(A) provide for the crediting of fees from the previous year to the next year if the Secretary overestimated the amount of the small business adjustment factor for such previous fiscal year; and

(B) consider the need to account for any adjustment of fees and such other factors as the Secretary determines appropriate.

(d) Use of fees

The Secretary shall make all of the fees collected pursuant to subparagraphs (A) and (B) of subsection (a)(1) available solely to pay for the costs of oversight of outsourcing facilities.

(e) Supplement not supplant

Funds received by the Secretary pursuant to this section shall be used to supplement and not supplant any other Federal funds available to carry out the activities described in this section.

(f) Crediting and availability of fees

Fees authorized under this section shall be collected and available for obligation only to the extent and in the amount provided in advance 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 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 purpose of paying the costs of oversight of outsourcing facilities.

(g) Collection of fees

(1) Establishment fee

An outsourcing facility shall remit the establishment fee due under this section in a fiscal year when submitting a registration pursuant to section 353b(b) of this title for such fiscal year.

(2) Reinspection fee

The Secretary shall specify in the Federal Register notice described in subsection (b)(2) the manner in which reinspection fees assessed under this section shall be collected and the timeline for payment of such fees. Such a fee shall be collected after the Secretary has conducted a reinspection of the outsourcing facility involved.

(3) Effect of failure to pay fees

(A) Registration

An outsourcing facility shall not be considered registered under section 353b(b) of this title in a fiscal year until the date that the outsourcing facility remits the establishment fee under this subsection for such fiscal year.

(B) Misbranding

All drugs manufactured, prepared, propagated, compounded, or processed by an outsourcing facility for which any establishment fee or reinspection fee has not been paid, as required by this section, shall be deemed misbranded under section 352 of this title until the fees owed for such outsourcing facility under this section have been paid.

(4) Collection of unpaid fees

In any case where the Secretary does not receive payment of a fee assessed under this section within 30 calendar 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.

(h) Annual report to Congress

Not later than 120 calendar days after each fiscal year in which fees are assessed and collected 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 such year, a summary description of entities paying the fees, a description of the hiring and placement of new staff, a description of the use of fee resources to support inspecting outsourcing facilities, and the number of inspections and reinspections of such facilities performed each year.

(i) Authorization of appropriations

For fiscal year 2014 and each subsequent fiscal year, there is authorized to be appropriated for fees under this section an amount equivalent to the total amount of fees assessed for such fiscal year under this section.

(June 25, 1938, ch. 675, § 744K, as added Pub. L. 113–54, title I, § 102(b), Nov. 27, 2013, 127 Stat. 594.)

SUBPART 10—FEES RELATING TO OVER-THE-COUNTER DRUGS

§ 379j–71. Definitions

In this subpart:

(1) 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.

(2) The term ''contract manufacturing organization facility'' means an OTC monograph drug facility where neither the owner of such manufacturing facility nor any affiliate of such owner or facility sells the OTC monograph drug produced at such facility directly to wholesalers, retailers, or consumers in the United States.

(3) The term ''costs of resources allocated for OTC monograph drug activities'' means the expenses in connection with OTC monograph drug activities for—

(A) officers and employees of the Food and Drug Administration, contractors of the Food and Drug Administration, advisory committees, and costs related to such officers, employees, and committees and costs related to contracts with such contractors;

(B) management of information, and the acquisition, maintenance, and repair of computer resources;

(C) leasing, maintenance, renovation, and repair of facilities and acquisition, maintenance, and repair of fixtures, furniture, sci-

entific equipment, and other necessary materials and supplies; and

(D) collecting fees under section 379j–72 of this title and accounting for resources allocated for OTC monograph drug activities.

(4) The term ''FDA establishment identifier'' is the unique number automatically generated by Food and Drug Administration's Field Accomplishments and Compliance Tracking System (FACTS) (or any successor system).

(5) The term ''OTC monograph drug'' means a nonprescription drug without an approved new drug application which is governed by the provisions of section 355h of this title.

(6) The term ''OTC monograph drug activities'' means activities of the Secretary associated with OTC monograph drugs and inspection of facilities associated with such products, including the following activities:

(A) The activities necessary for review and evaluation of OTC monographs and OTC monograph order requests, including—

(i) orders proposing or finalizing applicable conditions of use for OTC monograph drugs;

(ii) orders affecting status regarding general recognition of safety and effectiveness of an OTC monograph ingredient or combination of ingredients under specified conditions of use;

(iii) all OTC monograph drug development and review activities, including intra-agency collaboration;

(iv) regulation and policy development activities related to OTC monograph drugs;

(v) development of product standards for products subject to review and evaluation;

(vi) meetings referred to in section 355h(i) of this title;

(vii) review of labeling prior to issuance of orders related to OTC monograph drugs or conditions of use; and

(viii) regulatory science activities related to OTC monograph drugs.

(B) Inspections related to OTC monograph drugs.

(C) Monitoring of clinical and other research conducted in connection with OTC monograph drugs.

(D) Safety activities with respect to OTC monograph drugs, including—

(i) collecting, developing, and reviewing safety information on OTC monograph drugs, including adverse event reports;

(ii) developing and using improved adverse event data-collection systems, including information technology systems; and

(iii) developing and using improved analytical tools to assess potential safety risks, including access to external databases.

(E) Other activities necessary for implementation of section 355h of this title.

(7) The term ''OTC monograph order request'' means a request for an order submitted under section 355h(b)(5) of this title.

(8) The term ''Tier 1 OTC monograph order request'' means any OTC monograph order request not determined to be a Tier 2 OTC monograph order request.

(9)(A) The term ''Tier 2 OTC monograph order request'' means, subject to subparagraph (B), an OTC monograph order request for—

(i) the reordering of existing information in the drug facts label of an OTC monograph drug;

(ii) the addition of information to the other information section of the drug facts label of an OTC monograph drug, as limited by section 201.66(c)(7) of title 21, Code of Federal Regulations (or any successor regulations);

(iii) modification to the directions for use section of the drug facts label of an OTC monograph drug, if such changes conform to changes made pursuant to section 355h(c)(3)(A) of this title;

(iv) the standardization of the concentration or dose of a specific finalized ingredient within a particular finalized monograph;

(v) a change to ingredient nomenclature to align with nomenclature of a standards-setting organization; or

(vi) addition of an interchangeable term in accordance with section 330.1 of title 21, Code of Federal Regulations (or any successor regulations).

(B) The Secretary may, based on program implementation experience or other factors found appropriate by the Secretary, characterize any OTC monograph order request as a Tier 2 OTC monograph order request (including recharacterizing a request from Tier 1 to Tier 2) and publish such determination in a proposed order issued pursuant to section 355h of this title.

(10)(A) The term ''OTC monograph drug facility'' means a foreign or domestic business or other entity that—

(i) is—

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

(II) at one geographic location or address engaged in manufacturing or processing the finished dosage form of an OTC monograph drug;

(ii) includes a finished dosage form manufacturer facility in a contractual relationship with the sponsor of one or more OTC monograph drugs to manufacture or process such drugs; and

(iii) does not include a business or other entity whose only manufacturing or processing activities are one or more of the following: production of clinical research supplies, testing, or placement of outer packaging on packages containing multiple products, for such purposes as creating multipacks, when each monograph drug product contained within the overpackaging is already in a final packaged form prior to placement in the outer overpackaging.

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

(i) closely related to the same business enterprise;

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

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

(C) If a business or other entity would meet criteria specified in subparagraph (A), 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.

(11) The term ''OTC monograph drug meeting'' means any meeting regarding the content of a proposed OTC monograph order request.

(12) The term ''person'' includes an affiliate of a person.

(13) The terms ''requestor'' and ''sponsor'' have the meanings given such terms in section 355h of this title.

(June 25, 1938, ch. 675, § 744L, as added Pub. L. 116–136, div. A, title III, § 3862, Mar. 27, 2020, 134 Stat. 459.)

Statutory Notes and Related Subsidiaries

FINDING

Pub. L. 116–136, div. A, title III, § 3861, Mar. 27, 2020, 134 Stat. 458, provided that: ''The Congress finds that the fees authorized by the amendments made in this part [part II of subtitle F of title III of div. A of Pub. L. 116–136, enacting this subpart] will be dedicated to OTC monograph drug activities, as set forth in the goals identified for purposes of part 10 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.''

§ 379j–72. Authority to assess and use OTC monograph fees

(a) Types of fees

Beginning with fiscal year 2021, the Secretary shall assess and collect fees in accordance with this section as follows:

(1) Facility fee

(A) In general

Each person that owns a facility identified as an OTC monograph drug facility on December 31 of the fiscal year or at any time during the preceding 12-month period shall be assessed an annual fee for each such facility as determined under subsection (c).

(B) Exceptions

(i) Facilities that cease activities

A fee shall not be assessed under subparagraph (A) if the identified OTC monograph drug facility—

(I) has ceased all activities related to OTC monograph drugs prior to December 31 of the year immediately preceding the applicable fiscal year; and

(II) has updated its registration to reflect such change under the requirements for drug establishment registration set forth in section 360 of this title.

(ii) Contract manufacturing organizations

The amount of the fee for a contract manufacturing organization facility shall be equal to two-thirds of the amount of the fee for an OTC monograph drug facility that is not a contract manufacturing organization facility.

(C) Amount

The amount of fees established under subparagraph (A) shall be established under subsection (c).

(D) Due date

(i) For first program year

For fiscal year 2021, the facility fees required under subparagraph (A) shall be due on the later of—

(I) the first business day of July of 2020; or

(II) 45 calendar days after publication of the Federal Register notice provided for under subsection (c)(4)(A).

(ii) Subsequent fiscal years

For each fiscal year after fiscal year 2021, the facility fees required under subparagraph (A) shall be due on the later of—

(I) the first business day of June of such year; or

(II) the first business day after the enactment of an appropriations Act providing for the collection and obligation of fees under this section for such year.

(2) OTC monograph order request fee

(A) In general

Each person that submits an OTC monograph order request shall be subject to a fee for an OTC monograph order request. The amount of such fee shall be—

(i) for a Tier 1 OTC monograph order request, $500,000, adjusted for inflation for the fiscal year (as determined under subsection (c)(1)(B)); and

(ii) for a Tier 2 OTC monograph order request, $100,000, adjusted for inflation for the fiscal year (as determined under subsection (c)(1)(B)).

(B) Due date

The OTC monograph order request fees required under subparagraph (A) shall be due on the date of submission of the OTC monograph order request.

(C) Exception for certain safety changes

A person who is named as the requestor in an OTC monograph order shall not be subject to a fee under subparagraph (A) if the Secretary finds that the OTC monograph order request seeks to change the drug facts labeling of an OTC monograph drug in a way that would add to or strengthen—

(i) a contraindication, warning, or precaution;

(ii) a statement about risk associated with misuse or abuse; or

(iii) an instruction about dosage and administration that is intended to increase the safe use of the OTC monograph drug.