and medical evaluation and recommend controls under the Controlled Substances Act [21 U.S.C. 801 et seq.], a determination to grant the request to add such drug to the index shall not take effect until the interim final rule controlling the drug is issued in accordance with section 201(j) of the Controlled Substances Act [21 U.S.C. 811(j)].

(June 25, 1938, ch. 675, § 572, as added Pub. L. 108–282, title I, § 102(b)(4), Aug. 2, 2004, 118 Stat. 896; amended Pub. L. 114–89, § 2(a)(3)(C), Nov. 25, 2015, 129 Stat. 699.)

REFERENCES IN TEXT

The National Environmental Policy Act of 1969, referred to in subsec. (c)(1)(E), is Pub. L. 91–190, Jan. 1, 1970, 83 Stat. 852, as amended, which is classified generally to chapter 55 (§ 4321 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 4321 of Title 42 and Tables.

The Federal Advisory Committee Act, referred to in subsec. (d)(3)(C), is Pub. L. 92–463, Oct. 6, 1972, 86 Stat. 770, as amended, which is set out in the Appendix to Title 5, Government Organization and Employees.

The Controlled Substances Act, referred to in subsec. (k), is title II of Pub. L. 91–513, Oct. 27, 1970, 84 Stat. 1242, which is classified principally to subchapter I (§ 801 et seq.) of chapter 13 of this title. For complete classification of this Act to the Code, see Short Title note set out under section 801 of this title and Tables.

AMENDMENTS

2015—Subsec. (k). Pub. L. 114–89 added subsec. (k).

§ 360ccc–2. Designated new animal drugs for minor use or minor species

(a) Designation

(1) The manufacturer or the sponsor of a new animal drug for a minor use or use in a minor species may request that the Secretary declare that drug a ''designated new animal drug''. A request for designation of a new animal drug shall be made before the submission of an application under section 360b(b) of this title or section 360ccc of this title for the new animal drug.

(2) The Secretary may declare a new animal drug a ''designated new animal drug'' if—

(A) it is intended for a minor use or use in a minor species; and

(B) the same drug in the same dosage form for the same intended use is not approved under section 360b or 360ccc of this title or designated under this section at the time the request is made.

(3) Regarding the termination of a designation—

(A) the sponsor of a new animal drug shall notify the Secretary of any decision to discontinue active pursuit of approval under section 360b or 360ccc of this title of an application for a designated new animal drug. The Secretary shall terminate the designation upon such notification;

(B) the Secretary may also terminate designation if the Secretary independently determines that the sponsor is not actively pursuing approval under section 360b or 360ccc of this title with due diligence;

(C) the sponsor of an approved designated new animal drug shall notify the Secretary of any discontinuance of the manufacture of such new animal drug at least one year before discontinuance. The Secretary shall terminate the designation upon such notification; and

(D) the designation shall terminate upon the expiration of any applicable exclusivity period under subsection (c).

(4) Notice respecting the designation or termination of designation of a new animal drug shall be made available to the public.

(b) Grants and contracts for development of designated new animal drugs

(1) The Secretary may make grants to and enter into contracts with public and private entities and individuals to assist in defraying the costs of qualified safety and effectiveness testing expenses and manufacturing expenses incurred in connection with the development of designated new animal drugs.

(2) For purposes of paragraph (1) of this section—

(A) The term ''qualified safety and effectiveness testing'' means testing—

(i) which occurs after the date such new animal drug is designated under this section and before the date on which an application with respect to such drug is submitted under section 360b of this title; and

(ii) which is carried out under an investigational exemption under section 360b(j) of this title.

(B) The term ''manufacturing expenses'' means expenses incurred in developing processes and procedures associated with manufacture of the designated new animal drug which occur after the new animal drug is designated under this section and before the date on which an application with respect to such new animal drug is submitted under section 360b or 360ccc of this title.

(c) Exclusivity for designated new animal drugs

(1) Except as provided in subsection (c)(2), if the Secretary approves or conditionally approves an application for a designated new animal drug, the Secretary may not approve or conditionally approve another application submitted for such new animal drug with the same intended use as the designated new animal drug for another applicant before the expiration of seven years from the date of approval or conditional approval of the application.

(2) If an application filed pursuant to section 360b of this title or section 360ccc of this title is approved for a designated new animal drug, the Secretary may, during the 7-year exclusivity period beginning on the date of the application approval or conditional approval, approve or conditionally approve another application under section 360b of this title or section 360ccc of this title for such drug for such minor use or minor species for another applicant if—

(A) the Secretary finds, after providing the holder of such an approved application notice and opportunity for the submission of views, that in the granted exclusivity period the holder of the approved application cannot assure the availability of sufficient quantities of the drug to meet the needs for which the drug was designated; or

(B) such holder provides written consent to the Secretary for the approval or conditional approval of other applications before the expiration of such exclusivity period.

(3) For purposes of determining the 7-year period of exclusivity under paragraph (1) for a drug for which the Secretary intends to issue a scientific and medical evaluation and recommend controls under the Controlled Substances Act [21 U.S.C. 801 et seq.], the drug shall not be considered approved or conditionally approved until the date that the interim final rule controlling the drug is issued in accordance with section 201(j) of the Controlled Substances Act [21 U.S.C. 811(j)].

(June 25, 1938, ch. 675, § 573, as added Pub. L. 108–282, title I, § 102(b)(4), Aug. 2, 2004, 118 Stat. 900; amended Pub. L. 114–89, § 2(a)(4), Nov. 25, 2015, 129 Stat. 700.)

REFERENCES IN TEXT

The Controlled Substances Act, referred to in subsec. (c)(3), is title II of Pub. L. 91–513, Oct. 27, 1970, 84 Stat. 1242, which is classified principally to subchapter I (§ 801 et seq.) of chapter 13 of this title. For complete classification of this Act to the Code, see Short Title note set out under section 801 of this title and Tables.

AMENDMENTS

2015—Subsec. (c)(3). Pub. L. 114–89 added par. (3).

PART G—MEDICAL GASES

§ 360ddd. Definitions

In this part:

(1) The term ''designated medical gas'' means any of the following:

(A) Oxygen that meets the standards set forth in an official compendium.

(B) Nitrogen that meets the standards set forth in an official compendium.

(C) Nitrous oxide that meets the standards set forth in an official compendium.

(D) Carbon dioxide that meets the standards set forth in an official compendium.

(E) Helium that meets the standards set forth in an official compendium.

(F) Carbon monoxide that meets the standards set forth in an official compendium.

(G) Medical air that meets the standards set forth in an official compendium.

(H) Any other medical gas deemed appropriate by the Secretary, after taking into account any investigational new drug application or investigational new animal drug application for the same medical gas submitted in accordance with regulations applicable to such applications in title 21 of the Code of Federal Regulations, unless any period of exclusivity for a new drug under section 355(c)(3)(E)(ii) of this title or section 355(j)(5)(F)(ii) of this title, or the extension of any such period under section 355a of this title, or any period of exclusivity for a new animal drug under section 360b(c)(2)(F) of this title, applicable to such medical gas has not expired.

(2) The term ''medical gas'' means a drug that—

(A) is manufactured or stored in a liquefied, nonliquefied, or cryogenic state; and

(B) is administered as a gas.

(June 25, 1938, ch. 675, § 575, as added Pub. L. 112–144, title XI, § 1111, July 9, 2012, 126 Stat. 1108; amended Pub. L. 114–255, div. A, title III, § 3101(a)(2)(R), Dec. 13, 2016, 130 Stat. 1155.)

AMENDMENTS

2016—Par. (1)(H). Pub. L. 114–255 inserted ''for a new drug'' after ''any period of exclusivity'' and ''or any period of exclusivity for a new animal drug under section 360b(c)(2)(F) of this title,'' after ''section 355a of this title,''.

CHANGES TO REGULATIONS

Pub. L. 112–144, title XI, § 1112, July 9, 2012, 126 Stat. 1111, provided that:

''(a) REPORT.—Not later than 18 months after the date of the enactment of this Act [July 9, 2012], the Secretary, after obtaining input from medical gas manufacturers and any other interested members of the public, shall—

''(1) determine whether any changes to the Federal drug regulations are necessary for medical gases; and

''(2) submit to the Committee on Health, Education, Labor, and Pensions of the Senate and the Committee on Energy and Commerce of the House of Representatives a report regarding any such changes.

''(b) REGULATIONS.—If the Secretary determines under subsection (a) that changes to the Federal drug regulations are necessary for medical gases, the Secretary shall issue final regulations revising the Federal drug regulations with respect to medical gases not later than 48 months after the date of the enactment of this Act [July 9, 2012].

''(c) DEFINITIONS.—In this section:

''(1) The term 'Federal drug regulations' means regulations in title 21 of the Code of Federal Regulations pertaining to drugs.

''(2) The term 'medical gas' has the meaning given to such term in section 575 of the Federal Food, Drug, and Cosmetic Act [21 U.S.C. 360ddd], as added by section 1111 of this Act.

''(3) The term 'Secretary' means the Secretary of Health and Human Services, acting through the Commissioner of Food and Drugs.''

RULES OF CONSTRUCTION

Pub. L. 112–144, title XI, § 1113, July 9, 2012, 126 Stat. 1112, provided that: ''Nothing in this subtitle [subtitle B (§§ 1111–1113) of title XI of Pub. L. 112–144, enacting this section and sections 360ddd–1 and 360ddd–2 of this title and provisions set out as notes under this section] and the amendments made by this subtitle applies with respect to—

''(1) a drug that is approved prior to May 1, 2012, pursuant to an application submitted under section 505 or 512 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355, 360b);

''(2) any gas listed in subparagraphs (A) through (G) of section 575(1) of the Federal Food, Drug, and Cosmetic Act [21 U.S.C. 360ddd(1)], as added by section 1111 of this Act, or any combination of any such gases, for an indication that—

''(A) is not included in, or is different from, those specified in subclauses (I) through (VII) of section 576(a)(3)(A)(i) of such Act [21 U.S.C. 360ddd–1(a)(3)(A)(i)]; and

''(B) is approved on or after May 1, 2012, pursuant to an application submitted under section 505 or 512 [21 U.S.C. 355, 360b]; or

''(3) any designated medical gas added pursuant to subparagraph (H) of section 575(1) of such Act [21 U.S.C. 360ddd(1)] for an indication that—

''(A) is not included in, or is different from, those originally added pursuant to subparagraph (H) of section 575(1) [21 U.S.C. 360ddd(1)(H)] and section 576(a)(3)(A)(i)(VIII) [21 U.S.C. 360ddd–1(a)(3)(A)(i)(VIII)]; and