of fees paid for each such type of application or notification, from businesses with gross receipts or sales from $0 to $100,000,000, with such businesses categorized in $10,000,000 intervals; and

''(2) a certification by the Secretary that the amounts appropriated for salaries and expenses of the Food and Drug Administration for such fiscal year and obligated by the Secretary for the performance of any function relating to devices that is not for the process for the review of device applications, as defined in paragraph (5) [now (8)] of section 737 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 379i), are not less than such amounts for fiscal year 2002 multiplied by the adjustment factor, as defined in paragraph (7) [now (10)] of such section 737.''

STUDY

Pub. L. 107–250, title I, §104(b), Oct. 26, 2002, 116 Stat. 1601, directed the Secretary of Health and Human Services to conduct a study for the purpose of making certain determinations regarding the medical device user-fee program established under the amendment made by section 102 of Pub. L. 107–250 and to submit a report to Congress by Jan. 10, 2007.

CONSULTATION

Pub. L. 107–250, title I, §105, Oct. 26, 2002, 116 Stat. 1601, provided that:

''(a) IN GENERAL.—In developing recommendations to the Congress for the goals and plans for meeting the goals for the process for the review of medical device applications for fiscal years after fiscal year 2007, and for the reauthorization of sections 737 and 738 of the Federal Food, Drug, and Cosmetic Act [21 U.S.C. 379i, 379j], the Secretary of Health and Human Services (referred to in this section as the 'Secretary') shall consult with the Committee on Energy and Commerce of the House of Representatives, the Committee on Health, Education, Labor, and Pensions of the Senate, appropriate scientific and academic experts, health care professionals, representatives of patient and consumer advocacy groups, and the regulated industry.

''(b) RECOMMENDATIONS.—The Secretary shall publish in the Federal Register recommendations under subsection (a), after negotiations with the regulated industry; shall present such recommendations to the congressional committees specified in such paragraph; shall hold a meeting at which the public may present its views on such recommendations; and shall provide for a period of 30 days for the public to provide written comments on such recommendations.''

### § 379j. Authority to assess and use device fees

#### (a) Types of fees

##### (1) In general

Beginning in fiscal year 2023, the Secretary shall assess and collect fees in accordance with this section.

##### (2) Premarket application, premarket report, supplement, and submission fee, and annual fee for periodic reporting concerning a class III device

###### (A) In general

Except as provided in subparagraph (B) and subsections (d) and (e), each person who submits any of the following, on or after October 1, 2022, shall be subject to a fee established under subsection (c) for the fiscal year involved in accordance with the following:

(i) A premarket application.

(ii) For a premarket report, a fee equal to the fee that applies under clause (i).

(iii) For a panel track supplement, a fee equal to 80 percent of the fee that applies under clause (i).

(iv) For a 180-day supplement, a fee equal to 15 percent of the fee that applies under clause (i).

(v) For a real-time supplement, a fee equal to 7 percent of the fee that applies under clause (i).

(vi) For a 30-day notice, a fee equal to 1.6 percent of the fee that applies under clause (i).

(vii) For an efficacy supplement, a fee equal to the fee that applies under clause (i).

(viii) For a premarket notification submission, a fee equal to 4.5 percent of the fee that applies under clause (i).

(ix) For a request for classification information, a fee equal to 1.35 percent of the fee that applies under clause (i).

(x) For periodic reporting concerning a class III device, an annual fee equal to 3.5 percent of the fee that applies under clause (i).

(xi) For a de novo classification request, a fee equal to 30 percent of the fee that applies under clause (i).

###### (B) Exceptions

###### (i) Humanitarian device exemption

An application under section 360j(m) of this title is not subject to any fee under subparagraph (A).

###### (ii) Further manufacturing use

No fee shall be required under subparagraph (A) for the submission of a premarket application under section 262 of title 42 for a product licensed for further manufacturing use only.

###### (iii) State or Federal Government sponsors

No fee shall be required under subparagraph (A) for a premarket application, premarket report, supplement, premarket notification submission, or de novo classification request submitted by a State or Federal Government entity unless the device involved is to be distributed commercially.

###### (iv) Premarket notifications by third parties

No fee shall be required under subparagraph (A) for a premarket notification submission reviewed by an accredited person pursuant to section 360m of this title.

###### (v) Pediatric conditions of use

###### (I) In general

No fee shall be required under subparagraph (A) for a premarket application, premarket report, premarket notification submission, or de novo classification request if the proposed conditions of use for the device involved are solely for a pediatric population. No fee shall be required under such subparagraph for a supplement if the sole purpose of the supplement is to propose conditions of use for a pediatric population.

###### (II) Subsequent proposal of adult conditions of use

In the case of a person who submits a premarket application or premarket re-

port for which, under subclause (I), a fee under subparagraph (A) is not required, any supplement to such application that proposes conditions of use for any adult population is subject to the fee that applies under such subparagraph for a premarket application.

**(C) Payment**

The fee required by subparagraph (A) shall be due upon submission of the premarket application, premarket report, supplement, premarket notification submission, 30-day notice, request for classification information, periodic reporting concerning a class III device, or de novo classification request. Applicants submitting portions of applications pursuant to section 360e(c)(4) of this title shall pay such fees upon submission of the first portion of such applications.

**(D) Refunds**

**(i) Application refused for filing**

The Secretary shall refund 75 percent of the fee paid under subparagraph (A) for any application, report, or supplement that is refused for filing.

**(ii) Application withdrawn before filing**

The Secretary shall refund 75 percent of the fee paid under subparagraph (A) for any application, report, or supplement that is withdrawn prior to the filing decision of the Secretary.

**(iii) Application withdrawn before first action**

After receipt of a request for a refund of the fee paid under subparagraph (A) for a premarket application, premarket report, or supplement that is withdrawn after filing but before a first action, the Secretary may return some or all of the fee. The amount of refund, if any, shall be based on the level of effort already expended on the review of such application, report, or supplement.

**(iv) Modular applications withdrawn before first action**

The Secretary shall refund 75 percent of the application fee paid for an application submitted under section 360e(c)(4) of this title that is withdrawn before a second portion is submitted and before a first action on the first portion.

**(v) Later withdrawn modular applications**

If an application submitted under section 360e(c)(4) of this title is withdrawn after a second or subsequent portion is submitted but before any first action, the Secretary may return a portion of the fee. The amount of refund, if any, shall be based on the level of effort already expended on the review of the portions submitted.

**(vi) Sole discretion to refund**

The Secretary shall have sole discretion to refund a fee or portion of the fee under clause (iii) or (v). A determination by the Secretary concerning a refund under clause (iii) or (v) shall not be reviewable.

**(3) Annual establishment registration fee**

**(A) In general**

Except as provided in subparagraph (B), each establishment subject to a registration fee shall be subject to a fee for each initial or annual registration under section 360 of this title beginning with its registration for fiscal year 2008.

**(B) Exception**

**(i) In general**

No fee shall be required under subparagraph (A) for an establishment operated by a State or Federal governmental entity or an Indian tribe (as defined in the Indian Self Determination and Educational Assistance Act[1] [25 U.S.C. 5301 et seq.]), unless a device manufactured by the establishment is to be distributed commercially.

**(ii) Small businesses fee waiver**

**(I) Definition of small business**

For purposes of this clause, the term ''small business'' means an entity that reported $1,000,000 or less of gross receipts or sales in its most recent Federal income tax return for a taxable year, including such returns of all of its affiliates.

**(II) Waiver**

The Secretary may grant a waiver of the fee required under subparagraph (A) for the annual registration (excluding the initial registration) of an establishment for a year, beginning on October 1, 2024, if the Secretary finds that the establishment is a small business and paying the fee for such year represents a financial hardship to the establishment as determined by the Secretary.

**(III) Firms submitting tax returns to the United States Internal Revenue Service**

The establishment shall support its claim that it meets the definition under subclause (I) by submission of a copy of its most recent Federal income tax return for a taxable year, and a copy of such returns of its affiliates, which show an amount of gross sales or receipts that is less than the maximum established in subclause (I). The establishment, and each of such affiliates, shall certify that the information provided is a true and accurate copy of the actual tax forms they submitted to the Internal Revenue Service. If no tax forms are submitted for any affiliate, the establishment shall certify that the establishment has no affiliates.

**(IV) Firms not submitting tax returns to the United States Internal Revenue Service**

In the case of an establishment that has not previously submitted a Federal

[1] See References in Text note below.

income tax return, the establishment and each of its affiliates shall demonstrate that it meets the definition under subclause (I) by submission of a signed certification, in such form as the Secretary may direct through a notice published in the Federal Register, that the establishment or affiliate meets the criteria for a small business and a certification, in English, from the national taxing authority, if extant, of the country in which the establishment or, if applicable, affiliate is headquartered. The certification from such taxing authority shall bear the official seal of such taxing authority and shall provide the establishment's or affiliate's gross receipts or sales for the most recent year in both the local currency of such country and in United States dollars, the exchange rate used in converting such local currency to dollars, and the dates during which these receipts or sales were collected. The establishment shall also submit a statement signed by the head of the establishment's firm or by its chief financial officer that the establishment has submitted certifications for all of its affiliates, or that the establishment has no affiliates.

**(V) Request for waiver**

An establishment seeking a fee waiver for a year under this clause shall submit supporting information to the Secretary at least 60 days before the fee is required pursuant to subparagraph (C). The decision of the Secretary regarding whether an entity may receive the waiver for such year is not reviewable.

**(C) Payment**

The fee required under subparagraph (A) shall be due once each fiscal year, upon the later of—

(i) the initial or annual registration (as applicable) of the establishment under section 360 of this title; or

(ii) the first business day after the date of enactment of an appropriations Act providing for the collection and obligation of fees for such year under this section.

**(b) Fee Amounts**

**(1) In general**

Subject to subsections (c), (d), (e), and (h), for each of fiscal years 2023 through 2027, fees under subsection (a) shall be derived from the base fee amounts specified in paragraph (2), to generate the total revenue amounts specified in paragraph (3).

**(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 |

**(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**

**(1) In general**

The Secretary shall, 60 days before the start of each fiscal year after September 30, 2022, establish fees under subsection (a), based on amounts specified under subsection (b) and the adjustments provided under this subsection, and publish such fees, and the rationale for any adjustments to such fees, in the Federal Register.

**(2) Inflation adjustments**

**(A) Adjustment to total revenue amounts**

For fiscal year 2023 and each subsequent fiscal year, the Secretary shall adjust the total revenue amount specified in subsection (b)(3) for such fiscal year by multiplying such amount by the applicable inflation adjustment under subparagraph (B) for such year.

**(B) Applicable inflation adjustment**

The applicable inflation adjustment for fiscal year 2023 and each subsequent fiscal year is the product of—

(i) the base inflation adjustment under subparagraph (C) for such fiscal year; and

(ii) the product of the base inflation adjustment under subparagraph (C) for each of the fiscal years preceding such fiscal year, beginning with fiscal year 2022.

**(C) Base inflation adjustment**

**(i) In general**

Subject to further adjustment under clause (ii), the base inflation adjustment for a fiscal year is the sum of one plus—

(I) the average annual percent change in the cost, per full-time equivalent position of the Food and Drug Administration, of all personnel compensation and benefits paid with respect to such positions for the first 3 years of the preceding 4 fiscal years, multiplied by 0.60; and

(II) the average annual percent change that occurred in the Consumer Price Index for urban consumers (Washington-Arlington-Alexandria, DC–VA–MD–WV; Not Seasonally Adjusted; All items; Annual Index) for the first 3 years of the

preceding 4 years of available data multiplied by 0.40.

**(ii) Limitations**

For purposes of subparagraph (B), if the base inflation adjustment for a fiscal year under clause (i)—

(I) is less than 1, such adjustment shall be considered to be equal to 1; or

(II) is greater than 1.04, such adjustment shall be considered to be equal to 1.04.

**(D) Adjustment to base fee amounts**

For each of fiscal years 2023 through 2027, the Secretary shall—

(i) adjust the base fee amounts specified in subsection (b)(2) for such fiscal year by multiplying such amounts by the applicable inflation adjustment under subparagraph (B) for such year; and

(ii) if the Secretary determines necessary, increase (in addition to the adjustment under clause (i)) such base fee amounts, on a uniform proportionate basis, to generate the total revenue amounts under subsection (b)(3), as adjusted for inflation under subparagraph (A).

**(3) Volume-based adjustments to establishment registration base fees**

For each of fiscal years 2023 through 2027, after the base fee amounts specified in subsection (b)(2) are adjusted under paragraph (2)(D), the base establishment registration fee amounts specified in such subsection shall be increased, as the Secretary estimates is necessary in order for total fee collections for such fiscal year to generate the total revenue amounts, as adjusted under paragraph (2).

**(4) Performance improvement adjustment**

**(A) In general**

For each of fiscal years 2025 through 2027, after the adjustments under paragraphs (2) and (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 2001(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) Presubmission amount**

For purposes of subparagraph (A), with respect to the Presubmission 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 request 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 amount**

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 4 goals for fiscal year 2023 are met.

(II) For fiscal year 2027:

(aa) $1,020,000 if the 4 goals for fiscal year 2023 are met and one or more of the 4 goals for fiscal year 2024 are not met.

(bb) $3,906,000 if the 4 goals for fiscal year 2024 are met.

**(C) Performance calculation**

For purposes of this paragraph, performance of the following goals shall be determined as specified in the letters described in section 2001(b) of the Medical Device User Fee Amendments of 2022 and based on data available, as follows:

(i) The performance of the Presubmission 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 ''Presubmission 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 2001(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 (2), (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 collections 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 threshold is 123 hires for fiscal year 2023.

(ii) For fiscal year 2026, the threshold is 38 hires for fiscal year 2024.

(iii) For fiscal year 2027, the threshold is—

(I) 22 hires for fiscal year 2025 if the base establishment registration fees are not increased by the amount determined under paragraph (4)(A)(i); or

(II) 75 hires for fiscal year 2025 if such fees are so increased.

**(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 for a fiscal year shall be determined by the Secretary as set forth in the letters described in section 2001(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 adjustments under paragraphs (2), (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) 1 month of operating reserves maintained pursuant to 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).

**(7) Limit**

The total amount of fees charged, as adjusted under this subsection, for a fiscal year may not exceed the total costs for such fiscal year for the resources allocated for the process for the review of device applications.

**(8) Supplement**

**(A) In general**

The Secretary may use unobligated carryover balances from fees collected in previous fiscal years to ensure that sufficient fee revenues are available in that fiscal year, so long as the Secretary maintains unobligated carryover balances of not less than 1 month of operating reserves for the first month of the next fiscal year.

**(B) Notice to Congress**

Not later than 14 days before the Secretary anticipates the use of funds described in subparagraph (A), the Secretary shall provide

notice to the Committee on Health, Education, Labor, and Pensions and the Committee on Appropriations of the Senate and the Committee on Energy and Commerce and the Committee on Appropriations of the House of Representatives.

**(d) Small businesses; fee waiver and fee reduction regarding premarket approval fees**

**(1) In general**

The Secretary shall grant a waiver of the fee required under subsection (a) for one premarket application, or one premarket report, where the Secretary finds that the applicant involved is a small business submitting its first premarket application to the Secretary, or its first premarket report, respectively, for review. For the purposes of this paragraph, the term ''small business'' means an entity that reported $30,000,000 or less of gross receipts or sales in its most recent Federal income tax return for a taxable year, including such returns of all of its affiliates. In addition, for subsequent premarket applications, premarket reports, and supplements where the Secretary finds that the applicant involved is a small business, the fees specified in clauses (i) through (vii) and clauses (ix), (x), and (xi) of subsection (a)(2)(A) may be paid at a reduced rate in accordance with paragraph (2)(C).

**(2) Rules relating to premarket approval fees**

**(A) Definition**

For purposes of this paragraph, the term ''small business'' means an entity that reported $100,000,000 or less of gross receipts or sales in its most recent Federal income tax return for a taxable year, including such returns of all of its affiliates.

**(B) Evidence of qualification**

**(i) In general**

An applicant shall pay the higher fees established by the Secretary each year unless the applicant submits evidence that it qualifies for a waiver of the fee or the lower fee rate.

**(ii) Firms submitting tax returns to the United States Internal Revenue Service**

The applicant shall support its claim that it meets the definition under subparagraph (A) by submission of a copy of its most recent Federal income tax return for a taxable year, and a copy of such returns of its affiliates, which show an amount of gross sales or receipts that is less than the maximum established in subparagraph (A). The applicant, and each of such affiliates, shall certify that the information provided is a true and accurate copy of the actual tax forms they submitted to the Internal Revenue Service. If no tax forms are submitted for any affiliate, the applicant shall certify that the applicant has no affiliates.

**(iii) Firms not submitting tax returns to the United States Internal Revenue Service**

In the case of an applicant that has not previously submitted a Federal income tax return, the applicant and each of its affiliates shall demonstrate that it meets the definition under subparagraph (A) by submission of a signed certification, in such form as the Secretary may direct through a notice published in the Federal Register, that the applicant or affiliate meets the criteria for a small business and a certification, in English, from the national taxing authority, if extant, of the country in which the applicant or, if applicable, affiliate is headquartered. The certification from such taxing authority shall bear the official seal of such taxing authority and shall provide the applicant's or affiliate's gross receipts or sales for the most recent year in both the local currency of such country and in United States dollars, the exchange rate used in converting such local currency to dollars, and the dates during which these receipts or sales were collected. The applicant shall also submit a statement signed by the head of the applicant's firm or by its chief financial officer that the applicant has submitted certifications for all of its affiliates, or that the applicant has no affiliates.

**(C) Reduced fees**

Where the Secretary finds that the applicant involved meets the definition under subparagraph (A), the fees established under subsection (c)(1) may be paid at a reduced rate of—

(i) 25 percent of the fee established under such subsection for a premarket application, a premarket report, a supplement, periodic reporting concerning a class III device, or a de novo classification request; and

(ii) 50 percent of the fee established under such subsection for a 30-day notice or a request for classification information.

**(D) Request for fee waiver or reduction**

An applicant seeking a fee waiver or reduction under this subsection shall submit supporting information to the Secretary at least 60 days before the fee is required pursuant to subsection (a). The decision of the Secretary regarding whether an entity qualifies for such a waiver or reduction is not reviewable.

**(e) Small businesses; fee reduction regarding premarket notification submissions**

**(1) In general**

For fiscal year 2008 and each subsequent fiscal year, where the Secretary finds that the applicant involved is a small business, the fee specified in subsection (a)(2)(A)(viii) may be paid at a reduced rate in accordance with paragraph (2)(C).

**(2) Rules relating to premarket notification submissions**

**(A) Definition**

For purposes of this subsection, the term ''small business'' means an entity that reported $100,000,000 or less of gross receipts or sales in its most recent Federal income tax return for a taxable year, including such returns of all of its affiliates.

**(B) Evidence of qualification**

**(i) In general**

An applicant shall pay the higher fees established by the Secretary each year unless the applicant submits evidence that it qualifies for the lower fee rate.

**(ii) Firms submitting tax returns to the United States Internal Revenue Service**

The applicant shall support its claim that it meets the definition under subparagraph (A) by submission of a copy of its most recent Federal income tax return for a taxable year, and a copy of such returns of its affiliates, which show an amount of gross sales or receipts that is less than the maximum established in subparagraph (A). The applicant, and each of such affiliates, shall certify that the information provided is a true and accurate copy of the actual tax forms they submitted to the Internal Revenue Service. If no tax forms are submitted for any affiliate, the applicant shall certify that the applicant has no affiliates.

**(iii) Firms not submitting tax returns to the United States Internal Revenue Service**

In the case of an applicant that has not previously submitted a Federal income tax return, the applicant and each of its affiliates shall demonstrate that it meets the definition under subparagraph (A) by submission of a signed certification, in such form as the Secretary may direct through a notice published in the Federal Register, that the applicant or affiliate meets the criteria for a small business and a certification, in English, from the national taxing authority, if extant, of the country in which the applicant or, if applicable, affiliate is headquartered. The certification from such taxing authority shall bear the official seal of such taxing authority and shall provide the applicant's or affiliate's gross receipts or sales for the most recent year in both the local currency of such country and in United States dollars, the exchange rate used in converting such local currency to dollars, and the dates during which these receipts or sales were collected. The applicant shall also submit a statement signed by the head of the applicant's firm or by its chief financial officer that the applicant has submitted certifications for all of its affiliates, or that the applicant has no affiliates.

**(C) Reduced fees**

For fiscal year 2008 and each subsequent fiscal year, where the Secretary finds that the applicant involved meets the definition under subparagraph (A), the fee for a premarket notification submission may be paid at 25 percent of the fee that applies under subsection (a)(2)(A)(viii), and as established under subsection (c)(1).

**(D) Request for reduction**

An applicant seeking a fee reduction under this subsection shall submit supporting information to the Secretary at least 60 days before the fee is required pursuant to subsection (a). The decision of the Secretary regarding whether an entity qualifies for such a reduction is not reviewable.

**(f) Effect of failure to pay fees**

**(1) No acceptance of submissions**

A premarket application, premarket report, supplement, premarket notification submission, 30-day notice, request for classification information, periodic reporting concerning a class III device, or de novo classification request submitted by a person subject to fees under subsections (a)(2) and (a)(3) shall be considered incomplete and shall not be accepted by the Secretary until all such fees owed by such person have been paid.

**(2) No registration**

Registration information submitted under section 360 of this title by an establishment subject to a registration fee shall be considered incomplete and shall not be accepted by the Secretary until the registration fee under subsection (a)(3) owed for the establishment has been paid. Until the fee is paid and the registration is complete, the establishment is deemed to have failed to register in accordance with section 360 of this title.

**(g) Conditions**

**(1) Performance goals; termination of program**

With respect to the amount that, under the salaries and expenses account of the Food and Drug Administration, is appropriated for a fiscal year for devices and radiological products, fees may not be assessed under subsection (a) for the fiscal year, and the Secretary is not expected to meet any performance goals identified for the fiscal year, if—

(A) the amount so appropriated for the fiscal year, excluding the amount of fees appropriated for the fiscal year, is more than 1 percent less than $398,566,000 multiplied by the adjustment factor applicable to such fiscal year; or

(B) fees were not assessed under subsection (a) for the previous fiscal year.

**(2) Authority**

If the Secretary does not assess fees under subsection (a) during any portion of a fiscal year because of paragraph (1) and if at a later date in such fiscal year the Secretary may assess such fees, the Secretary may assess and collect such fees, without any modification in the rate for premarket applications, supplements, premarket reports, premarket notification submissions, 30-day notices, requests for classification information, periodic reporting concerning a class III device, de novo classification requests, and establishment registrations at any time in such fiscal year, notwithstanding the provisions of subsection (a) relating to the date fees are to be paid.

**(3) Limitation**

Beginning on October 1, 2023, the authorities under section 379i(10)(C) of this title shall include only leasing and necessary scientific equipment.

**(h) Crediting and availability of fees**

**(1) In general**

Subject to paragraph (2)(C), fees authorized under subsection (a) shall be collected and available for obligation only to the extent and in the amount provided in advance in appropriation Acts. Such fees are authorized to be appropriated to remain available until expended. Such sums as may be necessary may be transferred from the Food and Drug Administration salaries and expenses appropriation account without fiscal year limitation to such appropriation account for salaries and expenses with such fiscal year limitation. The sums transferred shall be available solely for the process for the review of device applications.

**(2) Collections and appropriation acts**

**(A) In general**

The fees authorized by this section—

(i) subject to subparagraph (C), shall be collected and available in each fiscal year in an amount not to exceed the amount specified in appropriation Acts, or otherwise made available for obligation, for such fiscal year, and

(ii) shall be available—

(I) for fiscal year 2023, to defray increases in the costs of the resources allocated for the process for the review of device applications (including increases in such costs for an additional number of full-time equivalent positions in the Department of Health and Human Services to be engaged in such process) over such costs, excluding costs paid from fees collected under this section, for fiscal year 2009 multiplied by the adjustment factor; and

(II) for fiscal year 2024 and each subsequent fiscal year, to defray the costs of the resources allocated for the process for the review of device applications (including such costs for an additional number of full-time equivalent positions in the Department of Health and Human Services to be engaged in such process), only if the sum of the amounts allocated by the Secretary for such costs, excluding costs paid from fees collected under this section, plus other costs for the maintenance, renovation, and repair of facilities and acquisition, maintenance, and repair of fixtures, furniture and other necessary materials and supplies in connection with the process for the review of device applications, is no less than the amount allocated for such costs, excluding any such costs paid from fees collected under this section, for fiscal year 2009 multiplied by the adjustment factor.

**(B) Compliance**

**(i) In general**

The Secretary shall be considered to have met the requirements of subparagraph (A)(ii) in any fiscal year if the costs funded by appropriations and allocated as described in subclause (I) or (II) of such subparagraph, as applicable—

(I) are not more than 3 percent below the level specified in subparagraph (A)(ii); or

(II)(aa) are more than 3 percent below the level specified in subparagraph (A)(ii), and fees assessed for a subsequent fiscal year are decreased by the amount in excess of 3 percent by which such costs fell below the level specified in such subparagraph; and

(bb) such costs are not more than 5 percent below the level specified in such subparagraph.

**(ii) More than 5 percent**

To the extent such costs are more than 5 percent below the specified level in subparagraph (A)(ii), fees may not be collected under this section for that fiscal year.

**(C) Provision for early payments**

Payment of fees authorized under this section for a fiscal year, prior to the due date for such fees, may be accepted by the Secretary in accordance with authority provided in advance in a prior year appropriations Act.

**(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 (2) and (3) of subsection (c); and

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

**(C) Amount of 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.

**(i) Collection of unpaid fees**

In any case where the Secretary does not receive payment of a fee assessed under subsection (a) within 30 days after it is due, such fee shall be treated as a claim of the United States Government subject to subchapter II of chapter 37 of title 31.

**(j) Written requests for refunds**

To qualify for consideration for a refund under subsection (a)(2)(D), a person shall submit to the

Secretary a written request for such refund not later than 180 days after such fee is due.

**(k) Construction**

This section may not be construed to require that the number of full-time equivalent positions in the Department of Health and Human Services, for officers, employees, and advisory committees not engaged in the process of the review of device applications, be reduced to offset the number of officers, employees, and advisory committees so engaged.

(June 25, 1938, ch. 675, § 738, as added Pub. L. 107–250, title I, § 102(a), Oct. 26, 2002, 116 Stat. 1591; amended Pub. L. 108–214, § 2(a)(2), (d)(2)(A), (B), (3)(A), Apr. 1, 2004, 118 Stat. 572, 576, 577; Pub. L. 109–43, § 2(a), Aug. 1, 2005, 119 Stat. 439; Pub. L. 110–85, title II, § 212, Sept. 27, 2007, 121 Stat. 844; Pub. L. 112–144, title II, § 203(a)–(f), July 9, 2012, 126 Stat. 1002; Pub. L. 112–193, § 2(b)(1), Oct. 5, 2012, 126 Stat. 1443; Pub. L. 115–52, title II, § 203(a)–(f)(1), (2)(B)–(i), title IX, § 905(b)(2), Aug. 18, 2017, 131 Stat. 1013–1016, 1090; Pub. L. 117–180, div. F, title II, § 2003, Sept. 30, 2022, 136 Stat. 2148; Pub. L. 117–328, div. FF, title III, §§ 3309, 3625(d), (e)(1), Dec. 29, 2022, 136 Stat. 5836, 5882.)

TERMINATION OF SECTION

*For termination of section by section 2007(a) of Pub. L. 117–180, see Effective and Termination Dates note below.*

**Editorial Notes**

REFERENCES IN TEXT

The Indian Self Determination and Educational Assistance Act, referred to in subsec. (a)(3)(B)(i), probably means the Indian Self-Determination and Education Assistance Act, Pub. L. 93–638, Jan. 4, 1975, 88 Stat. 2203, which is classified principally to chapter 46 (§ 5301 et seq.) of Title 25, Indians. For complete classification of this Act to the Code, see Short Title note set out under section 5301 of Title 25 and Tables.

Section 2001(b) of the Medical Device User Fee Amendments of 2022, referred to in subsec. (c)(4)(A), (C), (D), (5)(E), is section 2001(b) of title II of div. F of Pub. L. 117–180, which is set out as a note under section 379i of this title.

510(k), referred to in subsec. (c)(4)(B)(iii), (C)(ii), (D), means section 510(k) of the Federal Food, Drug, and Cosmetic Act, act June 25, 1938, ch. 675, which is classified to section 360(k) of this title.

AMENDMENTS

2022—Subsec. (a)(1). Pub. L. 117–180, § 2003(a)(1), substituted ''fiscal year 2023'' for ''fiscal year 2018''.

Subsec. (a)(2)(A). Pub. L. 117–180, § 2003(a)(2)(A)(i), substituted ''October 1, 2022'' for ''October 1, 2017'' in introductory provisions.

Subsec. (a)(2)(A)(iii). Pub. L. 117–180, § 2003(a)(2)(A)(ii), substituted ''80 percent'' for ''75 percent''.

Subsec. (a)(2)(A)(viii). Pub. L. 117–180, § 2003(a)(2)(A)(iii), substituted ''4.5 percent'' for ''3.4 percent''.

Subsec. (a)(2)(B)(iii). Pub. L. 117–180, § 2003(a)(2)(B), substituted ''premarket notification submission, or de novo classification request'' for ''or premarket notification submission''.

Subsec. (a)(2)(C). Pub. L. 117–180, § 2003(a)(2)(C), substituted ''periodic reporting concerning a class III device, or de novo classification request'' for ''or periodic reporting concerning a class III device''.

Subsec. (a)(3)(B). Pub. L. 117–328, § 3309(a), designated existing provisions as cl. (i), inserted heading, and added cl. (ii).

Subsec. (b)(1). Pub. L. 117–180, § 2003(b)(1), substituted ''2023 through 2027'' for ''2018 through 2022''.

Subsec. (b)(2). Pub. L. 117–180, § 2003(b)(2), amended par. (2) generally. Prior to amendment, par. (2) specified base fee amounts for fiscal years 2018 to 2022.

Subsec. (b)(3). Pub. L. 117–180, § 2003(b)(3), amended par. (3) generally. Prior to amendment, par. (3) specified total revenue amounts for fiscal years 2018 to 2022.

Subsec. (c)(1). Pub. L. 117–180, § 2003(c)(1), substituted ''2022'' for ''2017''.

Subsec. (c)(2)(A). Pub. L. 117–180, § 2003(c)(2)(A), substituted ''2023'' for ''2018''.

Subsec. (c)(2)(B). Pub. L. 117–180, § 2003(c)(2)(B)(i), substituted ''fiscal year 2023'' for ''fiscal year 2018'' in introductory provisions.

Subsec. (c)(2)(B)(ii). Pub. L. 117–180, § 2003(c)(2)(B)(ii), substituted ''fiscal year 2022'' for ''fiscal year 2016''.

Subsec. (c)(2)(C)(i)(II). Pub. L. 117–180, § 2003(c)(2)(C), substituted ''Washington-Arlington-Alexandria, DC–VA–MD–WV'' for ''Washington-Baltimore, DC–MD–VA–WV''.

Subsec. (c)(2)(D). Pub. L. 117–180, § 2003(c)(2)(D), substituted ''fiscal years 2023 through 2027'' for ''fiscal years 2018 through 2022'' in introductory provisions.

Subsec. (c)(3). Pub. L. 117–180, § 2003(c)(3), substituted ''2023 through 2027'' for ''2018 through 2022''.

Subsec. (c)(4) to (8). Pub. L. 117–180, § 2003(c)(4), (5), added pars. (4) to (6) and redesignated former pars. (4) and (5) as (7) and (8), respectively.

Subsec. (d)(2)(B)(iii). Pub. L. 117–328, § 3309(b), inserted '', if extant,'' after ''national taxing authority''.

Subsec. (e)(2)(B)(iii). Pub. L. 117–328, § 3625(d)(1), inserted '', if extant,'' after ''national taxing authority''.

Subsec. (g)(1)(A). Pub. L. 117–180, § 2003(d)(1), substituted ''$398,566,000'' for ''$320,825,000''.

Subsec. (g)(2). Pub. L. 117–180, § 2003(d)(2), inserted ''de novo classification requests,'' after ''class III device,''.

Subsec. (g)(3). Pub. L. 117–328, § 3625(e)(1), which directed technical correction to directory language of Pub. L. 115–52, § 905(b)(2), was executed by making technical correction to that section as if the amendment were retroactive to the effective date of the amendment by Pub. L. 115–52 to reflect the probable intent of Congress. See 2017 Amendment note below.

Pub. L. 117–328, § 3625(d)(3), substituted ''379i(10)(C) of this title'' for ''section 379i(9)(C) of this title''.

Subsec. (h)(2)(A)(ii). Pub. L. 117–328, § 3625(d)(2)(A), substituted ''shall be available—'' for ''shall be available to defray'', designated remainder of existing provisions as subcl. (I), inserted ''for fiscal year 2023, to defray'' before ''increases in the costs'', and added subcl. (II).

Subsec. (h)(2)(B)(i). Pub. L. 117–328, § 3625(d)(2)(B), substituted ''as described in subclause (I) or (II) of such subparagraph, as applicable'' for ''for the process for the review of device applications'' in introductory provisions.

Subsec. (h)(3). Pub. L. 117–180, § 2003(e), amended par. (3) generally. Prior to amendment, text read as follows: ''For each of the fiscal years 2018 through 2022, there is authorized to be appropriated for fees under this section an amount equal to the total revenue amount specified under subsection (b)(3) for the fiscal year, as adjusted under subsection (c).''

2017—Subsec. (a)(1). Pub. L. 115–52, § 203(a)(1), substituted ''fiscal year 2018'' for ''fiscal year 2013''.

Subsec. (a)(2)(A). Pub. L. 115–52, § 203(f)(2)(B)(ii), substituted ''(d) and (e)'' for ''(d), (e), and (f)'' in introductory provisions.

Pub. L. 115–52, § 203(a)(2)(A)(i), substituted ''October 1, 2017'' for ''October 1, 2012'' in introductory provisions.

Subsec. (a)(2)(A)(viii). Pub. L. 115–52, § 203(a)(2)(A)(ii), substituted ''3.4 percent'' for ''2 percent''.

Subsec. (a)(2)(A)(xi). Pub. L. 115–52, § 203(a)(2)(A)(iii), added cl. (xi).

Subsec. (a)(2)(B)(v)(I). Pub. L. 115–52, § 203(a)(2)(B), substituted ''premarket notification submission, or de novo classification request'' for ''or premarket notification submission''.

Subsec. (a)(3)(A). Pub. L. 115–52, § 203(f)(2)(B)(iii), struck out ''and subsection (f)'' after ''subparagraph (B)''.

Subsec. (b). Pub. L. 115–52, §203(b), amended subsec. (b) generally. Prior to amendment, subsec. (b) listed fee amounts for fiscal years 2013 to 2017.

Subsec. (c)(1). Pub. L. 115–52, §203(c)(1), substituted ''2017'' for ''2012''.

Subsec. (c)(2)(A). Pub. L. 115–52, §203(c)(2)(A), substituted ''2018'' for ''2014''.

Subsec. (c)(2)(B). Pub. L. 115–52, §203(c)(2)(B), added subpar. (B) and struck out former subpar. (B). Prior to amendment, text read as follows: ''The applicable inflation adjustment for a fiscal year is—

''(i) for fiscal year 2014, the base inflation adjustment under subparagraph (C) for such fiscal year; and

''(ii) for fiscal year 2015 and each subsequent fiscal year, the product of—

''(I) the base inflation adjustment under subparagraph (C) for such fiscal year; and

''(II) the product of the base inflation adjustment under subparagraph (C) for each of the fiscal years preceding such fiscal year, beginning with fiscal year 2014.''

Subsec. (c)(2)(C). Pub. L. 115–52, §203(c)(2)(C), struck out ''to total revenue amounts'' after ''adjustment'' in heading.

Subsec. (c)(2)(D). Pub. L. 115–52, §203(c)(2)(D), amended subpar. (D) generally. Prior to amendment, text read as follows: ''For each of fiscal years 2014 through 2017, the base fee amounts specified in subsection (b)(2) shall be adjusted as needed, on a uniform proportionate basis, to generate the total revenue amounts under subsection (b)(3), as adjusted for inflation under subparagraph (A).''

Subsec. (c)(3). Pub. L. 115–52, §203(c)(3), substituted ''2018 through 2022'' for ''2014 through 2017'' and ''increased'' for ''further adjusted''.

Subsec. (d)(1). Pub. L. 115–52, §203(d)(1), substituted ''specified in clauses (i) through (vii) and clauses (ix), (x), and (xi)'' for ''specified in clauses (i) through (v) and clauses (vii), (ix), and (x)''.

Subsec. (d)(2)(C)(i). Pub. L. 115–52, §203(d)(2), substituted ''supplement,'' for ''supplement, or'' and inserted '', or a de novo classification request'' after ''class III device''.

Subsec. (e)(2)(C). Pub. L. 115–52, §203(e), substituted ''25 percent'' for ''50 percent''.

Subsec. (f). Pub. L. 115–52, §203(f)(1), (2)(B)(i), redesignated subsec. (g) as (f) and struck out former subsec. (f) which authorized the Secretary to grant waivers or reductions of fees under subsec. (a)(2) or (3) until Oct. 1, 2017.

Subsec. (f)(1). Pub. L. 115–52, §203(g), substituted ''periodic reporting concerning a class III device, or de novo classification request'' for ''or periodic reporting concerning a class III device'' and ''all such fees'' for ''all fees''.

Subsec. (g). Pub. L. 115–52, §203(f)(2)(B)(i), redesignated subsec. (h) as (g). Former subsec. (g) redesignated (f).

Subsec. (g)(1)(A). Pub. L. 115–52, §203(h), substituted ''$320,825,000'' for ''$280,587,000''.

Subsec. (h). Pub. L. 115–52, §203(f)(2)(B)(i), redesignated subsec. (i) as (h). Former subsec. (h) redesignated (g).

Subsec. (h)(3). Pub. L. 115–52, §203(i)(1), substituted ''2018 through 2022'' for ''2013 through 2017'' and ''subsection (c).'' for ''subsection (c) and, for fiscal year 2017 only, as further adjusted under paragraph (4).''

Pub. L. 115–52, §905(b)(2), as amended by Pub. L. 117–328, §3625(e)(1), added par. (3), effective Aug. 18, 2017. Subsec. (h) subsequently redesignated (g) effective Oct. 1, 2017, by Pub. L. 115–52, §203(f)(2)(B)(i). See Amendment note above.

Subsec. (h)(4). Pub. L. 115–52, §203(i)(2), struck out par. (4). Text read as follows: ''If the cumulative amount of fees collected during fiscal years 2013, 2014, and 2015, added to the amount estimated to be collected for fiscal year 2016, which estimate shall be based upon the amount of fees received by the Secretary through June 30, 2016, exceeds the cumulative amount appropriated pursuant to paragraph (3) for these four fiscal years, the excess shall be credited to the appropriation account of the Food and Drug Administration as provided in paragraph (1), and shall be subtracted from the amount of fees that would otherwise be authorized to be collected under this section pursuant to appropriation Acts for fiscal year 2017.''

Subsecs. (i) to (*l*). Pub. L. 115–52, §203(f)(2)(B)(i), redesignated subsecs. (j) to (*l*) as (i) to (k), respectively. Former subsec. (i) redesignated (h).

2012—Subsec. (a)(1). Pub. L. 112–144, §203(a)(1), substituted ''fiscal year 2013'' for ''fiscal year 2008''.

Subsec. (a)(2)(A). Pub. L. 112–144, §203(a)(2)(A), substituted ''subsections (d), (e), and (f)'' for ''subsections (d) and (e)'', ''October 1, 2012'' for ''October 1, 2002'', and ''subsection (c)'' for ''subsection (c)(1)'' in introductory provisions.

Subsec. (a)(2)(A)(viii). Pub. L. 112–144, §203(a)(2)(B), substituted ''2'' for ''1.84''.

Subsec. (a)(3)(A). Pub. L. 112–144, §203(a)(3)(A), inserted ''and subsection (f)'' after ''subparagraph (B)''.

Subsec. (a)(3)(C). Pub. L. 112–144, §203(a)(3)(B), substituted ''later of—'' for ''initial registration of the establishment or upon the annual registration under section 360 of this title.'' and added cls. (i) and (ii).

Subsec. (b). Pub. L. 112–144, §203(b), amended subsec. (b) generally. Prior to amendment, subsec. (b) listed fee amounts for fiscal years 2008 to 2012.

Subsec. (c). Pub. L. 112–144, §203(c), inserted ''; adjustments'' after ''setting'' in heading, added pars. (1) to (3), redesignated former pars. (3) and (4) as (4) and (5), respectively, and struck out former pars. (1) and (2) which related to annual publication and adjustment of fees.

Subsecs. (f) to (h). Pub. L. 112–144, §203(d), added subsec. (f) and redesignated former subsecs. (f) and (g) as (g) and (h), respectively. Former subsec. (h) redesignated (i).

Subsec. (h)(1)(A). Pub. L. 112–144, §203(e), substituted ''$280,587,000'' for ''$205,720,000''.

Subsec. (i). Pub. L. 112–144, §203(d)(1), redesignated subsec. (h) as (i). Former subsec. (i) redesignated (j).

Subsec. (i)(1). Pub. L. 112–144, §203(f)(1), substituted ''Subject to paragraph (2)(C), fees authorized'' for ''Fees authorized''.

Subsec. (i)(2)(A)(i). Pub. L. 112–144, §203(f)(2)(A)(i), substituted ''subject to subparagraph (C), shall be collected and available'' for ''shall be retained''.

Subsec. (i)(2)(A)(ii). Pub. L. 112–193 substituted ''shall be available'' for ''shall only be available''.

Pub. L. 112–144, §203(f)(2)(A)(ii), substituted ''shall only be available'' for ''shall only be collected and available'' and ''fiscal year 2009'' for ''fiscal year 2002''.

Subsec. (i)(2)(C). Pub. L. 112–144, §203(f)(2)(B), added subpar. (C).

Subsec. (i)(3). Pub. L. 112–144, §203(f)(3), amended par. (3) generally. Prior to amendment, par. (3) authorized appropriations for fiscal years 2008 to 2012.

Subsec. (i)(4). Pub. L. 112–144, §203(f)(4), substituted ''fiscal years 2013, 2014, and 2015'' for ''fiscal years 2008, 2009, and 2010'', ''fiscal year 2016'' for ''fiscal year 2011'', ''June 30, 2016'' for ''June 30, 2011'', ''the cumulative amount appropriated pursuant to'' for ''the amount of fees specified in aggregate in'', and ''fiscal year 2017'' for ''fiscal year 2012'' and struck out ''aggregate amount in'' before ''excess shall be credited''.

Subsecs. (j) to (*l*). Pub. L. 112–144, §203(d)(1), redesignated subsecs. (i) to (k) as (j) to (*l*), respectively.

2007—Subsec. (a)(1). Pub. L. 110–85, §212(a)(1)(A), substituted ''Beginning in fiscal year 2008'' for ''Beginning on October 26, 2002''.

Subsec. (a)(2). Pub. L. 110–85, §212(a)(1)(B), amended heading generally. Prior to amendment, heading read as follows: ''Premarket application, premarket report, supplement, and submission fee''.

Subsec. (a)(2)(A)(iii). Pub. L. 110–85, §212(a)(2)(A), substituted ''a fee equal to 75 percent of the fee that applies'' for ''a fee equal to the fee that applies''.

Subsec. (a)(2)(A)(iv). Pub. L. 110–85, §212(a)(2)(B), substituted ''15 percent'' for ''21.5 percent''.

Subsec. (a)(2)(A)(v). Pub. L. 110–85, §212(a)(2)(C), substituted ''7 percent'' for ''7.2 percent''.

Subsec. (a)(2)(A)(vi), (vii). Pub. L. 110–85, § 212(a)(2)(D), (E), added cl. (vi) and redesignated former cl. (vi) as (vii). Former cl. (vii) redesignated (viii).

Subsec. (a)(2)(A)(viii). Pub. L. 110–85, § 212(a)(2)(D), (F), redesignated cl. (vii) as (viii), substituted ''1.84 percent'' for ''1.42 percent'', and struck out '', subject to any adjustment under subsection (e)(2)(C)(ii) of this section'' before period at end.

Subsec. (a)(2)(A)(ix), (x). Pub. L. 110–85, § 212(a)(2)(G), added cls. (ix) and (x).

Subsec. (a)(2)(C). Pub. L. 110–85, § 212(a)(3), amended subpar. (C) generally. Prior to amendment, text read as follows: ''The fee required by subparagraph (A) shall be due upon submission of the premarket application, premarket report, supplement, or premarket notification submission except that invoices for applications submitted between October 1, 2002, and October 26, 2002, shall be payable on October 30, 2002. Applicants submitting portions of applications pursuant to section 360e(c)(3) of this title shall pay such fees upon submission of the first portion of such applications. The fees credited to fiscal year 2003 under this section shall include all fees payable from October 1, 2002, through September 30, 2003.''

Subsec. (a)(2)(D)(iii). Pub. L. 110–85, § 212(a)(4)(A), struck out at end ''The Secretary shall have sole discretion to refund a fee or portion of the fee under this subparagraph. A determination by the Secretary concerning a refund under this paragraph shall not be reviewable.''

Subsec. (a)(2)(D)(iv) to (vi). Pub. L. 110–85, § 212(a)(4)(B), added cls. (iv) to (vi).

Subsec. (a)(3). Pub. L. 110–85, § 212(a)(5), added par. (3).

Subsec. (b). Pub. L. 110–85, § 212(b), amended subsec. (b) generally. Prior to amendment, text read as follows: ''Except as provided in subsections (c), (d), (e), (g), and (h) of this section, the fees under subsection (a) of this section shall be established to generate the following revenue amounts: $25,125,000 in fiscal year 2003; $27,255,000 in fiscal year 2004; and $29,785,000 in fiscal year 2005. If legislation is enacted after October 26, 2002, requiring the Secretary to fund additional costs of the retirement of Federal personnel, fee revenue amounts under this subsection shall be increased in each year by the amount necessary to fully fund the portion of such additional costs that are attributable to the process for the review of device applications.''

Subsec. (c). Pub. L. 110–85, § 212(c)(1)(A), made technical amendment to heading.

Subsec. (c)(1). Pub. L. 110–85, § 212(c)(1)(B), struck out at end ''The fees established for fiscal year 2006 shall be based on a premarket application fee of $259,600, and the fees established for fiscal year 2007 shall be based on a premarket application fee of $281,600.''

Subsec. (c)(2), (3). Pub. L. 110–85, § 212(c)(2)(A), (B), added par. (2) and redesignated former par. (2) as (3). Former par. (3) redesignated (4).

Subsec. (c)(4). Pub. L. 110–85, § 212(c)(2)(A), (C), redesignated par. (3) as (4) and substituted in subpar. (A) ''The Secretary'' for ''For fiscal years 2006 and 2007, the Secretary'' and ''for the first month of the next fiscal year'' for ''for the first month of fiscal year 2008''.

Subsec. (d)(1). Pub. L. 110–85, § 212(d)(1), struck out '', partners, and parent firms'' after ''affiliates'' and substituted ''clauses (i) through (v) and clauses (vii), (ix), and (x) of subsection (a)(2)(A)'' for ''clauses (i) through (vi) of subsection (a)(2)(A) of this section''.

Subsec. (d)(2)(A). Pub. L. 110–85, § 212(d)(2)(A), struck out '', partners, and parent firms'' before period at end.

Subsec. (d)(2)(B). Pub. L. 110–85, § 212(d)(2)(B)(i), (ii), designated first sentence as cl. (i) and second to fourth sentences as cl. (ii) and inserted cl. headings.

Subsec. (d)(2)(B)(ii). Pub. L. 110–85, § 212(d)(2)(B)(iii), (iv), struck out '', partners, and parent firms'' after ''its affiliates'' and after ''such affiliates'' and substituted ''If no tax forms are submitted for any affiliate, the applicant shall certify that the applicant has no affiliates.'' for ''If no tax forms are submitted for affiliates, partners, or parent firms, the applicant shall certify that the applicant has no affiliates, partners, or parent firms, respectively.''

Subsec. (d)(2)(B)(iii). Pub. L. 110–85, § 212(d)(2)(B)(v), added cl. (iii).

Subsec. (d)(2)(C). Pub. L. 110–85, § 212(d)(3), amended subpar. (C) generally. Prior to amendment, text read as follows: ''Where the Secretary finds that the applicant involved meets the definition under subparagraph (A), the fees established under subsection (c)(1) of this section may be paid at a reduced rate of 38 percent of the fee established under such subsection for a premarket application, a premarket report, or a supplement.''

Subsec. (e)(1). Pub. L. 110–85, § 212(e)(1), substituted ''2008'' for ''2004'' and ''(a)(2)(A)(viii)'' for ''(a)(2)(A)(vii)''.

Subsec. (e)(2)(A). Pub. L. 110–85, § 212(e)(2)(A), struck out '', partners, and parent firms'' before period at end.

Subsec. (e)(2)(B). Pub. L. 110–85, § 212(e)(2)(B)(i), (ii), inserted cl. headings and designated first sentence as cl. (i) and second to fourth sentences as cl. (ii).

Subsec. (e)(2)(B)(ii). Pub. L. 110–85, § 212(e)(2)(B)(iii), (iv), struck out '', partners, and parent firms'' after ''its affiliates'' and after ''such affiliates'' and substituted ''If no tax forms are submitted for any affiliate, the applicant shall certify that the applicant has no affiliates.'' for ''If no tax forms are submitted for affiliates, partners, or parent firms, the applicant shall certify that the applicant has no affiliates, partners, or parent firms, respectively.''

Subsec. (e)(2)(B)(iii). Pub. L. 110–85, § 212(e)(2)(B)(v), added cl. (iii).

Subsec. (e)(2)(C). Pub. L. 110–85, § 212(e)(3), amended subpar. (C) generally. Prior to amendment, subpar. (C) contained provisions, for fiscal year 2004 and each subsequent fiscal year, authorizing in cl. (i) a reduced fee for a premarket notification submission, and directing in cl. (ii) the Secretary how to determine an adjustment per fee revenue amount.

Subsec. (f). Pub. L. 110–85, § 212(f), amended subsec. (f) generally. Prior to amendment, text read as follows: ''A premarket application, premarket report, supplement, or premarket notification submission submitted by a person subject to fees under subsection (a) of this section shall be considered incomplete and shall not be accepted by the Secretary until all fees owed by such person have been paid.''

Subsec. (g)(1). Pub. L. 110–85, § 212(g)(1), added par. (1) and struck out former par. (1). Prior to amendment, par. (1) related to performance goals for fiscal years 2003 through 2005, with respect to the amount appropriated under the salaries and expenses account of the Food and Drug Administration, for devices and radiological products, and termination of the program after fiscal year 2005.

Subsec. (g)(2). Pub. L. 110–85, § 212(g)(2), amended par. (2) generally. Prior to amendment, text read as follows: ''If the Secretary does not assess fees under subsection (a) of this section during any portion of a fiscal year because of subparagraph (C) or (D) of paragraph (1) and if at a later date in such fiscal year the Secretary may assess such fees, the Secretary may assess and collect such fees, without any modification in the rate for premarket applications, supplements, premarket reports, and premarket notification submissions, and at any time in such fiscal year, notwithstanding the provisions of subsection (a) of this section relating to the date fees are to be paid.''

Subsec. (h)(3). Pub. L. 110–85, § 212(h)(1), amended par. (3) generally, substituting provisions authorizing appropriations for fiscal years 2008 to 2012 for provisions authorizing appropriations for fiscal years 2003 to 2007.

Subsec. (h)(4). Pub. L. 110–85, § 212(h)(2), amended par. (4) generally. Prior to amendment, text read as follows: ''Any amount of fees collected for a fiscal year under this section that exceeds the amount of fees specified in appropriation Acts for such fiscal year shall be credited to the appropriation account of the Food and Drug Administration as provided in paragraph (1), and shall be subtracted from the amount of fees that would otherwise be authorized to be collected under this section pursuant to appropriation Acts for a subsequent fiscal year.''

2005—Subsec. (a)(2)(A). Pub. L. 109–43, §2(a)(7), substituted ''subsection (c)(1)'' for ''subsection (c)(5)''.

Subsec. (b). Pub. L. 109–43, §2(a)(1), inserted ''and'' after ''2004;'' and substituted ''2005'' for ''2005; $32,615,000 in fiscal year 2006, and $35,000,000 in fiscal year 2007''.

Subsec. (c). Pub. L. 109–43, §2(a)(2)(A), substituted ''Annual fee setting'' for ''Adjustments'' in heading.

Subsec. (c)(1). Pub. L. 109–43, §2(a)(2)(B)–(D), redesignated par. (5) as (1), substituted ''In general'' for ''Annual fee setting'' in heading, ''publish in the Federal Register fees under subsection (a) of this section. The fees'' for ''establish, for the next fiscal year, and publish in the Federal Register, fees under subsection (a) of this section, based on the revenue amounts established under subsection (b) of this section and the adjustment provided under this subsection and subsection (e)(2)(C)(ii) of this section, except that the fees'', ''2006'' for ''2003'', and ''$259,600, and the fees established for fiscal year 2007 shall be based on a premarket application fee of $281,600.'' for ''$154,000.'' in text, and struck out former par. (1) which required an annual inflation adjustment of the revenues established in subsec. (b).

Subsec. (c)(2). Pub. L. 109–43, §2(a)(2)(B), (C), redesignated par. (6) as (2) and struck out former par. (2) which required an annual adjustment of the fee revenues established in subsec. (b) to reflect changes in the workload of the Secretary for the process for the review of device applications.

Subsec. (c)(3). Pub. L. 109–43, §2(a)(2)(B), (E), added par. (3) and struck out former par. (3) which required an annual compensating adjustment of the fee revenues established in subsec. (b).

Subsec. (c)(4). Pub. L. 109–43, §2(a)(2)(B), struck out par. (4) which provided for a fiscal year 2007 adjustment of the fee revenues established in subsec. (b) to provide for operating reserves of carryover user fees.

Subsec. (c)(5), (6). Pub. L. 109–43, §2(a)(2)(C), redesignated pars. (5) and (6) as (1) and (2), respectively.

Subsec. (d)(1). Pub. L. 109–43, §2(a)(3)(A), inserted after first sentence ''For the purposes of this paragraph, the term 'small business' means an entity that reported $30,000,000 or less of gross receipts or sales in its most recent Federal income tax return for a taxable year, including such returns of all of its affiliates, partners, and parent firms.''

Subsec. (d)(2)(A). Pub. L. 109–43, §2(a)(3)(B), struck out cl. (i) designation and heading before ''For purposes'', substituted ''paragraph,'' for ''subsection,'' and ''$100,000,000'' for ''$30,000,000'', and struck out heading and text of clause (ii). Text read as follows: ''The Secretary may adjust the $30,000,000 threshold established in clause (i) if the Secretary has evidence from actual experience that this threshold results in a reduction in revenues from premarket applications, premarket reports, and supplements that is 16 percent or more than would occur without small business exemptions and lower fee rates. To adjust this threshold, the Secretary shall publish a notice in the Federal Register setting out the rationale for the adjustment, and the new threshold.''

Subsec. (d)(2)(C). Pub. L. 109–43, §2(a)(7), substituted ''subsection (c)(1)'' for ''subsection (c)(5)''.

Subsec. (e)(2)(A). Pub. L. 109–43, §2(a)(4), substituted ''$100,000,000'' for ''$30,000,000''.

Subsec. (e)(2)(C). Pub. L. 109–43, §2(a)(7), substituted ''subsection (c)(1)'' for ''subsection (c)(5)'' in cls. (i) and (ii).

Subsec. (g)(1)(B)(i). Pub. L. 109–43, §2(a)(5)(A)(i), added cl. (i) and struck out former cl. (i) which read as follows: ''For fiscal year 2005, the Secretary is expected to meet all of the performance goals identified for the fiscal year if the total of the amounts so appropriated for fiscal years 2003 through 2005, excluding the amount of fees appropriated for such fiscal years, is equal to or greater than the sum of—

''(I) $205,720,000 multiplied by the adjustment factor applicable to fiscal year 2003;

''(II) $205,720,000 multiplied by the adjustment factor applicable to fiscal year 2004; and

''(III) $205,720,000 multiplied by the adjustment factor applicable to fiscal year 2005.''

Subsec. (g)(1)(B)(ii). Pub. L. 109–43, §2(a)(5)(A)(ii), added introductory provisions and struck out former introductory provisions which read as follows: ''For fiscal year 2005, if the total of the amounts so appropriated for fiscal years 2003 through 2005, excluding the amount of fees appropriated for such fiscal years, is less than the sum that applies under clause (i) for fiscal year 2005, the following applies:''.

Subsec. (g)(1)(C). Pub. L. 109–43, §2(a)(5)(B)(i), substituted ''2005 and'' for ''2003 through'' and inserted ''more than 1 percent'' after ''years, is''.

Subsec. (g)(1)(C)(ii). Pub. L. 109–43, §2(a)(5)(B)(ii), substituted ''amount that applies'' for ''sum that applies''.

Subsec. (g)(1)(D)(i). Pub. L. 109–43, §2(a)(5)(C), inserted ''more than 1 percent'' after ''year, is''.

Subsec. (h)(3)(D), (E). Pub. L. 109–43, §2(a)(6), added subpar. (D) and struck out former subpars. (D) and (E) which read as follows:

''(D) $32,615,000 for fiscal year 2006; and

''(E) $35,000,000 for fiscal year 2007,''.

2004—Pub. L. 108–214, §2(d)(3)(A), made technical correction to directory language of Pub. L. 107–250, §102(a), which enacted this section.

Subsec. (a). Pub. L. 108–214, §2(d)(2)(A), designated introductory provisions of subsec. (a) as par. (1), inserted heading, substituted ''this section.'' for ''this section as follows:'', and redesignated former par. (1) as (2).

Subsec. (a)(1)(A). Pub. L. 108–214, §2(a)(2)(A)(i), substituted, in introductory provisions, ''subsections (d) and (e)'' for ''subsection (d)'', in cl. (iv), ''clause (i)'' for ''clause (i), subject to any adjustment under subsection (c)(3) of this section'', and, in cl. (vii), ''clause (i), subject to any adjustment under subsection (e)(2)(C)(ii)'' for ''clause (i), subject to any adjustment under subsection (c)(3) of this section and any adjustment under subsection (e)(2)(C)(ii)''.

Subsec. (a)(1)(D)(i), (ii). Pub. L. 108–214, §2(a)(2)(A)(ii), substituted ''application, report,'' for ''application''.

Subsec. (d)(1). Pub. L. 108–214, §2(d)(2)(B)(i), substituted ''subsection (a)(2)(A)'' for ''subsection (a)(1)(A)'' in last sentence.

Subsec. (d)(2)(B). Pub. L. 108–214, §2(a)(2)(B), substituted ''firms, which show'' for ''firms. which show'' in second sentence.

Subsec. (e)(1). Pub. L. 108–214, §2(a)(2)(C)(i), (d)(2)(B)(ii), substituted ''For fiscal year 2004 and each subsequent fiscal year, where'' for ''Where'' and ''subsection (a)(2)(A)(vii)'' for ''subsection (a)(1)(A)(vii)''.

Subsec. (e)(2)(B). Pub. L. 108–214, §2(a)(2)(C)(ii)(I), substituted ''firms, which show'' for ''firms. which show''.

Subsec. (e)(2)(C). Pub. L. 108–214, §2(a)(2)(C)(ii)(II), (d)(2)(B)(iii), substituted ''For fiscal year 2004 and each subsequent fiscal year, where'' for ''Where'' in cl. (i), ''subsection (a)(2)(A)(vii)'' for ''subsection (a)(1)(A)(vii)'' in cls. (i) and (ii), and ''subsection (a)(2)(A)(i)'' for ''subsection (a)(1)(A)(i)'' in cl. (ii).

Subsec. (f). Pub. L. 108–214, §2(a)(2)(D), struck out ''for filing'' after ''accepted''.

Subsec. (h)(2)(B). Pub. L. 108–214, §2(a)(2)(E), designated existing provisions as cl. (i), inserted heading, redesignated former cls. (i) and (ii) as subcls. (I) and (II), respectively, of cl. (i), redesignated former subcls. (I) and (II) of cl. (i) as items (aa) and (bb), respectively, of cl. (i)(II), and added cl. (ii).

Subsec. (j). Pub. L. 108–214, §2(d)(2)(B)(iv), substituted ''subsection (a)(2)(D)'' for ''subsection (a)(1)(D)''.

**Statutory Notes and Related Subsidiaries**

EFFECTIVE DATE OF 2022 AMENDMENT

Pub. L. 117–328, div. FF, title III, §3625(e)(2), Dec. 29, 2022, 136 Stat. 5882, provided that: ''The amendment made by paragraph (1) [amending this section] shall take effect as though included in the enactment of section 905 of the FDA Reauthorization Act of 2017 (Public Law 115–52) [Aug. 18, 2017].''

Amendments by Pub. L. 117–180 effective Oct. 1, 2022, with fees under this subpart to be assessed for all submissions listed in subsec. (a)(2)(A) of this section re-

ceived on or after Oct. 1, 2022, see section 2008 of Pub. L. 117–180, set out as a note under section 360d of this title.

EFFECTIVE DATE OF 2017 AMENDMENT

Amendment by section 203 of Pub. L. 115–52 effective Oct. 1, 2017, with fees under this subpart to be assessed for all submissions listed in subsec. (a)(2)(A) of this section received on or after Oct. 1, 2017, see section 209 of Pub. L. 115–52, set out as a note under section 379i of this title.

EFFECTIVE DATE OF 2012 AMENDMENT

Amendment by Pub. L. 112–144 effective Oct. 1, 2012, with fees under this subpart to be assessed for all submissions listed in subsection (a)(2)(A) of this section received on or after Oct. 1, 2012, see section 206 of Pub. L. 112–144, set out as a note under section 379i of this title.

EFFECTIVE DATE OF 2007 AMENDMENT

Amendment by Pub. L. 110–85 effective Oct. 1, 2007, except for certain premarket fees under this subpart, see section 216 of Pub. L. 110–85, set out as an Effective and Termination Dates of 2007 Amendment note under section 379i of this title.

EFFECTIVE AND TERMINATION DATES

Section ceases to be effective Oct. 1, 2027, see section 2007(a) of Pub. L. 117–180, set out as a note under section 379i of this title.

Section effective Oct. 26, 2002, except for certain premarket fees, see section 106 of Pub. L. 107–250, set out as a note under section 379i of this title.

FEE EXEMPTION FOR CERTAIN ENTITIES SUBMITTING PREMARKET REPORTS

Pub. L. 107–250, title I, §102(b), Oct. 26, 2002, 116 Stat. 1600, as amended by Pub. L. 108–214, §2(d)(2)(C), (3)(B), Apr. 1, 2004, 118 Stat. 577, provided that: ''A person submitting a premarket report to the Secretary of Health and Human Services is exempt from the fee under section 738(a)(2)(A)(ii) of the Federal Food, Drug, and Cosmetic Act [21 U.S.C. 379j(a)(2)(A)(ii)] (as added by subsection (a) of this section) if—

''(1) the premarket report is the first such report submitted to the Secretary by the person; and

''(2) before October 1, 2002, the person submitted a premarket application to the Secretary for the same device as the device for which the person is submitting the premarket report.''

## § 379j–1. Reauthorization; reporting requirements

### (a) Reports

#### (1) Performance report

##### (A) In general

###### (i) General requirements

Beginning with fiscal year 2023, for each fiscal year for which fees are collected under this subpart, the Secretary shall prepare and submit to the Committee on Health, Education, Labor, and Pensions of the Senate and the Committee on Energy and Commerce of the House of Representatives annual reports concerning the progress of the Food and Drug Administration in achieving the goals identified in the letters described in section 201(b)[1] of the Medical Device User Fee Amendments of 2022 during such fiscal year and the future plans of the Food and Drug Administration for meeting the goals.

###### (ii) Additional information

Beginning with fiscal year 2023, the annual report under this subparagraph shall include the progress of the Center for Devices and Radiological Health in achieving the goals, and future plans for meeting the goals, including—

(I) the number of premarket applications filed under section 360e of this title per fiscal year for each review division;

(II) the number of reports submitted under section 360(k) of this title per fiscal year for each review division;

(III) the number of expedited development and priority review designations under section 360e–3[1] of this title per fiscal year;

(IV) the number of investigational device exemption applications submitted under section 360j(g) of this title per fiscal year, including for each review division; and

(V) the number of expedited development and priority review requests and designations under section 360e–3 of this title per fiscal year, including for each review division.

Nothing in this clause shall be construed to authorize the disclosure of information that is prohibited from disclosure under section 331(j) of this title or section 1905 of title 18 or that is subject to withholding under section 552(b)(4) of title 5.

###### (iii) Real time reporting

###### (I) In general

Not later than 30 calendar days after the end of the second quarter of fiscal year 2023, and not later than 30 calendar days after the end of each quarter of each fiscal year thereafter, the Secretary shall post the data described in subclause (II) on the internet website of the Food and Drug Administration for such quarter and on a cumulative basis for such fiscal year, and may remove duplicative data from the annual report under this subparagraph.

###### (II) Data

The Secretary shall post the following data in accordance with subclause (I):

(aa) The number and titles of draft and final guidance on topics related to the process for the review of devices, and whether such guidances were issued as required by statute or pursuant to the letters described in section 201(b)[1] of the Medical Device User Fee Amendments of 2022; and

(bb) The number and titles of public meetings held on topics related to the process for the review of devices, and if such meetings were required by statute or pursuant to a commitment under the letters described in section 201(b)[1] of the Medical Device User Fee Amendments of 2022.

[1] See References in Text note below.