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 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, 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.)

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

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

§ 360ddd–1. Regulation of medical gases

(a) Certification of designated medical gases

(1) Submission

Beginning 180 days after July 9, 2012, any person may file with the Secretary a request for certification of a medical gas as a designated medical gas. Any such request shall contain the following information:

(A) A description of the medical gas.

(B) The name and address of the sponsor.

(C) The name and address of the facility or facilities where the medical gas is or will be manufactured.

(D) Any other information deemed appropriate by the Secretary to determine whether the medical gas is a designated medical gas.

(2) Grant of certification

The certification requested under paragraph (1) is deemed to be granted unless, within 60 days of the filing of such request, the Secretary finds that—

(A) the medical gas subject to the certification is not a designated medical gas;

(B) the request does not contain the information required under paragraph (1) or otherwise lacks sufficient information to permit the Secretary to determine that the medical gas is a designated medical gas; or

(C) denying the request is necessary to protect the public health.