COMPRESSED GAS ASSOCIATION, INC.
1725 Jefferson Davis Highway ■ Suite 1004 ■ Arlington, VA 22202-4102
(703) 412-0900 ■ Fax: (703) 412-0128 ■ E-mail: cga@cganet.com ■ Web Site: www.cganet.com

June 28, 2001

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

Re: Docket No. 01D-0131

The Compressed Gas Association (CGA), founded in 1913, represents approximately one hundred and fifty member companies world wide in the development and promotion of safety standards and safe practices in the medical and industrial gas industry. The Association represents all facets of the industry – manufacturers, distributors, suppliers, and transporters. Through the committee system CGA creates technical specifications, safety standards, training, and educational materials; and also works with government agencies to formulate responsible regulations and standards and to promote compliance with these regulations.

The Compressed Gas Association (CGA) supports the Food and Drug Administration (FDA) in their efforts to heighten awareness to the hazards associated with medical gas mix-ups.

CGA would like to formally respond to the *Guidance for Hospitals, Nursing Homes, and Other Health Care Facilities* notice that appeared in the Federal Register on April 6, 2001 (FR Vol. 66 No. 67/Friday, April 6, 2001 – page 18257). We respectfully submit the following comments and suggestions regarding this document.

Item 1 - Page 3, paragraph 1

"• Although recommended by the Compressed Gas Association, many of the large cryogenic vessels used to contain medical gases do not have permanently brazed, or welded, connections or fittings that cannot be removed."

Response

We believe this statement may be misleading to the reader. As written, this sentence infers that there has been a long-standing practice in place that has gone unheeded. The CGA would like the Agency to change the wording of this sentence to read *"Although recently recommended by the Compressed Gas Association (CGA) in a safety bulletin published on December 8, 2000, many of the portable cryogenic vessels..."*, as we feel this more accurately states the CGA's current position on this practice.

CGA published a safety bulletin on December 8, 2000, entitled CGA SB-26, *Cylinder Connections on Portable Liquid Cryogenic Cylinders.* SB-26 states that the outlet fittings on medical containers be permanently brazed or welded in place, or be a permanent and integral part of the valve body. CGA had recognized this practice as a possible deterrent to the inadvertent connection of the wrong product and had been developing recommendations, which have subsequently been issued in SB-26. SB-26 provides for a one-year implementation period.

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Item 2 - Page 3, paragraph 2

"• Unfortunately, not all medical gas vessels are labeled using 360-degree wrap-around labels."

Response

CGA believes the drug product label provides the primary drug product identification and there may be alternate means of secondary identification. Therefore, CGA recommends that this statement be changed to read, "*The drug product label is the primary means of identifying the contents of a medical gas container. Not all medical gas containers contain a secondary means of identification (e.g., 360-degree wrap-around tape or another means).*"

The emphasis on the use of secondary identification (such as 360-degree wrap-around tape) may cause the user to ignore the warnings and other precautionary wording contained in the primary drug label. If the use of secondary identification is believed beneficial, we would suggest that alternate means be considered. Some manufacturers use an identification label under, or tags on, each valve outlet, while others may use color coding, etc.

Item 3 - Page 3, paragraph 3

"• Separate storage areas often are not provided either in the delivering vehicle or at the receiving facility to sufficiently separate medical grade products from industrial grade products."

Response

CGA recommends deleting this paragraph. Typically, hospitals do not use delivery vehicles. Should they have delivery vehicles, or should the intent of this proposed guidance include a supplier's delivery vehicle, these vehicles often deliver both medical and industrial cylinders to the same area within hospitals, nursing homes, and health care facilities.

There are other government regulations that could potentially conflict with this statement. The Department of Transportation (DOT) regulates the loading and marking of delivery vehicles. The DOT requires separation of certain gases depending on the hazards associated with them without distinction to whether they are empty or full. There are DOT and safety requirements to have the vehicle weight evenly distributed to prevent an unsafe condition. It may not be possible to make deliveries with the full and empty medical and industrial cylinders separated. Compliance with this proposed policy would cause non-compliance with DOT regulations. Even if medical gases were delivered on a separate vehicle, this would not prevent mix-ups, as they are delivered to a common receiving area and stored together. Hospitals are often bound by space restraints that restrict them from having a separate room for every gas they use.

Item 4 - Page 3, paragraph 4

"As a result, many medical gases are improperly or poorly labeled; the wrong gases are delivered accidentally to hospitals, nursing homes, and other health care facilities; and poorly trained personnel are connecting the wrong vessels to oxygen supply systems, despite connection incompatibilities. Patients continue to suffer injury or death."

The bullet points above this statement do not fully substantiate this conclusion. CGA recommends replacing this statement with: *"On rare occasions the wrong gases are delivered accidentally to hospitals, nursing homes, and other health care facilities; and poorly trained personnel are connecting the wrong vessels to oxygen supply systems, despite connection incompatibilities. Patients continue to suffer injury or death. The primary causes for the accidents were the availability of the wrong gas, changing of the cylinder's fittings, a disregard of the label, and a lack of training."*

The statement incorrectly implies that it is a common practice for medical gas cylinders to be delivered that are improperly or poorly labeled. In addition, it incorrectly implies that a 360-degree wrap-around tape is a legal requirement.

CGA agrees that proper training of facility and delivery personnel is key to preventing product mix-ups with medical gases, and will minimize, if not eliminate, patient injury or death.

Item 5 – Page 3, paragraph 6

"If your facility receives medical gas deliveries, you should store medical grade products separately from industrial grade products. The storage area for medical grade products should be well defined with one area for receiving full cryogenic vessels and another area for storing empty vessels."

Response

CGA recommends changing this paragraph to the following: "*If your facility receives medical gas deliveries, you should utilize a storage and handling system that clearly identifies medical grade products, industrial grade products, and empty and full vessels and cylinders. Cylinder storage areas should be well defined in the system using one of many methods (e.g., signage, floor markings, storage racks, chains, identifying tape, etc.).*"

CGA recommends changing this paragraph to provide broad definitions for segregation of medical and industrial grade products. Hospitals and health care facilities are often bound by space restraints that restrict them from having a separate room for every gas they use.

Item 6 – Page 3, paragraph 8

"If your supplier uses 360-degree wrap-around labels to designate medical oxygen, personnel should be specifically trained to make sure each vessel they connect to the oxygen system bears such a label."

Response

CGA recommends that this statement be changed to read, "*Even if your supplier uses a secondary means of identification (e.g., 360-degree wrap-around tape or another means) to designate medical oxygen, personnel should be specifically trained to make sure each vessel they connect to the oxygen system bears the primary drug label and not rely on any secondary identification.*"

Because 360-degree wrap-around tape is not common industry practice and for the reasons associated with secondary indicators as identified in our response to Item 2 above, identification of the product using the primary drug label must be promoted.

Item 7 – Page 4, paragraph 1

"You should emphasize repeatedly that the fittings on these vessels should ***not be changed*** *under any circumstances. If a cryogenic vessel fitting does not seem to connect to the oxygen supply system fitting, the supplier should be contacted immediately. The vessel should be returned to the supplier to determine the fitting or connection problem."*

Response

We agree with this statement and would add that this problem is not unique to cryogenic containers. CGA recommends revising the statement to include high pressure cylinders as follows: "*You should emphasize repeatedly that the fittings on any cryogenic vessel or high pressure cylinder should* ***not be changed nor should adaptors be used*** *under any circumstances. If* ***any*** *cryogenic vessel or high pressure cylinder does not readily connect to the*

utilization equipment the gas should not be used and the supplier should be contacted immediately. The cryogenic vessel or high pressure cylinder should be returned to the supplier to determine the fitting or connection problem."

Conclusion

CGA agrees with the Agency that training of personnel is vital for the prevention of all medical gas mix-ups as described in the proposed guidance. In addition, CGA believes that training should include the recognition of hazards, warnings, and precautionary statements associated with the handling of medical gases as described on the drug product label, as well as the properties of common compressed gases. Training should also include recognition of the proper connection requirements of both the container and the equipment to which the medical gas will be attached.

CGA also agrees that the brazing or welding of outlet connections should be performed in accordance with SB-26, which also addresses the installation of tamper resistant devices on liquid containers for industrial service.

CGA cannot over emphasize the importance of initial and recurrent training for all personnel involved in the distribution, use, and connection of compressed medical gases.

Sincerely,

Compressed Gas Association, Inc.
Carl Johnson
President

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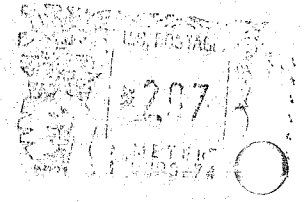
COMPRESSED GAS ASSOCIATION, INC.
1725 Jefferson Davis Highway ■ Suite 1004
Arlington, VA 22202-4102



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