

Food, Drug, and Cosmetic Act (21 U.S.C. 379j-22) would cease to be effective Jan. 31, 2019, was repealed by Pub.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 L. 110-316 (enacting this section) would cease to be effective Jan. 31, 2014, was repealed by Pub.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)<sup>1</sup> 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)<sup>1</sup> of this title) and an importer who does not comply with a recall order under section 350i 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)<sup>1</sup> 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>2</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.

<sup>1</sup> See References in Text note below.

<sup>2</sup> So in original. No subcl. (I) has been enacted.

**(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>3</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)<sup>1</sup> 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

<sup>3</sup> So in original. Probably should be "clauses".

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”—

(A) means an application submitted under section 355(j) of this title, an abbreviated application submitted under section 357 of this title (as in effect on the day before November 21, 1997), or an abbreviated new drug application submitted pursuant to regulations in effect prior to the implementation of the Drug Price Competition and Patent Term Restoration Act of 1984; and

(B) does not include an application—

(i) for a positron emission tomography drug; or

(ii) submitted by a State or Federal governmental entity for a drug that is not distributed commercially.

(2) The term “active pharmaceutical ingredient” means—

(A) a substance, or a mixture when the substance is unstable or cannot be transported on its own, intended—

(i) to be used as a component of a drug; and

(ii) to furnish pharmacological activity or other direct effect in the diagnosis, cure, mitigation, treatment, or prevention of disease, or to affect the structure or any function of the human body; or

(B) a substance intended for final crystallization, purification, or salt formation, or any combination of those activities, to

become a substance or mixture described in subparagraph (A).

(3) The term “adjustment factor” means a factor applicable to a fiscal year that is the Consumer Price Index for all urban consumers (all items; United States city average) for October of the preceding fiscal year divided by such Index for October 2011.

(4) The term “affiliate” means a business entity that has a relationship with a second business entity if, directly or indirectly—

(A) one business entity controls, or has the power to control, the other business entity; or

(B) a third party controls, or has power to control, both of the business entities.

(5) The term “contract manufacturing organization facility” means a manufacturing facility of a finished dosage form of a drug approved pursuant to an abbreviated new drug application, where such manufacturing facility is not identified in an approved abbreviated new drug application held by the owner of such facility or an affiliate of such owner or facility.

(6)(A) The term “facility”—

(i) means a business or other entity—

(I) under one management, either direct or indirect; and

(II) at one geographic location or address engaged in manufacturing or processing an active pharmaceutical ingredient or a finished dosage form; and

(ii) does not include a business or other entity whose only manufacturing or processing activities are one or more of the following: repackaging, relabeling, or testing.

(B) For purposes of subparagraph (A), separate buildings within close proximity are considered to be at one geographic location or address if the activities in them are—

(i) closely related to the same business enterprise;

(ii) under the supervision of the same local management; and

(iii) capable of being inspected by the Food and Drug Administration during a single inspection.

(C) If a business or other entity would meet the definition of a facility under this paragraph but for being under multiple management, the business or other entity is deemed to constitute multiple facilities, one per management entity, for purposes of this paragraph.

(7) The term “finished dosage form” means—

(A) a drug product in the form in which it will be administered to a patient, such as a tablet, capsule, solution, or topical application;

(B) a drug product in a form in which reconstitution is necessary prior to administration to a patient, such as oral suspensions or lyophilized powders; or

(C) any combination of an active pharmaceutical ingredient with another component of a drug product for purposes of production of a drug product described in subparagraph (A) or (B).