

(June 25, 1938, ch. 675, § 539, formerly act July 1, 1944, ch. 373, title III, § 539, formerly § 360C, as added Pub. L. 90-602, § 2(3), Oct. 18, 1968, 82 Stat. 1184; renumbered § 539 and amended Pub. L. 101-629, § 19(a)(1)(B), (2)(G), (3), (4), Nov. 28, 1990, 104 Stat. 4529, 4530; Pub. L. 103-80, § 4(a)(2), Aug. 13, 1993, 107 Stat. 779.)

CODIFICATION

Section was classified to section 263k 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 263k of Title 42, The Public Health and Welfare, as this section.

1990—Subsec. (a). Pub. L. 101-629, § 19(a)(2)(G)(i), (ii), substituted “section 360oo” for “section 263j” and “section 360kk” for “section 263f”.

Subsec. (b)(1). Pub. L. 101-629, § 19(a)(2)(G)(ii), substituted “section 360oo” for “section 263j” in two places.

Subsec. (d). Pub. L. 101-629, § 19(a)(1)(B), substituted “this part” for “this subpart” in two places.

Subsec. (e). Pub. L. 101-629, § 19(a)(1)(B), (2)(G)(iii), substituted “section 360ss” for “section 263n” and “this part” for “this subpart”.

Subsec. (f). Pub. L. 101-629, § 19(a)(1)(B), substituted “this part” for “this subpart”.

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.

§ 360qq. Repealed. Pub. L. 105-362, title VI, § 601(a)(2)(A), Nov. 10, 1998, 112 Stat. 3285

Section, act June 25, 1938, ch. 675, § 540, formerly act July 1, 1944, ch. 373, title III, § 540, formerly § 360D, as added Pub. L. 90-602, § 2(3), Oct. 18, 1968, 82 Stat. 1185; renumbered § 540 and amended Pub. L. 101-629, § 19(a)(1)(B), (3), (4), Nov. 28, 1990, 104 Stat. 4529, 4530; Pub. L. 103-80, § 4(a)(2), Aug. 13, 1993, 107 Stat. 779, related to annual report on administration of electronic product radiation control program.

§ 360rr. Federal-State cooperation

The Secretary is authorized (1) to accept from State and local authorities engaged in activities related to health or safety or consumer protection, on a reimbursable basis or otherwise, any assistance in the administration and enforcement of this part which he may request and which they may be able and willing to provide and, if so agreed, may pay in advance or otherwise for the reasonable cost of such assistance, and (2) he may, for the purpose of conducting examinations, investigations, and inspections, commission any officer or employee of any such authority as an officer of the Department.

(June 25, 1938, ch. 675, § 541, formerly act July 1, 1944, ch. 373, title III, § 541, formerly § 360E, as added Pub. L. 90-602, § 2(3), Oct. 18, 1968, 82 Stat. 1186; renumbered § 541 and amended Pub. L. 101-629, § 19(a)(1)(B), (3), (4), Nov. 28, 1990, 104 Stat. 4529, 4530; Pub. L. 103-80, § 4(a)(2), Aug. 13, 1993, 107 Stat. 779.)

CODIFICATION

Section was classified to section 263m 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 263m of Title 42, The Public Health and Welfare, as this section.

1990—Pub. L. 101-629, § 19(a)(1)(B), substituted “this part” for “this subpart”.

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.

§ 360ss. State standards

Whenever any standard prescribed pursuant to section 360kk of this title with respect to an aspect of performance of an electronic product is in effect, no State or political subdivision of a State shall have any authority either to establish, or to continue in effect, any standard which is applicable to the same aspect of performance of such product and which is not identical to the Federal standard. Nothing in this part shall be construed to prevent the Federal Government or the government of any State or political subdivision 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.)

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”.

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

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.

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 di-

agnosis, 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 device submits to the Secretary a clinical protocol consistent with the provisions of section 355(i) or 360j(g) of this title, including any regulations promulgated under section 355(i) or 360j(g) of this title, describing the use of the investigational drug or investigational device in a single patient or a small group of patients.

(c) Treatment investigational new drug applications and treatment investigational device exemptions

Upon submission by a sponsor or a physician of a protocol intended to provide widespread access to an investigational drug or investigational device for eligible patients (referred to in this subsection as an "expanded access protocol"), the Secretary shall permit such investigational drug or investigational device to be made available for expanded access under a treatment investigational new drug application or treatment investigational device exemption if the Secretary determines that—

(1) under the treatment investigational new drug application or treatment investigational device exemption, the investigational drug or investigational device is intended for use in the diagnosis, monitoring, or treatment of a serious or immediately life-threatening disease or condition;

(2) there is no comparable or satisfactory alternative therapy available to diagnose, monitor, or treat that stage of disease or condition in the population of patients to which the investigational drug or investigational device is intended to be administered;

(3)(A) the investigational drug or investigational device is under investigation in a controlled clinical trial for the use described in paragraph (1) under an investigational drug application in effect under section 355(i) of this title or investigational device exemption in effect under section 360j(g) of this title; or

(B) all clinical trials necessary for approval of that use of the investigational drug or investigational device have been completed;

(4) the sponsor of the controlled clinical trials is actively pursuing marketing approval of the investigational drug or investigational