

“(5) Before 1983, some 38 orphan drugs had been developed. Since the enactment of the Orphan Drug Act [Jan. 4, 1983], more than 220 new orphan drugs have been approved and marketed in the United States and more than 800 additional drugs are in the research pipeline.

“(6) Despite the tremendous success of the Orphan Drug Act, rare diseases and disorders deserve greater emphasis in the national biomedical research enterprise.

“(7) The Food and Drug Administration supports small clinical trials through Orphan Products Research Grants. Such grants embody successful partnerships of government and industry, and have led to the development of at least 23 drugs and four medical devices for rare diseases and disorders. Yet the appropriations in fiscal year 2001 for such grants were less than in fiscal year 1995.

“(b) PURPOSES.—The purpose of this Act [see Short Title of 2002 Amendments note set out under section 301 of this title] is to increase the national investment in the development of diagnostics and treatments for patients with rare diseases and disorders.”

#### PART C—ELECTRONIC PRODUCT RADIATION CONTROL

##### CODIFICATION

This part was classified to subpart 3 (§263c et seq.) of part F of subchapter II of chapter 6A of Title 42, The Public Health and Welfare, prior to its renumbering by Pub. L. 101-629, §19(a)(4), Nov. 28, 1990, 104 Stat. 4530, as amended by Pub. L. 103-80, §4(a)(2), Aug. 13, 1993, 107 Stat. 779.

#### § 360hh. Definitions

As used in this part—

(1) the term “electronic product radiation” means—

(A) any ionizing or non-ionizing electromagnetic or particulate radiation, or

(B) any sonic, infrasonic, or ultrasonic wave, which is emitted from an electronic product as the result of the operation of an electronic circuit in such product;

(2) the term “electronic product” means (A) any manufactured or assembled product which, when in operation, (i) contains or acts as part of an electronic circuit and (ii) emits (or in the absence of effective shielding or other controls would emit) electronic product radiation, or (B) any manufactured or assembled article which is intended for use as a component, part, or accessory of a product described in clause (A) and which when in operation emits (or in the absence of effective shielding or other controls would emit) such radiation;

(3) the term “manufacturer” means any person engaged in the business of manufacturing, assembling, or importing of electronic products;

(4) the term “commerce” means (A) commerce between any place in any State and any place outside thereof; and (B) commerce wholly within the District of Columbia; and

(5) the term “State” includes the District of Columbia, the Commonwealth of Puerto Rico, the Northern Mariana Islands, the Virgin Islands, Guam, and American Samoa.

(June 25, 1938, ch. 675, §531, formerly act July 1, 1944, ch. 373, title III, §531, formerly §355, as added Pub. L. 90-602, §2(3), Oct. 18, 1968, 82 Stat.

1174; amended Pub. L. 94-484, title IX, §905(b)(1), Oct. 12, 1976, 90 Stat. 2325; renumbered §531 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 263c 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 263c 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” in introductory provisions.

1976—Par. (5). Pub. L. 94-484 defined “State” to include Northern Mariana Islands.

##### SHORT TITLE

For short title of Pub. L. 90-602, which enacted provisions now comprising this part (§§360hh to 360ss), as the “Radiation Control for Health and Safety Act of 1968”, see section 1 of Pub. L. 90-602, set out as a Short Title of 1968 Amendments note under section 301 of this title.

##### TRANSFER OF SUBPART; CONSTRUCTION

Section 19(c) of Pub. L. 101-629 provided that: “The transfer of subpart 3 of part F of title III of the Public Health Service Act [42 U.S.C. 263b et seq.] to the Federal Food, Drug, and Cosmetic Act [this chapter] does not change the application of the requirements of such subpart and such Act to electronic products which were in effect on the date of the enactment of this Act [Nov. 28, 1990].”

##### DEFINITION OF “SECRETARY” AND “DEPARTMENT”

Section 3 of Pub. L. 90-602, as amended Pub. L. 96-88, title V, §509(b), Oct. 17, 1979, 93 Stat. 695, provided that: “As used in the amendments made by section 2 of this Act [enacting provisions now comprising sections 360hh to 360ss of this title], except when otherwise specified, the term ‘Secretary’ means the Secretary of Health and Human Services, and the term ‘Department’ means the Department of Health and Human Services.”

##### NONINTERFERENCE WITH OTHER FEDERAL AGENCIES

Section 4 of Pub. L. 90-602 provided that: “The amendments made by section 2 of this Act [enacting provisions now comprising sections 360hh to 360ss of this title] shall not be construed as superseding or limiting the functions, under any other provision of law, of any officer or agency of the United States.”

#### § 360ii. Program of control

##### (a) Establishment

The Secretary shall establish and carry out an electronic product radiation control program designed to protect the public health and safety from electronic product radiation. As a part of such program, he shall—

(1) pursuant to section 360kk of this title, develop and administer performance standards for electronic products;

(2) plan, conduct, coordinate, and support research, development, training, and operational activities to minimize the emissions of and the exposure of people to, unnecessary electronic product radiation;

(3) maintain liaison with and receive information from other Federal and State departments and agencies with related interests, professional organizations, industry, industry

and labor associations, and other organizations on present and future potential electronic product radiation;

(4) study and evaluate emissions of, and conditions of exposure to, electronic product radiation and intense magnetic fields;

(5) develop, test, and evaluate the effectiveness of procedures and techniques for minimizing exposure to electronic product radiation; and

(6) consult and maintain liaison with the Secretary of Commerce, the Secretary of Defense, the Secretary of Labor, the Atomic Energy Commission, and other appropriate Federal departments and agencies on (A) techniques, equipment, and programs for testing and evaluating electronic product radiation, and (B) the development of performance standards pursuant to section 360kk of this title to control such radiation emissions.

#### (b) Powers of Secretary

In carrying out the purposes of subsection (a) of this section, the Secretary is authorized to—

(1)(A) collect and make available, through publications and other appropriate means, the results of, and other information concerning, research and studies relating to the nature and extent of the hazards and control of electronic product radiation; and (B) make such recommendations relating to such hazards and control as he considers appropriate;

(2) make grants to public and private agencies, organizations, and institutions, and to individuals for the purposes stated in paragraphs (2), (4), and (5) of subsection (a) of this section;

(3) contract with public or private agencies, institutions, and organizations, and with individuals, without regard to section 3324 of title 31 and section 6101 of title 41; and

(4) procure (by negotiation or otherwise) electronic products for research and testing purposes, and sell or otherwise dispose of such products.

#### (c) Record keeping

(1) Each recipient of assistance under this part pursuant to grants or contracts entered into under other than competitive bidding procedures shall keep such records as the Secretary shall prescribe, including records which fully disclose the amount and disposition by such recipient of the proceeds of such assistance, the total cost of the project or undertaking in connection with which such assistance is given or used, and the amount of that portion of the cost of the project or undertaking supplied by other sources, and such other records as will facilitate an effective audit.

(2) The Secretary and the Comptroller General of the United States, or any of their duly authorized representatives, shall have access for the purpose of audit and examination to any books, documents, papers, and records of the recipients that are pertinent to the grants or contracts entered into under this part under other than competitive bidding procedures.

(June 25, 1938, ch. 675, § 532, formerly act July 1, 1944, ch. 373, title III, § 532, formerly § 356, as added Pub. L. 90-602, § 2(3), Oct. 18, 1968, 82 Stat. 1174; renumbered § 532 and amended Pub. L.

101-629, § 19(a)(1)(B), (2)(A), (3), (4), Nov. 28, 1990, 104 Stat. 4529, 4530; Pub. L. 103-80, § 4(a)(2), Aug. 13, 1993, 107 Stat. 779.)

#### CODIFICATION

In subsec. (b)(3), “section 6101 of title 41” substituted for “section 3709 of the Revised Statutes of the United States (41 U.S.C. 5)” on authority of Pub. L. 111-350, § 6(c), Jan. 4, 2011, 124 Stat. 3854, which Act enacted Title 41, Public Contracts.

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

1990—Subsec. (a)(1), (6). Pub. L. 101-629, § 19(a)(2)(A)(i), substituted “section 360kk” for “section 263f”.

Subsec. (b)(3). Pub. L. 101-629, § 19(a)(2)(A)(ii), substituted reference to section 3324 of title 31 for reference to section 3648 of the Revised Statutes (31 U.S.C. 529).

Subsec. (c)(1), (2). Pub. L. 101-629, § 19(a)(1)(B), substituted “this part” for “this subpart”.

#### TRANSFER OF FUNCTIONS

Atomic Energy Commission abolished and functions transferred by sections 5814 and 5841 of Title 42, The Public Health and Welfare. See also Transfer of Functions notes set out under those sections.

#### 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 or 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.

### § 360jj. Studies by Secretary

#### (a) Report to Congress

The Secretary shall conduct the following studies, and shall make a report or reports of the results of such studies to the Congress on or before January 1, 1970, and from time to time thereafter as he may find necessary, together with such recommendations for legislation as he may deem appropriate:

(1) A study of present State and Federal control of health hazards from electronic product radiation and other types of ionizing radiation, which study shall include, but not be limited to—

(A) control of health hazards from radioactive materials other than materials regulated under the Atomic Energy Act of 1954 [42 U.S.C. 2011 et seq.];

(B) any gaps and inconsistencies in present controls;

(C) the need for controlling the sale of certain used electronic products, particularly antiquated X-ray equipment, without upgrading such products to meet the standards for new products or separate standards for used products;

(D) measures to assure consistent and effective control of the aforementioned health hazards;

(E) measures to strengthen radiological health programs of State governments; and

(F) the feasibility of authorizing the Secretary to enter into arrangements with indi-

vidual States or groups of States to define their respective functions and responsibilities for the control of electronic product radiation and other ionizing radiation;

(2) A study to determine the necessity for the development of standards for the use of non-medical electronic products for commercial and industrial purposes; and

(3) A study of the development of practicable procedures for the detection and measurement of electronic product radiation which may be emitted from electronic products manufactured or imported prior to the effective date of any applicable standard established pursuant to this part.

**(b) Participation of other Federal agencies**

In carrying out these studies, the Secretary shall invite the participation of other Federal departments and agencies having related responsibilities and interests, State governments—particularly those of States which regulate radioactive materials under section 274 of the Atomic Energy Act of 1954, as amended [42 U.S.C. 2021], and interested professional, labor, and industrial organizations. Upon request from congressional committees interested in these studies, the Secretary shall keep these committees currently informed as to the progress of the studies and shall permit the committees to send observers to meetings of the study groups.

**(c) Organization of studies and participation**

The Secretary or his designee shall organize the studies and the participation of the invited participants as he deems best. Any dissent from the findings and recommendations of the Secretary shall be included in the report if so requested by the dissenter.

(June 25, 1938, ch. 675, § 533, formerly act July 1, 1944, ch. 373, title III, § 533, formerly § 357, as added Pub. L. 90-602, § 2(3), Oct. 18, 1968, 82 Stat. 1176; renumbered § 533 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.)

REFERENCES IN TEXT

The Atomic Energy Act of 1954, referred to in subsec. (a)(1)(A), is act Aug. 1, 1946, ch. 724, as added by act Aug. 30, 1954, ch. 1073, § 1, 68 Stat. 921, and amended, which is classified generally to chapter 23 (§ 2011 et seq.) of Title 42, The Public Health and Welfare. For complete classification of this Act to the Code, see Short Title note set out under section 2011 of Title 42 and Tables.

CODIFICATION

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

1990—Subsec. (a)(3), 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 provi-

sion 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.

**§ 360kk. Performance standards for electronic products**

**(a) Promulgation of regulations**

(1) The Secretary shall by regulation prescribe performance standards for electronic products to control the emission of electronic product radiation from such products if he determines that such standards are necessary for the protection of the public health and safety. Such standards may include provisions for the testing of such products and the measurement of their electronic product radiation emissions, may require the attachment of warning signs and labels, and may require the provision of instructions for the installation, operation, and use of such products. Such standards may be prescribed from time to time whenever such determinations are made, but the first of such standards shall be prescribed prior to January 1, 1970. In the development of such standards, the Secretary shall consult with Federal and State departments and agencies having related responsibilities or interests and with appropriate professional organizations and interested persons, including representatives of industries and labor organizations which would be affected by such standards, and shall give consideration to—

(A) the latest available scientific and medical data in the field of electronic product radiation;

(B) the standards currently recommended by (i) other Federal agencies having responsibilities relating to the control and measurement of electronic product radiation, and (ii) public or private groups having an expertise in the field of electronic product radiation;

(C) the reasonableness and technical feasibility of such standards as applied to a particular electronic product;

(D) the adaptability of such standards to the need for uniformity and reliability of testing and measuring procedures and equipment; and

(E) in the case of a component, or accessory described in paragraph (2)(B) of section 360hh of this title, the performance of such article in the manufactured or assembled product for which it is designed.

(2) The Secretary may prescribe different and individual performance standards, to the extent appropriate and feasible, for different electronic products so as to recognize their different operating characteristics and uses.

(3) The performance standards prescribed under this section shall not apply to any electronic product which is intended solely for export if (A) such product and the outside of any shipping container used in the export of such product are labeled or tagged to show that such product is intended for export, and (B) such product meets all the applicable requirements of the country to which such product is intended for export.

(4) The Secretary may by regulation amend or revoke any performance standard prescribed under this section.

(5) The Secretary may exempt from the provisions of this section any electronic product in-

tended for use by departments or agencies of the United States provided such department or agency has prescribed procurement specifications governing emissions of electronic product radiation and provided further that such product is of a type used solely or predominantly by departments or agencies of the United States.

**(b) Administrative procedure**

The provisions of subchapter II of chapter 5 of title 5 (relating to the administrative procedure for rulemaking), and of chapter 7 of title 5 (relating to judicial review), shall apply with respect to any regulation prescribing, amending, or revoking any standard prescribed under this section.

**(c) Publication in Federal Register**

Each regulation prescribing, amending, or revoking a standard shall specify the date on which it shall take effect which, in the case of any regulation prescribing, or amending any standard, may not be sooner than one year or not later than two years after the date on which such regulation is issued, unless the Secretary finds, for good cause shown, that an earlier or later effective date is in the public interest and publishes in the Federal Register his reason for such finding, in which case such earlier or later date shall apply.

**(d) Judicial review**

(1) In a case of actual controversy as to the validity of any regulation issued under this section prescribing, amending, or revoking a performance standard, any person who will be adversely affected by such regulation when it is effective may at any time prior to the sixtieth day after such regulation is issued file a petition with the United States court of appeals for the circuit wherein such person resides or has his principal place of business, for a judicial review of such regulation. A copy of the petition shall be forthwith transmitted by the clerk of the court to the Secretary or other officer designated by him for that purpose. The Secretary thereupon shall file in the court the record of the proceedings on which the Secretary based the regulation, as provided in section 2112 of title 28.

(2) If the petitioner applies to the court for leave to adduce additional evidence, and shows to the satisfaction of the court that such additional evidence is material and that there were reasonable grounds for the failure to adduce such evidence in the proceeding before the Secretary, the court may order such additional evidence (and evidence in rebuttal thereof) to be taken before the Secretary, and to be adduced upon the hearing, in such manner and upon such terms and conditions as to the court may seem proper. The Secretary may modify his findings, or make new findings, by reason of the additional evidence so taken, and he shall file such modified or new findings, and his recommendations, if any, for the modification or setting aside of his original regulation, with the return of such additional evidence.

(3) Upon the filing of the petition referred to in paragraph (1) of this subsection, the court shall have jurisdiction to review the regulation in accordance with chapter 7 of title 5 and to

grant appropriate relief as provided in such chapter.

(4) The judgment of the court affirming or setting aside, in whole or in part, any such regulation of the Secretary shall be final, subject to review by the Supreme Court of the United States upon certiorari or certification as provided in section 1254 of title 28.

(5) Any action instituted under this subsection shall survive, notwithstanding any change in the person occupying the office of Secretary or any vacancy in such office.

(6) The remedies provided for in this subsection shall be in addition to and not in substitution for any other remedies provided by law.

**(e) Availability of record**

A certified copy of the transcript of the record and administrative proceedings under this section shall be furnished by the Secretary to any interested party at his request, and payment of the costs thereof, and shall be admissible in any criminal, exclusion of imports, or other proceeding arising under or in respect of this part irrespective of whether proceedings with respect to the regulation have previously been initiated or become final under this section.

**(f) Technical Electronic Product Radiation Safety Standards Committee**

(1)(A) The Secretary shall establish a Technical Electronic Product Radiation Safety Standards Committee (hereafter in this part referred to as the "Committee") which he shall consult before prescribing any standard under this section. The Committee shall be appointed by the Secretary, after consultation with public and private agencies concerned with the technical aspect of electronic product radiation safety, and shall be composed of fifteen members each of whom shall be technically qualified by training and experience in one or more fields of science or engineering applicable to electronic product radiation safety, as follows:

(i) Five members shall be selected from governmental agencies, including State and Federal Governments;

(ii) Five members shall be selected from the affected industries after consultation with industry representatives; and

(iii) Five members shall be selected from the general public, of which at least one shall be a representative of organized labor.

(B) The Committee may propose electronic product radiation safety standards to the Secretary for his consideration. All proceedings of the Committee shall be recorded and the record of each such proceeding shall be available for public inspection.

(2) Payments to members of the Committee who are not officers or employees of the United States pursuant to subsection (c) of section 210 of title 42 shall not render members of the Committee officers or employees of the United States for any purpose.

**(g) Review and evaluation**

The Secretary shall review and evaluate on a continuing basis testing programs carried out by industry to assure the adequacy of safeguards against hazardous electronic product radiation and to assure that electronic products comply with standards prescribed under this section.

**(h) Product certification**

Every manufacturer of an electronic product to which is applicable a standard in effect under this section shall furnish to the distributor or dealer at the time of delivery of such product, in the form of a label or tag permanently affixed to such product or in such manner as approved by the Secretary, the certification that such product conforms to all applicable standards under this section. Such certification shall be based upon a test, in accordance with such standard, of the individual article to which it is attached or upon a testing program which is in accord with good manufacturing practice and which has not been disapproved by the Secretary (in such manner as he shall prescribe by regulation) on the grounds that it does not assure the adequacy of safeguards against hazardous electronic product radiation or that it does not assure that electronic products comply with the standards prescribed under this section.

(June 25, 1938, ch. 675, § 534, formerly act July 1, 1944, ch. 373, title III, § 534, formerly § 358, as added Pub. L. 90-602, § 2(3), Oct. 18, 1968, 82 Stat. 1177; amended Pub. L. 91-515, title VI, § 601(b)(2), (3), Oct. 30, 1970, 84 Stat. 1311; renumbered § 534 and amended Pub. L. 101-629, § 19(a)(1)(B), (2)(B), (3), (4), Nov. 28, 1990, 104 Stat. 4529, 4530; Pub. L. 103-80, §§ 3(w), 4(a)(2), Aug. 13, 1993, 107 Stat. 778, 779.)

**CODIFICATION**

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

**AMENDMENTS**

1993—Pub. L. 103-80, § 4(a)(2), amended directory language of Pub. L. 101-629, § 19(a)(4), which renumbered section 263f of Title 42, The Public Health and Welfare, as this section.

Subsec. (f)(2). Pub. L. 103-80, § 3(w), made technical amendment to reference to section 210 of title 42 to reflect correction of corresponding provision of original act.

1990—Subsec. (a)(1)(E). Pub. L. 101-629, § 19(a)(2)(B), substituted "section 360hh" for "section 263c".

Subsecs. (e), (f)(1)(A). Pub. L. 101-629, § 19(a)(1)(B), substituted "this part" for "this subpart".

1970—Subsec. (f)(2). Pub. L. 91-515 struck out provisions related to payment of compensation and travel expenses of members of the Committee who are not officers or employees of the United States, and substituted "to members of the Committee who are not officers or employees of the United States pursuant to subsection (c) of section 210 of title 42" for "under this subsection".

**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.

**§ 360ll. Notification of defects in and repair or replacement of electronic products****(a) Notification; exemption**

(1) Every manufacturer of electronic products who discovers that an electronic product produced, assembled, or imported by him has a defect which relates to the safety of use of such product by reason of the emission of electronic

product radiation, or that an electronic product produced, assembled, or imported by him on or after the effective date of an applicable standard prescribed pursuant to section 360kk of this title fails to comply with such standard, shall immediately notify the Secretary of such defect or failure to comply if such product has left the place of manufacture and shall (except as authorized by paragraph (2)) with reasonable promptness furnish notification of such defect or failure to the persons (where known to the manufacturer) specified in subsection (b) of this section.

(2) If, in the opinion of such manufacturer, the defect or failure to comply is not such as to create a significant risk of injury, including genetic injury, to any person, he may, at the time of giving notice to the Secretary of such defect or failure to comply, apply to the Secretary for an exemption from the requirement of notice to the persons specified in subsection (b) of this section. If such application states reasonable grounds for such exemption, the Secretary shall afford such manufacturer an opportunity to present his views and evidence in support of the application, the burden of proof being on the manufacturer. If, after such presentation, the Secretary is satisfied that such defect or failure to comply is not such as to create a significant risk of injury, including genetic injury, to any person, he shall exempt such manufacturer from the requirement of notice to the persons specified in subsection (b) of this section and from the requirements of repair or replacement imposed by subsection (f) of this section.

**(b) Method of notification**

The notification (other than to the Secretary) required by paragraph (1) of subsection (a) of this section shall be accomplished—

(1) by certified mail to the first purchaser of such product for purposes other than resale, and to any subsequent transferee of such product; and

(2) by certified mail or other more expeditious means to the dealers or distributors of such manufacturer to whom such product was delivered.

**(c) Requisite elements of notification**

The notifications required by paragraph (1) of subsection (a) of this section shall contain a clear description of such defect or failure to comply with an applicable standard, an evaluation of the hazard reasonably related to such defect or failure to comply, and a statement of the measures to be taken to repair such defect. In the case of a notification to a person referred to in subsection (b) of this section, the notification shall also advise the person of his rights under subsection (f) of this section.

**(d) Copies to Secretary of communications by manufacturers to dealers or distributors regarding defects**

Every manufacturer of electronic products shall furnish to the Secretary a true or representative copy of all notices, bulletins, and other communications to the dealers or distributors of such manufacturer or to purchasers (or subsequent transferees) of electronic products of such manufacturer regarding any such

defect in such product or any such failure to comply with a standard applicable to such product. The Secretary shall disclose to the public so much of the information contained in such notice or other information obtained under section 360nn of this title as he deems will assist in carrying out the purposes of this part, but he shall not disclose any information which contains or relates to a trade secret or other matter referred to in section 1905 of title 18 unless he determines that it is necessary to carry out the purposes of this part.

**(e) Notice from Secretary to manufacturer of defects or failure to comply with standards**

If through testing, inspection, investigation, or research carried out pursuant to this part, or examination of reports submitted pursuant to section 360nn of this title, or otherwise, the Secretary determines that any electronic product—

(1) does not comply with an applicable standard prescribed pursuant to section 360kk of this title; or

(2) contains a defect which relates to the safety of use of such product by reason of the emission of electronic product radiation;

he shall immediately notify the manufacturer of such product of such defect or failure to comply. The notice shall contain the findings of the Secretary and shall include all information upon which the findings are based. The Secretary shall afford such manufacturer an opportunity to present his views and evidence in support thereof, to establish that there is no failure of compliance or that the alleged defect does not exist or does not relate to safety of use of the product by reason of the emission of such radiation hazard. If after such presentation by the manufacturer the Secretary determines that such product does not comply with an applicable standard prescribed pursuant to section 360kk of this title, or that it contains a defect which relates to the safety of use of such product by reason of the emission of electronic product radiation, the Secretary shall direct the manufacturer to furnish the notification specified in subsection (c) of this section to the persons specified in paragraphs (1) and (2) of subsection (b) of this section (where known to the manufacturer), unless the manufacturer has applied for an exemption from the requirement of such notification on the ground specified in paragraph (2) of subsection (a) of this section and the Secretary is satisfied that such noncompliance or defect is not such as to create a significant risk of injury, including genetic injury, to any person.

**(f) Correction of defects**

If any electronic product is found under subsection (a) or (e) of this section to fail to comply with an applicable standard prescribed under this part or to have a defect which relates to the safety of use of such product, and the notification specified in subsection (c) of this section is required to be furnished on account of such failure or defect, the manufacturer of such product shall (1) without charge, bring such product into conformity with such standard or remedy such defect and provide reimbursement for any expenses for transportation of such product incurred in connection with having such product

brought into conformity or having such defect remedied, (2) replace such product with a like or equivalent product which complies with each applicable standard prescribed under this part and which has no defect relating to the safety of its use, or (3) make a refund of the cost of such product. The manufacturer shall take the action required by this subsection in such manner, and with respect to such persons, as the Secretary by regulations shall prescribe.

**(g) Effective date**

This section shall not apply to any electronic product that was manufactured before October 18, 1968.

(June 25, 1938, ch. 675, §535, formerly act July 1, 1944, ch. 373, title III, §535, formerly §359, as added Pub. L. 90-602, §2(3), Oct. 18, 1968, 82 Stat. 1180; renumbered §535 and amended Pub. L. 101-629, §19(a)(1)(B), (2)(C), (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 263g 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 263g of Title 42, The Public Health and Welfare, as this section.

1990—Subsec. (a)(1). Pub. L. 101-629, §19(a)(2)(C)(i), substituted “section 360kk” for “section 263f”.

Subsec. (d). Pub. L. 101-629, §19(a)(1)(B), (2)(C)(ii), substituted “section 360nn” for “section 263i” and “this part” for “this subpart” in two places.

Subsec. (e). Pub. L. 101-629, §19(a)(1)(B), (2)(C), substituted “this part” for “this subpart” and “section 360nn” for “section 263i” in introductory provisions and “section 360kk” for “section 263f” in par. (1) and concluding provisions.

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

**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.

**§ 360mm. Imports**

**(a) Refusal of admission to noncomplying electronic products**

Any electronic product offered for importation into the United States which fails to comply with an applicable standard prescribed under this part, or to which is not affixed a certification in the form of a label or tag in conformity with section 360kk(h) of this title shall be refused admission into the United States. The Secretary of the Treasury shall deliver to the Secretary of Health and Human Services, upon the latter's request, samples of electronic products which are being imported or offered for import into the United States, giving notice thereof to the owner or consignee, who may have a hearing before the Secretary of Health and Human Services. If it appears from an examination of such samples or otherwise that any electronic product fails to comply with applicable standards

prescribed pursuant to section 360kk of this title, then, unless subsection (b) of this section applies and is complied with, (1) such electronic product shall be refused admission, and (2) the Secretary of the Treasury shall cause the destruction of such electronic product unless such article is exported, under regulations prescribed by the Secretary of the Treasury, within 90 days after the date of notice of refusal of admission or within such additional time as may be permitted by such regulations.

**(b) Bond**

If it appears to the Secretary of Health and Human Services that any electronic product refused admission pursuant to subsection (a) of this section can be brought into compliance with applicable standards prescribed pursuant to section 360kk of this title, final determination as to admission of such electronic product may be deferred upon filing of timely written application by the owner or consignee and the execution by him of a good and sufficient bond providing for the payment of such liquidated damages in the event of default as the Secretary of Health and Human Services may by regulation prescribe. If such application is filed and such bond is executed the Secretary of Health and Human Services may, in accordance with rules prescribed by him, permit the applicant to perform such operations with respect to such electronic product as may be specified in the notice of permission.

**(c) Liability of owner or consignee for expenses connected with refusal of admission**

All expenses (including travel, per diem or subsistence, and salaries of officers or employees of the United States) in connection with the destruction provided for in subsection (a) of this section and the supervision of operations provided for in subsection (b) of this section, and all expenses in connection with the storage, cartage, or labor with respect to any electronic product refused admission pursuant to subsection (a) of this section, shall be paid by the owner or consignee, and, in event of default, shall constitute a lien against any future importations made by such owner or consignee.

**(d) Designation of agent for purposes of service**

It shall be the duty of every manufacturer offering an electronic product for importation into the United States to designate in writing an agent upon whom service of all administrative and judicial processes, notices, orders, decisions, and requirements may be made for and on behalf of said manufacturer, and to file such designation with the Secretary, which designation may from time to time be changed by like writing, similarly filed. Service of all administrative and judicial processes, notices, orders, decisions, and requirements may be made upon said manufacturer by service upon such designated agent at his office or usual place of residence with like effect as if made personally upon said manufacturer, and in default of such designation of such agent, service of process, notice, order, requirement, or decision in any proceeding before the Secretary or in any judicial proceeding for enforcement of this part or any standards prescribed pursuant to this part may be made by

posting such process, notice, order, requirement, or decision in the Office of the Secretary or in a place designated by him by regulation.

(June 25, 1938, ch. 675, §536, formerly act July 1, 1944, ch. 373, title III, §536, formerly §360, as added Pub. L. 90-602, §2(3), Oct. 18, 1968, 82 Stat. 1181; renumbered §536 and amended Pub. L. 101-629, §19(a)(1)(B), (2)(D), (3), (4), Nov. 28, 1990, 104 Stat. 4529, 4530; Pub. L. 102-300, §6(b)(1), June 16, 1992, 106 Stat. 240; Pub. L. 103-80, §4(a)(2), Aug. 13, 1993, 107 Stat. 779.)

CODIFICATION

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

1992—Subsecs. (a), (b). Pub. L. 102-300 substituted “Health and Human Services” for “Health, Education, and Welfare” wherever appearing.

1990—Subsec. (a). Pub. L. 101-629, §19(a)(1)(B), (2)(D), substituted “this part” for “this subpart”, “section 360kk(h)” for “section 263f(h)”, and “section 360kk” for “section 263f”.

Subsec. (b). Pub. L. 101-629, §19(a)(2)(D), substituted “section 360kk” for “section 263f”.

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

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.

**§ 360nn. Inspection, records, and reports**

**(a) Inspection of premises**

If the Secretary finds for good cause that the methods, tests, or programs related to electronic product radiation safety in a particular factory, warehouse, or establishment in which electronic products are manufactured or held, may not be adequate or reliable, officers or employees duly designated by the Secretary, upon presenting appropriate credentials and a written notice to the owner, operator, or agent in charge, are thereafter authorized (1) to enter, at reasonable times, any area in such factory, warehouse, or establishment in which the manufacturer’s tests (or testing programs) required by section 360kk(h) of this title are carried out, and (2) to inspect, at reasonable times and within reasonable limits and in a reasonable manner, the facilities and procedures within such area which are related to electronic product radiation safety. Each such inspection shall be commenced and completed with reasonable promptness. In addition to other grounds upon which good cause may be found for purposes of this subsection, good cause will be considered to exist in any case where the manufacturer has introduced into commerce any electronic product which does not comply with an applicable standard prescribed under this part and with respect to which no exemption from the notification requirements has been granted by the Secretary under section 360ll(a)(2) or 360ll(e) of this title.

**(b) Record keeping**

Every manufacturer of electronic products shall establish and maintain such records (including testing records), make such reports, and provide such information, as the Secretary may reasonably require to enable him to determine whether such manufacturer has acted or is acting in compliance with this part and standards prescribed pursuant to this part and shall, upon request of an officer or employee duly designated by the Secretary, permit such officer or employee to inspect appropriate books, papers, records, and documents relevant to determining whether such manufacturer has acted or is acting in compliance with standards prescribed pursuant to this part.

**(c) Disclosure of technical data**

Every manufacturer of electronic products shall provide to the Secretary such performance data and other technical data related to safety as may be required to carry out the purposes of this part. The Secretary is authorized to require the manufacturer to give such notification of such performance and technical data at the time of original purchase to the ultimate purchaser of the electronic product, as he determines necessary to carry out the purposes of this part after consulting with the affected industry.

**(d) Public nature of reports**

Accident and investigation reports made under this part by any officer, employee, or agent of the Secretary shall be available for use in any civil, criminal, or other judicial proceeding arising out of such accident. Any such officer, employee, or agent may be required to testify in such proceedings as to the facts developed in such investigations. Any such report shall be made available to the public in a manner which need not identify individuals. All reports on research projects, demonstration projects, and other related activities shall be public information.

**(e) Trade secrets**

The Secretary or his representative shall not disclose any information reported to or otherwise obtained by him, pursuant to subsection (a) or (b) of this section, which concerns any information which contains or relates to a trade secret or other matter referred to in section 1905 of title 18, except that such information may be disclosed to other officers or employees of the Department and of other agencies concerned with carrying out this part or when relevant in any proceeding under this part. Nothing in this section shall authorize the withholding of information by the Secretary, or by any officers or employees under his control, from the duly authorized committees of the Congress.

**(f) Information required to identify and locate first purchasers of electronic products**

The Secretary may by regulation (1) require dealers and distributors of electronic products, to which there are applicable standards prescribed under this part and the retail prices of which is not less than \$50, to furnish manufacturers of such products such information as may be necessary to identify and locate, for purposes of section 360ll of this title, the first purchasers

of such products for purposes other than resale, and (2) require manufacturers to preserve such information. Any regulation establishing a requirement pursuant to clause (1) of the preceding sentence shall (A) authorize such dealers and distributors to elect, in lieu of immediately furnishing such information to the manufacturer, to hold and preserve such information until advised by the manufacturer or Secretary that such information is needed by the manufacturer for purposes of section 360ll of this title, and (B) provide that the dealer or distributor shall, upon making such election, give prompt notice of such election (together with information identifying the notifier and the product) to the manufacturer and shall, when advised by the manufacturer or Secretary, of the need therefor for the purposes of section 360ll of this title, immediately furnish the manufacturer with the required information. If a dealer or distributor discontinues the dealing in or distribution of electronic products, he shall turn the information over to the manufacturer. Any manufacturer receiving information pursuant to this subsection concerning first purchasers of products for purposes other than resale shall treat it as confidential and may use it only if necessary for the purpose of notifying persons pursuant to section 360ll(a) of this title.

(June 25, 1938, ch. 675, §537, formerly act July 1, 1944, ch. 373, title III, §537, formerly §360A, as added Pub. L. 90-602, §2(3), Oct. 18, 1968, 82 Stat. 1182; renumbered §537 and amended Pub. L. 101-629, §19(a)(1)(B), (2)(E), (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 263i 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 263i of Title 42, The Public Health and Welfare, as this section.

1990—Subsec. (a). Pub. L. 101-629, §19(a)(1)(B), (2)(E), substituted “section 360kk(h)” for “section 263f(h)”, “this part” for “this subpart”, and “section 360ll(a)(2) or 360ll(e)” for “section 263g(a)(2) or 263g(e)”.

Subsecs. (b) to (e). Pub. L. 101-629, §19(a)(1)(B), substituted “this part” for “this subpart” wherever appearing.

Subsec. (f). Pub. L. 101-629, §19(a)(1)(B), (2)(E)(ii), substituted “this part” for “this subpart”, “section 360ll” for “section 263g” in three places, and “section 360ll(a)” for “section 263g(a)”.

## 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.

**§ 360oo. Prohibited acts**

(a) It shall be unlawful—

(1) for any manufacturer to introduce, or to deliver for introduction, into commerce, or to import into the United States, any electronic product which does not comply with an applicable standard prescribed pursuant to section 360kk of this title;



(2) for any person to fail to furnish any notification or other material or information required by section 360ll or 360nn of this title; or to fail to comply with the requirements of section 360ll(f) of this title;

(3) for any person to fail or to refuse to establish or maintain records required by this part or to permit access by the Secretary or any of his duly authorized representatives to, or the copying of, such records, or to permit entry or inspection, as required by or pursuant to section 360nn of this title;

(4) for any person to fail or to refuse to make any report required pursuant to section 360nn(b) of this title or to furnish or preserve any information required pursuant to section 360nn(f) of this title; or

(5) for any person (A) to fail to issue a certification as required by section 360kk(h) of this title, or (B) to issue such a certification when such certification is not based upon a test or testing program meeting the requirements of section 360kk(h) of this title or when the issuer, in the exercise of due care, would have reason to know that such certification is false or misleading in a material respect.

(b) The Secretary may exempt any electronic product, or class thereof, from all or part of subsection (a) of this section, upon such conditions as he may find necessary to protect the public health or welfare, for the purpose of research, investigations, studies, demonstrations, or training, or for reasons of national security.

(June 25, 1938, ch. 675, § 538, formerly act July 1, 1944, ch. 373, title III, § 538, formerly § 360B, as added Pub. L. 90-602, § 2(3), Oct. 18, 1968, 82 Stat. 1184; renumbered § 538 and amended Pub. L. 101-629, § 19(a)(1)(B), (2)(F), (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 263j 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 263j of Title 42, The Public Health and Welfare, as this section.

1990—Subsec. (a)(1). Pub. L. 101-629, § 19(a)(2)(F)(i), substituted “section 360kk” for “section 263f”.

Subsec. (a)(2). Pub. L. 101-629, § 19(a)(2)(F)(ii), (iii), substituted “section 360ll or 360nn” for “section 263g or 263i” and “section 360ll(f)” for “section 263g(f)”.

Subsec. (a)(3). Pub. L. 101-629, § 19(a)(1)(B), (2)(F)(iii), substituted “this part” for “this subpart” and “section 360nn” for “section 263i”.

Subsec. (a)(4). Pub. L. 101-629, § 19(a)(2)(F)(iii), substituted “section 360nn(b)” for “section 263i(b)” and “section 360nn(f)” for “section 263i(f)”.

Subsec. (a)(5). Pub. L. 101-629, § 19(a)(2)(F)(i), substituted “section 360kk(h)” for “section 263f(h)” in two places.

#### 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.

## § 360pp. Enforcement

### (a) Jurisdiction of courts

The district courts of the United States shall have jurisdiction, for cause shown, to restrain violations of section 360oo of this title and to restrain dealers and distributors of electronic products from selling or otherwise disposing of electronic products which do not conform to an applicable standard prescribed pursuant to section 360kk of this title except when such products are disposed of by returning them to the distributor or manufacturer from whom they were obtained. The district courts of the United States shall also have jurisdiction in accordance with section 1355 of title 28 to enforce the provisions of subsection (b) of this section.

### (b) Penalties

(1) Any person who violates section 360oo of this title shall be subject to a civil penalty of not more than \$1,000. For purposes of this subsection, any such violation shall with respect to each electronic product involved, or with respect to each act or omission made unlawful by section 360oo of this title, constitute a separate violation, except that the maximum civil penalty imposed on any person under this subsection for any related series of violations shall not exceed \$300,000.

(2) Any such civil penalty may on application be remitted or mitigated by the Secretary. In determining the amount of such penalty, or whether it should be remitted or mitigated and in what amount, the appropriateness of such penalty to the size of the business of the person charged and the gravity of the violation shall be considered. The amount of such penalty, when finally determined, may be deducted from any sums owing by the United States to the person charged.

### (c) Venue; process

Actions under subsections (a) and (b) of this section may be brought in the district court of the United States for the district wherein any act or omission or transaction constituting the violation occurred, or in such court for the district where the defendant is found or transacts business, and process in such cases may be served in any other district of which the defendant is an inhabitant or wherever the defendant may be found.

### (d) Warnings

Nothing in this part shall be construed as requiring the Secretary to report for the institution of proceedings minor violations of this part whenever he believes that the public interest will be adequately served by a suitable written notice or warning.

### (e) Compliance with regulations

Except as provided in the first sentence of section 360ss of this title, compliance with this part or any regulations issued thereunder shall not relieve any person from liability at common law or under statutory law.

### (f) Additional remedies

The remedies provided for in this part shall be in addition to and not in substitution for any other remedies provided by law.

(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.