21 USC 360ddd: Definitions
Text contains those laws in effect on February 12, 2018

From Title 21-FOOD AND DRUGS
CHAPTER 9-FEDERAL FOOD, DRUG, AND COSMETIC ACT
SUBCHAPTER V-DRUGS AND DEVICES
Part G-Medical Gases

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§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

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§360ddd–1. Regulation of medical gases

(a) Certification of designated medical gases

(1) Submission

Beginning 180 days after July 9, 2012, any person who seeks to initially introduce or deliver for introduction a designated medical gas into interstate commerce 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 application 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 for a new drug 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 the 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 for a new drug 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.

(4) Withdrawal, suspension, or revocation of approval

(A) Withdrawal, suspension of approval

Nothing in this part limits the Secretary's authority to withdraw or suspend approval of a drug product, including a designated medical gas deemed under this section to have in effect an approved application under section 355 of this title or section 360b of this title.

(B) Revocation of certification

The Secretary may revoke the grant of a certification under paragraph (2) if the Secretary determines that the request for certification contains any material omission or falsification.

(b) Prescription requirement

(1) In general

A designated medical gas shall be subject to the requirements of section 353(b)(1) of this title unless the Secretary exercises the authority provided in section 353(b)(3) of this title to remove such medical gas from the requirements of section 353(b)(1) of this title, the gas is approved for use without a prescription pursuant to an application under section 355 or 360b of this title, or the use in question is authorized pursuant to another provision of this chapter relating to use of medical products in emergencies.

(2) Oxygen

(A) No prescription required for certain uses

Notwithstanding paragraph (1), oxygen may be provided without a prescription for the following uses:

(i) For use in the event of depressurization or other environmental oxygen deficiency.

(ii) For oxygen deficiency or for use in emergency resuscitation, when administered by properly trained personnel.

(B) Labeling

For oxygen provided pursuant to subparagraph (A), the requirements of section 353(b)(4) of this title shall be deemed to have been met if its labeling bears a warning that the oxygen can be used for emergency use only and for all other medical applications a prescription is required.

(June 25, 1938, ch. 675, §576, as added Pub. L. 112–144, title XI, §1111, July 9, 2012, 126 Stat. 1109 ; amended Pub. L. 114–255, div. A, title III, §3101(a)(2)(S), Dec. 13, 2016, 130 Stat. 1155 .)