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

SEC. 402. DEFINITIONS.

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

''(1) The term 'adjustment factor' applicable to a fiscal year is the Consumer Price Index for urban consumers (Washington-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)(A)(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 prod-

uct. 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, [$_____]; 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).''.

(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)(iii), 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) OPERATING RESERVE ADJUSTMENT.—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 Sec-

retary 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.''; 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 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 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, 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.