(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.

(D) Refund of fee if order request is recategorized as a Tier 2 OTC monograph order request

If the Secretary determines that an OTC monograph request initially characterized as Tier 1 shall be re-characterized as a Tier 2 OTC monograph order request, and the requestor has paid a Tier 1 fee in accordance with subparagraph (A)(i), the Secretary shall refund the requestor the difference between the Tier 1 and Tier 2 fees determined under subparagraphs (A)(i) and (A)(ii), respectively.

(E) Refund of fee if order request refused for filing or withdrawn before filing

The Secretary shall refund 75 percent of the fee paid under subparagraph (B) for any order request which is refused for filing or was withdrawn before being accepted or refused for filing.

(F) Fees for order requests previously refused for filing or withdrawn before filing

An OTC monograph order request that was submitted but was refused for filing, or was withdrawn before being accepted or refused for filing, shall be subject to the full fee under subparagraph (A) upon being resubmitted or filed over protest.

(G) Refund of fee if order request withdrawn

If an order request is withdrawn after the order request was filed, the Secretary may refund the fee or a portion of the fee if no substantial work was performed on the order request after the application was filed. The Secretary shall have the sole discretion to refund a fee or a portion of the fee under this subparagraph. A determination by the Secretary concerning a refund under this subparagraph shall not be reviewable.

(3) Refunds

(A) In general

Other than refunds provided pursuant to any of subparagraphs (D) through (G) of paragraph (2), the Secretary shall not refund any fee paid under paragraph (1) except as provided in subparagraph (B).

(B) Disputes concerning fees

To qualify for the return of a fee claimed to have been paid in error under paragraph (1) or (2), a person shall submit to the Secretary a written request justifying such return within 180 calendar days after such fee was paid.

(4) Notice

Within the timeframe specified in subsection (c), the Secretary shall publish in the Federal Register the amount of the fees under paragraph (1) for such fiscal year.

(b) Fee revenue amounts

(1) Fiscal year 2021

For fiscal year 2021, fees under subsection (a)(1) shall be established to generate a total facility fee revenue amount equal to the sum of—

(A) the annual base revenue for fiscal year 2021 (as determined under paragraph (3));

(B) the dollar amount equal to the operating reserve adjustment for the fiscal year, if applicable (as determined under subsection (c)(2)); and

(C) additional direct cost adjustments (as determined under subsection (c)(3)).

(2) Subsequent fiscal years

For each of the fiscal years 2022 through 2025, fees under subsection (a)(1) shall be established to generate a total facility fee revenue amount equal to the sum of—

(A) the annual base revenue for the fiscal year (as determined under paragraph (3));

(B) the dollar amount equal to the inflation adjustment for the fiscal year (as determined under subsection (c)(1));

(C) the dollar amount equal to the operating reserve adjustment for the fiscal year, if applicable (as determined under subsection (c)(2));

(D) additional direct cost adjustments (as determined under subsection (c)(3)); and

(E) additional dollar amounts for each fiscal year as follows:

(i) $7,000,000 for fiscal year 2022.

(ii) $6,000,000 for fiscal year 2023.

(iii) $7,000,000 for fiscal year 2024.

(iv) $3,000,000 for fiscal year 2025.

(3) Annual base revenue

For purposes of paragraphs (1)(A) and (2)(A), the dollar amount of the annual base revenue for a fiscal year shall be—

(A) for fiscal year 2021, $8,000,000; and

(B) for fiscal years 2022 through 2025, the dollar amount of the total revenue amount established under this subsection for the previous fiscal year, not including any adjustments made under subsection (c)(2) or (c)(3).

(c) Adjustments; annual fee setting

(1) Inflation adjustment

(A) In general

For purposes of subsection (b)(2)(B), the dollar amount of the inflation adjustment to the annual base revenue for fiscal year 2022 and each subsequent fiscal year shall be equal to the product of—

(i) such annual base revenue for the fiscal year under subsection (b)(2); and

(ii) the inflation adjustment percentage under subparagraph (C).

(B) OTC monograph order request fees

For purposes of subsection (a)(2), the dollar amount of the inflation adjustment to the fee for OTC monograph order requests for fiscal year 2022 and each subsequent fiscal year shall be equal to the product of—

(i) the applicable fee under subsection (a)(2) for the preceding fiscal year; and

(ii) the inflation adjustment percentage under subparagraph (C).

(C) Inflation adjustment percentage

The inflation adjustment percentage under this subparagraph for a fiscal year is equal to—

(i) for each of fiscal years 2022 and 2023, the average annual percent change that occurred in the Consumer Price Index for urban consumers (Washington-Baltimore, DC–MD–VA–WV; Not Seasonally Adjusted; All items; Annual Index) for the first 3 years of the preceding 4 years of available data; and

(ii) for each of fiscal years 2024 and 2025, the sum of—

(I) the average annual percent change in the cost, per full-time equivalent position of the Food and Drug Administration, of all personnel compensation and benefits paid with respect to such positions for the first 3 years of the preceding 4 fiscal years, multiplied by the proportion of personnel compensation and benefits costs to total costs of OTC monograph drug activities for the first 3 years of the preceding 4 fiscal years; and

(II) the average annual percent change that occurred in the Consumer Price Index for urban consumers (Washington-Baltimore, DC–MD–VA–WV; Not Seasonally Adjusted; All items; Annual Index) for the first 3 years of the preceding 4 years of available data multiplied by the proportion of all costs other than personnel compensation and benefits costs to total costs of OTC monograph drug activities for the first 3 years of the preceding 4 fiscal years.

(2) Operating reserve adjustment

(A) In general

For fiscal year 2021 and subsequent fiscal years, for purposes of subsections (b)(1)(B) and (b)(2)(C), the Secretary may, in addition to adjustments under paragraph (1), further increase the fee revenue and fees if such an adjustment is necessary to provide operating reserves of carryover user fees for OTC monograph drug activities for not more than the number of weeks specified in subparagraph (B).

(B) Number of weeks

The number of weeks specified in this subparagraph is—

(i) 3 weeks for fiscal year 2021;
(ii) 7 weeks for fiscal year 2022;
(iii) 10 weeks for fiscal year 2023;
(iv) 10 weeks for fiscal year 2024; and
(v) 10 weeks for fiscal year 2025.

(C) Decrease

If the Secretary has carryover balances for such process in excess of 10 weeks of the operating reserves referred to in subparagraph (A), the Secretary shall decrease the fee revenue and fees referred to in such subparagraph to provide for not more than 10 weeks of such operating reserves.

(D) Rationale for adjustment

If an adjustment under this paragraph is made, the rationale for the amount of the increase or decrease (as applicable) in fee revenue and fees shall be contained in the annual Federal Register notice under paragraph (4) establishing fee revenue and fees for the fiscal year involved.

(3) Additional direct cost adjustment

The Secretary shall, in addition to adjustments under paragraphs (1) and (2), further increase the fee revenue and fees for purposes of subsection (b)(2)(D) by an amount equal to—

(A) $14,000,000 for fiscal year 2021;
(B) $7,000,000 for fiscal year 2022;
(C) $4,000,000 for fiscal year 2023;
(D) $3,000,000 for fiscal year 2024; and
(E) $3,000,000 for fiscal year 2025.

(4) Annual fee setting

(A) Fiscal year 2021

The Secretary shall, not later than the second Monday in May of 2020—

(i) establish OTC monograph drug facility fees for fiscal year 2021 under subsection (a), based on the revenue amount for such year under subsection (b) and the adjustments provided under this subsection; and

(ii) publish fee revenue, facility fees, and OTC monograph order requests in the Federal Register.

(B) Subsequent fiscal years

The Secretary shall, for each fiscal year that begins after September 30, 2021, not later than the second Monday in March that precedes such fiscal year—

(i) establish for such fiscal year, based on the revenue amounts under subsection (b) and the adjustments provided under this subsection—

(I) OTC monograph drug facility fees under subsection (a)(1); and

(II) OTC monograph order request fees under subsection (a)(2); and

(ii) publish such fee revenue amounts, facility fees, and OTC monograph order request fees in the Federal Register.

(d) Identification of facilities

Each person that owns an OTC monograph drug facility shall submit to the Secretary the information required under this subsection each year. Such information shall, for each fiscal year—

(1) be submitted as part of the requirements for drug establishment registration set forth in section 360 of this title; and

(2) include for each such facility, at a minimum, identification of the facility's business operation as that of an OTC monograph drug facility.

(e) Effect of failure to pay fees

(1) OTC monograph drug facility fee

(A) In general

Failure to pay the fee under subsection (a)(1) within 20 calendar days of the due date as specified in subparagraph (D) of such subsection shall result in the following:

(i) The Secretary shall place the facility on a publicly available arrears list.

(ii) All OTC monograph drugs manufactured in such a facility or containing an ingredient manufactured in such a facility shall be deemed misbranded under section 352(ff) of this title.

(B) Application of penalties

The penalties under this paragraph shall apply until the fee established by subsection (a)(1) is paid.

(2) Order requests

An OTC monograph order request submitted by a person subject to fees under subsection (a) shall be considered incomplete and shall not be accepted for filing by the Secretary until all fees owed by such person under this section have been paid.

(3) Meetings

A person subject to fees under this section shall be considered ineligible for OTC monograph drug meetings until all such fees owed by such person have been paid.

(f) Crediting and availability of fees

(1) In general

Fees authorized under subsection (a) 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 OTC monograph drug activities.

(2) Collections and appropriation Acts

(A) In general

Subject to subparagraph (C), the fees authorized by this section shall be collected and available 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.

(B) Use of fees and limitation

The fees authorized by this section shall be available to defray increases in the costs of the resources allocated for OTC monograph drug activities (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 activities), only if the Secretary allocates for such purpose an amount for such fiscal year (excluding amounts from fees collected under this section) no less than $12,000,000, multiplied by the adjustment factor applicable to the fiscal year involved under subsection (c)(1).

(C) Compliance

The Secretary shall be considered to have met the requirements of subparagraph (B) in any fiscal year if the costs funded by appropriations and allocated for OTC monograph drug activities are not more than 15 percent below the level specified in such subparagraph.

(D) Provision for early payments in subsequent years

Payment of fees authorized under this section for a fiscal year (after fiscal year 2021), prior to the due date for such fees, may be accepted by the Secretary in accordance with authority provided in advance in a prior year appropriations Act.

(3) Authorization of appropriations

For each of the fiscal years 2021 through 2025, there is authorized to be appropriated for fees under this section an amount equal to the total amount of fees assessed for such fiscal year under this section.

(g) Collection of unpaid fees

In any case where the Secretary does not receive payment of a fee assessed under subsection (a) within 30 calendar 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.

(h) 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, employers, and advisory committees not engaged in OTC monograph drug activities, be reduced to offset the number of officers, employees, and advisory committees so engaged.

(June 25, 1938, ch. 675, §744M, as added Pub. L. 116–136, div. A, title III, §3862, Mar. 27, 2020, 134 Stat. 461.)

§379j–73. Reauthorization; reporting requirements

(a) Performance report

Beginning with fiscal year 2021, and not later than 120 calendar days after the end of each fiscal year thereafter for which fees are collected under this subpart, the Secretary shall prepare and submit to the Committee on Energy and Commerce of the House of Representatives and the Committee on Health, Education, Labor, and Pensions of the Senate a report concerning the progress of the Food and Drug Administration in achieving the goals identified in the letters described in section 3861(b)[1] of the CARES Act during such fiscal year and the future plans of the Food and Drug Administration for meeting such goals.

(b) Fiscal report

Not later than 120 calendar days after the end of fiscal year 2021 and each subsequent fiscal year for which fees are collected under this subpart, the Secretary shall prepare and submit to the Committee on Energy and Commerce of the House of Representatives and the Committee on Health, Education, Labor, and Pensions of the Senate 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 for such fiscal year.

(c) Public availability

The Secretary shall make the reports required under subsections (a) and (b) available to the public on the internet website of the Food and Drug Administration.

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[1] See References in Text note below.