

Can I use medical gases for industrial purposes?

There are a several reasons why you would not want to encourage a customer to use medical gases in a manner inconsistent with it's labeling. For example,

#1. The label displays the mandatory prescription legend, "Rx Only". This limits the use of the drug to medical purposes only. See the 21 USC 353, 503 reference below. This reference comes from the US Food, Drug and Cosmetic Act (see <http://www.fda.gov/RegulatoryInformation/Legislation/FederalFoodDrugandCosmeticActFDCAAct/FDCAActChapterVDrugsandDevices/ucm108068.htm>)

#2. Medical gases are unique drugs, in that the container/closure (cylinder/valve) are reused. The FDA has published in several documents the necessity of segregation of industrial and medical gas cylinders. In addition, if a cylinder is used in an industrial application, the cylinder must undergo special cleaning operations. When the empty cylinder returns to the firm to be refilled, it will be assumed by the medical gas supplier to be a medical cylinder and will not undergo any special cleaning. (See attached "Tab 10 Fresh Air _1 April 2009.pdf" page 7, "Tab 05 Draft Guidance _1 April 2009.pdf" page 12, for example.)

Thank you,
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Must I have a prescription in order to buy medical oxygen?

SEC. 503. [21 USC 353] Exemptions and Consideration for Certain Drugs, Devices, and Biological Products

(a) The Secretary is hereby directed to promulgate regulations exempting from any labeling or packaging requirement of this Act drugs and devices which are, in accordance with the practice of the trade, to be processed, labeled, or repacked in substantial quantities at establishments other than those where originally processed or packed, on condition that such drugs and devices are not adulterated or misbranded, under the provisions of this Act upon removal from such processing, labeling, or repacking establishment.

(b)(1) A drug intended for use by man which

(A) because of its toxicity or other potentiality for harmful effect, or the method of its use, or the collateral measures necessary to its use, is not safe for use except under the supervision of a practitioner licensed by law to administer such drug; or

(B) is limited by an approved application under section 505 to use under the professional supervision of a practitioner licensed by law to administer such drug; **shall be dispensed only**

(i) upon a written prescription of a practitioner licensed by law to administer such drug, or (ii) upon an oral prescription of such practitioner which is reduced promptly to writing and filed by the pharmacist, or

(iii) by refilling any such written or oral prescription if such refilling is authorized by the prescriber either in the original prescription or by oral order which is reduced promptly to writing and filed by the pharmacist. The act of dispensing a drug contrary to the provisions of this paragraph shall be deemed to be an act which results in the drug being misbranded while held for sale.

Must I be licensed to distribute medical oxygen as a wholesaler?

Also in SEC. 503. [21 USC 353]

(e)(1)(A) Each person who is engaged in the wholesale distribution of a drug subject to subsection (b) and who is not the manufacturer or an authorized distributor of record of such drug shall, before each wholesale distribution of such drug (including each distribution to an authorized distributor of record or to a retail pharmacy), provide to the person who receives the drug a statement (in such form and containing such information as the Secretary may require) identifying each prior sale, purchase, or trade of such drug (including the date of the transaction and the names and addresses of all parties to the transaction).

(B) Each manufacturer of a drug subject to subsection (b) shall maintain at its corporate offices a current list of the authorized distributors of record of such drug.

(2)(A) No person may engage in the wholesale distribution in interstate commerce of drugs subject to subsection (b) in a State unless such person is licensed by the State in accordance with the guidelines issued under subparagraph (B).

(B) The Secretary shall by regulation issue guidelines establishing minimum standards, terms, and conditions for the licensing of persons to make wholesale distributions in interstate commerce of drugs subject to subsection (b). Such guidelines shall prescribe requirements for the storage and handling of such drugs and for the establishment and maintenance of records of the distributions of such drugs.

(3) For the purposes of this subsection and subsection (d)—

(A) the term "authorized distributors of record" means those distributors with whom a manufacturer has established an ongoing relationship to distribute such manufacturer's products, and

(B) the term "wholesale distribution" means distribution of drugs subject to subsection (b) to other than the consumer or patient but does not include intracompany sales and does not include distributions of drugs described in subsection (c)(3)(B).

The state determines what licenses are required for wholesale distribution.