

“(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-