AIR PRODUCTS

Air Products Healthcare
101 West Elm Street, Suite 210
Conshohocken, PA 19428

Tel 888-243-3456
Tel 484-530-0880
Fax 484-530-0888

2914 '03 JUN 11 A9:23

Via FedEx, and via fax (301) 827-6070

June 9, 2003

Dockets Management Branch (HFA-305)
Food and Drug Administration
5630 Fishers Lane
Room 1061
Rockville, MD 20852

Re: Docket No. 02N-0204
Bar Code Label Requirements for Human Drug Products and Blood

Dear Sir or Madam:

Air Products Healthcare provides the following comments as they relate to the proposed rule, "Bar Code Label Requirements for Human Drug Products and Blood", Docket 02N-0204, appearing in the Federal Register on March 14, 2003 at pages 12500 through 12534. In response to question 8 on page 12529 in the Federal Register notice, Air Products Healthcare proposes that the agency exempt medical gases classified as drugs (as a class of products) from the proposed rule (21CFR §201.25 "Bar code label requirements").

Air Products Healthcare, a wholly-owned subsidiary of Air Products, Inc., provides comprehensive home healthcare services, including respiratory care services, home medical equipment, rehabilitation and assistive technology, and infusion therapy services, to over 100,000 Medicare and other government and private payor's beneficiaries. Our forty-four locations covering primarily the New England, Northeast and Mid-Atlantic regions, provide medical gases to respiratory patients at their residences. Therefore, our comments will be limited to medical gases classified as drugs.

In the Federal Register Notice for the proposed rule, the "Summary" on page 12500 states that bar coding will reduce medication errors, "by allowing healthcare professionals to use bar code scanning equipment to verify that the right drug (in the right dose and right route of administration) is being given to the right patient at the right time." As detailed in this letter, we believe that medical gases should be exempted from the proposed rule for the following reasons:

a) Medical gases are uniquely packaged and used.
b) Bar coding of medical gases will not reduce the number of medication errors in the homecare setting, in hospitals, and other health care settings.

02N-0204

C 54

Accredited by JCAHO

c) Bar coding of medical gases will not assist our home healthcare professionals with assuring the aforementioned five "rights".

Air Products Healthcare welcomes the opportunity to engage in further dialogue on this topic with the FDA.

Overview of Medical Gases and How They are Used in Healthcare Settings

Medical gases are classified as prescription drugs (i.e., Oxygen USP, Nitrogen NF, Medical Air USP, Nitrous Oxide USP, Carbon Dioxide USP, and Helium USP as well as some mixtures of these gases). In emergency situations and when administered by properly trained personnel, Oxygen USP may be administered without a prescription.

Medical gases, particularly oxygen, are administered in various settings. Homecare patients self-administer their oxygen. Ambulatory patients in certain institutional settings may also self-administer their oxygen (e.g., when filling their own portable liquid units). In the institutional setting, clinicians typically administer medical gases.

Air Products Healthcare provides home respiratory care patients with Oxygen via various modalities, including:

a) Large stationary and small portable high-pressure cylinders.
b) Stationary and portable liquid vessels (with proprietary connections).
c) Directly via oxygen concentrators (these medical devices do not require bar coding).
d) Indirectly via oxygen cylinders filled by concentrators. (These types of concentrators are designed to allow patients to fill cylinders with oxygen in their homes.) Neither the concentrator nor the cylinder would require a bar code under the proposed rule.

In hospitals, clinics or other institutional settings medical gases are typically administered via piping systems. Medical gases are supplied by bulk storage tanks, large cryogenic vessels, and/or high pressure cylinders that are connected in remote areas, away from the pharmacy and patient use areas. Although Air Products Healthcare does not supply bulk oxygen for storage tanks, some companies may supply smaller institutions with large cryogenic vessels connected to a manifold and piped throughout the facility. The piping will end in the patient use area with a labeled and gas-specific wall outlet.

Medical gases may also be administered in these environments via small high-pressure cylinders or liquid containers. These small containers are very large in comparison to unit dose packaging. Medical gas container connections themselves are gas-specific and gas-property specific.

At times, Air Products Healthcare also provides physicians, dentists, and those involved in first aid/emergency care with medical gases in labeled and color-coded high-pressure cylinders with gas-specific connections.

Air Products Healthcare Rationale for Exemption of Medical Gases from Proposed Rule

- Medical gases are produced by a very large number of manufacturers/fillers, each with relatively limited geographical distribution. Due to the modality of the gas provided, and the patient-population served, medical gas manufacturers and distributors often have significant overlap within limited geographical areas. This is in contrast to typical pharmaceutical packages, which are produced by a limited number of manufacturers or repackagers with nationwide or regional distribution.

  An electronic search on the trade name "OXYGEN" yields well over a thousand NDC labeler codes, with a multitude of product and package codes. A similar search on "IBUPROFEN" yields less than 175 NDC labeler codes. Most medical gas manufacturers and private label distributors provide medical gases in two different modalities requiring two different NDC labeler codes for the same "gas". This is due to differences in the safe handling and storage directions on the container labels. For example, Oxygen USP may be provided in gaseous form in high pressure compressed gas cylinders, or in cryogenic liquid form in cryogenic containers. The labels and NDC codes would be different for these two containers, even though the Oxygen gas inhaled by the patient meets the same USP specifications.

  Air Products Healthcare questions the ability for hospitals and other health care entities to maintain a database that may require multiple thousands of NDC labeler and product code combinations just for medical gases, and also the software that would allow several NDC codes (that include company, product, and package code information) to be "scanned" for the same drug.

- Filling liquid oxygen home vessels curbside (at the patient's residence), although conducted in a retail capacity, is considered to be performing a manufacturing activity, and would fall under this proposed rule. Our locations are not exempt from the establishment registration and listing requirements (per section 510(g)(1) of the Act). The rationale provided by the agency for omitting prescription drug samples from the proposed bar code requirement, "because patients would not have or be inclined to buy bar code scanners for their own use in the immediate future", should also apply to oxygen supplied to patients at their residence.

- Patients utilizing an oxygen concentrator (a device not requiring bar code) in their homes, also utilize high-pressure cylinders (drug product containers subject to the proposed rule) as their back-up source in case of power failure. Even though the oxygen strength differs between the output of a concentrator and that provided in the cylinder, the gases are therapeutically equivalent. One product would require a bar code and the other would not. Bar coding medical gases will not assist in preventing medication errors in the home as further described below with respect to the five "rights".

- **NDC Labeler Code Bar Codes on Medical Gases Will Not Assure "Right Drug":**

  Placing bar codes on high-pressure cylinders or cryogenic vessels is unlikely to prevent "wrong drug" medication errors. When the relatively few medical gas mix-ups have occurred at healthcare facilities, existing safety systems had been compromised. Either the medical gas manufacturer or the person installing the container on the utilization or distribution equipment, had compromised the safety systems by removing, changing, or modifying the gas property-specific connection(s) on the gas container or gas utilization equipment, or by using cross-product adapters. Current regulations and regulatory initiatives already address the issues that have resulted in medical gas mix-ups.

  Medical oxygen, in almost all instances, is the only medical gas prescribed for use in the home, meaning no other medical gases are available to the patient. Even if a patient had more than one medical gas (and had a scanner), the inherent safety systems (different label, connection, and color code) would need to be circumvented in order to have a mix-up at the patient's home.

- **NDC Labeler Code Bar Code on Medical Gases Will Not Assure "Right Dose":**

  While bar coding unit dose packaging may assist with the "right dose" aspect of many traditional pharmaceuticals, medical gases are not produced in unit dose packages. In addition, labeling cannot indicate the number of "doses" contained in a medical gas cylinder or cryogenic vessel. Bar coding labels on medical gas containers would therefore not assist with administering the "right dose" for medical gases.

  As discussed previously, high-pressure cylinders are available in a multitude of sizes, with capacities ranging from less than one-hundred liters to several thousand liters of gas. Liquid containers are capable of holding significantly more (hundreds of thousands of liters). Container size or net contents have no bearing on dose. "Doses" prescribed by a physician for a patient in a healthcare facility, or at a patient's residence, are controlled by a pressure-regulator/gas flow meter (medical device), typically providing from less than 1 liter per minute to up to 10 liters per minute.

  A physician would not prescribe "one cylinder of oxygen" or "use on liquid oxygen home vessel." Instead, a physician would prescribe a specific flow rate for a specific duration of time (e.g., Oxygen via nasal cannula at 2 liters/minute for 24 hours per day).

  As the cylinder or vessel could be used to provide a variety of "dosages" (liter flows and durations), bar coding would have little bearing on providing on the correct dose to the patient.

- **NDC Labeler Code Bar Code on Medical Gases Will Not Assure "Right Patient":**

  Unlike in institutional settings, homecare services are provided at the patient's residence where computers would not be readily available to immediately confirm the patient's identity via bar code. Homecare patients do not wear identification wristbands that are commonly found in the acute and sub-acute care setting. However, there currently are patient-identifiers inherent to the homecare setting that assure "right patient" such as a delivery ticket that would include a unique address and patient identification numbers, and even provider familiarity with the homecare patient.

- **NDC Labeler Code Bar Code on Medical Gases Will Not Assure "Right Route of Administration":**

  Aside from the use of some cryogenic liquids in surgical applications and lab use (where again, the containers utilize unique fittings to prevent mix-ups), medical gases have only one route of administration – inhalation. Basic training of our employee and the education of homecare patients themselves help to assure that medical gases are administered via the proper route of administration.

  Medical gases are administered by inhalation via nasal cannula, mask, endotracheal or tracheostomy tube. It is unnecessary to rely on a bar-coded label on a cylinder or container to assure the medical gases "right route of administration".

- **NDC Labeler Code Bar Code on Medical Gases Will Not Assure "Right Time":**

  Unlike traditional pharmaceuticals dispensed at certain intervals, "right time" medication administration errors (e.g., failing to provide the drug at the correct time or providing it at multiple times) do not apply to medical gases. Medical oxygen in the home care setting is to be used for the duration prescribed by the physician (e.g., 24 hours per day, for nocturnal use, during exercise, etc.). Particularly in the home care setting, bar coding of medical gases would have no impact on the patients using their oxygen according to their physicians' order.

- From our review of the studies cited in the Federal Register notice, it is evident that medical gases were not included in the medication error data (perhaps because there have been very few medical gas medication errors when compared to other pharmaceutical medication errors). In addition, medical gases and the homecare industry were not included in the economic impact data presented. Our understanding is that over fifty percent of all drug manufacturers registered with the agency are medical gas firms, and many of those would be classified as small business. The financial impact of this rule on these firms as well as larger regional and nationwide homecare companies, such as Air Products Healthcare, would be very significant, unless an exemption for this class of products is granted.

> As opposed to stemming the increased cost of healthcare in the United States, this rule will significantly add cost to the manufacture and distribution of medical gases. This proposed rule will even add cost to users (healthcare institutions and patients) of medical gases, with little or no health benefit, and may jeopardize user access to medical gases as well.

Air Products Healthcare firmly believes our arguments provide adequate rationale for the agency to exempt medical gases from the requirements of proposed 21 CFR 201.25. If the agency does not concur with our request to exempt medical gases from the rule, we strongly recommend that, prior to publishing this as a final rule, the agency meet with the American Association for Homecare. The purpose of this meeting would be to discuss the degree this regulation will impact our industry, and to further discuss the minimal potential health benefit, if any, that this regulation will have on the administration of medical gases.

We appreciate the opportunity to comment on this proposed rule. If there are any questions regarding this request for exemption, please do not hesitate to contact me at 1-888-243-3456, ext. 226.

Thank you for your consideration.

Sincerely,

Bob Cucuel
President and Chief Executive Officer
Air Products Healthcare

Cc: Nitin Patel, Sr. Vice President of Operations
Mindy Eberhart, Corporate Director of Regulatory & Clinical Affairs