

CODIFICATION

Section was enacted as part of the Orphan Drug Act, and not as part of the Federal Food, Drug, and Cosmetic Act which comprises this chapter.

AMENDMENTS

2007—Subsec. (c). Pub. L. 110-85 amended subsec. (c) generally. Prior to amendment, subsec. (c) read as follows: “For grants and contracts under subsection (a) of this section, there are authorized to be appropriated such sums as already have been appropriated for fiscal year 2002, and \$25,000,000 for each of the fiscal years 2003 through 2006.”

2002—Subsec. (c). Pub. L. 107-281 amended subsec. (c) generally. Prior to amendment, subsec. (c) read as follows: “For grants and contracts under subsection (a) of this section there are authorized to be appropriated \$10,000,000 for fiscal year 1988, \$12,000,000 for fiscal year 1989, \$14,000,000 for fiscal year 1990.”

1997—Subsec. (b)(1)(A)(ii), (B). Pub. L. 105-115 struck out “or 357” after “355(b)”.

1988—Subsec. (a). Pub. L. 100-290, §3(a)(1), (b)(1), inserted “(1)” after “assist in” and added cls. (2) and (3).

Subsec. (b)(2). Pub. L. 100-290, §3(a)(2), (b)(2), inserted “(1) in the case of a drug,” after “means”, added cls. (2) and (3), and substituted “under section 360bb of this title” for “under this subsection” in last sentence.

Subsec. (b)(3). Pub. L. 100-290, §3(b)(3), added par. (3).

Subsec. (c). Pub. L. 100-290, §3(c), amended subsec. (c) generally. Prior to amendment, subsec. (c) read as follows: “For grants and contracts under subsection (a) of this section there are authorized to be appropriated \$4,000,000 for fiscal year 1986, \$4,000,000 for fiscal year 1987, and \$4,000,000 for fiscal year 1988.”

1985—Subsec. (a). Pub. L. 99-91, §5(a)(1), struck out “clinical” before “testing”.

Subsec. (b)(1). Pub. L. 99-91, §5(a)(2), substituted provisions defining “qualified testing” for provisions defining “qualified clinical testing”.

Subsec. (c). Pub. L. 99-91, §5(b), substituted provisions authorizing appropriations for fiscal years 1986 to 1988, for provisions authorizing appropriations for fiscal years 1983 and the two succeeding fiscal years.

1984—Subsec. (b)(2). Pub. L. 98-551 substituted “which (A) affects less than 200,000 persons in the United States, or (B) affects more than 200,000 in the United States and for which” for “which occurs so infrequently in the United States that”.

EFFECTIVE DATE OF 1985 AMENDMENT

Amendment by Pub. L. 99-91 effective Oct. 1, 1985, see section 8(a) of Pub. L. 99-91, set out as a note under section 360aa of this title.

FINDINGS AND PURPOSES

Pub. L. 107-281, §2, Nov. 6, 2002, 116 Stat. 1992, provided that:

“(a) FINDINGS.—Congress makes the following findings:

“(1) Rare diseases and disorders are those which affect small patient populations, typically populations smaller than 200,000 individuals in the United States. Such diseases and conditions include Huntington’s disease, amyotrophic lateral sclerosis (Lou Gehrig’s disease), Tourette syndrome, Crohn’s disease, cystic fibrosis, cystinosis, and Duchenne muscular dystrophy.

“(2) For many years, the 25,000,000 Americans suffering from the over 6,000 rare diseases and disorders were denied access to effective medicines because prescription drug manufacturers could rarely make a profit from marketing drugs for such small groups of patients. The prescription drug industry did not adequately fund research into such treatments. Despite the urgent health need for these medicines, they came to be known as ‘orphan drugs’ because no companies would commercialize them.

“(3) During the 1970s, an organization called the National Organization for Rare Disorders (NORD) was

founded to provide services and to lobby on behalf of patients with rare diseases and disorders. NORD was instrumental in pressing Congress for legislation to encourage the development of orphan drugs.

“(4) The Orphan Drug Act [see Short Title of 1983 Amendments note set out under section 301 of this title] created financial incentives for the research and production of such orphan drugs. New Federal programs at the National Institutes of Health and the Food and Drug Administration encouraged clinical research and commercial product development for products that target rare diseases. An Orphan Products Board was established to promote the development of drugs and devices for rare diseases or disorders.

“(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 5 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.