. 409I. PROGRAM FOR PEDIATRIC STUDIES OF DRUGS.

(a) LIST OF PRIORITY ISSUES IN PEDIATRIC THERAPEUTICS.—

(1) IN GENERAL.—Not later than one year after the date of the enactment of the Best Pharmaceuticals for Children Act of 2007, the Secretary, acting through the Director of the National Institutes of Health and in consultation with the Commissioner of Food and Drugs and experts in pediatric research, shall develop and publish a priority list of needs in pediatric therapeutics, including drugs, biological products, or indications that require study. The list shall be revised every three years.

(2) CONSIDERATION OF AVAILABLE INFORMATION.—In developing and prioritizing the list under paragraph (1), the Secretary—

(A) shall consider—

(i) therapeutic gaps in pediatrics that may include developmental pharmacology, pharmacogenetic determinants of drug response, metabolism of drugs and biologics in children, and pediatric clinical trials;

(ii) particular pediatric diseases, disorders or conditions where more complete knowledge and testing of therapeutics, including drugs and biologics, and identification of biomarkers for such diseases, disorders, or conditions, may be beneficial in pediatric populations; and

(iii) the adequacy of necessary infrastructure to conduct pediatric pharmacological research, including research networks and trained pediatric investigators; and

(B) may consider the availability of qualified countermeasures (as defined in section 319F–1), security countermeasures (as defined in section 319F–2), and qualified pandemic or epidemic products (as defined in section 319F–3) to address the needs of pediatric populations, in consultation with the Assistant Secretary for Preparedness and Response, consistent with the purposes of this section.

(b) PEDIATRIC STUDIES AND RESEARCH.—The Secretary, acting through the National Institutes of Health, shall award funds to entities that have the expertise to conduct pediatric clinical trials or other research (including qualified universities, hospitals, laboratories, contract research organizations, practice groups, federally funded programs such as pediatric pharmacology research units, other public or private institutions, or individuals) to enable the entities to conduct the drug studies or other research on the issues described in paragraphs (1) and (2)(A) of subsection (a). The Secretary may use contracts, grants, or other appropriate funding mechanisms to award funds under this subsection.

(c) PROCESS FOR PROPOSED PEDIATRIC STUDY REQUESTS AND LABELING CHANGES.—

(1) SUBMISSION OF PROPOSED PEDIATRIC STUDY REQUEST.—The Director of the National Institutes of Health shall, as appropriate, submit proposed pediatric study requests for consideration by the Commissioner of Food and Drugs for pediatric studies of a specific pediatric indication identified under subsection (a). Such a proposed pediatric study request shall be made in a manner equivalent to a written request made under subsection (b) or (c) of section 505A of the Federal Food, Drug, and Cosmetic Act, or section 351(m) of this Act, including with respect to the information provided on the pediatric studies to be conducted pursuant to the request. The Director of the National Institutes of Health may submit a proposed pediatric study request for a drug for which—

(A)(i) there is an approved application under section 505(j) of the Federal Food, Drug, and Cosmetic Act or section 351(k) of this Act; or

(ii) there is a submitted application that could be approved under the criteria of such section; and

(B) there remains no patent listed pursuant to section 505(b)(1) of the Federal Food, Drug, and Cosmetic Act, and every three-year and five-year period referred to in sub-

section (c)(3)(E)(ii), (c)(3)(E)(iii), (c)(3)(E)(iv), (j)(5)(F)(ii), (j)(5)(F)(iii), or (j)(5)(F)(iv) of section 505 of the Federal Food, Drug, and Cosmetic Act, or applicable twelve-year period referred to in section 351(k)(7) of this Act, and any seven-year period referred to in section 527 of the Federal Food, Drug, and Cosmetic Act has ended for at least one form of the drug; and

(C) additional studies are needed to assess the safety and effectiveness of the use of the drug in the pediatric population.

(2) WRITTEN REQUEST TO HOLDERS OF APPROVED APPLICATIONS.—The Commissioner of Food and Drugs, in consultation with the Director of the National Institutes of Health, may issue a written request based on the proposed pediatric study request for the indication or indications submitted pursuant to paragraph (1) (which shall include a timeframe for negotiations for an agreement) for pediatric studies concerning a drug identified under subsection (a) to all holders of an approved application for the drug. Such a written request shall be made in a manner equivalent to the manner in which a written request is made under subsection (b) or (c) of section 505A of the Federal Food, Drug, and Cosmetic Act or section 351(m) of this Act, including with respect to information provided on the pediatric studies to be conducted pursuant to the request and using appropriate formulations for each age group for which the study is requested.

(3) REQUESTS FOR PROPOSALS.—If the Commissioner of Food and Drugs does not receive a response to a written request issued under paragraph (2) not later than 30 days after the date on which a request was issued, the Secretary, acting through the Director of the National Institutes of Health and in consultation with the Commissioner of Food and Drugs, shall publish a request for proposals to conduct the pediatric studies described in the written request in accordance with subsection (b).

(4) DISQUALIFICATION.—A holder that receives a first right of refusal shall not be entitled to respond to a request for proposals under paragraph (3).

(5) CONTRACTS, GRANTS, OR OTHER FUNDING MECHANISMS.—A contract, grant, or other funding may be awarded under this section only if a proposal is submitted to the Secretary in such form and manner, and containing such agreements, assurances, and information as the Secretary determines to be necessary to carry out this section.

(6) REPORTING OF STUDIES.—

(A) IN GENERAL.—On completion of a pediatric study in accordance with an award under this section, a report concerning the study shall be submitted to the Director of the National Institutes of Health and the Commissioner of Food and Drugs. The report shall include all data generated in connection with the study, including a written request if issued.

(B) AVAILABILITY OF REPORTS.—

(i) IN GENERAL.—Each report submitted under subparagraph (A) shall be considered to be in the public

domain (subject to section 505A(d)(4) of the Federal Food, Drug, and Cosmetic Act) and not later than 90 days after submission of such report, shall be—

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

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

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

(II) assigned a docket number by the Commissioner of Food and Drugs and made available for the submission of public comments.

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

(C) ACTION BY COMMISSIONER.—The Commissioner of Food and Drugs shall take action in a timely and appropriate manner in response to the reports submitted under subparagraph (A), and shall begin such action upon receipt of the report under subparagraph (A), in accordance with paragraph (7).

(7) REQUESTS FOR LABELING CHANGE.—Within the 180-day period after the date on which a report is submitted under paragraph (6)(A), the Commissioner of Food and Drugs shall—

(A) review the report and such other data as are available concerning the safe and effective use in the pediatric population of the drug studied;

(B) negotiate with the holders of approved applications for the drug studied for any labeling changes that the Commissioner of Food and Drugs determines to be appropriate and requests the holders to make; and

(C)(i) include in the public docket file a reference to the location of the report on the internet website of the National Institutes of Health and a copy of any requested labeling changes; and

(ii) publish through a posting on the Web site of the Food and Drug Administration a summary of the report and a copy of any requested labeling changes.

(8) DISPUTE RESOLUTION.—

(A) REFERRAL TO PEDIATRIC ADVISORY COMMITTEE.—If, not later than the end of the 180-day period specified in paragraph (7), the holder of an approved application for the drug involved does not agree to any labeling change requested by the Commissioner of Food and Drugs under that paragraph, the Commissioner of Food and Drugs shall refer the request to the Pediatric Advisory Committee.

(B) ACTION BY THE PEDIATRIC ADVISORY COMMITTEE.—Not later than 90 days after receiving a referral under subparagraph (A), the Pediatric Advisory Committee shall—

(i) review the available information on the safe and effective use of the drug in the pediatric population, including study reports submitted under this section; and

(ii) make a recommendation to the Commissioner of Food and Drugs as to appropriate labeling changes, if any.

(9) FDA DETERMINATION.—Not later than 30 days after receiving a recommendation from the Pediatric Advisory Committee under paragraph (8)(B)(ii) with respect to a drug, the Commissioner of Food and Drugs shall consider the recommendation and, if appropriate, make a request to the holders of approved applications for the drug to make any labeling change that the Commissioner of Food and Drugs determines to be appropriate.

(10) FAILURE TO AGREE.—If a holder of an approved application for a drug, within 30 days after receiving a request to make a labeling change under paragraph (9), does not agree to make a requested labeling change, the Commissioner of Food and Drugs may deem the drug to be misbranded under the Federal Food, Drug, and Cosmetic Act.

(11) NO EFFECT ON AUTHORITY.—Nothing in this subsection limits the authority of the United States to bring an enforcement action under the Federal Food, Drug, and Cosmetic Act when a drug lacks appropriate pediatric labeling. Neither course of action (the Pediatric Advisory Committee process or an enforcement action referred to in the preceding sentence) shall preclude, delay, or serve as the basis to stay the other course of action.

(d) AUTHORIZATION OF APPROPRIATIONS.—

(1) IN GENERAL.—There are authorized to be appropriated to carry out this section, $25,000,000 for each of fiscal years [2018 through 2022] *2023 through 2027*.

(2) AVAILABILITY.—Any amount appropriated under paragraph (1) shall remain available to carry out this section until expended.

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PEDIATRIC MEDICAL DEVICE SAFETY AND IMPROVEMENT ACT OF 2007

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TITLE III—PEDIATRIC MEDICAL DEVICE SAFETY AND IMPROVEMENT ACT OF 2007

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SEC. 305. DEMONSTRATION GRANTS FOR IMPROVING PEDIATRIC DEVICE AVAILABILITY.

(a) IN GENERAL.—

(1) REQUEST FOR PROPOSALS.—Not later than 90 days after the date of the enactment of this Act, the Secretary of Health and Human Services shall issue a request for proposals for 1 or more grants or contracts to nonprofit consortia for demonstration projects to promote pediatric device development.

(2) DETERMINATION ON GRANTS OR CONTRACTS.—Not later than 180 days after the date the Secretary of Health and Human Services issues a request for proposals under paragraph (1), the Secretary shall make a determination on the grants or contracts under this section.

(b) APPLICATION.—A nonprofit consortium that desires to receive a grant or contract under this section shall submit an application to the Secretary of Health and Human Services at such time, in such manner, and containing such information as the Secretary may require.

(c) USE OF FUNDS.—A nonprofit consortium that receives a grant or contract under this section shall facilitate the development, production, and distribution of pediatric medical devices by—

(1) encouraging innovation and connecting qualified individuals with pediatric device ideas with potential manufacturers;

(2) mentoring and managing pediatric device projects through the development process, including product identification, prototype design, device development, and marketing;

(3) connecting innovators and physicians to existing Federal and non-Federal resources, including resources from the Food and Drug Administration, the National Institutes of Health, the Small Business Administration, the Department of Energy, the Department of Education, the National Science Foundation, the Department of Veterans Affairs, the Agency for Healthcare Research and Quality, and the National Institute of Standards and Technology;

(4) assessing the scientific and medical merit of proposed pediatric device projects;

(5) providing assistance and advice as needed on business development, personnel training, prototype development, postmarket needs, and other activities consistent with the purposes of this section; and

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

(d) COORDINATION.—

(1) NATIONAL INSTITUTES OF HEALTH.—Each consortium that receives a grant or contract under this section shall—

(A) coordinate with the National Institutes of Health's pediatric device contact point or office, designated under section 402(b)(23) of the Public Health Service Act, as added by section 304(a) of this Act; and

(B) provide to the National Institutes of Health any identified pediatric device needs that the consortium lacks sufficient capacity to address or those needs in which the consortium has been unable to stimulate manufacturer interest.

(2) FOOD AND DRUG ADMINISTRATION.—Each consortium that receives a grant or contract under this section shall coordinate with the Commissioner of Food and Drugs and device companies to facilitate the application for approval or clearance of devices labeled for pediatric use.

(3) EFFECTIVENESS AND OUTCOMES.—Each consortium that receives a grant or contract under this section shall annually report to the Secretary of Health and Human Services on the status of pediatric device development, production, and distribution that has been facilitated by the consortium.

(e) AUTHORIZATION OF APPROPRIATIONS.—There are authorized to be appropriated to carry out this section $5,250,000 for each of fiscal years ⟦2018 through 2022⟧ *2023 through 2027*.

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ORPHAN DRUG ACT

GRANTS AND CONTRACTS FOR DEVELOPMENT OF DRUGS FOR RARE DISEASES AND CONDITIONS

SEC. 5. (a) The Secretary may make grants to and enter into contracts with public and private entities and individuals to assist in (1) defraying the costs of developing drugs for rare diseases or conditions, including qualified testing expenses, (2) defraying the costs of developing medical devices for rare diseases or conditions, ⟦and (3)⟧ *(3)* defraying the costs of developing medical foods for rare diseases or conditions*, and (4) developing regulatory science pertaining to the chemistry, manufacturing, and controls of individualized medical products to treat individuals with rare diseases or conditions*.

(b) For purposes of subsection (a):

(1) The term "qualified testing" means—

(A) human clinical testing—

(i) which is carried out under an exemption for a drug for a rare disease or condition under section 505(i) of the Federal Food, Drug, and Cosmetic Act (or regulations issued under such section); and

(ii) which occurs before the date on which an application with respect to such drug is submitted under section 505(b) of such Act or under section 351 of the Public Health Service Act;

(B) preclinical testing involving a drug for a rare disease or condition which occurs after the date such drug is designated under section 526 of such Act and before the date on which an application with respect to such drug is submitted under section 505(b) of such Act or under section 351 of the Public Health Service Act; and

(C) prospectively planned and designed observational studies and other analyses conducted to assist in the understanding of the natural history of a rare disease or condition and in the development of a therapy, including studies and analyses to—

(i) develop or validate a drug development tool related to a rare disease or condition; or

(ii) understand the full spectrum of the disease manifestations, including describing genotypic and phenotypic variability and identifying and defining distinct subpopulations affected by a rare disease or condition.

(2) The term "rare disease or condition" means (1) in the case of a drug, any disease or condition which (A) affects less than 200,000 persons in the United States, or (B) affects more than 200,000 in the United States and for which there is no reasonable expectation that the cost of developing and making available in the United States a drug for such disease or condition will be recovered from sales in the United States of such drugs, (2) in the case of a medical device, any disease or condition that occurs so infrequently in the United States that there is no reasonable expectation that a medical device for such disease or condition will be developed without assistance under subsection (a), and (3) in the case of a medical food, any disease or condition that occurs so infrequently in the United States that there is no reasonable expectation that a medical food for such disease or condition will be developed without assistance under subsection (a). Determinations under the preceding sentence with respect to any drug shall be made on the basis of the facts and circumstances as of the date the request for designation of the drug under section 526 of the Federal Food, Drug, and Cosmetic Act is made.

(3) The term "medical food" means a food which is formulated to be consumed or administered enterally under the supervision of a physician and which is intended for the specific dietary management of a disease or condition for which distinctive nutritional requirements, based on recognized scientific principles, are established by medical evaluation.

(c) AUTHORIZATION OF APPROPRIATIONS.—For grants and contracts under subsection (a), there is authorized to be appropriated $30,000,000 for each of fiscal years **[**2018 through 2022**]** *2023 through 2027*.

21ST CENTURY CURES ACT

SECTION 1. SHORT TITLE; TABLE OF CONTENTS.

(a) SHORT TITLE.—This Act may be cited as the "21st Century Cures Act".

(b) TABLE OF CONTENTS.—The table of contents for this Act is as follows:

DIVISION A—21ST CENTURY CURES

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TITLE III—DEVELOPMENT

Subtitle A—Patient-Focused Drug Development

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[SEC. 3003. STREAMLINING PATIENT INPUT.

[Chapter 35 of title 44, United States Code, shall not apply to the collection of information to which a response is voluntary, that is initiated by the Secretary under section 569C of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360bbb-8c) (as amended by section 3001) or section 3002.]

SEC. 3003. STREAMLINING PATIENT AND BLOOD DONOR INPUT.

Chapter 35 of title 44, United States Code, shall not apply to the collection of information to which a response is voluntary, to solicit—

(1) the views and perspectives of patients under section 569C of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360bbb–8c) (as amended by section 3001) or section 3002; or

(2) information from blood donors or potential blood donors to support the development of recommendations by the Secretary of Health and Human Services acting through the Commissioner of Food and Drugs concerning blood donation.

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