(B) Application

To qualify for the exception under this paragraph, a small business shall submit to the Secretary a written request for such exception, in a format specified by the Secretary in guidance, certifying its gross annual sales for the 12 months ending April 1 of the fiscal year immediately preceding the fiscal year in which fees under this subsection are assessed. Any such application shall be submitted to the Secretary not later than April 30 of such immediately preceding fiscal year.

(5) Crediting of fees

In establishing the small business adjustment factor under paragraph (3) for a fiscal year, the Secretary shall—

(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.)

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.)

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 subparagraph (C), presubmissions and submissions for devices described in paragraph (1) (and any appeals of action taken by the Secretary with respect to such presubmissions or submissions) shall be submitted solely in such electronic format as specified by the Secretary in such guidance.

(B) Draft guidance

The Secretary shall, not later than October 1, 2019, issue draft guidance providing for—

(i) any further standards for the submission by electronic format required under subparagraph (A);

(ii) a timetable for the establishment by the Secretary of such further standards; and

(iii) criteria for waivers of and exemptions from the requirements of this subsection.

(C) Final guidance

The Secretary shall, not later than 1 year after the close of the public comment period on the draft guidance issued under subparagraph (B), issue final guidance.

(June 25, 1938, ch. 675, § 745A, as added Pub. L. 112–144, title XI, § 1136, July 9, 2012, 126 Stat. 1123; amended Pub. L. 115–52, title II, § 207, Aug. 18, 2017, 131 Stat. 1019.)

AMENDMENTS

2017—Subsec. (b)(3). Pub. L. 115–52 added par. (3).

EFFECTIVE DATE OF 2017 AMENDMENT

Amendment by title II of Pub. L. 115–52, effective Oct. 1, 2017, except that fees under subpart 3 of part C of this subchapter to be assessed for all submissions listed in section 379j(a)(2)(A) of this title received on or after Oct. 1, 2017, see section 209 of Pub. L. 115–52, set out as a note under section 379i of this title.

§ 379l. Education

(a) In general

The Secretary shall conduct training and education programs for the employees of the Food and Drug Administration relating to the regulatory responsibilities and policies established by this chapter, including programs for—

(1) scientific training;

(2) training to improve the skill of officers and employees authorized to conduct inspections under section 374 of this title;

(3) training to achieve product specialization in such inspections; and

(4) training in administrative process and procedure and integrity issues.

(b) Intramural fellowships and other training programs

The Secretary, acting through the Commissioner, may, through fellowships and other training programs, conduct and support intramural research training for predoctoral and postdoctoral scientists and physicians. Any such fellowships and training programs under this section or under section 379dd(d)(2)(A)(ix) of this title may include provision by such scientists and physicians of services on a voluntary and uncompensated basis, as the Secretary determines appropriate. Such scientists and physicians shall be subject to all legal and ethical requirements otherwise applicable to officers or employees of the Department of Health and Human Services.

(June 25, 1938, ch. 675, § 746, formerly § 742, as added Pub. L. 105–115, title IV, § 408(a), Nov. 21, 1997, 111 Stat. 2371; amended Pub. L. 110–85, title VI, § 601(c), Sept. 27, 2007, 121 Stat. 897; renumbered § 746, Pub. L. 110–316, title II, § 202(a), Aug. 14, 2008, 122 Stat. 3515.)