

1 **TITLE II—FEES RELATING TO**
2 **DEVICES**

3 **SEC. 201. SHORT TITLE; FINDING.**

4 (a) **SHORT TITLE.**—This title may be cited as the
5 “Medical Device User Fee Amendments of 2022”.

6 (b) **FINDING.**—The Congress finds that the fees au-
7 thorized under the amendments made by this title will be
8 dedicated toward expediting the process for the review of
9 device applications and for assuring the safety and effec-
10 tiveness of devices, as set forth in the goals identified for
11 purposes of part 3 of subchapter C of chapter VII of the
12 Federal Food, Drug, and Cosmetic Act (21 U.S.C. 379i
13 et seq.) in the letters from the Secretary of Health and
14 Human Services to the Chairman of the Committee on
15 Health, Education, Labor, and Pensions of the Senate and
16 the Chairman of the Committee on Energy and Commerce
17 of the House of Representatives, as set forth in the Con-
18 gressional Record.

19 **SEC. 202. DEFINITIONS.**

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

22 (1) in paragraph (9)—

1 (A) in the matter preceding subparagraph
2 (A), by striking “and premarket notification
3 submissions” and inserting “premarket notifica-
4 tion submissions, and de novo classification re-
5 quests”;

6 (B) in subparagraph (D), by striking “and
7 submissions” and inserting “submissions, and
8 requests”;

9 (C) in subparagraph (F), by striking “and
10 premarket notification submissions” and insert-
11 ing “premarket notification submissions, and de
12 novo classification requests”;

13 (D) in each of subparagraphs (G) and (H),
14 by striking “or submissions” and inserting
15 “submissions, or requests”; and

16 (E) in subparagraph (K), by striking “or
17 premarket notification submissions” and insert-
18 ing “premarket notification submissions, or de
19 novo classification requests”; and

20 (2) in paragraph (11), by striking “2016” and
21 inserting “2021”.

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

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

1 (1) in paragraph (1), by striking “fiscal year
2 2018” and inserting “fiscal year 2023”; and

3 (2) in paragraph (2)—

4 (A) in subparagraph (A)—

5 (i) in the matter preceding clause (i),
6 by striking “October 1, 2017” and insert-
7 ing “October 1, 2022”;

8 (ii) in clause (iii), by striking “75 per-
9 cent” and inserting “80 percent”; and

10 (iii) in clause (viii), by striking “3.4
11 percent” and inserting “4.5 percent”;

12 (B) in subparagraph (B)(iii), by striking
13 “or premarket notification submission” and in-
14 serting “premarket notification submission, or
15 de novo classification request”; and

16 (C) in subparagraph (C), by striking “or
17 periodic reporting concerning a class III device”
18 and inserting “periodic reporting concerning a
19 class III device, or de novo classification re-
20 quest”.

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

24 (1) in paragraph (1), by striking “2018
25 through 2022” and inserting “2023 through 2027”;

1 (2) by amending paragraph (2) to read as fol-
2 lows:

3 “(2) BASE FEE AMOUNTS SPECIFIED.—For
4 purposes of paragraph (1), the base fee amounts
5 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

6 (3) by amending paragraph (3) to read as fol-
7 lows:

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

11 “(A) \$312,606,000 for fiscal year 2023.

12 “(B) \$335,750,000 for fiscal year 2024.

13 “(C) \$350,746,400 for fiscal year 2025.

14 “(D) \$366,486,300 for fiscal year 2026.

15 “(E) \$418,343,000 for fiscal year 2027.”.

16 (c) ANNUAL FEE SETTING; ADJUSTMENTS.—Section
17 738(c) of the Federal Food, Drug, and Cosmetic Act (21
18 U.S.C. 379j(c)) is amended—

19 (1) in paragraph (1), by striking “2017” and
20 inserting “2022”;

21 (2) in paragraph (2)—

22 (A) in subparagraph (A), by striking
23 “2018” and inserting “2023”;

1 (B) by striking subparagraph (B)—

2 (i) in the matter preceding clause (i),
3 by striking “fiscal year 2018” and insert-
4 ing “fiscal year 2023”; and

5 (ii) in clause (ii), by striking “fiscal
6 year 2016” and inserting “fiscal year
7 2022”;

8 (C) in subparagraph (C), by striking
9 “Washington-Baltimore, DC–MD–VA–WV”
10 and inserting “Washington-Arlington-Alexan-
11 dria, DC–VA–MD–WV”.

12 (D) in subparagraph (D), in the matter
13 preceding clause (i), by striking “fiscal years
14 2018 through 2022” and inserting “fiscal years
15 2023 through 2027”;

16 (3) in paragraph (3), by striking “2018
17 through 2022” and inserting “2023 through 2027”;

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

20 (5) by inserting after paragraph (3) the fol-
21 lowing:

22 “(4) PERFORMANCE IMPROVEMENT ADJUST-
23 MENT.—

24 “(A) IN GENERAL.—For each of fiscal
25 years 2025 through 2027, after the adjustment

1 under paragraph (3), the base establishment
2 registration fee amounts for such fiscal year
3 shall be increased to reflect changes in the re-
4 source needs of the Secretary due to improved
5 review performance goals for the process for the
6 review of device applications identified in the
7 letters described in section 201(b) of the Med-
8 ical Device User Fee Amendments of 2022, as
9 the Secretary determines necessary to achieve
10 an increase in total fee collections for such fis-
11 cal year equal to the following amounts, as ap-
12 plicable:

13 “(i) For fiscal year 2025, the product
14 of—

15 “(I) the amount determined
16 under subparagraph (B)(i)(I); and

17 “(II) the applicable inflation ad-
18 justment under paragraph (2)(B) for
19 such fiscal year.

20 “(ii) For fiscal year 2026, the product
21 of—

22 “(I) the sum of the amounts de-
23 termined under subparagraphs
24 (B)(i)(II), (B)(ii)(I), and (B)(iii)(I);
25 and

1 “(II) the applicable inflation ad-
2 justment under paragraph (2)(B) for
3 such fiscal year.

4 “(iii) For fiscal year 2027, the prod-
5 uct of—

6 “(I) the sum of the amounts de-
7 termined under subparagraphs
8 (B)(i)(III), (B)(ii)(II), and
9 (B)(iii)(II); and

10 “(II) the applicable inflation ad-
11 justment under paragraph (2)(B) for
12 such fiscal year.

13 “(B) AMOUNTS.—

14 “(i) PRE-SUBMISSION AMOUNT.—For
15 purposes of subparagraph (A), with respect
16 to the pre-submission written feedback
17 goal, the amounts determined under this
18 subparagraph are as follows:

19 “(I) For fiscal year 2025,
20 \$15,396,600 if such goal for fiscal
21 year 2023 is met.

22 “(II) For fiscal year 2026:

23 “(aa) \$15,396,600 if such
24 goal for fiscal year 2023 is met

1 and such goal for fiscal year
2 2024 is not met.

3 “(bb) \$36,792,200 if such
4 goal for fiscal year 2024 is met.

5 “(III) For fiscal year 2027:

6 “(aa) \$15,396,600 if such
7 goal for fiscal year 2023 is met
8 and such goal for each of fiscal
9 years 2024 and 2025 is not met.

10 “(bb) \$36,792,200 if such
11 goal for fiscal year 2024 is met
12 and such goal for fiscal year
13 2025 is not met.

14 “(cc) \$40,572,600 if such
15 goal for fiscal year 2025 is met.

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

21 “(I) For fiscal year 2026,
22 \$6,323,500 if such goal for fiscal year
23 2023 is met.

24 “(II) For fiscal year 2027—

1 “(aa) \$6,323,500 if such
2 goal for fiscal year 2023 is met
3 and such goal for fiscal year
4 2024 is not met.

5 “(bb) \$11,765,400 if such
6 goal for fiscal year 2024 is met.

7 “(iii) PREMARKET NOTIFICATION AND
8 PREMARKET APPROVAL.—For purposes of
9 subparagraph (A), with respect to the
10 510(k) decision goal, 510(k) shared out-
11 come total time to decision goal, PMA de-
12 cision goal, and PMA shared outcome total
13 time to decision goal, the amounts deter-
14 mined under this subparagraph are as fol-
15 lows:

16 “(I) For fiscal year 2026,
17 \$1,020,000 if the four goals for fiscal
18 year 2023 are met.

19 “(II) For fiscal year 2027:

20 “(aa) \$1,020,000 if the four
21 goals for fiscal year 2023 are met
22 and one or more of the four goals
23 for fiscal year 2024 is not met.

1 “(bb) \$3,906,000 if the four
2 goals for fiscal year 2024 are
3 met.

4 “(C) PERFORMANCE CALCULATION.—For
5 purposes of this paragraph, performance of the
6 goals listed in subparagraph (D) shall be deter-
7 mined as specified in the letters described in
8 section 201(b) of the Medical Device User Fee
9 Amendments of 2022 and based on data avail-
10 able as of the following dates:

11 “(i) The performance of the pre-sub-
12 mission written feedback goal shall be
13 based on data available as of—

14 “(I) for fiscal year 2023, March
15 31, 2024;

16 “(II) for fiscal year 2024, March
17 31, 2025; and

18 “(III) for fiscal year 2025,
19 March 31, 2026.

20 “(ii) The performance of the de novo
21 decision goal, 510(k) decision goal, 510(k)
22 shared outcome total time to decision goal,
23 PMA decision goal, and PMA shared out-
24 come total time to decision goal shall be
25 based on data available as of—

1 “(I) for fiscal year 2023, March
2 31, 2025; and

3 “(II) for fiscal year 2024, March
4 31, 2026.

5 “(D) GOALS DEFINED.—For purposes of
6 this paragraph, the terms ‘pre-submission writ-
7 ten feedback goal’, ‘de novo decision goal’,
8 ‘510(k) decision goal’, ‘510(k) shared outcome
9 total time to decision goal’, ‘PMA decision
10 goal’, and ‘PMA shared outcome total time to
11 decision goal’ refer to the goals identified by the
12 same names in the letters described in section
13 201(b) of the Medical Device User Fee Amend-
14 ments of 2022.

15 “(5) HIRING ADJUSTMENT.—

16 “(A) IN GENERAL.—For each of fiscal
17 years 2025 through 2027, after the adjust-
18 ments under paragraphs (3) and (4), if applica-
19 ble, if the number of hires to support the proc-
20 ess for the review of device applications falls
21 below the thresholds specified in subparagraph
22 (B) for the applicable fiscal years, the base es-
23 tablishment registration fee amounts shall be
24 decreased as the Secretary determines nec-
25 essary to achieve a reduction in total fee collec-

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

3 “(B) THRESHOLDS.—The thresholds speci-
4 fied in this subparagraph are as follows:

5 “(i) For fiscal year 2025, the applica-
6 ble threshold is 85 percent of the hiring
7 goal specified in subparagraph (D) for fis-
8 cal year 2023.

9 “(ii) For fiscal year 2026, the applica-
10 ble threshold is 90 percent of the hiring
11 goal specified in subparagraph (D) for fis-
12 cal year 2024.

13 “(iii) For fiscal year 2027, the appli-
14 cable threshold is 90 percent of the hiring
15 goal specified in subparagraph (D) for fis-
16 cal year 2025.

17 “(C) HIRING ADJUSTMENT AMOUNT.—The
18 hiring adjustment amount for fiscal year 2025
19 and each subsequent fiscal year is the product
20 of—

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

25 “(ii) \$72,877; and

1 “(iii) the applicable inflation adjust-
2 ment under paragraph (2)(B) for the fiscal
3 year for which the hiring goal was not met.

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

7 “(i) For fiscal year 2023, 144 hires.

8 “(ii) For fiscal year 2024, 42 hires.

9 “(iii) For fiscal year 2025:

10 “(I) 24 hires if the base estab-
11 lishment registration fees are not in-
12 creased by the amount determined
13 under paragraph (4)(A)(i).

14 “(II) 83 hires if the base estab-
15 lishment registration fees are in-
16 creased by the amount determined
17 under paragraph (4)(A)(i).

18 “(E) NUMBER OF HIRES.—For purposes
19 of this paragraph, the number of hires shall be
20 determined by the Secretary as set forth in the
21 letters described in section 201(b) of the Med-
22 ical Device User Fee Amendments of 2022.

23 “(6) OPERATING RESERVE ADJUSTMENT.—

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

1 ments under paragraphs (3), (4), and (5), if ap-
2 plicable, if the Secretary has operating reserves
3 of carryover user fees for the process for the re-
4 view of device applications in excess of the des-
5 ignated amount in subparagraph (B), the Sec-
6 retary shall decrease the base establishment
7 registration fee amounts to provide for not
8 more than such designated amount of operating
9 reserves.

10 “(B) DESIGNATED AMOUNT.—Subject to
11 subparagraph (C), for each fiscal year, the des-
12 ignated amount in this subparagraph is equal
13 to the sum of—

14 “(i) 13 weeks of operating reserves of
15 carryover user fees; and

16 “(ii) the 1 month of operating re-
17 serves **【described in paragraph (8)】**.

18 “(C) EXCLUDED AMOUNT.—For the period
19 of fiscal years 2023 through 2026, a total
20 amount equal to \$118,000,000 shall not be con-
21 sidered part of the designated amount under
22 subparagraph (B) and shall not be subject to
23 the decrease under subparagraph (A).”.

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

1 ed in each of subsections (d)(2)(B)(iii) and (e)(2)(B)(iii)
2 by inserting “, if extant,” after “national taxing author-
3 ity”.

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

7 (1) in paragraph (1)(A), by striking
8 “\$320,825,000” and inserting “\$398,566,000”; and

9 (2) in paragraph (2), by inserting “de novo
10 classification requests,” after “class III device,”.

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

14 “(3) AUTHORIZATION OF APPROPRIATIONS.—

15 “(A) IN GENERAL.—For each of fiscal
16 years 2023 through 2027, there is authorized to
17 be appropriated for fees under this section an
18 amount equal to the revenue amount deter-
19 mined under subparagraph (B), less the
20 amount of reductions determined under sub-
21 paragraph (C).

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

1 “(i) the total revenue amount under
2 subsection (b)(3) for the fiscal year, as ad-
3 justed under paragraphs (1), (2), and (3)
4 of subsection (c); and

5 “(ii) the performance improvement
6 adjustment amount for the fiscal year
7 under subsection (c)(4), if applicable.

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

11 “(i) the hiring adjustment amount for
12 the fiscal year under subsection (c)(5), if
13 applicable; and

14 “(ii) the operating reserve adjustment
15 amount for the fiscal year under sub-
16 section (c)(6), if applicable.”.

17 **SEC. 204. REAUTHORIZATION; REPORTING REQUIREMENTS.**

18 (a) PERFORMANCE REPORTS.—Section 738A(a) of
19 the Federal Food, Drug, and Cosmetic Act (21 U.S.C.
20 379j–1(a)) is amended—

21 (1) by striking “fiscal year 2018” each place it
22 appears and inserting “fiscal year 2023”; and

23 (2) in paragraph (4), by striking “2018
24 through 2022” and inserting “2023 through 2027”.

1 (b) REAUTHORIZATION.—Section 738A(b) of the
2 Federal Food, Drug, and Cosmetic Act (21 U.S.C. 379j–
3 1(b)) is amended—

4 (1) in paragraph (1), by striking “2022” and
5 inserting “2027”; and

6 (2) in paragraph (5), by striking “2022” and
7 inserting “2027”.

8 **[SEC. 205. CONFORMITY ASSESSMENT PILOT PROGRAM.]**

9 Section 514(d) of the Federal Food, Drug, and Cos-
10 metic Act (21 U.S.C. 360d(d)) is amended to read as fol-
11 lows:】

12 **【“(d) ACCREDITATION SCHEME FOR CONFORMITY**
13 **ASSESSMENT.—】**

14 **【“(1) IN GENERAL.—The Secretary shall estab-**
15 **lish a program under which—】**

16 **【“(A) testing laboratories meeting criteria**
17 **specified in guidance by the Secretary may be**
18 **accredited by accreditation bodies meeting cri-**
19 **teria specified in guidance by the Secretary, to**
20 **conduct testing to support the assessment of**
21 **the conformity of a device to certain standards**
22 **recognized under this section; and】**

23 **【“(B) subject to paragraph (2), results**
24 **from tests conducted by testing laboratories ac-**
25 **credited to support the assessment of con-**

1 conformity of devices as described in subparagraph
2 (A) shall be accepted by the Secretary for pur-
3 poses of demonstrating such conformity unless
4 the Secretary finds that certain results of such
5 tests should not be so accepted.】

6 【“(2) SECRETARIAL REVIEW OF ACCREDITED
7 LABORATORY RESULTS.—The Secretary may—】

8 【“(A) review the results of tests conducted
9 by testing laboratories accredited pursuant to
10 this subsection, including by conducting peri-
11 odic audits of such results or of the processes
12 of accredited bodies or testing laboratories;】

13 【“(B) following such review, take addi-
14 tional measures under this Act, as the Sec-
15 retary determines appropriate, such as—】

16 【“(i) suspension or withdrawal of ac-
17 creditation of a testing laboratory or rec-
18 ognition of an accreditation body under
19 paragraph (1)(A); or】

20 【“(ii) requesting additional informa-
21 tion with respect to a device; and】

22 【“(C) if the Secretary becomes aware of
23 information materially bearing on the safety or
24 effectiveness of a device assessed for conformity
25 by a testing laboratory accredited under this

1 subsection, take such additional measures under
2 this Act, as the Secretary determines appro-
3 priate, such as—】

4 【“(i) suspension or withdrawal of ac-
5 creditation of a testing laboratory or rec-
6 ognition of an accreditation body under
7 paragraph (1)(A); or】

8 【“(ii) requesting additional informa-
9 tion with regard to such device.】

10 【“(3) IMPLEMENTATION AND REPORTING.—】

11 【“(A) PUBLIC MEETING.—The Secretary
12 shall publish in the Federal Register a notice of
13 a public meeting to be held no later than Sep-
14 tember 30, 2018, to discuss and obtain input
15 and recommendations from stakeholders regard-
16 ing the goals and scope of, and a suitable
17 framework and procedures and requirements
18 for, the pilot program under this subsection.】

19 【“(B) PILOT PROGRAM GUIDANCE.—The
20 Secretary shall—】

21 【“(i) not later than September 30,
22 2019, issue draft guidance regarding the
23 goals and implementation of the pilot pro-
24 gram under this subsection; and】

1 【“(ii) not later than September 30,
2 2021, issue final guidance with respect to
3 the implementation of such program.】

4 【“(C) PILOT PROGRAM INITIATION AND
5 TRANSITION.—Not later than September 30,
6 2020, the Secretary shall initiate the pilot pro-
7 gram under this subsection. After September
8 30, 2023, such pilot program will be considered
9 to be completed, and the Secretary may con-
10 tinue operating a program consistent with this
11 subsection.】

12 【“(D) REPORT.—The Secretary shall
13 make available on the internet website of the
14 Food and Drug Administration an annual re-
15 port on the progress of the pilot program under
16 this subsection.”.】

17 **[SEC. 206. REAUTHORIZATION OF THIRD-PARTY REVIEW**
18 **PROGRAM.]**

19 Section 523(c) of the Federal Food, Drug, and Cos-
20 metic Act (21 U.S.C. 360m(c)) is amended by striking
21 “2022” and inserting “2027”.】

22 **SEC. 207. SAVINGS CLAUSE.**

23 Notwithstanding the amendments made by this title,
24 part 3 of subchapter C of chapter VII of the Federal Food,
25 Drug, and Cosmetic Act (21 U.S.C. 379i et seq.), as in

1 effect on the day before the date of the enactment of this
2 title, shall continue to be in effect with respect to the sub-
3 missions listed in section 738(a)(2)(A) of such Act (as de-
4 fined in such part as of such day) that on or after October
5 1, 2017, but before October 1, 2022, were accepted by
6 the Food and Drug Administration for filing with respect
7 to assessing and collecting any fee required by such part
8 for a fiscal year prior to fiscal year 2023.

9 **SEC. 208. EFFECTIVE DATE.**

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

18 **SEC. 209. SUNSET DATES.**

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

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

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