

- (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.)

Editorial Notes

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.”

Statutory Notes and Related Subsidiaries

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 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 ap-

proved 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.)

Editorial Notes

AMENDMENTS

2016—Subsec. (a)(1). Pub. L. 114-255, §3101(a)(2)(S)(i), inserted “who seeks to initially introduce or deliver for introduction a designated medical gas into interstate commerce” after “any person” in introductory provisions.

Subsec. (a)(3)(A)(i)(VIII). Pub. L. 114-255, §3101(a)(2)(S)(ii)(I)(aa), inserted “for a new drug” after “any period of exclusivity”.

Subsec. (a)(3)(A)(ii). Pub. L. 114-255, §3101(a)(2)(S)(ii)(I)(bb), inserted “the” before “final use” in introductory provisions.

Subsec. (a)(3)(B)(i). Pub. L. 114-255, §3101(a)(2)(S)(ii)(II)(aa), inserted “for a new drug” after “any period of exclusivity”.

Subsec. (a)(3)(B)(ii). Pub. L. 114-255, §3101(a)(2)(S)(ii)(II)(bb), inserted comma after “drug product”.

§ 360ddd-2. Inapplicability of drug fees to designated medical gases

A designated medical gas, alone or in combination with another designated gas or gases (as medically appropriate) deemed under section 360ddd-1 of this title to have in effect an approved application shall not be assessed fees under section 379h(a) or 379j-12(a) of this title on the basis of such deemed approval.

(June 25, 1938, ch. 675, §577, as added Pub. L. 112-144, title XI, §1111, July 9, 2012, 126 Stat. 1111; amended Pub. L. 114-255, div. A, title III, §3101(a)(2)(T), Dec. 13, 2016, 130 Stat. 1155.)

Editorial Notes

AMENDMENTS

2016—Pub. L. 114-255 inserted “or 379j-12(a)” after “section 379h(a)”.

PART H—PHARMACEUTICAL DISTRIBUTION SUPPLY CHAIN

§ 360eee. Definitions

In this part:

(1) Affiliate

The term “affiliate” means a business entity that has a relationship with a second business entity if, directly or indirectly—

(A) one business entity controls, or has the power to control, the other business entity; or

(B) a third party controls, or has the power to control, both of the business entities.

(2) Authorized

The term “authorized” means—

(A) in the case of a manufacturer or repackager, having a valid registration in accordance with section 360 of this title;

(B) in the case of a wholesale distributor, having a valid license under State law or section 360eee-2 of this title, in accordance with section 360eee-1(a)(6) of this title, and complying with the licensure reporting requirements under section 353(e) of this title;

(C) in the case of a third-party logistics provider, having a valid license under State law or section 360eee-3(a)(1) of this title, in accordance with section 360eee-1(a)(7) of this title, and complying with the licensure reporting requirements under section 360eee-3(b) of this title; and

(D) in the case of a dispenser, having a valid license under State law.

(3) Dispenser

The term “dispenser”—

(A) means a retail pharmacy, hospital pharmacy, a group of chain pharmacies under common ownership and control that do not act as a wholesale distributor, or any other person authorized by law to dispense or administer prescription drugs, and the affiliated warehouses or distribution centers of such entities under common ownership and control that do not act as a wholesale distributor; and

(B) does not include a person who dispenses only products to be used in animals in accordance with section 360b(a)(5) of this title.

(4) Disposition

The term “disposition”, with respect to a product within the possession or control of an entity, means the removal of such product from the pharmaceutical distribution supply chain, which may include disposal or return of the product for disposal or other appropriate handling and other actions, such as retaining a sample of the product for further additional physical examination or laboratory analysis of the product by a manufacturer or regulatory or law enforcement agency.

(5) Distribute or distribution

The term “distribute” or “distribution” means the sale, purchase, trade, delivery, handling, storage, or receipt of a product, and does not include the dispensing of a product pursuant to a prescription executed in accordance with section 353(b)(1) of this title or the dispensing of a product approved under section 360b(b) of this title.

(6) Exclusive distributor

The term “exclusive distributor” means the wholesale distributor that directly purchased the product from the manufacturer and is the sole distributor of that manufacturer’s product to a subsequent repackager, wholesale distributor, or dispenser.

(7) Homogeneous case

The term “homogeneous case” means a sealed case containing only product that has a single National Drug Code number belonging to a single lot.

(8) Illegitimate product

The term “illegitimate product” means a product for which credible evidence shows that the product—

(A) is counterfeit, diverted, or stolen;

(B) is intentionally adulterated such that the product would result in serious adverse health consequences or death to humans;

(C) is the subject of a fraudulent transaction; or