

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.

§ 379I. Education

(a) In general

The Secretary shall conduct training and education programs for the employees of the Food