AIR LIQUIDE

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April 28, 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

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Dear Sir or Madam:

Air Liquide America L.P. has several comments concerning the referenced proposed regulation.

In 1999 the Institute of Medicine (IOM) reported that in 1993, an estimated 7,000 deaths were attributed to medication errors. The IOM report said that deaths due to medication errors could be prevented and cited bar coding as one way to prevent them.

The Food and Drug Administration (FDA) has proposed a new rule, 201.25 (21 CFR 201.25), to help reduce the number of medication errors in hospitals and other health care settings. This reduction in medication errors would result from health care professionals using bar code scanning equipment to verify that the correct drug, in the correct dose and route of administration, is being given to the correct patient, at the right time.

We recognize the need to reduce medication mix-ups, and therefore, fully support the intent and implementation of the proposed rule. We also agree with your conclusion that an exemption provision should not be created based solely upon product container size. However, we do believe that an exemption provision should be allowed for compressed and liquid medical gases, and specifically, Nitrogen (NF) and Oxygen (USP).

There are several compelling reasons for this exemption to be provided. First, the stated rationale of the proposed regulation in part to, *"... help reduce the number of medication errors in hospitals and other health care settings by allowing health care professionals to use bar code scanning equipment to verify that the right drug (in the right dose and right*

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route of administration) is being given to the right patient at the right time," is not meaningful when applied to medical gases administered by health care professionals. Medical gases used in hospitals setting, or at other healthcare facilities are delivered to patients in two manners. Medical gases are routinely administered at the patient treatment area (usually at bedside) through an aerator mask connected to a central supply system, or provided to ambulatory patients in small, portable cylinders.

Medical gases that are delivered via mask, cannula or other breathing apparatus are generally taken from a central supply through a quick connect plastic cannula or hose. The central supply may be near the treatment area, but due to safety concerns is usually in an isolated area away from the patient population. In any event, if the bar code were on the supply container or cylinder, the location of the raw medical gas supply prohibits convenient bar code scanning.

Additionally, since it is a common and usual practice for hospitals to utilize more than one supplier of medical gases, and since all medical gases are piped into hospitals through common pipes and manifold systems, there is no practical method for providing a bar code at the quick connect patient usage area that would designate the product manufacturer.

Other significant reasons that exemption from the rule should be provided for liquid and compressed medical gas containers are that the bases (NAICS 32 5412 and 325414) used for determining economic impact and total number of establishments affected did not include the medical gas industry. The omission is significant! There are more than 1000 members alone that belong to the gases and Welding Distributors Association. Of these, approximately 600 package or distribute medical gases. Additionally, there are approximately 10 major manufacturers of medical gas products in the USA. Many of the major manufacturers either own or directly control an estimated 200 locations that either repackage or distribute medical gas products.

The omission of this large population of manufacturer, packages and distributors of medical gas products is a significant oversight in the rationale for the rule, and for determination of the estimation of "4,229 packaging lines" and your conclusion that there are "1,447 establishments," as detailed on page 12519, section E2.

A review of the type of products involved in medication mix-ups and the number of packaging lines established by the NAICS clearly show that since no medical gas products were considered in the NAICS data. Hence, one must conclude that either the incidence of medication errors involving medical gas products was too low to be significant, the omission was an oversight, or because this commodity type is not intended, prepared or delivered in a dose form.

We do not believe that compressed medical gases were considered for all of the reason outlined above. However the clear distinction between unit dosage drugs and medical gases establishes a clear need to also distinguish between unit dosage form drugs that should fall under the proposed rule, and medical gases that should not. This compelling

distinction between unit dose drugs and medical gases provides sufficient support for providing an exemption from the proposed rule. This is further supported by the fact that medication errors due to medical gases were not part of the data collected (NAICS 325412 and 325414).

Therefore, the basis of FDA's analysis of the affected sectors, the estimated regulatory cost of the proposed rule, and analysis of the financial impact on small medical gas manufacturers/repackagers should not be extended to medical gases.

We respectfully submit that based on the above comments, FDA consider granting an exemption to the requirements for bar boding as established in the proposed regulation.

Please direct your response or requests for additional information to Harold Jones, Director FDA-CGA Liaison at the address below, or call 713-402-2157

Respectfully,

Harold L. Jones

Harold L. Jones
Director FDA/CGA Liaison

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