**(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.

(June 25, 1938, ch. 675, §745A, as added Pub. L. 112–144, title XI, §1136, July 9, 2012, 126 Stat. 1123.)

**§ 379*l*. 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.)

PRIOR PROVISIONS

A prior section 746 of act June 25, 1938, was renumbered section 749 and is classified to section 379*o* of this title.

AMENDMENTS

2007—Subsec. (b). Pub. L. 110–85 inserted at end ''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