

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(B) Draft guidance

The Secretary shall, not later than October 1, 2019, issue draft guidance providing for—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The Secretary shall, not later than 1 year after the close of the public comment period on the draft guidance issued under subparagraph (B), issue final guidance.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