TITLE II—FEES RELATING TO DEVICES

SEC. 201. SHORT TITLE; FINDING.

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

(b) FINDING.—The Congress finds that the fees authorized under the amendments made by this title will be dedicated toward expediting the process for the review of device applications and for assuring the safety and effectiveness of devices, as set forth in the goals identified for purposes of part 3 of subchapter C of chapter VII of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 379i et seq.) in the letters from the Secretary of Health and Human Services to the Chairman of the Committee on Health, Education, Labor, and Pensions of the Senate and the Chairman of the Committee on Energy and Commerce of the House of Representatives, as set forth in the Congressional Record.

SEC. 202. DEFINITIONS.

Section 737 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 379i) is amended—

(1) in paragraph (9)—

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

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

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

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

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

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

SEC. 203. AUTHORITY TO ASSESS AND USE DEVICE FEES.

(a) TYPES OF FEES.—Section 738(a) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 379j(a)) is amended—

(1) in paragraph (1), by striking ''fiscal year 2018'' and inserting ''fiscal year 2023''; and

(2) in paragraph (2)—

(A) in subparagraph (A)—

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

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

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

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

(C) in subparagraph (C), by striking ''or periodic reporting concerning a class III device'' and inserting ''periodic reporting concerning a class III device, or de novo classification request''.

(b) FEE AMOUNTS.—Section 738(b) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 379j(b)) is amended—

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

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

''(2) BASE FEE AMOUNTS SPECIFIED.—For purposes of paragraph (1), the base fee amounts specified in this paragraph are as follows:

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

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

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

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

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

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

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

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

(c) ANNUAL FEE SETTING; ADJUSTMENTS.—Section 738(c) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 379j(c)) is amended—

(1) in paragraph (1), by striking ''2017'' and inserting ''2022'';

(2) in paragraph (2)—

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

(B) by striking subparagraph (B)—

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

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

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

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

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

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

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

''(4) PERFORMANCE IMPROVEMENT ADJUSTMENT.—

''(A) IN GENERAL.—For each of fiscal years 2025 through 2027, after the 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) PRE-SUBMISSION AMOUNT.—For purposes of subparagraph (A), with respect to the pre-submission written feedback goal, the amounts determined under this subparagraph are as follows:

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

"(II) For fiscal year 2026:

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

and such goal for fiscal year 2024 is not met.

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

"(III) For fiscal year 2027:

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

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

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

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

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

"(II) For fiscal year 2027—

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

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

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

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

"(II) For fiscal year 2027:

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

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

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

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

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

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

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

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

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

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

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

"(5) HIRING ADJUSTMENT.—

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

tions equal to the hiring adjustment amount under subparagraph (C).

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

''(i) For fiscal year 2025, the applicable threshold is 85 percent of the hiring goal specified in subparagraph (D) for fiscal year 2023.

''(ii) For fiscal year 2026, the applicable threshold is 90 percent of the hiring goal specified in subparagraph (D) for fiscal year 2024.

''(iii) For fiscal year 2027, the applicable threshold is 90 percent of the hiring goal specified in subparagraph (D) for fiscal year 2025.

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

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

''(ii) $72,877; and

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

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

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

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

"(iii) For fiscal year 2025:

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

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

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

"(6) OPERATING RESERVE ADJUSTMENT.—

"(A) IN GENERAL.—For each of fiscal years 2023 through 2027, after the adjust-

ments 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) SMALL BUSINESSES.—Section 738 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 379j) is amend-

ed in each of subsections (d)(2)(B)(iii) and (e)(2)(B)(iii) by inserting ", if extant," after "national taxing authority".

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

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

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

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

"(3) AUTHORIZATION OF APPROPRIATIONS.—

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

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

''(i) the total revenue amount under subsection (b)(3) for the fiscal year, as adjusted under paragraphs (1), (2), and (3) of subsection (c); and

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

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

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

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

SEC. 204. REAUTHORIZATION; REPORTING REQUIREMENTS.

(a) PERFORMANCE REPORTS.—Section 738A(a) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 379j–1(a)) is amended—

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

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

(b) REAUTHORIZATION.—Section 738A(b) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 379j–1(b)) is amended—

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

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

[SEC. 205. CONFORMITY ASSESSMENT PILOT PROGRAM.

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

[''(d) ACCREDITATION SCHEME FOR CONFORMITY ASSESSMENT.—]

[''(1) IN GENERAL.—The Secretary shall establish a program under which—]

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

[''(B) subject to paragraph (2), results from tests conducted by testing laboratories accredited to support the assessment of con-

formity of devices as described in subparagraph (A) shall be accepted by the Secretary for purposes of demonstrating such conformity unless the Secretary finds that certain results of such tests should not be so accepted.**]**

[''(2) SECRETARIAL REVIEW OF ACCREDITED LABORATORY RESULTS.—The Secretary may—**]**

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

[''(B) following such review, take additional measures under this Act, as the Secretary determines appropriate, such as—**]**

[''(i) suspension or withdrawal of accreditation of a testing laboratory or recognition of an accreditation body under paragraph (1)(A); or**]**

[''(ii) requesting additional information with respect to a device; and**]**

[''(C) if the Secretary becomes aware of information materially bearing on the safety or effectiveness of a device assessed for conformity by a testing laboratory accredited under this

subsection, take such additional measures under this Act, as the Secretary determines appropriate, such as—]

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

[“(ii) requesting additional information with regard to such device.]

[“(3) IMPLEMENTATION AND REPORTING.—]

[“(A) PUBLIC MEETING.—The Secretary shall publish in the Federal Register a notice of a public meeting to be held no later than September 30, 2018, to discuss and obtain input and recommendations from stakeholders regarding the goals and scope of, and a suitable framework and procedures and requirements for, the pilot program under this subsection.]

[“(B) PILOT PROGRAM GUIDANCE.—The Secretary shall—]

[“(i) not later than September 30, 2019, issue draft guidance regarding the goals and implementation of the pilot program under this subsection; and]

[''(ii) not later than September 30, 2021, issue final guidance with respect to the implementation of such program.]

[''(C) PILOT PROGRAM INITIATION AND TRANSITION.—Not later than September 30, 2020, the Secretary shall initiate the pilot program under this subsection. After September 30, 2023, such pilot program will be considered to be completed, and the Secretary may continue operating a program consistent with this subsection.]

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

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

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

SEC. 207. 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 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.

SEC. 208. EFFECTIVE DATE.

The amendments made by this title shall take effect on October 1, 2022, or the date of the enactment of this Act, whichever is later, except that fees under part 3 of subchapter C of chapter VII of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 379i et seq.) shall be assessed for all submissions listed in section 738(a)(2)(A) of such Act received on or after October 1, 2022, regardless of the date of the enactment of this Act.

SEC. 209. SUNSET DATES.

(a) AUTHORIZATION.—Sections 737 and 738 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 739i; 739j) shall cease to be effective October 1, 2027.

(b) REPORTING REQUIREMENTS.—Section 738A (21 U.S.C. 739j– 1) of the Federal Food, Drug, and Cosmetic Act (regarding reauthorization and reporting requirements) shall cease to be effective January 31, 2028.

(c) PREVIOUS SUNSET PROVISIONS.—Effective October 1, 2022, subsections (a) and (b) of section 210 of the Medical Device User Fee Amendments of 2017 (Public Law 115–52) are repealed.