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May 19, 2003

Dockets Management Branch (HFA-305)  
U.S. Public Health Service  
Food and Drug Administration  
5600 Fishers Lane  
Room 1061  
Rockville, MD 20852

RE: [Docket No. 02N0204]  
Comments to proposed rule – Bar Code Label Requirement for Human Drug  
Products and Blood

Dear Sir or Madam:

Airgas, Inc. (NYSE: ARG) is the largest U.S. distributor of industrial, medical and specialty gases, welding, safety and related products. Its integrated network of nearly 800 locations includes branches, retail stores, gas fill plants, specialty gas labs, production facilities and distribution centers. Airgas also distributes its products and services through eBusiness, catalog and telesales channels.

Airgas is very concerned about the recent proposed rule appearing in the Friday, March 14, 2003 Federal Register that may require bar coding to be placed on all prescription drug products. This would include compressed medical gases.

Airgas agrees that medication errors are a serious problem and that the numbers need to be reduced.

Airgas is requesting that the compressed gas industry be exempted from this requirement. It is not our intention to create any unintended administrative problems and consume agency resources. Nor are we claiming that bar coding of compressed gases is not technologically feasible. Rather, we believe that bar coding of compressed medical gas cylinders would not have any positive impact on patient safety or prevent medication errors.

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To that end, Airgas, Inc. would like to offer the following information in support of our position:

Bar coding of compressed medical gases would not ensure that patients are given the right drug and the right dose, right route of administration to right patient at the right time.

## **Right Drug**

Unlike traditional drug containers, medical gases are packaged in specialized containers. They are contained in high-pressure cylinders. There are approximately five medical gases that are inspired as drugs. No other drug but medical gas can be put into high-pressure cylinders. Additionally, these cylinders have proprietary valves that are gas specific to the medical gas contained therein.

High-pressure cylinders are also color coded to give the user a quick indication of which cylinder to choose before reading the label.

Most medical gas mix-ups that have occurred involving medical gases have been the direct result of someone intentionally circumventing the safety precautions already in place. A bar code will not prevent a mix-up if the person administering the gas is prone to ignore safety devices.

We believe that based on these safeguards, high-pressure cylinders have an advantage that other containers do not (e.g., a pill bottle can contain any kind of pill, a cylinder cannot).

Hospitals and healthcare facilities often use more than one supplier for their medical gas needs. To have more than one supplier using different bar code systems could lead to confusion.

## **Right Dose**

Compressed medical gases do not vary by strength under the same name (e.g., USP oxygen is required to be 99.0% or greater. There is no 20 mg, 40 mg, 60 mg, etc.). High-pressure cylinders can contain anywhere from a few hundred to over one thousand liters of gaseous product. The dosage varies from patient to patient (e.g., one patient may be on 2 liters per minute, the next may be 10 liters per minute, etc.). A bar code cannot distinguish the patient's needs at the time it is filled. Unlike a prescription drug that is individually filled for a specific patient pursuant to a doctor's order, compressed medical gases are filled for administration by a trained professional with the requirement determined at the time of need. The amount of flow often varies with the same patient based on their blood oxygen levels. Compressed gas cylinders are not and cannot be filled on a dose level.

## **Right Route of Administration**

Compressed medical gases are not subject to various routes of administration such as other drugs might be. The primary route of administration is by inhalations. While the method of inhalation may vary somewhat, (e.g., nasal cannula, endotracheal, etc.), the primary route of administration is still by inhalation.

## **Right Patient**

Ensuring the right patient is of utmost concern with the dispensing of any prescription drug. Human beings must have oxygen to sustain life. Normal blood oxygen saturation levels are about 99% oxygen. U.S.P. oxygen is 99.0% or greater. Therefore, giving someone oxygen that is not scheduled to receive oxygen, would in most cases not have any adverse affect on the patient.

Medical gases are typically administered to patients in two ways. One is by either connecting a mask or nasal cannula to a high-pressure cylinder via a pressure-reducing regulator, then placing the mask or nasal cannula over the patient's nose and/or mouth. The second method is bedside at the hospital where the mask or cannula is connected to a wall outlet that is connected to the hospital's central supply system. Because equipment is not required to be bar coded, there is no benefit to requiring bar codes in this instance.

## **Right Time**

Compressed medical gases are not dispensed at regular intervals. Generally, the patient is placed on oxygen and remains on oxygen until such time that the physician deems that it is no longer necessary. For this reason, there would be no scheduled doses where there could be a possibility for a mix-up to occur.

After a review of the "5 Rights" mentioned in the Federal Register notice, it is obvious to us that there is no benefit for bar coding compressed medical gases. We would also note that the numbers of medical gas mix-ups involving compressed medical gases are very small when they stand-alone. When compared to the numbers of mix-ups occurring with other prescription drugs we doubt that the numbers could even be graphed, as they are so minuscule. When mix-ups have occurred with medical gases, most have been due to a deliberate act of the end user circumventing the safety precautions already in place. In such cases, bar codes would not have offered any additional benefit if the person has demonstrated a willingness to ignore the proprietary valve, color and product label.

There was also some mention in the notice about ensuring that no OTC drugs could interact with prescription drugs administered at the hospital or affect another drug's performance. Medical oxygen has been in use for almost 100 years. We know of no adverse reactions between medical gases and other prescription drugs.

Airgas, Inc. is concerned with the data mentioned in the notice. There are over 3,000 registered medical gas firms in the FDA's database. Some of these companies own or control as many as 200 or more locations each. We believe the 1,447 establishments detailed on Page 12516 and Page 12519, (Section E, 2), did not include medical gas production sites as that number could have easily exceeded 3,000 locations alone.

It was also reported that in 1993, 7,391 deaths were attributed to medication errors (Page 12500), while no deaths occurred as a result of medical gas medication errors. CGA records date back to 1913. Out of the thousands upon thousands of patients that are administered medical gases every day, we in the compressed gas industry know of no deaths or serious adverse events that can be attributed to medication errors. The only recorded deaths involving medical gases, less than 20 in nearly 90 years, can usually be traced back to a lack of training.

The July 26, 2002, public meeting was well attended by members of the CGA. While we did not take the podium to voice our disagreement with the policy, most of the support we witnessed was from bar code equipment manufacturers and salesmen. The CGA did not get any mention of its attendance in the notice.

We also disagree with the estimated cost for manufacturers to comply. Airgas, Inc. estimates it will cost approximately five million dollars to comply. That is just the implementation cost. The annual maintenance cost and cost of materials cannot be accurately estimated at this time. Initial estimates put the cost to implement a bar code system industry wide at over 100 million dollars.

With less than ten incidents in over 30 years and with no positive impact on patient safety from the proposed rule, we believe medical gases should be exempted.

We appreciate your consideration in these matters. Please feel free to contact me if you have any further questions or comments.

Sincerely,

Wade Holt