enacting section 379j–1 of this title and amending this section and section 379j of this title] shall take effect on October 1, 2007, or the date of the enactment of this Act [Sept. 27, 2007], whichever is later, except that fees under part 3 of subchapter C of chapter VII of the Federal Food, Drug, and Cosmetic Act [this subpart] shall be assessed for all premarket applications, premarket reports, supplements, 30-day notices, and premarket notification submissions received on or after October 1, 2007, regardless of the date of the enactment of this Act.''

Pub. L. 110–85, title II, § 217, Sept. 27, 2007, 121 Stat. 852, provided that: ''The amendments made by this subtitle [subtitle A (§§ 211–217) of title II of Pub. L. 110–85, enacting section 379j–1 of this title and amending this section and section 379j of this title] cease to be effective October 1, 2012, except that section 738A of the Federal Food, Drug, and Cosmetic Act [21 U.S.C. 379j–1] (regarding annual performance and financial reports) ceases to be effective January 31, 2013.''

EFFECTIVE AND TERMINATION DATES

Pub. L. 107–250, title I, § 106, Oct. 26, 2002, 116 Stat. 1602, provided that: ''The amendments made by this title [enacting this subpart] shall take effect on the date of the enactment of this Act [Oct. 26, 2002], except that fees shall be assessed for all premarket applications, premarket reports, supplements, and premarket notification submissions received on or after October 1, 2002, regardless of the date of enactment.''

Pub. L. 107–250, title I, § 107, Oct. 26, 2002, 116 Stat. 1602, provided that: ''The amendments made by this title [enacting this subpart] cease to be effective October 1, 2007, except that section 103 [set out as a note below] with respect to annual reports ceases to be effective January 31, 2008.''

SAVINGS PROVISION

Pub. L. 110–85, title II, § 214, Sept. 27, 2007, 121 Stat. 852, provided that: ''Notwithstanding section 107 of the Medical Device User Fee and Modernization Act of 2002 (Public Law 107–250) [set out as an Effective and Termination Dates note above], and notwithstanding the amendments made by this subtitle [subtitle A (§§ 211–217) of title II of Pub. L. 110–85, enacting section 379j–1 of this title and amending this section and section 379j of this title], part 3 of subchapter C of chapter VII of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 379i et seq.), as in effect on the day before the date of the enactment of this subtitle [Sept. 27, 2007], shall continue to be in effect with respect to premarket applications, premarket reports, premarket notification submissions, and supplements (as defined in such part as of such day) that on or after October 1, 2002, but before October 1, 2007, were accepted by the Food and Drug Administration for filing with respect to assessing and collecting any fee required by such part for a fiscal year prior to fiscal year 2008.''

FINDINGS

Pub. L. 110–85, title II, § 201(c), Sept. 27, 2007, 121 Stat. 842, provided that: ''The Congress finds that the fees authorized under the amendments made by this title [enacting section 379j–1 of this title and amending this section and sections 333, 360, 360i, 360m, 374, and 379j of this title] will be dedicated toward expediting the process for the review of device applications and for assuring the safety and effectiveness of devices, as set forth in the goals identified for purposes of part 3 of subchapter C of chapter VII of the Federal Food, Drug, and Cosmetic Act [this subpart] in the letters from the Secretary of Health and Human Services to the Chairman of the Committee on Health, Education, Labor, and Pensions of the Senate and the Chairman of the Committee on Energy and Commerce of the House of Representatives, as set forth in the Congressional Record.''

Pub. L. 107–250, title I, § 101, Oct. 26, 2002, 116 Stat. 1589, provided that: ''The Congress finds that—

''(1) prompt approval and clearance of safe and effective devices is critical to the improvement of the public health so that patients may enjoy the benefits of devices to diagnose, treat, and prevent disease;

''(2) the public health will be served by making additional funds available for the purpose of augmenting the resources of the Food and Drug Administration that are devoted to the process for the review of devices and the assurance of device safety and effectiveness so that statutorily mandated deadlines may be met; and

''(3) the fees authorized by this title [enacting this subpart and provisions set out as notes under this section and section 379j of this title] will be dedicated to meeting the goals identified in the letters from the Secretary of Health and Human Services to the Committee on Energy and Commerce of the House of Representatives and the Committee on Health, Education, Labor, and Pensions of the Senate, as set forth in the Congressional Record.''

ANNUAL REPORTS

Pub. L. 107–250, title I, § 103, Oct. 26, 2002, 116 Stat. 1600, as amended by Pub. L. 109–43, § 2(b), Aug. 1, 2005, 119 Stat. 441, which directed the Secretary of Health and Human Services to submit annual reports to Congress on progress in achieving goals identified in section 101(3), set out above, and implementation of authority for and use of fees collected under the medical device user-fee program established under this subpart, ceased to be effective Jan. 31, 2008. See Effective and Termination Dates note above.

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 2008, 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) of this section, each person who submits any of the following, on or after October 1, 2002, shall be subject to a fee established under subsection (c)(1) 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 1.84 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, premarket 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), 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 Act[1] [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 initial registration of the establishment or upon the annual registration under section 360 of this title.

(b) Fee amounts

Except as provided in subsections (c), (d), (e), and (h) the fees under subsection (a) shall be based on the following fee amounts:

Fee Type	Fiscal Year 2008	Fiscal Year 2009	Fiscal Year 2010	Fiscal Year 2011	Fiscal Year 2012
Premarket Application	$185,000	$200,725	$217,787	$236,298	$256,384
Establishment Registration	$1,706	$1,851	$2,008	$2,179	$2,364.

(c) Annual fee setting

(1) In general

The Secretary shall, 60 days before the start of each fiscal year after September 30, 2002, publish in the Federal Register fees under subsection (a) of this section.

(2) Adjustment

(A) In general

When setting fees for fiscal year 2010, the Secretary may increase the fee under subsection (a)(3)(A) (applicable to establishments subject to registration) only if the Secretary estimates that the number of establishments submitting fees for fiscal year 2009 is fewer than 12,250. The percentage increase shall be the percentage by which the estimate of establishments submitting fees in fiscal year 2009 is fewer than 12,750, but in no case may the percentage increase be more than 8.5 percent over that specified in subsection (b) for fiscal year 2010. If the Secretary makes any adjustment to the fee under subsection (a)(3)(A) for fiscal year 2010, then such fee for fiscal years 2011 and 2012 shall be adjusted so that such fee for fiscal year 2011 is equal to the adjusted fee for fiscal year 2010 increased by 8.5 percent, and such fee for fiscal year 2012 is equal to the adjusted fee for fiscal year 2011 increased by 8.5 percent.

(B) Publication

For any adjustment made under subparagraph (A), the Secretary shall publish in the Federal Register the Secretary's determination to make the adjustment and the rationale for the determination.

(3) 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.

(4) 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) 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, re-

[1] See References in Text note below.

spectively, 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 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 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, 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.

(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 $205,720,000 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.

(h) Crediting and availability of fees

(1) In general

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) shall be retained 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 only be collected and 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 2002 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.

(3) Authorizations of appropriations

There are authorized to be appropriated for fees under this section—

(A) $48,431,000 for fiscal year 2008;
(B) $52,547,000 for fiscal year 2009;
(C) $57,014,000 for fiscal year 2010;
(D) $61,860,000 for fiscal year 2011; and
(E) $67,118,000 for fiscal year 2012.

(4) Offset

If the cumulative amount of fees collected during fiscal years 2008, 2009, and 2010, added to the amount estimated to be collected for fiscal year 2011, which estimate shall be based upon the amount of fees received by the Secretary through June 30, 2011, exceeds the amount of fees specified in aggregate in paragraph (3) for these four fiscal years, the aggregate amount in 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 2012.

(i) 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.

(j) 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.

(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.)

AMENDMENT OF SECTION

For termination of amendment by section 217 of Pub. L. 110–85, see Effective and Termination Dates of 2007 Amendment note below.

TERMINATION OF SECTION

For termination of section by section 107 of Pub. L. 107–250, see Effective and Termination Dates note set out under section 379i of this title.

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

2007—Subsec. (a)(1). Pub. L. 110–85, §§ 212(a)(1)(A), 217, temporarily substituted ''Beginning in fiscal year 2008'' for ''Beginning on October 26, 2002''. See Effective and Termination Dates of 2007 Amendment note below.

Subsec. (a)(2). Pub. L. 110–85, §§ 212(a)(1)(B), 217, temporarily amended heading generally. Prior to amendment, heading read as follows: ''Premarket application, premarket report, supplement, and submission fee''. See Effective and Termination Dates of 2007 Amendment note below.

Subsec. (a)(2)(A)(iii). Pub. L. 110–85, §§ 212(a)(2)(A), 217, temporarily substituted ''a fee equal to 75 percent of the fee that applies'' for ''a fee equal to the fee that applies''. See Effective and Termination Dates of 2007 Amendment note below.

Subsec. (a)(2)(A)(iv). Pub. L. 110–85, §§ 212(a)(2)(B), 217, temporarily substituted ''15 percent'' for ''21.5 percent''. See Effective and Termination Dates of 2007 Amendment note below.

Subsec. (a)(2)(A)(v). Pub. L. 110–85, §§ 212(a)(2)(C), 217, temporarily substituted ''7 percent'' for ''7.2 percent''.

See Effective and Termination Dates of 2007 Amendment note below.

Subsec. (a)(2)(A)(vi), (vii). Pub. L. 110–85, §§ 212(a)(2)(D), (E), 217, temporarily added cl. (vi) and redesignated former cl. (vi) as (vii). Former cl. (vii) redesignated (viii). See Effective and Termination Dates of 2007 Amendment note below.

Subsec. (a)(2)(A)(viii). Pub. L. 110–85, §§ 212(a)(2)(D), (F), 217, temporarily 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. See Effective and Termination Dates of 2007 Amendment note below.

Subsec. (a)(2)(A)(ix), (x). Pub. L. 110–85, §§ 212(a)(2)(G), 217, temporarily added cls. (ix) and (x). See Effective and Termination Dates of 2007 Amendment note below.

Subsec. (a)(2)(C). Pub. L. 110–85, §§ 212(a)(3), 217, temporarily 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.'' See Effective and Termination Dates of 2007 Amendment note below.

Subsec. (a)(2)(D)(iii). Pub. L. 110–85, §§ 212(a)(4)(A), 217, temporarily 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.'' See Effective and Termination Dates of 2007 Amendment note below.

Subsec. (a)(2)(D)(iv) to (vi). Pub. L. 110–85, §§ 212(a)(4)(B), 217, temporarily added cls. (iv) to (vi). See Effective and Termination Dates of 2007 Amendment note below.

Subsec. (a)(3). Pub. L. 110–85, §§ 212(a)(5), 217, temporarily added par. (3). See Effective and Termination Dates of 2007 Amendment note below.

Subsec. (b). Pub. L. 110–85, §§ 212(b), 217, temporarily 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.'' See Effective and Termination Dates of 2007 Amendment note below.

Subsec. (c). Pub. L. 110–85, §§ 212(c)(1)(A), 217, temporarily made technical amendment to heading. See Effective and Termination Dates of 2007 Amendment note below.

Subsec. (c)(1). Pub. L. 110–85, §§ 212(c)(1)(B), 217, temporarily 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.''. See Effective and Termination Dates of 2007 Amendment note below.

Subsec. (c)(2), (3). Pub. L. 110–85, §§ 212(c)(2)(A), (B), 217, temporarily added par. (2) and redesignated former par. (2) as (3). Former par. (3) redesignated (4). See Effective and Termination Dates of 2007 Amendment note below.

Subsec. (c)(4). Pub. L. 110–85, §§ 212(c)(2)(A), (C), 217, temporarily 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''. See Effective and Termination Dates of 2007 Amendment note below.

Subsec. (d)(1). Pub. L. 110–85, §§ 212(d)(1), 217, temporarily 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''. See Effective and Termination Dates of 2007 Amendment note below.

Subsec. (d)(2)(A). Pub. L. 110–85, §§ 212(d)(2)(A), 217, temporarily struck out '', partners, and parent firms'' before period at end. See Effective and Termination Dates of 2007 Amendment note below.

Subsec. (d)(2)(B). Pub. L. 110–85, §§ 212(d)(2)(B)(i), (ii), 217, temporarily designated first sentence as cl. (i) and second to fourth sentences as cl. (ii) and inserted cl. headings. See Effective and Termination Dates of 2007 Amendment note below.

Subsec. (d)(2)(B)(ii). Pub. L. 110–85, §§ 212(d)(2)(B)(iii), (iv), 217, temporarily 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.'' See Effective and Termination Dates of 2007 Amendment note below.

Subsec. (d)(2)(B)(iii). Pub. L. 110–85, §§ 212(d)(2)(B)(v), 217, temporarily added cl. (iii). See Effective and Termination Dates of 2007 Amendment note below.

Subsec. (d)(2)(C). Pub. L. 110–85, §§ 212(d)(3), 217, temporarily 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.'' See Effective and Termination Dates of 2007 Amendment note below.

Subsec. (e)(1). Pub. L. 110–85, §§ 212(e)(1), 217, temporarily substituted ''2008'' for ''2004'' and ''(a)(2)(A)(viii)'' for ''(a)(2)(A)(vii)''. See Effective and Termination Dates of 2007 Amendment note below.

Subsec. (e)(2)(A). Pub. L. 110–85, §§ 212(e)(2)(A), 217, temporarily struck out '', partners, and parent firms'' before period at end. See Effective and Termination Dates of 2007 Amendment note below.

Subsec. (e)(2)(B). Pub. L. 110–85, §§ 212(e)(2)(B)(i), (ii), 217, temporarily inserted cl. headings and designated first sentence as cl. (i) and second to fourth sentences as cl. (ii). See Effective and Termination Dates of 2007 Amendment below.

Subsec. (e)(2)(B)(ii). Pub. L. 110–85, §§ 212(e)(2)(B)(iii), (iv), 217, temporarily 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.'' See Effective and Termination Dates of 2007 Amendment note below.

Subsec. (e)(2)(B)(iii). Pub. L. 110–85, §§ 212(e)(2)(B)(v), 217, temporarily added cl. (iii). See Effective and Termination Dates of 2007 Amendment note below.

Subsec. (e)(2)(C). Pub. L. 110–85, §§ 212(e)(3), 217, temporarily 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. See Effective and Termination Dates of 2007 Amendment note below.

Subsec. (f). Pub. L. 110–85, §§ 212(f), 217, temporarily 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.'' See Effective and Termination Dates of 2007 Amendment note below.

Subsec. (g)(1). Pub. L. 110–85, §§212(g)(1), 217, temporarily 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. See Effective and Termination Dates of 2007 Amendment note below.

Subsec. (g)(2). Pub. L. 110–85, §§212(g)(2), 217, temporarily 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.'' See Effective and Termination Dates of 2007 Amendment note below.

Subsec. (h)(3). Pub. L. 110–85, §§212(h)(1), 217, temporarily amended par. (3) generally, substituting provisions authorizing appropriations for fiscal years 2008 to 2012 for provisions authorizing appropriations for fiscal years 2003 to 2007. See Effective and Termination Dates of 2007 Amendment note below.

Subsec. (h)(4). Pub. L. 110–85, §§212(h)(2), 217, temporarily 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.'' See Effective and Termination Dates of 2007 Amendment note below.

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 AND TERMINATION DATES OF 2007 AMENDMENT

Amendment by Pub. L. 110–85 effective Oct. 1, 2007, except for certain premarket fees under this subpart, and ceases to be effective Oct. 1, 2012, see sections 216 and 217 of Pub. L. 110–85, set out as notes under section 379i of this title.

EFFECTIVE AND TERMINATION DATES

Section effective Oct. 26, 2002, except for certain premarket fees, and ceases to be effective Oct. 1, 2007, see sections 106 and 107 of Pub. L. 107–250, set out as notes 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

For fiscal years 2008 through 2012, 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 concerning the progress of the Food and Drug Administration in achieving the goals identified in the letters described in section 201(c) of the Food and Drug Administration Amendments Act of 2007 during such fiscal year and the future plans of the Food and Drug Administration for meeting the goals. The report for a fiscal year shall include 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 2008 through 2012, 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 2012, 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.