

(D) hold a meeting at which the public may present its views on such recommendations; and

(E) after consideration of such public views and comments, revise such recommendations as necessary.

**(5) Transmittal of recommendations**

Not later than January 15, 2013, the Secretary shall transmit to Congress the revised recommendations under paragraph (4), a summary of the views and comments received under such paragraph, and any changes made to the recommendations in response to such views and comments.

**(6) Minutes of negotiation meetings**

**(A) Public availability**

Before presenting the recommendations developed under paragraphs (1) through (5) to Congress, the Secretary shall make publicly available, on the Internet Web site of the Food and Drug Administration, minutes of all negotiation meetings conducted under this subsection between the Food and Drug Administration and the regulated industry.

**(B) Content**

The minutes described under subparagraph (A) shall summarize any substantive proposal made by any party to the negotiations as well as significant controversies or differences of opinion during the negotiations and their resolution.

(June 25, 1938, ch. 675, §742, as added Pub. L. 110-316, title II, §203, Aug. 14, 2008, 122 Stat. 3522.)

TERMINATION OF SECTION

*For termination of section by section 204(b) of Pub. L. 110-316, see Termination Date note below.*

REFERENCES IN TEXT

Section 201(3) of the Animal Generic Drug User Fee Act of 2008, referred to in subsec. (a), probably means section 201(b)(3) of Pub. L. 110-316, which is set out as a note under section 379j-21 of this title.

PRIOR PROVISIONS

A prior section 742 of act June 25, 1938, was renumbered section 746 and is classified to section 379l of this title.

TERMINATION DATE

Pub. L. 110-316, title II, §204(b), Aug. 14, 2008, 122 Stat. 3524, provided that: "The amendment made by section 203 [enacting this section] shall cease to be effective January 31, 2014."

SUBPART 6—FEES RELATED TO FOOD

**§ 379j-31. Authority to collect and use fees**

**(a) In general**

**(1) Purpose and authority**

For fiscal year 2010 and each subsequent fiscal year, the Secretary shall, in accordance with this section, assess and collect fees from—

(A) the responsible party for each domestic facility (as defined in section 350d(b) of this title) and the United States agent for each foreign facility subject to a reinspection in

such fiscal year, to cover reinspection-related costs for such year;

(B) the responsible party for a domestic facility (as defined in section 350d(b) of this title) and an importer who does not comply with a recall order under section 350l of this title or under section 350a(f) of this title in such fiscal year, to cover food recall activities associated with such order performed by the Secretary, including technical assistance, follow-up effectiveness checks, and public notifications, for such year;

(C) each importer participating in the voluntary qualified importer program under section 384b of this title in such year, to cover the administrative costs of such program for such year; and

(D) each importer subject to a reinspection in such fiscal year, to cover reinspection-related costs for such year.

**(2) Definitions**

For purposes of this section—

(A) the term "reinspection" means—

(i) with respect to domestic facilities (as defined in section 350d(b) of this title), 1 or more inspections conducted under section 374 of this title subsequent to an inspection conducted under such provision which identified noncompliance materially related to a food safety requirement of this chapter, specifically to determine whether compliance has been achieved to the Secretary's satisfaction; and

(ii) with respect to importers, 1 or more examinations conducted under section 381 of this title subsequent to an examination conducted under such provision which identified noncompliance materially related to a food safety requirement of this chapter, specifically to determine whether compliance has been achieved to the Secretary's satisfaction;

(B) the term "reinspection-related costs" means all expenses, including administrative expenses, incurred in connection with—

(i) arranging, conducting, and evaluating the results of reinspections; and

(ii) assessing and collecting reinspection fees under this section; and

(C) the term "responsible party" has the meaning given such term in section 350f(a)(1) of this title.

**(b) Establishment of fees**

**(1) In general**

Subject to subsections (c) and (d), the Secretary shall establish the fees to be collected under this section for each fiscal year specified in subsection (a)(1), based on the methodology described under paragraph (2), and shall publish such fees in a Federal Register notice not later than 60 days before the start of each such year.

**(2) Fee methodology**

**(A) Fees**

Fees amounts established for collection—

(i) under subparagraph (A) of subsection (a)(1) for a fiscal year shall be based on the

Secretary's estimate of 100 percent of the costs of the reinspection-related activities (including by type or level of reinspection activity, as the Secretary determines applicable) described in such subparagraph (A) for such year;

(ii) under subparagraph (B) of subsection (a)(1) for a fiscal year shall be based on the Secretary's estimate of 100 percent of the costs of the activities described in such subparagraph (B) for such year;

(iii) under subparagraph (C) of subsection (a)(1) for a fiscal year shall be based on the Secretary's estimate of 100 percent of the costs of the activities described in such subparagraph (C) for such year; and

(iv) under subparagraph (D) of subsection (a)(1) for a fiscal year shall be based on the Secretary's estimate of 100 percent of the costs of the activities described in such subparagraph (D) for such year.

**(B) Other considerations**

**(i) Voluntary qualified importer program**

In establishing the fee amounts under subparagraph (A)(iii) for a fiscal year, the Secretary shall provide for the number of importers who have submitted to the Secretary a notice under section 384b(c) of this title informing the Secretary of the intent of such importer to participate in the program under section 384b of this title in such fiscal year.

**(II)<sup>1</sup> Recoupment**

In establishing the fee amounts under subparagraph (A)(iii) for the first 5 fiscal years after January 4, 2011, the Secretary shall include in such fee a reasonable surcharge that provides a recoupment of the costs expended by the Secretary to establish and implement the first year of the program under section 384b of this title.

**(ii) Crediting of fees**

In establishing the fee amounts under subparagraph (A) for a fiscal year, the Secretary shall provide for the crediting of fees from the previous year to the next year if the Secretary overestimated the amount of fees needed to carry out such activities, and consider the need to account for any adjustment of fees and such other factors as the Secretary determines appropriate.

**(iii) Published guidelines**

Not later than 180 days after January 4, 2011, the Secretary shall publish in the Federal Register a proposed set of guidelines in consideration of the burden of fee amounts on small business. Such consideration may include reduced fee amounts for small businesses. The Secretary shall provide for a period of public comment on such guidelines. The Secretary shall adjust the fee schedule for small businesses subject to such fees only through notice and comment rulemaking.

**(3) Use of fees**

The Secretary shall make all of the fees collected pursuant to clause<sup>2</sup> (i), (ii), (iii), and (iv) of paragraph (2)(A) available solely to pay for the costs referred to in such clause (i), (ii), (iii), and (iv) of paragraph (2)(A), respectively.

**(c) Limitations**

**(1) In general**

Fees under subsection (a) shall be refunded for a fiscal year beginning after fiscal year 2010 unless the amount of the total appropriations for food safety activities at the Food and Drug Administration for such fiscal year (excluding the amount of fees appropriated for such fiscal year) is equal to or greater than the amount of appropriations for food safety activities at the Food and Drug Administration for fiscal year 2009 (excluding the amount of fees appropriated for such fiscal year), multiplied by the adjustment factor under paragraph (3).

**(2) Authority**

If—

(A) the Secretary does not assess fees under subsection (a) for a portion of a fiscal year because paragraph (1) applies; and

(B) at a later date in such fiscal year, such paragraph (1) ceases to apply,

the Secretary may assess and collect such fees under subsection (a), without any modification to the rate of such fees, notwithstanding the provisions of subsection (a) relating to the date fees are to be paid.

**(3) Adjustment factor**

**(A) In general**

The adjustment factor described in paragraph (1) shall be the total percentage change that occurred in the Consumer Price Index for all urban consumers (all items; United States city average) for the 12-month period ending June 30 preceding the fiscal year, but in no case shall such adjustment factor be negative.

**(B) Compounded basis**

The adjustment under subparagraph (A) made each fiscal year shall be added on a compounded basis to the sum of all adjustments made each fiscal year after fiscal year 2009.

**(4) Limitation on amount of certain fees**

**(A) In general**

Notwithstanding any other provision of this section and subject to subparagraph (B), the Secretary may not collect fees in a fiscal year such that the amount collected—

(i) under subparagraph (B) of subsection (a)(1) exceeds \$20,000,000; and

(ii) under subparagraphs (A) and (D) of subsection (a)(1) exceeds \$25,000,000 combined.

**(B) Exception**

If a domestic facility (as defined in section 350d(b) of this title) or an importer becomes

<sup>1</sup> So in original. No subcl. (I) has been enacted.

<sup>2</sup> So in original. Probably should be "clauses".

subject to a fee described in subparagraph (A), (B), or (D) of subsection (a)(1) after the maximum amount of fees has been collected by the Secretary under subparagraph (A), the Secretary may collect a fee from such facility or importer.

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

Fees authorized under subsection (a) shall be collected and available for obligation only to the extent and in the amount provided in appropriations Acts. Such fees are authorized to remain available until expended. Such sums as may be necessary may be transferred from the Food and Drug Administration salaries and expenses 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 purpose of paying the operating expenses of the Food and Drug Administration employees and contractors performing activities associated with these food safety fees.

**(e) Collection of fees**

**(1) In general**

The Secretary shall specify in the Federal Register notice described in subsection (b)(1) the time and manner in which fees assessed under this section shall be collected.

**(2) Collection of unpaid fees**

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

**(f) Annual report to Congress**

Not later than 120 days after each fiscal year for which fees are assessed under this section, the Secretary shall submit a report to the Committee on Health, Education, Labor, and Pensions of the Senate and the Committee on Energy and Commerce of the House of Representatives, to include a description of fees assessed and collected for each such year and a summary description of the entities paying such fees and the types of business in which such entities engage.

**(g) Authorization of appropriations**

For fiscal year 2010 and each fiscal year thereafter, there is authorized to be appropriated for fees under this section an amount equal to the total revenue amount determined under subsection (b) for the fiscal year, as adjusted or otherwise affected under the other provisions of this section.

(June 25, 1938, ch. 675, §743, as added Pub. L. 111-353, title I, §107(a), Jan. 4, 2011, 124 Stat. 3906.)

CONSTRUCTION

Nothing in this section to be construed to apply to certain alcohol-related facilities, to alter jurisdiction and authorities established under certain other Acts, or in a manner inconsistent with international agreements to which the United States is a party, see sections 2206, 2251, and 2252 of this title.

PART D—INFORMATION AND EDUCATION

**§ 379k. Information system**

The Secretary shall establish and maintain an information system to track the status and progress of each application or submission (including a petition, notification, or other similar form of request) submitted to the Food and Drug Administration requesting agency action.

(June 25, 1938, ch. 675, §745, formerly §741, as added Pub. L. 105-115, title IV, §407(a), Nov. 21, 1997, 111 Stat. 2370; renumbered §745, Pub. L. 110-316, title II, §202(a), Aug. 14, 2008, 122 Stat. 3515.)

AMENDMENT OF SECTION

*For termination of amendment renumbering this section by section 204(a) of Pub. L. 110-316, see Termination Date of 2008 Amendment note below.*

TERMINATION DATE OF 2008 AMENDMENT

Amendment by Pub. L. 110-316 to cease to be effective Oct. 1, 2013, see section 204(a) of Pub. L. 110-316, set out as a Termination Date note under section 379j-21 of this title.

EFFECTIVE DATE

Section effective 90 days after Nov. 21, 1997, except as otherwise provided, see section 501 of Pub. L. 105-115, set out as an Effective Date of 1997 Amendment note under section 321 of this title.

REPORT ON STATUS OF SYSTEM

Section 407(b) of Pub. L. 105-115 provided that not later than 1 year after Nov. 21, 1997, Secretary of Health and Human Services was to submit report to Congress on status of system to be established under this section, including projected costs of system and concerns about confidentiality.

**§ 379l. Education**

**(a) In general**

The Secretary shall conduct training and education programs for the employees of the Food and Drug Administration relating to the regulatory responsibilities and policies established by this chapter, including programs for—

- (1) scientific training;
- (2) training to improve the skill of officers and employees authorized to conduct inspections under section 374 of this title;
- (3) training to achieve product specialization in such inspections; and
- (4) training in administrative process and procedure and integrity issues.

**(b) Intramural fellowships and other training programs**

The Secretary, acting through the Commissioner, may, through fellowships and other training programs, conduct and support intramural research training for predoctoral and postdoctoral scientists and physicians. Any such fellowships and training programs under this section or under section 379dd(d)(2)(A)(ix) of this title may include provision by such scientists and physicians of services on a voluntary and uncompensated basis, as the Secretary determines appropriate. Such scientists and physicians shall be subject to all legal and ethical requirements otherwise applicable to officers or