COMPRESSED GAS ASSOCIATION
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CHANTILLY, VA 20151-2923

FAX

Date: June 17, 2003 Number of pages: 6

Please deliver

To:	Dockets Management Branch (HFA-305) U.S. Public Health Service/FDA	**From:**	Carl T. Johnson President
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☒ **Urgent** ☒ **For Review** ☐ **Reply Requested**

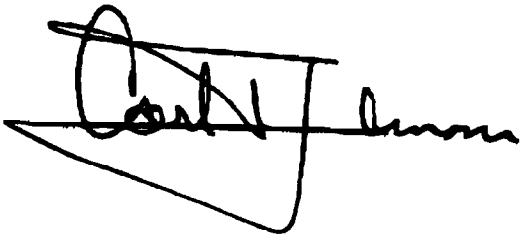
Message:

Attached is the letter the Compressed Gas Association sent on June 4, 2003, regarding Docket No. 02N0204: Comments to Proposed Rule - Bar Code Label Requirement for Human Drug Products and Blood.

We request that our comments on this docket be considered.

The letter was sent out with an incorrect address. The UPS Tracking Detail indicates delivery attemps on June 5, and that it was returned to us on June 9, however, we have no record of it being returned. Attached is the UPS Tracking Detail from the UPS website.

We appreciate your consideration.



02N-0204

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June 4, 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:

The Compressed Gas Association (CGA) and the Gases and Welding Distributors Association (GAWDA), on behalf of our member companies, requests an exemption from the proposed bar coding regulation (21CFR Section 201.25 Bar Code Label Requirements) as defined in Docket No. 02N0204 issued in the *Federal Register* dated March 14, 2003.

The CGA, founded in 1913, is dedicated to the development and promotion of safety standards and safe practices in the industrial and medical gas industry. The Association represents all facets of the industry – manufacturers, distributors, suppliers, and transporters of gases, cryogenic liquids, and related products and services. Through the committee system, CGA creates technical specifications, safety standards, training and educational materials; and works with government agencies to formulate responsible regulations and standards and to promote compliance with these regulations.

The GAWDA, founded in 1946, is dedicated to the safe operations and economic vitality of independent distributors of industrial and medical gases and equipment. The Association provides compliance assistance and guidance directly to members through internal consultants. GAWDA is also very active in providing training and educational materials that promote safe operations and GMP compliance. GAWDA participates actively with the CGA and its activities to create and promote responsible regulations and standards for the industry.

The CGA and GAWDA agree that medical gas medication errors, defined as medical gas mix-ups, are a serious issue. The medical gas industry is encouraged by its many interactions with the FDA on this and similar issues over the last year. As the FDA is aware, several proposals have been made to address the potential for medical gas mix-ups, including specific labeling (e.g., 360-degree wrap-around labels for medical gas cylinders), color coding, user education, and now, bar coding. The medical gas industry is now considering these and other specific recommendations as set forth in the Draft Guidance for Industry on the Current Good Manufacturing Practices for Medical Gases (announced in the May 6, 2003, *Federal Register*).

The CGA and GAWDA do not believe that the proposed bar coding rule would help reduce the risk of medication errors for medical gases. The industry coalition therefore requests that FDA and the medical gas industry continue to address medical gas mix-ups and that medical gases be exempt from the scope of the proposed rule per Section VIII Question 8 on page 12529 of Docket No. 02N0204.

Upon careful review we conclude that bar coding of compressed medical gas containers would not ensure that patients are given the right drug, in the right dose, via the right route of administration, to the right patient, at the right time. The compressed gas industry offers the following information in support of this position.

Right Drug
The major medical gases that are administered as drugs are Oxygen USP, Nitrogen NF, Carbon Dioxide USP, Nitrous Oxide USP, Helium USP, Medical Air USP, and mixtures of these components. Unlike traditional drug containers, medical gases are only provided in distinctively large specialized containers that could never be confused with traditional pharmaceutical packaging. These containers used in the healthcare environment have unique connectors and valves that are specific to the medical gas contained therein and require matching dispensing equipment to withdraw the medical gas. These design features provide both a safety system and a method to prevent medication errors.

Among the few medical gas mix-ups that have occurred, the overwhelming majority have been the result of personnel circumventing the safety system by removing or modifying the connection. A bar code will not prevent a mix-up if the person supplying or administering the gas is willing to circumvent physical safety devices and the facility's procedures.

We believe medical gas containers, with the current system of engineered safeguards, already provide an inherently greater degree of safety than a bar coding system can provide. Additionally, the typical scenario for medical gas use would be that the actual container or cylinder would not be in the immediate environment of the patient and that the contemplated bar coding checks would not be feasible.

Further complicating the situation is that hospitals may receive medical gases from multiple suppliers, all of which are provided to patients using the same central supply lines. The proposed rule does not accommodate or give direction on how such a remote relationship between patient and drug container, with multiple drug doses being dispensed through the same supply system, could be managed.

Right Dose
Medical gas containers cannot be labeled to a specific unit dose; nor can they be labeled to specify the number of unit doses they contain. Medical gases are not dispensed as a particular dose, rather, they are dispensed based on a particular patient's need and adjusted accordingly.

For example, oxygen dosage varies from patient to patient (e.g., one patient may be at 2 liters per minute, the next may be at 10 liters per minute,). Additionally, dosage often varies with the same patient based on their blood oxygen levels. Unlike other prescription drugs that may be manufactured, packaged and identified by bar code at a specific unit dose level, medical gas products cannot be packaged as unit doses. Medical gases are filled to a uniform strength (irrespective of the net quantity per container) for administration by a licensed medical professional, pursuant to a doctor's order, with the dosage requirement determined at the time of need.

Right Route of Administration
Unlike other pharmaceuticals, administration of medical gases requires specific dispensing equipment with inherent safety design features (e.g., gas specific outlet connections, pressure reducing regulators, or wall outlets, hoses, nasal cannulas, masks, endotracheal tubes, etc).

The requirement to use this specific equipment to dispense the gas eliminates the potential to administer the gas via the wrong route. A bar code on a cylinder or container will not add value in assuring the right route of administration.

Right Patient
Medical gas dispensing equipment (pressure reducing regulator and/or wall outlet) is not required to be bar coded and in most cases, where the medical gas container is in a remote location, there will be no benefit to ensuring the "right patient" receives the "right drug". In situations where medical gas containers are in close proximity with the patient and a proper patient bar coding system is in place, a minimal positive effect on reducing patient mix-ups may be achieved.

Right Time
Medical gases, unlike traditional pharmaceuticals dispensed at certain intervals, are not subject to "right time" errors. Medical gases are either used for the duration necessary (e.g., nitrous oxide given with oxygen for the duration of a medical procedure), or continuously until a physician determines it is no longer necessary (e.g., oxygen 24 hours per day). For this reason, there would be no missed, late, early, or additional doses.

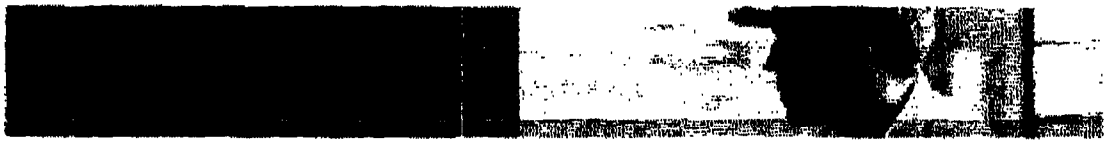
Conclusion

After a review of the "5 Rights" mentioned in the *Federal Register* notice, we submit that there is no benefit for bar coding medical gas containers. We also note that the numbers of medical gas medication errors are very small when compared to the numbers of medication errors occurring with other prescription drugs. When medication errors have occurred with medical gases, the overwhelming majority have been due to a deliberate act of circumventing inherent safety design features already in place. Industry review of these incidents leads us to conclude that application of a bar code system would not have offered any additional patient protection, because persons were willing to ignore or circumvent the inherent safety design features of the medical gas distribution systems.

The notice also presented a goal of ensuring that no over-the-counter (OTC) drugs could interact with prescription drugs administered at the hospital or affect another drug's performance. We know of no adverse reactions between medical gases and other prescription or OTC drugs.

The CGA and GAWDA believe that the information provided in these comments provides an adequate basis for the FDA to exempt medical gases from the requirements of proposed 21 CFR 201.25. The CGA and GAWDA also believe that the medical gas industry should continue working closely with FDA on avenues to eliminate medication errors involving medical gases.

The *Federal Register* notice for the proposed bar coding rule presents data indicating that a significant number of deaths are attributed to medication errors every year. For example in 1993, 7,391 deaths were attributed to medication errors (Page 12500). Based on a review of the aforementioned draft Medical Gas CGMP Guidance, there were eight fatalities from four incidents involving medical gas mix-ups over the last 20 years, each of which involved the circumvention of the engineered safety systems. As noted during our meetings with FDA and internally, as an industry, bar coding has been evaluated as a potential solution to address medical gas mix-up issues but industry has concluded that it will not add any safety value.

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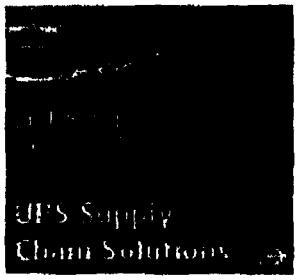

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Package Progress:

Date	Time	Location	Activity
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Jun 6, 2003	5:59 P.M.	CHANTILLY, VA, US	RECEIVER NOT IN ON 1ST DELIVERY ATTEMPT
Jun 5, 2003	5:22 P.M.	LAUREL, MD, US	INCOMPLETE ADDRESS, NOT DELIVERED;PACKAGE RETURNED TO SENDER
	1:21 P.M.	LAUREL, MD, US	CORRECT STREET # NEEDED, NOT DELIVERED
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Jun 4, 2003	11:44 P.M.	LAUREL, MD, US	ARRIVAL SCAN
	9:46 P.M.	CHANTILLY, VA, US	DEPARTURE SCAN
	6:33 P.M.	CHANTILLY, VA, US	ORIGIN SCAN
	3:27 P.M.	US	BILLING INFORMATION RECEIVED
~~Jun 10, 2002~~	~~10:25 A.M.~~	~~HUNTSVILLE, AL, US~~	~~DELIVERY~~

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The CGA and GAWDA are also concerned with other data presented in the *Federal Register* notice. According to FDA sources, there are over 3,000 registered medical gas establishments in the United States. It is apparent that the 1,447 establishments detailed on Pages 12516 and 12519, (Section E, 2) did not include medical gas establishments. These sites were not included in the economic impact data reported, and it is possible that because there have been very few medical gas medication errors, when compared to other pharmaceutical medication errors, that they were not included in the medication error data as well. If medical gas products are to be included in this proposal, the cost implications would need to be recalculated. We feel that the equipment purchase, validation, procedure modifications, training, and on-going operating and maintenance factors would be much costlier than the projections given if the medical gas industry is considered. Of related significance, many manufacturers and distributors of medical gases are small entities that would be significantly adversely impacted by the provisions of FDA's proposed bar code rule.

If after reviewing the industry's concerns as outlined in this letter the FDA determines that the rule does apply to medical gases, we strongly recommend that prior to publishing this rule as a final rule, the FDA meet with the CGA and GAWDA. The purpose of this meeting would be to discuss the degree to which this regulation would impact the medical gas industry, weighed against the minimal patient protection value that it will have on reducing medication errors involving medical gases.

The CGA and GAWDA 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 Carl Johnson at CGA via e-mail at cjohnson@cganet.com, or via phone at 703-788-2712. We will contact the FDA shortly to verify this correspondence has been received.

Thank you for your consideration.

Sincerely,

Carl T. Johnson
President
Compressed Gas Association

Henry W. Doyle, III

Henry W. Doyle (III)
Executive Director
Gases and Welding Distributors Association

cc: David Horowitz, Director, Office of Compliance, Center for Drug Evaluation and Research, FDA