

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) of this section, 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.

(June 25, 1938, ch. 675, §573, as added Pub. L. 108–282, title I, §102(b)(4), Aug. 2, 2004, 118 Stat. 900.)

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)(i) of this title or section 355(j)(5)(F)(i) 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.

(3) Effect of certification

(A) In general

(i) Approved uses

A designated medical gas for which a certification is granted under paragraph (2) is deemed, alone or in combination, as medically appropriate, with another designated medical gas or gases for which a certification or certifications have been granted, to have in effect an approved ap-

plication under section 355 or 360b of this title, subject to all applicable postapproval requirements, for the following indications for use:

(I) In the case of oxygen, the treatment or prevention of hypoxemia or hypoxia.

(II) In the case of nitrogen, use in hypoxic challenge testing.

(III) In the case of nitrous oxide, analgesia.

(IV) In the case of carbon dioxide, use in extracorporeal membrane oxygenation therapy or respiratory stimulation.

(V) In the case of helium, the treatment of upper airway obstruction or increased airway resistance.

(VI) In the case of medical air, to reduce the risk of hyperoxia.

(VII) In the case of carbon monoxide, use in lung diffusion testing.

(VIII) Any other indication for use for a designated medical gas or combination of designated medical gases deemed appropriate by the Secretary, unless any period of exclusivity under clause (iii) or (iv) of section 355(c)(3)(E) of this title, clause (iii) or (iv) of section 355(j)(5)(F) of this title, or section 360cc of this title, or the extension of any such period under section 355a of this title, applicable to such indication for use for such gas or combination of gases has not expired.

(ii) Labeling

The requirements of sections 353(b)(4) and 352(f) of this title are deemed to have been met for a designated medical gas if the labeling on final use container for such medical gas bears—

(I) the information required by section 353(b)(4) of this title;

(II) a warning statement concerning the use of the medical gas as determined by the Secretary by regulation; and

(III) appropriate directions and warnings concerning storage and handling.

(B) Inapplicability of exclusivity provisions

(i) No exclusivity for a certified medical gas

No designated medical gas deemed under subparagraph (A)(i) to have in effect an approved application is eligible for any period of exclusivity under section 355(c), 355(j), or 360cc of this title, or the extension of any such period under section 355a of this title, on the basis of such deemed approval.

(ii) Effect on certification

No period of exclusivity under section 355(c), 355(j), or section 360cc of this title, or the extension of any such period under section 355a of this title, with respect to an application for a drug product shall prohibit, limit, or otherwise affect the submission, grant, or effect of a certification under this section, except as provided in subsection (a)(3)(A)(i)(VIII) and section 360ddd(1)(H) of this title.