

try; 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 2013, 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), (e), and (f) of this section, each person who submits any of the following, on or after October 1, 2012, shall be subject to a fee established under subsection (c) of this section 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 75 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 2 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).

(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, pre-

market report, supplement, or premarket notification submission 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, or premarket notification submission 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 report 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, or periodic reporting concerning a class III device. 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) and subsection (f), 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

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 Act¹ [25 U.S.C. 450 et seq.]), unless a device manufactured by the establishment is to be distributed commercially.

(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), (f), and (i), for each of fiscal years 2013 through 2017, 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 2013	Fiscal Year 2014	Fiscal Year 2015	Fiscal Year 2016	Fiscal Year 2017
Premarket Application	\$248,000	\$252,960	\$258,019	\$263,180	\$268,443
Establishment Registration	\$2,575	\$3,200	\$3,750	\$3,872	\$3,872

(3) Total revenue amounts specified

For purposes of paragraph (1), the total revenue amounts specified in this paragraph are as follows:

- (A) \$97,722,301 for fiscal year 2013.
- (B) \$112,580,497 for fiscal year 2014.
- (C) \$125,767,107 for fiscal year 2015.
- (D) \$129,339,949 for fiscal year 2016.
- (E) \$130,184,348 for fiscal year 2017.

(c) Annual fee setting; adjustments

(1) In general

The Secretary shall, 60 days before the start of each fiscal year after September 30, 2012, 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 2014 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 to total revenue amounts

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.

¹ See References in Text note below.

(C) Base inflation adjustment to total revenue amounts**(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-Baltimore, DC-MD-VA-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 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).

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

For each of fiscal years 2014 through 2017, 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 further adjusted, 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) 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.

(5) 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 sub-

paragraph (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) of this section 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 (v) and clauses (vii), (ix), and (x) 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 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, or periodic reporting concerning a class III device; 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) of this section. 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) of this section 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 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 50 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 in-

formation to the Secretary at least 60 days before the fee is required pursuant to subsection (a) of this section. The decision of the Secretary regarding whether an entity qualifies for such a reduction is not reviewable.

(f) Fee waiver or reduction

(1) In general

The Secretary may, at the Secretary's sole discretion, grant a waiver or reduction of fees under subsection (a)(2) or (a)(3) if the Secretary finds that such waiver or reduction is in the interest of public health.

(2) Limitation

The sum of all fee waivers or reductions granted by the Secretary in any fiscal year under paragraph (1) shall not exceed 2 percent of the total fee revenue amounts established for such year under subsection (c).

(3) Duration

The authority provided by this subsection terminates October 1, 2017.

(g) 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, or periodic reporting concerning a class III device 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 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.

(h) 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 \$280,587,000 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, 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.

(i) Crediting and availability of fees

(1) In general

Subject to paragraph (2)(C), fees authorized under subsection (a) of this section 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 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.

(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 for the process for the review of device applications—

(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) Authorizations of appropriations

For each of the fiscal years 2013 through 2017, 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) and, for fiscal year 2017 only, as further adjusted under paragraph (4).

(4) Offset

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.

(j) Collection of unpaid fees

In any case where the Secretary does not receive payment of a fee assessed under subsection (a) of this section 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.

(k) Written requests for refunds

To qualify for consideration for a refund under subsection (a)(2)(D) of this section, a person shall submit to the Secretary a written request for such refund not later than 180 days after such fee is due.

(l) 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.)

TERMINATION OF SECTION

For termination of section by section 207(a) of Pub. L. 112-144, see Effective and Termination Dates note below.

REFERENCES IN TEXT

The Indian Self Determination and Educational Assistance Act, referred to in subsec. (a)(3)(B), 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 subchapter II (§450 et seq.) of chapter 14 of Title 25, Indians. For complete classification of this Act to the Code, see Short Title note set out under section 450 of Title 25 and Tables.

AMENDMENTS

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 provi-

sions 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)”.

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, 2017, see section 207(a) of Pub. L. 112-144, 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

Beginning with fiscal year 2013, 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) of the Medical Device User Fee Amendments of 2012 during such fiscal year and the future plans of the Food and Drug Administration for meeting the goals.

(B) Publication

With regard to information to be reported by the Food and Drug Administration to industry on a quarterly and annual basis pursuant to the letters described in section 201(b) of the Medical Device User Fee Amendments Act of 2012, the Secretary shall make such information publicly available on the Internet Web site of the Food and Drug Administration not later than 60 days after the end of each quarter or 120 days after the end of each fiscal year, respectively, to

which such information applies. This information shall include the status of the independent assessment identified in the letters described in such section 201(b).

(C) Updates

The Secretary shall include in each report under subparagraph (A) information on all previous cohorts for which the Secretary has not given a complete response on all device premarket applications and reports, supplements, and premarket notifications in the cohort.

(2) Fiscal report

For fiscal years 2013 through 2017, not later than 120 days after the end of each fiscal year during 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, a report on the implementation of the authority for such fees during such fiscal year and the use, by the Food and Drug Administration, of the fees collected during such fiscal year for which the report is made.

(3) Public availability

The Secretary shall make the reports required under paragraphs (1) and (2) available to the public on the Internet Web site of the Food and Drug Administration.

(b) Reauthorization

(1) Consultation

In developing recommendations to present to Congress with respect to the goals, and plans for meeting the goals, for the process for the review of device applications for the first 5 fiscal years after fiscal year 2017, and for the reauthorization of this subpart for such fiscal years, the Secretary shall consult with—

- (A) the Committee on Energy and Commerce of the House of Representatives;
- (B) the Committee on Health, Education, Labor, and Pensions of the Senate;
- (C) scientific and academic experts;
- (D) health care professionals;
- (E) representatives of patient and consumer advocacy groups; and
- (F) the regulated industry.

(2) Prior public input

Prior to beginning negotiations with the regulated industry on the reauthorization of this subpart, the Secretary shall—

- (A) publish a notice in the Federal Register requesting public input on the reauthorization;
- (B) hold a public meeting at which the public may present its views on the reauthorization, including specific suggestions for changes to the goals referred to in subsection (a)(1);
- (C) provide a period of 30 days after the public meeting to obtain written comments from the public suggesting changes to this subpart; and
- (D) publish the comments on the Food and Drug Administration's Internet Web site.