

commitment to pay for the user fee to be assessed in accordance with this section.

“(B) TRANSFER AFTER NOTICE.—The sponsor of a human drug application that provides notification of the intent of such sponsor to use the voucher for the human drug application under subparagraph (A) may transfer the voucher after such notification is provided, if such sponsor has not yet submitted the human drug application described in the notification.”

Subsec. (b)(5). Pub. L. 114–255 added par. (5) and struck out former par. (5). Prior to amendment, text read as follows: “The Secretary may not award any priority review vouchers under paragraph (1) after December 31, 2016.”

Pub. L. 114–229, §2(a)(2)(B), added par. (5) and struck out former par. (5). Prior to amendment, text read as follows: “The Secretary may not award any priority review vouchers under paragraph (1) after September 30, 2016.”

Subsec. (g). Pub. L. 114–229, §2(a)(3), inserted before period at end “, except that no sponsor of a rare pediatric disease product application may receive more than one priority review voucher issued under any section of this chapter with respect to the drug for which the application is made.”

2015—Subsec. (b)(5). Pub. L. 114–113 substituted “September 30, 2016.” for “the last day of the 1-year period that begins on the date that the Secretary awards the third rare pediatric disease priority voucher under this section.”

Statutory Notes and Related Subsidiaries

CONSTRUCTION

Pub. L. 114–229, §2(b), Sept. 30, 2016, 130 Stat. 944, provided that: “Nothing in this Act [amending this section and enacting provisions set out as a note under section 301 of this title], or the amendments made by this Act, shall be construed to affect the validity of a priority review voucher that was issued under section 529 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360ff) before the date of enactment of this Act [Sept. 30, 2016].”

§ 360ff–1. Targeted drugs for rare diseases

(a) Purpose

The purpose of this section, through the approach provided for in subsection (b), is to—

(1) facilitate the development, review, and approval of genetically targeted drugs and variant protein targeted drugs to address an unmet medical need in one or more patient subgroups, including subgroups of patients with different mutations of a gene, with respect to rare diseases or conditions that are serious or life-threatening; and

(2) maximize the use of scientific tools or methods, including surrogate endpoints and other biomarkers, for such purposes.

(b) Leveraging of data from previously approved drug application or applications

The Secretary may, consistent with applicable standards for approval under this chapter or section 351(a) of the Public Health Service Act [42 U.S.C. 262(a)], allow the sponsor of an application under section 355(b)(1) of this title or section 351(a) of the Public Health Service Act for a genetically targeted drug or a variant protein targeted drug to rely upon data and information—

(1) previously developed by the same sponsor (or another sponsor that has provided the sponsor with a contractual right of reference to such data and information); and

(2) submitted by a sponsor described in paragraph (1) in support of one or more previously approved applications that were submitted under section 355(b)(1) of this title or section 351(a) of the Public Health Service Act,

for a drug that incorporates or utilizes the same or similar genetically targeted technology as the drug or drugs that are the subject of an application or applications described in paragraph (2) or for a variant protein targeted drug that is the same or incorporates or utilizes the same variant protein targeted drug, as the drug or drugs that are the subject of an application or applications described in paragraph (2).

(c) Definitions

For purposes of this section—

(1) the term “genetically targeted drug” means a drug that—

(A) is the subject of an application under section 355(b)(1) of this title or section 351(a) of the Public Health Service Act [42 U.S.C. 262(a)] for the treatment of a rare disease or condition (as such term is defined in section 360bb of this title) that is serious or life-threatening;

(B) may result in the modulation (including suppression, up-regulation, or activation) of the function of a gene or its associated gene product; and

(C) incorporates or utilizes a genetically targeted technology;

(2) the term “genetically targeted technology” means a technology comprising non-replicating nucleic acid or analogous compounds with a common or similar chemistry that is intended to treat one or more patient subgroups, including subgroups of patients with different mutations of a gene, with the same disease or condition, including a disease or condition due to other variants in the same gene; and

(3) the term “variant protein targeted drug” means a drug that—

(A) is the subject of an application under section 355(b)(1) of this title or section 351(a) of the Public Health Service Act [42 U.S.C. 262(a)] for the treatment of a rare disease or condition (as such term is defined in section 360bb of this title) that is serious or life-threatening;

(B) modulates the function of a product of a mutated gene where such mutation is responsible in whole or in part for a given disease or condition; and

(C) is intended to treat one or more patient subgroups, including subgroups of patients with different mutations of a gene, with the same disease or condition.

(d) Rule of construction

Nothing in this section shall be construed to—

(1) alter the authority of the Secretary to approve drugs pursuant to this chapter or section 351 of the Public Health Service Act [42 U.S.C. 262] (as authorized prior to December 13, 2016), including the standards of evidence, and applicable conditions, for approval under such applicable chapter or Act; or

(2) confer any new rights, beyond those authorized under this chapter or the Public

Health Service Act [42 U.S.C. 201 et seq.] prior to December 13, 2016, with respect to the permissibility of a sponsor referencing information contained in another application submitted under section 355(b)(1) of this title or section 351(a) of the Public Health Service Act [42 U.S.C. 262(a)].

(June 25, 1938, ch. 675, §529A, as added Pub. L. 114-255, div. A, title III, §3012, Dec. 13, 2016, 130 Stat. 1091.)

Editorial Notes

REFERENCES IN TEXT

The Public Health Service Act, referred to in subsec. (d)(2), is act July 1, 1944, ch. 373, 58 Stat. 682, which is classified generally to chapter 6A (§201 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 201 of Title 42 and Tables.

PART C—ELECTRONIC PRODUCT RADIATION CONTROL

Editorial Notes

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.)

Editorial Notes

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.

Statutory Notes and Related Subsidiaries

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

Pub. L. 101-629, §19(c), Nov. 28, 1990, 104 Stat. 4530, 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”

Pub. L. 90-602, §3, Oct. 18, 1968, 82 Stat. 1186, as amended by 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

Pub. L. 90-602, §4, Oct. 18, 1968, 82 Stat. 1187, 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