(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; amended Pub. L. 113–14, title II, § 203, June 13, 2013, 127 Stat. 472; Pub. L. 115–234, title II, § 203, Aug. 14, 2018, 132 Stat. 2435; Pub. L. 118–15, div. B, title III, § 2313, Sept. 30, 2023, 137 Stat. 93.)

TERMINATION OF SECTION

For termination of section by section 2316(b) of Pub. L. 118–15, see Termination Date note below.

Editorial Notes

REFERENCES IN TEXT

Section 201(b) of the Animal Generic Drug User Fee Amendments of 2023, referred to in subsec. (a), probably should be a reference to section 2311(b) of the Animal Generic Drug User Fee Amendments of 2023, chapter 2 of subtitle A of title III of div. B of Pub. L. 118–15, which is set out as a note under section 379j–21 of this title. The Animal Generic Drug User Fee Amendments of 2023 does not contain a section 201(b).

PRIOR PROVISIONS

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

AMENDMENTS

2023—Subsec. (a). Pub. L. 118–15, § 2313(1), (2), substituted ''2024'' for ''2019'' and ''2023'' for ''2018''.

Subsec. (b). Pub. L. 118–15, § 2313(2), substituted ''2024'' for ''2019''.

Subsec. (d)(1), (5). Pub. L. 118–15, § 2313(3), substituted ''2028'' for ''2023''.

2018—Subsec. (a). Pub. L. 115–234, § 203(1), (3), substituted ''2019'' for ''2014'' and ''2018'' for ''2013''.

Subsec. (b). Pub. L. 115–234, § 203(2), (3), substituted ''2019'' for ''2014'' and ''to the Committee on Health, Education, Labor and Pensions'' for ''to Committee on Health, Education, Labor, and Pensions''.

Subsec. (d)(1), (5). Pub. L. 115–234, § 203(4), substituted ''2023'' for ''2018''.

2013—Pub. L. 113–14 amended section generally. Prior to amendment, section related to reauthorization of this subpart and reporting requirements.

Statutory Notes and Related Subsidiaries

EFFECTIVE DATE OF 2023 AMENDMENT

Amendment by Pub. L. 118–15 effective Oct. 1, 2023, and fees under part 5 of subchapter C of chapter VII of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 379j–21 et seq.), as amended, to be assessed for abbreviated applications for a generic new animal drug and supplemental abbreviated applications for a generic new animal drug received on or after Oct. 1, 2023, see section 2315 of Pub. L. 118–15, set out as a note under section 379j–21 of this title.

EFFECTIVE DATE OF 2018 AMENDMENT

Amendment by Pub. L. 115–234 effective on Oct. 1, 2018, and fees under part 5 of subchapter C of chapter VII of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 379j–21 et seq.), as amended, to be assessed for abbreviated applications for a generic new animal drug and supplemental abbreviated applications for a generic new animal drug received on or after Oct. 1, 2018, see section 205 of Pub. L. 115–234, set out as a note under section 379j–21 of this title.

EFFECTIVE DATE OF 2013 AMENDMENT

Amendment by Pub. L. 113–14 effective Oct. 1, 2013, see section 205 of Pub. L. 113–14, set out as a note under section 379j–21 of this title.

TERMINATION DATE

Pub. L. 118–15, div. B, title III, § 2316(b), Sept. 30, 2023, 137 Stat. 94, provided that: ''Section 742 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 379j–22) shall cease to be effective January 31, 2029.''

Pub. L. 115–234, title II, § 206(b), Aug. 14, 2018, 132 Stat. 2435, which provided that section 742 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 379j–22) would cease to be effective Jan. 31, 2024, was repealed by Pub. L. 118–15, div. B, title III, § 2316(c), Sept. 30, 2023, 137 Stat. 94, effective Oct. 1, 2023.

Pub. L. 113–14, title II, § 206(b), June 13, 2013, 127 Stat. 474, which provided that section 742 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 379j–22) would cease to be effective Jan. 31, 2019, was repealed by Pub. L. 115–234, title II, § 206(c), Aug. 14, 2018, 132 Stat. 2435, effective Oct. 1, 2018.

Pub. L. 110–316, title II, § 204(b), Aug. 14, 2008, 122 Stat. 3524, which provided that the amendment made by section 203 of Pub. L. 110–316 (enacting this section) would cease to be effective Jan. 31, 2014, was repealed by Pub. L. 113–14, title II, § 206(c)(1), June 13, 2013, 127 Stat. 474.

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)[1] 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)[1] of this title) and an importer who does not comply with a recall order under section 350*l* 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

[1] See References in Text note below.

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)[1] 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)[2] 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[3] (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 appropria-

[2] So in original. No subcl. (I) has been enacted.

[3] So in original. Probably should be ''clauses''.

tions 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)[1] of this title) or an importer becomes 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.)

Editorial Notes

REFERENCES IN TEXT

Section 350d(b) of this title, referred to in subsecs. (a)(1)(A), (B), (2)(A)(i) and (c)(4)(B), was redesignated section 350d(c) by Pub. L. 111–353, title I, § 102(b)(1)(B), Jan. 4, 2011, 124 Stat. 3887.

Statutory Notes and Related Subsidiaries

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.

SUBPART 7—FEES RELATING TO GENERIC DRUGS

§ 379j–41. Definitions

For purposes of this subpart:

(1) The term ''abbreviated new drug application''—