

paragraph (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(B) Draft guidance

The Secretary shall, not later than October 1, 2019, issue draft guidance providing for—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The Secretary shall, not later than 1 year after the close of the public comment period on the draft guidance issued under subparagraph (B), issue final guidance.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.)

Editorial Notes

AMENDMENTS

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

Statutory Notes and Related Subsidiaries

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.

§ 379f. 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.)

Editorial Notes

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.”

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.

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.)

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.

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), 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), 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

(C) would not unduly burden interstate commerce.

(2) Timely action

The Secretary shall make a decision on the exemption of a State or political subdivision requirement under paragraph (1) not later than 120 days after receiving the application of the State or political subdivision under paragraph (1).

(c) Scope

(1) In general

This section shall not apply to—

(A) any State or political subdivision requirement that relates to the practice of pharmacy; or

(B) any State or political subdivision requirement that a drug be dispensed only upon the prescription of a practitioner licensed by law to administer such drug.

(2) Safety or effectiveness

For purposes of subsection (a), a requirement that relates to the regulation of a drug shall be deemed to include any requirement relating to public information or any other form of public communication relating to a warning of any kind for a drug.

(d) Exceptions

(1) In general

In the case of a drug described in subsection (a)(1) that is not the subject of an application approved under section 355 of this title or sec-

tion 357 of this title (as in effect on the day before November 21, 1997) or a final order under section 355h of this title by the Secretary establishing conditions under which the drug is generally recognized as safe and effective, subsection (a) shall apply only with respect to a requirement of a State or political subdivision of a State that relates to the same subject as, but is different from or in addition to, or that is otherwise not identical with—

(A) a regulation or order in effect with respect to the drug pursuant to a statute described in subsection (a)(2); or

(B) any other requirement in effect with respect to the drug pursuant to an amendment to such a statute made on or after November 21, 1997.

(2) State initiatives

This section shall not apply to a State requirement adopted by a State public initiative or referendum enacted prior to September 1, 1997.

(e) No effect on product liability law

Nothing in this section shall be construed to modify or otherwise affect any action or the liability of any person under the product liability law of any State.

(f) State enforcement authority

Nothing in this section shall prevent a State or political subdivision thereof from enforcing, under any relevant civil or other enforcement authority, a requirement that is identical to a requirement of this chapter.

(June 25, 1938, ch. 675, §751, as added Pub. L. 105-115, title IV, §412(a), Nov. 21, 1997, 111 Stat. 2373; amended Pub. L. 116-136, div. A, title III, §3851(c), Mar. 27, 2020, 134 Stat. 454.)

Editorial Notes

REFERENCES IN TEXT

The Poison Prevention Packaging Act of 1970, referred to in subsec. (a)(2), is Pub. L. 91-601, Dec. 30, 1970, 84 Stat. 1670, which is classified principally to chapter 39A (§1471 et seq.) of Title 15, Commerce and Trade. For complete classification of this Act to the Code, see Short Title note set out under section 1471 of Title 15 and Tables.

The Fair Packaging and Labeling Act, referred to in subsec. (a)(2), is Pub. L. 89-755, Nov. 3, 1966, 80 Stat. 1296, which is classified generally to chapter 39 (§1451 et seq.) of Title 15, Commerce and Trade. For complete classification of this Act to the Code, see Short Title note set out under section 1451 of Title 15 and Tables.

AMENDMENTS

2020—Subsec. (d)(1). Pub. L. 116-136, §3851(c)(1), in introductory provisions, substituted “final order under section 355h of this title” for “final regulation promulgated” and struck out “and not misbranded” after “safe and effective”.

Subsec. (d)(1)(A). Pub. L. 116-136, §3851(c)(2), substituted “regulation or order in effect” for “regulation in effect”.

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.