division thereof from establishing a requirement with respect to emission of radiation from electronic products procured for its own use if such requirement imposes a more restrictive standard than that required to comply with the otherwise applicable Federal standard.

(June 25, 1938, ch. 675, §542, formerly act July 1, 1944, ch. 373, title III, §542, formerly §360F, as added Pub. L. 90–602, §2(3), Oct. 18, 1968, 82 Stat. 1186; renumbered §542 and amended Pub. L. 101–629, §19(a)(1)(B), (2)(H), (3), (4), Nov. 28, 1990, 104 Stat. 4529, 4530; Pub. L. 103–80, §4(a)(2), Aug. 13, 1993, 107 Stat. 779.)

Editorial Notes

CODIFICATION

Section was classified to section 263n of Title 42, The Public Health and Welfare, prior to renumbering by Pub. L. 101–629.

AMENDMENTS

1993—Pub. L. 103–80 amended directory language of Pub. L. 101–629, §19(a)(4), which renumbered section 263n of Title 42, The Public Health and Welfare, as this section.

1990—Pub. L. 101–629, §19(a)(1)(B), (2)(H), substituted ''section 360kk'' for ''section 263f'' and ''this part'' for ''this subpart''.

Statutory Notes and Related Subsidiaries

NONINTERFERENCE WITH OTHER FEDERAL AGENCIES

Enactment of this section not to be construed to supersede or limit the functions under any other provision of law of any officer or agency of the United States, see section 4 of Pub. L. 90–602, set out as a note under section 360hh of this title.

PART D—DISSEMINATION OF TREATMENT INFORMATION

§§ 360aaa to 360aaa–6. Omitted

Editorial Notes

CODIFICATION

Sections 360aaa to 360aaa–6 ceased to be effective pursuant to section 401(e) of Pub. L. 105–115, set out as an Effective and Termination Dates note below.

Section 360aaa, act June 25, 1938, ch. 675, §551, as added Pub. L. 105–115, title IV, §401(a), Nov. 21, 1997, 111 Stat. 2356, related to requirements for dissemination of treatment information on drugs or devices.

Section 360aaa–1, act June 25, 1938, ch. 675, §552, as added Pub. L. 105–115, title IV, §401(a), Nov. 21, 1997, 111 Stat. 2358, related to information authorized to be disseminated under section 360aaa.

Section 360aaa–2, act June 25, 1938, ch. 675, §553, as added Pub. L. 105–115, title IV, §401(a), Nov. 21, 1997, 111 Stat. 2359, related to establishment of list of articles and publications disseminated and list of providers that received articles and reference publications.

Section 360aaa–3, act June 25, 1938, ch. 675, §554, as added Pub. L. 105–115, title IV, §401(a), Nov. 21, 1997, 111 Stat. 2359, related to requirement regarding submission of supplemental application for new use and an exemption from that requirement.

Section 360aaa–4, act June 25, 1938, ch. 675, §555, as added Pub. L. 105–115, title IV, §401(a), Nov. 21, 1997, 111 Stat. 2361, related to corrective actions and cessation of dissemination.

Section 360aaa–5, act June 25, 1938, ch. 675, §556, as added Pub. L. 105–115, title IV, §401(a), Nov. 21, 1997, 111 Stat. 2362, related to definitions.

Section 360aaa–6, act June 25, 1938, ch. 675, §557, as added Pub. L. 105–115, title IV, §401(a), Nov. 21, 1997, 111 Stat. 2363, related to rules of construction.

Statutory Notes and Related Subsidiaries

EFFECTIVE AND TERMINATION DATES

Pub. L. 105–115, title IV, §401(d), Nov. 21, 1997, 111 Stat. 2364, provided that: ''The amendments made by this section [enacting this part and amending section 331 of this title] shall take effect 1 year after the date of enactment of this Act [Nov. 21, 1997], or upon the Secretary's issuance of final regulations pursuant to subsection (c) [section 401(c) of Pub. L. 105–115 set out below] [Such regulations were issued effective Nov. 20, 1998. See 63 F.R. 64556.], whichever is sooner.''

Pub. L. 105–115, title IV, §401(e), Nov. 21, 1997, 111 Stat. 2364, provided that: ''The amendments made by this section [enacting this part and amending section 331 of this title] cease to be effective September 30, 2006, or 7 years after the date on which the Secretary promulgates the regulations described in subsection (c) [section 401(c) of Pub. L. 105–115 set out below] [Such regulations were issued effective Nov. 20, 1998. See 63 F.R. 64556.], whichever is later.''

REGULATIONS

Pub. L. 105–115, title IV, §401(c), Nov. 21, 1997, 111 Stat. 2364, provided that: ''Not later than 1 year after the date of enactment of this Act [Nov. 21, 1997], the Secretary of Health and Human Services shall promulgate regulations to implement the amendments made by this section [enacting this part and amending section 331 of this title].''

PART E—GENERAL PROVISIONS RELATING TO DRUGS AND DEVICES

§360bbb. Expanded access to unapproved therapies and diagnostics

(a) Emergency situations

The Secretary may, under appropriate conditions determined by the Secretary, authorize the shipment of investigational drugs or investigational devices for the diagnosis, monitoring, or treatment of a serious disease or condition in emergency situations.

(b) Individual patient access to investigational products intended for serious diseases

Any person, acting through a physician licensed in accordance with State law, may request from a manufacturer or distributor, and any manufacturer or distributor may, after complying with the provisions of this subsection, provide to such physician an investigational drug or investigational device for the diagnosis, monitoring, or treatment of a serious disease or condition if—

(1) the licensed physician determines that the person has no comparable or satisfactory alternative therapy available to diagnose, monitor, or treat the disease or condition involved, and that the probable risk to the person from the investigational drug or investigational device is not greater than the probable risk from the disease or condition;

(2) the Secretary determines that there is sufficient evidence of safety and effectiveness to support the use of the investigational drug or investigational device in the case described in paragraph (1);

(3) the Secretary determines that provision of the investigational drug or investigational device will not interfere with the initiation, conduct, or completion of clinical investigations to support marketing approval; and

(4) the sponsor, or clinical investigator, of the investigational drug or investigational de-