II

117TH CONGRESS
2D SESSION

S. 4535

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

IN THE SENATE OF THE UNITED STATES

JULY 14, 2022

Mr. BURR introduced the following bill; which was read twice and referred to the Committee on Health, Education, Labor, and Pensions

---

A BILL

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

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

SECTION 1. SHORT TITLE; TABLE OF CONTENTS.

(a) SHORT TITLE.—This Act may be cited as the ''Food and Drug Administration Simple Reauthorization Act of 2022'' or the ''FDASRA Act of 2022''.

(b) TABLE OF CONTENTS.—The table of contents for this Act is as follows:

TITLE I—FEES RELATING TO DRUGS

SEC. 101. SHORT TITLE; FINDING.

(a) SHORT TITLE.—This title may be cited as the ''Prescription Drug User Fee Amendments of 2022''.

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

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

(1) in paragraph (1), in the matter following subparagraph (B), by striking ''an allergenic extract product, or'' and inserting ''does not include an application with respect to an allergenic extract prod-

uct 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'';

(2) in paragraph (3), in the matter following subparagraph (C)—

(A) by inserting ''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,'' after ''an allergenic extract product''; and

(B) by adding at the end the following: ''If a written request to place a product in the discontinued section of either of the lists described in subparagraph (C) is submitted to the Secretary on behalf of an applicant, and the request identifies the date the product is, or will

be, 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. For purposes of subparagraph (C), 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.''; and

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

(1) in the matter preceding paragraph (1), by striking "2018" and inserting "2023";

(2) in paragraph (1)—

(A) in subparagraph (A), by striking ''subsection (c)(5)'' each place it appears and inserting ''subsection (c)(6)'';

(B) in subparagraph (C), by inserting ''prior to approval'' after ''or was withdrawn''; and

(C) 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).''; and

(3) in paragraph (2)—

(A) in subparagraph (A)—

(i) by striking ''subsection (c)(5)'' and inserting ''subsection (c)(6)'';

(ii) by striking ''Except as provided'' and inserting the following:

''(i) PAYMENT OF FEES.—Except as provided''; and

(iii) by adding at the end the following:

''(ii) PREVIOUSLY DISCONTINUED DRUG PRODUCTS.—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 identified in section 735(3), 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, 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 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 pre-

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

(1) in paragraph (1)—

(A) in the matter preceding subparagraph (A), by striking "2018 through 2022" and inserting "2023 through 2027";

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

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

''(C) The dollar amount equal to the strategic hiring and retention adjustment for the fiscal year (as determined under subsection (c)(2));'';

(D) in subparagraph (D), as so redesignated, by striking ''(c)(2)'' and inserting ''(c)(3)'';

(E) in subparagraph (E), as so redesignated, by striking ''(c)(3)'' and inserting ''(c)(4)'';

(F) in subparagraph (F), as so redesignated, by striking ''(c)(4)'' and inserting ''(c)(5)''; and

(G) in subparagraph (G), as so redesignated, by striking clauses (i) through (v) and inserting the following:

''(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."; and

(2) in paragraph (3)—

(A) in subparagraph (A), by striking "2018, $878,590,000" and inserting "2023, $1,151,522,958"; and

(B) in subparagraph (B)—

(i) by striking "2019 through 2022" and inserting "2024 through 2027"; and

(ii) by striking "subsection (c)(3) or (c)(4)" and inserting "subsection (c)(4) or (c)(5)".

(c) ADJUSTMENTS; ANNUAL FEE SETTING.—Section 736(c) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 379h(c)) is amended—

(1) in paragraph (1)(B)(ii), by striking "Washington-Baltimore, DC–MD–VA–WV" and inserting "Washington–Arlington–Alexandria, DC–VA–MD–WV";

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

(3) 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—

''(A) for fiscal year 2023, by $9,000,000; and

''(B) for fiscal year 2024 and each subsequent fiscal year, by $4,000,000.'';

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

(A) in subparagraph (A)—

(i) by striking ''for inflation''; and

(ii) by striking ''paragraph (1)'' and inserting ''paragraphs (1) and (2)'';

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

''(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' (85 Fed. Reg. 46651; August 3, 2020). The workload categories used in forecasting shall include only

the activities described in such notice and, as feasible, additional activities that are 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 forecasting any non-core review activities, including any activities that the Secretary referenced for potential future use in such notice but did not utilize in the setting fees for fiscal year 2021.'';

(C) by striking subparagraph (C);

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

(E) in subparagraph (C), as so redesignated—

(i) by striking ''year) and'' and inserting ''year),''; and

(ii) by striking the period and inserting ", and subsection (b)(1)(C) (the dollar amount of the strategic hiring and retention adjustment)."; and

(F) in subparagraph (D), as so redesignated, by striking "paragraph (5)" and inserting "paragraph (6)";

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

(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 at least the following amounts of operating reserves of carryover user fees for the process for the review of human drug applications for each fiscal year, as follows:

"(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)'';

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

''(5) ADDITIONAL DIRECT COST ADJUSTMENT.—The Secretary shall, in addition to adjustments under paragraphs (1), (2), (3), and (4), further increase the fee revenue and fees—

''(A) for fiscal year 2023, by $44,386,150; and

''(B) for fiscal years 2024 through 2027, by the amount set forth in clauses (i) through (iv), 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—

''(i) for fiscal year 2024, $60,967,993;

''(ii) for fiscal year 2025, $35,799,314;

"(iii) for fiscal year 2026, $35,799,314; and

"(iv) for fiscal year 2027, $35,799,314."; and

(7) in paragraph (6), as so redesignated, by striking "2017" and inserting "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 "2018 through 2022" and inserting "2023 through 2027".

(e) WRITTEN REQUESTS FOR WAIVERS, REDUCTIONS, AND REFUNDS.—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 submit to the Secretary a written request justifying such waiver, reduction, exemption, or return 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.".

(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) in paragraph (2), by striking ''that its gross annual revenues'' and all that follows through the period at the end and inserting ''supported by tax returns submitted to the Internal Revenue Service, or, as necessary, by other appropriate financial information, that its 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.''.

SEC. 104. REAUTHORIZATION; REPORTING REQUIREMENT.

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

(1) by striking ''2018'' each place it appears and inserting ''2023'';

(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)(4), by striking ''2020'' and inserting ''2023''; and

(4) in subsection (f), by striking ''2022'' each place it appears and inserting ''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 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 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.—Congress finds that the fees authorized under the amendments made by this title will be dedicated toward expediting the process for the review of device applications and for assuring the safety and effectiveness of devices, as set forth in the goals identified for purposes of part 3 of subchapter C of chapter VII of the Federal Food, Drug, and Cosmetic Act in the letters from the Secretary of Health and Human Services to the Chairman of the Committee on Health, Education, Labor, and Pen-

sions 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 de novo classification requests'';

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

(D) in subparagraphs (G) and (H), by striking ''or submissions'' each place it appears and inserting ''submissions, or requests''; and

(E) in subparagraph (K), by striking ''or premarket notification submissions'' and insert-

ing ''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 ''2018'' and inserting ''2023''; and

(2) in paragraph (2)—

(A) in subparagraph (A)—

(i) in the matter preceding clause (i), by striking ''2017'' and inserting ''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 the table in paragraph (2) to read 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) in paragraph (3), by amending subparagraphs (A) through (E) to read 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) by striking ''2018'' each place it appears and inserting ''2023'';

(B) in subparagraph (B)(ii), by striking ''2016'' and inserting ''2022'';

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

(D) in subparagraph (D), by striking ''2022'' and inserting ''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 adjustment under paragraph (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, as applicable:

''(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) PRESUBMISSION AMOUNT.—For purposes of subparagraph (A), with respect to the presubmission written feedback goal, the amounts determined under this subparagraph are as follows:

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

"(II) For fiscal year 2026—

"(aa) $15,396,600 if the goal for fiscal year 2023 is met

and the goal for fiscal year 2024 is missed; or

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

"(III) For fiscal year 2027—

"(aa) $15,396,600 if the goal for fiscal year 2023 is met and the goal for each of fiscal years 2024 and 2025 is missed;

"(bb) $36,792,200 if the goal for fiscal year 2024 is met and the goal for fiscal year 2025 is missed; or

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

"(ii) DE NOVO CLASSIFICATION REQUEST 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 the goal for fiscal year 2023 is met.

"(II) For fiscal year 2027—

"(aa) $6,323,500 if the goal for fiscal year 2023 is met and the goal for fiscal year 2024 is missed; or

"(bb) $11,765,400 if the 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 4 goals for fiscal year 2023 are met.

"(II) For fiscal year 2027—

"(aa) $1,020,000 if the 4 goals for fiscal year 2023 are met and one or more of the 4 goals for fiscal year 2024 is missed; or

"(bb) $3,906,000 if the 4 goals for fiscal year 2024 are met.

"(C) PERFORMANCE CALCULATION.—For purposes of this paragraph, performance of the following goals 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 applicable dates as follows:

"(i) The performance of the pre-submission written feedback goal—

"(I) for fiscal year 2023, shall be based on data available as of March 31, 2024;

"(II) for fiscal year 2024, shall be based on data available as of March 31, 2025; and

"(III) for fiscal year 2025, shall be based on data available as of 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—

"(I) for fiscal year 2023, shall be based on data available as of March 31, 2025; and

"(II) for fiscal year 2024, shall be based on data available as of March 31, 2026.

"(D) DEFINITIONS.—For purposes of this paragraph, the terms 'presubmission 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' have the meanings given such terms in the goals identified 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 (3) and (4), if applicable, 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 (B), if the number of hires to support the process for the review of device applications falls below the following thresholds for the applicable fiscal years:

"(i) For fiscal year 2025, 85 percent of the hiring goal specified in subparagraph (C) for fiscal year 2023.

"(ii) For fiscal year 2026, 90 percent of the hiring goal specified in subparagraph (C) for fiscal year 2024.

"(iii) For fiscal year 2027, 90 percent of the hiring goal specified in subparagraph (C) for fiscal year 2025.

"(B) 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 (C) for the fiscal year before the prior fiscal year was missed;

"(ii) $72,877; and

"(iii) the applicable inflation adjustment under paragraph (2)(B) for the fiscal year for which the hiring goal was missed.

"(C) HIRING GOALS.—

"(i) IN GENERAL.—For purposes of subparagraph (B), 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—

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

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

"(ii) NUMBER OF HIRES.—For purposes of this paragraph, the number of

hires for a fiscal year 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 (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) the 1 month of operating reserves described in 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) 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,''.

(e) AUTHORIZATION OF APPROPRIATIONS.—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 the fiscal years 2023 through 2027, there is authorized to be appropriated for fees under this section an amount equal to the revenue amount determined in subparagraph (B), less the amount of reductions determined in 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 subsection (c)(2); and

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

''(C) AMOUNT OF 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 REQUIREMENT.

(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) (relating to rationale for MDUFA program changes), 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. ACCREDITATION PROGRAMS.

(a) ACCREDITATION SCHEME FOR CONFORMITY ASSESSMENT.—Section 514(d) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360d(d)) is amended—

(1) in the subsection heading, by striking ''PILOT'';

(2) in paragraph (1)—

(A) in the matter preceding subparagraph (A), by striking ''pilot'';

(B) in subparagraph (A)—

(i) by inserting ''meeting criteria specified by the Secretary in guidance'' after ''testing laboratories'';

(ii) by inserting ''in guidance'' after ''by the Secretary''; and

(iii) by striking ''assess the conformance of a device with'' and inserting ''conduct testing to support the assessment of the conformance of a device to''; and

(C) in subparagraph (B)—

(i) by striking ''determinations'' and inserting ''results'';

(ii) by inserting ''to support'' after ''so accredited''; and

(iii) by striking ''a particular such determination'' and inserting ''particular such results'';

(3) in paragraph (2)—

(A) in the paragraph heading, by striking ''DETERMINATIONS'' and inserting ''RESULTS'';

(B) in subparagraph (A)—

(i) by striking ''determinations by testing laboratories'' and all that follows through ''such determinations or'' and inserting ''results by testing laboratories accredited pursuant to this subsection, including by conducting periodic audits of such results or of the'';

(ii) by inserting a comma after ''or testing laboratories'';

(iii) by inserting ''or recognition of an accreditation body'' after ''accreditation of such testing laboratory''; and

(iv) by striking ''such device'' and inserting ''a device''; and

(C) in subparagraph (B)—

(i) by striking ''by a testing laboratory so accredited'' and inserting ''under this subsection''; and

(ii) by inserting ''or recognition of an accreditation body'' before ''under paragraph (1)(A)'';

(4) in paragraph (3)(C)—

(A) in the subparagraph heading, by inserting ''AND TRANSITION'' after ''INITIATION''; and

(B) by adding at the end the following: ''After September 30, 2023, such pilot program will be considered to be completed, and the Secretary shall have the authority to continue operating a program consistent with this subsection.''; and

(5) by striking paragraph (4).

(b) ACCREDITED PERSONS.—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. 206. SUNSET DATES.

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

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

(c) PREVIOUS SUNSET PROVISION.—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. 207. 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. 208. SAVINGS CLAUSE.

Notwithstanding the amendments made by this title, part 3 of subchapter C of chapter VII of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 379i et seq.), as in effect on the day before the date of the enactment of this title, shall continue to be in effect with respect to the submissions listed in section 738(a)(2)(A) of such Act (as defined in such part as of such day) that on or after October 1, 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 in this title will be dedicated to human generic drug activities, as set forth in the goals identified for purposes of part 7 of subchapter C of chapter VII of the Federal Food, Drug, and Cosmetic Act, in the letters from the Secretary of Health and Human Services to the Chairman of the Committee on Health, Education, Labor, and Pensions of the Senate and the Chairman of the Committee on Energy and Commerce of the House of Representatives, as set forth in the Congressional Record.

SEC. 302. 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 ''2018'' and inserting ''2023'';

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

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

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

(5) in paragraph (5)(D), by striking ''fiscal years 2018 through 2022'' and inserting ''fiscal years 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) in subparagraph (B)—

(i) in the heading, by striking ''2019 THROUGH 2022'' and inserting ''2024 THROUGH 2027'';

(ii) by striking ''For each'' and inserting the following:

''(i) IN GENERAL.—For each'';

(iii) by striking ''2019 through 2022'' and inserting ''2024 through 2027'';

(iv) by striking ''$493,600,000'' and inserting ''the base revenue amount under clause (ii)''; and

(v) by adding at the end the following:

''(ii) BASE REVENUE AMOUNT.—The base revenue amount for a fiscal year is 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 ''24 percent'';

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

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

(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 ''the product of the total revenues established in such notice for the prior fiscal year'' and inserting ''the base revenue amount for the fiscal year determined under subsection (b)(1)(B)(ii)''; 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' as announced in the Federal Register on August 3, 2020 (85 Fed. Reg. 46658); and

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

"(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) ADDITIONAL LIMITATION.—An adjustment under this paragraph shall not exceed 3 percent of the sum described in clause (i) for the fiscal year, except that such limitation shall be 4 percent if—

''(I) for purposes of an adjustment for fiscal year 2024, 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 let-

ters described in section 301(b) of the Generic Drug User Fee Amendments of 2022);

"(II) for purposes of an adjustment for fiscal year 2025, 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 an adjustment for fiscal year 2026, 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 an adjustment for fiscal year 2027, 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 under 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 subsequent fiscal years, the Secretary may, in addition to adjustments under paragraphs (1) and (2), further increase the fee revenue and fees under this section 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).

''(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 heading, by striking ''2018 THROUGH 2022'' and inserting ''2023 THROUGH 2027'';

(2) by striking ''more'' and inserting ''later''; and

(3) by striking ''2018 through 2022'' and inserting ''2023 through 2027''.

(e) 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''.

(f) 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 ''2018 through 2022'' and inserting ''2023 through 2027''.

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)—

(A) by striking ''2018'' each place it appears and inserting ''2023''; and

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

(2) in subsection (b), by striking ''2018'' and inserting ''2023'';

(3) in subsection (c)—

(A) by striking ''2018'' and inserting ''2023''; and

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

(4) in subsection (f)—

(A) in paragraph (1), by striking ''2022'' and inserting ''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, 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.—Congress finds that the fees authorized by the amendments made in this title will be dedicated to expediting the process for the review of biosimilar biological product applications, including postmarket safety activities, as set forth in the goals identified for purposes of part 8 of subchapter C of chapter VII of the Federal Food, Drug, and Cosmetic Act (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.

Section 744G of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 379j–51) is amended—

(1) in paragraph (1)—

(A) by striking ''Washington-Baltimore, DC–MD–VA–WV'' and inserting ''Washington–Arlington–Alexandria, DC–VA–MD–WV'';

(B) by striking ''October of'' and inserting ''September of''; and

(C) by striking ''October 2011'' and inserting ''September 2011''; and

(2) in paragraph (4)(B)(iii)—

(A) by striking subclause (II); and

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

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

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

(1) in the matter preceding paragraph (1), by striking ''2018'' and inserting ''2023'';

(2) in paragraph (1)—

(A) in subparagraph (A)—

(i) in clause (iv)(I), by striking ''5 days'' and inserting ''7 days''; and

(ii) in clause (v)(II), by striking ''5 days'' and inserting ''7 days'';

(B) in subparagraph (B)—

(i) in clause (i), by inserting '', except that, in the case that 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, such licensee, assignee or successor shall pay the annual biosimilar biological product development fee'' before the period;

(ii) in clause (iii)—

(I) in subclause (I), by striking ''; or'' and inserting a semicolon;

(II) in subclause (II), by striking the period 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

(iii) in clause (iv), by striking ''accepted for filing on or after October 1 of such fiscal year'' and inserting ''subsequently accepted for filing'';

(C) in subparagraph (D)—

(i) in clause (i)—

(I) in the matter preceding subclause (I), by striking ''shall, if the person seeks to resume participation in such program, pay'' and inserting ''or who has been administratively removed from such 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'';

(II) in subclause (I)—

(aa) by striking ''5 days'' and inserting ''7 days''; and

(bb) by inserting ''or the date of administrative removal, as applicable'' after ''discontinued''; and

(III) in subclause (II), by inserting ''or the date of administrative removal, as applicable'' after ''discontinued''; and

(ii) in clause (ii), by inserting '', except that, in the case that 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, such licensee, assignee or successor shall pay the annual biosimilar biological product development fee'' before the period at the end; and

(D) in subparagraph (E), 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 2 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.'';

(3) in paragraph (2)(D), by inserting ''prior to approval'' after ''withdrawn'';

(4) in paragraph (3)—

(A) in subparagraph (A)—

(i) in clause (i), by striking ''; and'' and inserting a semicolon;

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

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

''(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) WRITTEN REQUEST TO PLACE ON DISCONTINUED LIST.—

''(I) IN GENERAL.—If a written request to place a product on the list of discontinued biosimilar biological products referred to in subparagraph (A)(iii) is submitted to the Secretary on behalf of an applicant, and the request identifies the date the product is, or will be, 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—

''(aa) the date such request was received; or

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

"(II) WITHDRAWN FROM SALE DEFINED.—For purposes of this clause, 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.

"(ii) PRODUCTS REMOVED FROM DISCONTINUED LIST.—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 of discontinued biosimilar biological products referred to in subparagraph (A)(iii), and on any subsequent day during such fiscal year the biosimilar bio-

logical product does not appear on such list, except as provided in subparagraph (D), each person who is named as the applicant in the biosimilar biological product application 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 product for each fiscal year.''; and

(5) by striking paragraph (4).

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

(1) by striking paragraph (1);

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

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

(A) in the paragraph heading, by striking ''SUBSEQUENT FISCAL YEARS'' and inserting ''IN GENERAL'';

(B) in the matter preceding subparagraph (A), by striking ''2019 through 2022'' and inserting ''2023 through 2027'';

(C) in subparagraph (A), by striking ''paragraph (4)'' and inserting ''paragraph (3)'';

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

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

''(C) the dollar amount equal to the strategic hiring and retention adjustment (as determined under subsection (c)(2));'';

(F) in subparagraph (D), as so redesignated, by striking ''subsection (c)(2)); and'' and inserting ''subsection (c)(3));'';

(G) in subparagraph (E), as so redesignated, by striking ''subsection (c)(3)).'' and inserting ''subsection (c)(4)); and''; and

(H) by adding at the end the following:

''(F) for fiscal years 2023 and 2024, additional dollar amounts equal to—

''(i) $4,428,886 for fiscal year 2023; and

''(ii) $320,569 for fiscal year 2024.'';

(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 subaparagraphs (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).''.

(c) 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 paragraph (4);

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

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

''(2) STRATEGIC HIRING AND RETENTION ADJUSTMENT.—For each fiscal year beginning in fiscal year 2023, 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.'';

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

(A) in subparagraph (A)—

(i) by striking ''Beginning with the fiscal year described in subparagraph

(B)(ii)(II)'' and inserting ''For each fiscal year''; and

(ii) by striking ''adjustment under paragraph (1), further increase'' and inserting ''adjustments under paragraphs (1) and (2), further adjust'';

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

''(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' (85 Fed. Reg. 47220; August 4, 2020). The workload categories used in forecasting shall include only the activities described in such 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 and 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 forecasting any non-core review activities, including any activities that the Secretary referenced for potential future use in such notice but did not utilize in setting fees for fiscal year 2021.''; and

(C) in subparagraph (C)—

(i) by striking ''subsections (b)(2)(A)'' and inserting ''subsections (b)(1)(A)'';

(ii) by striking ''and (b)(2)(B)'' and inserting '', (b)(1)(B)''; and

(iii) by inserting '', and (b)(1)(C) (the dollar amount of the strategic hiring and retention adjustment)'' before the period at the end;

(6) by amending paragraph (4), as so redesignated, to read as follows:

''(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 re-

serves 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 the process for the review of biosimilar biological product applications 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 the process for the review of biosimilar biological product applications 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 the process for the review of biosimilar biological product applications 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 (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.''; and

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

(d) CREDITING AND AVAILABILITY OF FEES.—Section 744H(f)(3) 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''.

(e) WRITTEN REQUESTS FOR WAIVERS AND REFUNDS.—Subsection (h) of section 744H of the Federal

Food, Drug, and Cosmetic Act (21 U.S.C. 379j–52) 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 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) by striking ''2018'' each place it appears and inserting ''2023'';

(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)(4), by striking ''2020'' and inserting ''2023''; and

(4) in subsection (f), by striking ''2022'' each place it appears and inserting ''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 (21 U.S.C. 379j–53) 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—OTHER REAUTHORIZATIONS

SEC. 501. REAUTHORIZATION OF THE CRITICAL PATH PUBLIC-PRIVATE PARTNERSHIP.

Section 566(f) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360bbb–5(f)) is amended by striking ''2018 through 2022'' and inserting ''2023 through 2027''.

SEC. 502. REAUTHORIZATION OF THE BEST PHARMACEUTICALS FOR CHILDREN PROGRAM.

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. 503. REAUTHORIZATION OF THE HUMANITARIAN DEVICE EXEMPTION INCENTIVE.

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''.

SEC. 504. REAUTHORIZATION OF THE PEDIATRIC DEVICE CONSORTIA PROGRAM.

Section 305(e) of the Food and Drug Administration Amendments Act of 2007 (Public Law 110–85; 42 U.S.C. 282 note) is amended by striking ''$5,250,000 for each of fiscal years 2018 through 2022'' and inserting ''$7,000,000 for each of fiscal years 2023 through 2027''.

SEC. 505. REAUTHORIZATION OF PROVISION PERTAINING TO 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 ''October 1, 2022'' and inserting ''October 1, 2027''.

SEC. 506. REAUTHORIZATION OF ORPHAN DRUG GRANTS.

Section 5(c) of the Orphan Drug Act (21 U.S.C. 360ee(c)) is amended by striking ''2018 through 2022'' and inserting ''2023 through 2027''.

SEC. 507. REAUTHORIZATION OF CERTAIN DEVICE INSPECTIONS.

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''.

○