(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.

[1] See References in Text note below.

(d) Reauthorization

(1) Consultation

In developing recommendations to present to the Congress with respect to the goals described in subsection (a), and plans for meeting the goals, for OTC monograph drug activities for the first 5 fiscal years after fiscal year 2025, and for the reauthorization of this subpart for such fiscal years, the Secretary shall consult with—

(A) the Committee on Energy and Commerce of the House of Representatives;

(B) the Committee on Health, Education, Labor, and Pensions of the Senate;

(C) scientific and academic experts;

(D) health care professionals;

(E) representatives of patient and consumer advocacy groups; and

(F) the regulated industry.

(2) Public review of recommendations

After negotiations with the regulated industry, the Secretary shall—

(A) present the recommendations developed under paragraph (1) to the congressional committees specified in such paragraph;

(B) publish such recommendations in the Federal Register;

(C) provide for a period of 30 calendar days for the public to provide written comments on such recommendations;

(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.

(3) Transmittal of recommendations

Not later than January 15, 2025, the Secretary shall transmit to the Congress the revised recommendations under paragraph (2), 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.

(June 25, 1938, ch. 675, § 744N, as added Pub. L. 116–136, div. A, title III, § 3862, Mar. 27, 2020, 134 Stat. 468.)

Editorial Notes

REFERENCES IN TEXT

Section 3861(b) of the CARES Act, referred to in subsec. (a), probably means section 3861 of Pub. L. 116–136, div. A, title III, Mar. 27, 2020, 134 Stat. 458, which is set out as a note under section 379j–71 of this title. Section 3861 of Pub. L. 116–136 does not contain subsecs.

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.)

Statutory Notes and Related Subsidiaries

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

Pub. L. 105–115, title IV, § 407(b), Nov. 21, 1997, 111 Stat. 2370, 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.

§ 379k–1. Electronic format for submissions

(a) Drugs and biologics

(1) In general

Beginning no earlier than 24 months after the issuance of a final guidance issued after public notice and opportunity for comment, submissions under subsection (b), (i), or (j) of section 355 of this title or subsection (a) or (k) of section 262 of title 42 shall be submitted in such electronic format as specified by the Secretary in such guidance.

(2) Guidance contents

In the guidance under paragraph (1), the Secretary may—

(A) provide a timetable for establishment by the Secretary of further standards for electronic submission as required by such paragraph; and

(B) set forth criteria for waivers of and exemptions from the requirements of this subsection.

(3) Exception

This subsection shall not apply to submissions described in section 360bbb of this title.

(b) Devices

(1) In general

Beginning after the issuance of final guidance implementing this paragraph, presubmissions and submissions for devices under section 360(k), 360c(f)(2)(A), 360e(c), 360e(d), 360e(f), 360j(g), 360j(m), or 360bbb–3 of this title or section 262 of title 42, and any supplements to such presubmissions or submissions, shall include an electronic copy of such presubmissions or submissions.

(2) Guidance contents

In the guidance under paragraph (1), the Secretary may—

(A) provide standards for the electronic copy required under such paragraph; and

(B) set forth criteria for waivers of and exemptions from the requirements of this subsection.

(3) Presubmissions and submissions solely in electronic format

(A) In general

Beginning on such date as the Secretary specifies in final guidance issued under sub-