Erie MEDICAL
A Division of Ocenco Incorporated

10225 82nd Avenue
Pleasant Prairie, WI U S.A.
53158-5801

Order Desk: (800) 932-2293
Phone: (262) 947-9000
Fax: (262) 947-9020
www.eriemedical.com

April 30, 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

Gentlemen:

Erie Medical is a manufacturer of medical devices used in the care and treatment patients with respiratory disease in the home, in hospitals, as well as in emergency care. We are pleased to respond to the request for comments on the referenced docket. While we feel it is wise to support the use of bar coding in pharmaceuticals, we feel that extending this requirement to medical gases, is not justified. We base our comments on the following:

1) Medical gases used in hospitals (specifically Medical Oxygen USP and Medical Air USP) are typically piped throughout the facility and delivered from gas specific outlets in the room above the patient's bed or in various treatment rooms throughout the hospital. The actual source of the drug product is extremely remote from the site of delivery to the patient; oxygen is typically delivered from a liquid stand tank located outside the building where it is accessible for refilling on a routine basis by the gas supplier. Compressed air is likewise generated by a compressor located somewhere within the facility and piped to the site of need. Bar coding of the liquid stand tank or compressor would not provide assurance at the site of delivery to the patient that the product is correct. Likewise, bar coding of the outlets above the bed would not guarantee that the correct gas would come through the piped system from the remote supply of medical oxygen or medical air.

2) In emergency care, the Paramedic / EMT services responding to patients in cardiac / respiratory distress typically act with extreme haste in delivering oxygen at the site of the emergency. It is unlikely they will have bar code scanning equipment on the emergency vehicle, or would take the time to scan a bar code, before delivering lifesaving treatment to the victim. Additionally, these groups frequently use a single cylinder on multiple patients before the gas container needs refilling.

3) In homecare, bar code reading equipment would never be available in private homes to scan a product bar code label. Homecare dealers fill liquid oxygen systems from a vessel in a truck or deliver multiples of cylinders to a patient's home on a single delivery and it is not feasible financially to equip every delivery

02N-0204

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vehicle with bar code reading equipment. The oxygen being delivered has already undergone USP testing prior to being filled in the truck mounted vessel or high pressure cylinders for product purity and identity. Bar coding of product for home use therefore seems unnecessary, unwarranted, and adds nothing to patient safety.

4) Cylinders and liquid vessels come in a wide variety of sizes. If a bar code labels were required for each size of cylinder or liquid container in current distribution, the removal of the container label every time the reusable container is refilled would present a significant hardship both in terms of cost of labor and multiple labels required by manufacturers and distributors. We foresee a significantly increased potential for label mix-ups.

5) The medical gas industry is unique in that gas containers (cylinders and liquid vessels) are re-used where pharmaceutical drug containers are single use containers and are disposed after a single use. Also unique is that labeling is allowed to remain on the container as long as it is legible and current. If a bar code were to be applied to the drug product label on a medical gas container, it would require complete label removal at each refill to remove the identity of the previous filler. We feel that the present system has been effective and should remain "as is".

6) Oxygen dosages vary significantly from patient to patient. While one patient may be on 1 or 2 liters per minute, others may be on 3 or 4 or more liters per minute flow. While it may be possible to include dosage on pharmaceutical product bar codes, it is not feasible to include such information on medical gases because of the dosage variation.

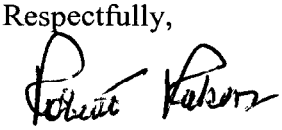
In reviewing the incidents related to medical gas mix-ups, it is apparent that the cause of the incidents is directly related to carelessness of personnel who have the responsibility of attaching the gas container to the gas delivery system (piping) which carries medical gas throughout the institution. Bar coding will not prevent carelessness.

The Compressed Gas Association, comprised of over 150 companies which produce medical gases and equipment, has developed safety systems used around the world to minimize the potential for gas mix-ups which, unfortunately, have occurred. It is extremely unlikely that any of the previous medical gas mix-ups would have been prevented by bar coding. These safety systems include color coding of gas containers, gas specific connections for all medical gases, and detailed product labeling developed in conjunction with the Food and Drug Administration. If used properly, these systems provide the necessary safety procedures to protect patients from administration errors. The addition of a bar code will not improve safety; safety will only be achieved through education which must be an ongoing policy at the institution level, perhaps as part of JCAH certification where the institution would be

required to retain training records for individuals responsible for medical gas handling and distribution systems.

In summary, we feel that medical gases and medical equipment should be exempted from the bar code requirement being proposed in the referenced docket. We feel that the unique conditions under which medical gases and medical equipment are used make bar coding impractical and would not contribute to patient safety.

Respectfully,



Robert C. Rakers
Vice President