

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.

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

§ 379I. 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 379o 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

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.”

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.

PART E—ENVIRONMENTAL IMPACT REVIEW

§ 379o. Environmental impact

Notwithstanding any other provision of law, an environmental impact statement prepared in accordance with the regulations published in part 25 of title 21, Code of Federal Regulations (as in effect on August 31, 1997) in connection with an action carried out under (or a recommendation or report relating to) this chapter, shall be considered to meet the requirements for a detailed statement under section 4332(2)(C) of title 42.

(June 25, 1938, ch. 675, §749, formerly §746, as added Pub. L. 105-115, title IV, §411, Nov. 21, 1997, 111 Stat. 2373; renumbered §749, 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.

PART F—NATIONAL UNIFORMITY FOR NON-PRESCRIPTION DRUGS AND PREEMPTION FOR LABELING OR PACKAGING OF COSMETICS

§ 379r. National uniformity for nonprescription drugs

(a) In general

Except as provided in subsection (b), (c)(1), (d), (e), or (f) of this section, no State or political subdivision of a State may establish or continue in effect any requirement—

(1) that relates to the regulation of a drug that is not subject to the requirements of section 353(b)(1) or 353(f)(1)(A) of this title; and

(2) that is different from or in addition to, or that is otherwise not identical with, a requirement under this chapter, the Poison Prevention Packaging Act of 1970 (15 U.S.C. 1471 et seq.), or the Fair Packaging and Labeling Act (15 U.S.C. 1451 et seq.).

(b) Exemption

(1) In general

Upon application of a State or political subdivision thereof, the Secretary may by regulation, after notice and opportunity for written and oral presentation of views, exempt from subsection (a) of this section, under such conditions as may be prescribed in such regulation, a State or political subdivision requirement that—

(A) protects an important public interest that would otherwise be unprotected, including the health and safety of children;

(B) would not cause any drug to be in violation of any applicable requirement or prohibition under Federal law; and