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 ''fiscal year 2018'' and inserting ''fiscal year 2023'';

(2) in paragraph (1)(E), by striking ''October 1, 2022'' and inserting ''October 1, 2027'';

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

(4) in paragraph (3)—

(A) in subparagraph (B), by striking ''2018 through 2022'' and inserting ''2023 through 2027''; and

(B) in subparagraph (F), in the matter preceding clause (i), by striking ''2017'' and inserting ''2022'';

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

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

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

(1) in paragraph (1)—

(A) in subparagraph (A)—

(i) in the heading, by striking ''2018'' and inserting ''2023'';

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

(iii) by striking ''$493,600,000'' and inserting [''$582,500,000'']; and

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

''(B) FISCAL YEARS 2024 THROUGH 2027.—

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

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

(2) in paragraph (2)—

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

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

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

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

(1) in paragraph (1)—

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

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

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

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

(2) by striking paragraphs (2) and (3) and inserting the following:

''(2) CAPACITY PLANNING ADJUSTMENT.—

''(A) IN GENERAL.—Beginning with fiscal year 2024, the Secretary shall, in addition to the adjustment under paragraph (1), further increase the fee revenue and fees under this section for a fiscal year, in accordance with this paragraph, to reflect changes in the resource capacity needs of the Secretary for human generic drug activities.

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

''(i) be derived from the methodology and recommendations made in the report titled 'Independent Evaluation of the GDUFA Resource Capacity Planning Adjustment Methodology: Evaluation and

Recommendations' announced in the Federal Register on August 3, 2020;

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

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

''(C) LIMITATIONS.—

''(i) IN GENERAL.—Under no circumstances shall an adjustment under this paragraph result in fee revenue for a fiscal year that is less than the sum of the amounts under subsection (b)(1)(B)(ii) (the base revenue amount for the fiscal year) and paragraph (1) (the dollar amount of the inflation adjustment for the fiscal year).

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

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

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

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

"(II) for purposes of a fiscal year 2025 adjustment, the Secretary determines that during the period from

April 1, 2022, through March 31, 2024—

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

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

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

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

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

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

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

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

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

"(3) OPERATING RESERVE ADJUSTMENT.—

"(A) IN GENERAL.—For fiscal year 2024 and each subsequent fiscal year, the Secretary may, in addition to adjustments under paragraphs (1) and (2), further increase the fee revenue and fees under this section for such fiscal

year if such an adjustment is necessary to provide operating reserves of carryover user fees for human generic drug activities for not more than the number of weeks specified in subparagraph (B) with respect to that fiscal year.

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

''(i) 8 weeks for fiscal year 2024;

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

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

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

''(D) RATIONALE FOR ADJUSTMENT.—If an adjustment under this paragraph is made, the rationale for the amount of the increase or decrease (as applicable) in fee revenue and fees shall be contained in the annual Federal Register notice under subsection (a) publishing the

fee revenue and fees for the fiscal year involved.''.

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

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

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

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

SEC. 303. REAUTHORIZATION; REPORTING REQUIREMENTS.

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

(1) in subsection (a)(1), by striking ''Beginning with fiscal year 2018, not'' and inserting ''Not'';

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

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

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

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

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

(7) in subsection (f)—

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

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

SEC. 304. SUNSET DATES.

(a) AUTHORIZATION.—Sections 744A and 744B of the Federal Food, Drug, and Cosmetic Act (21 U.S.C.

379j–41; 379j–42) shall cease to be effective October 1, 2027.

(b) REPORTING REQUIREMENTS.—Section 744C of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 379j–43) shall cease to be effective January 31, 2028.

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

SEC. 305. EFFECTIVE DATE.

The amendments made by this title shall take effect on October 1, 2022, or the date of the enactment of this Act, whichever is later, except that fees under part 7 of subchapter C of chapter VII of the Federal Food, Drug, and Cosmetic Act 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.