

“(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