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

SEC. 102. DEFINITIONS.

(a) 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'' and inserting the following:

''(B) Such term does not include'';

(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(A)(iii) is submitted to the Secretary on behalf of an applicant, and the request identifies the date the product is withdrawn from sale, then for purposes of assessing the prescription drug program fee under section 736(a)(2), the Secretary shall consider such product to have been in-

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''(II) if the product will be withdrawn from sale on a future date, such future date when the product is withdrawn from sale.

''(ii) For purposes of this subparagraph, a product shall be considered withdrawn from sale once the applicant has ceased its own distribution of the product, whether or not the applicant has ordered recall of all previously distributed lots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.''.

(b) 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) IN GENERAL.—The matter preceding paragraph (1) in section 736(a) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 379h(a)) is

amended by striking ''fiscal year 2018'' and inserting ''fiscal year 2023''.

(2) HUMAN DRUG APPLICATION FEE.—Section 736(a)(1) 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 after ''or was withdrawn'' the following: ''prior to approval'';

(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).''.

(3) 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) and in clause (ii) of this subparagraph'';

(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 reserve 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, [$_____]; 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 for inflation 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 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 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 justi-

fying 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) other appropriate financial information, as necessary.''.

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)(4), 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. 105. ANNUAL REPORT ON INSPECTIONS.

Section 902 of the FDA Reauthorization Act of 2017 (21 U.S.C. 355 note; Public Law 115–52) is amended, in the matter preceding paragraph (1)—

(1) by striking ''Not later than March 1 of each year'' and inserting ''Not later than 120 days after the end of each fiscal year''; and

(2) by striking ''previous calendar year'' and inserting ''previous fiscal year''.

SEC. 106. 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 105 of the FDA Reauthorization Act of 2017 (Public Law 115–52) are repealed.

SEC. 107. 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 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. 108. SAVINGS CLAUSE.

Notwithstanding the amendments made by this title, part 2 of subchapter C of chapter VII of the Federal Food, Drug, and Cosmetic Act, as in effect on the day before the date of the enactment of this title, shall continue to be in effect with respect to human drug applications and supplements (as defined in such part as of such day) that on or after October 1, 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.