GASREGSINC

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Via FedEx, and via fax (301) 827-6070

June 9, 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

Dear Sir or Madam:

Gas Regs, Inc. provides the following comments as they relate to the proposed rule, "Bar Code Label Requirements for Human Drug Products and Blood", Docket 02N-0204, appearing in the Federal Register on March 14, 2003 at pages 12500 through 12534. In response to question 8 on page 12529 in the Federal Register notice, Gas Regs, Inc., proposes the agency exempt medical gases classified as drugs (as a class of products) from the proposed rule (21CFR §201.25 "Bar code label requirements") for the reasons specified in this letter.

Gas Regs, Inc., is a Quality Assurance / Regulatory Affairs consulting firm dedicated to assisting companies who manufacture, fill, distribute and/or use medical gases with their quality and FDA regulatory compliance activities. Gas Regs. Inc.'s, clients include national, regional, and single site home care companies; international, national and regional industrial gas firms (e.g., air liquefaction, bulk gas manufacturing, and container filling operations); as well as regional and single site cylinder filling operations. Gas Regs, Inc., therefore limits its comments to medical gases classified as drugs.

In the Federal Register Notice for the proposed rule, the "Summary" (page 12500) states that bar coding will reduce medication errors, "by allowing healthcare professionals to use bar code scanning equipment to verify that the right drug (in the right dose and right route of administration) is being given to the right patient at the right time." As detailed in this letter, we believe medical gases warrant an exemption, given:

a) medical gases are uniquely packaged and used,
b) bar coding medical gases will not reduce the number of medication errors in hospitals and other health care settings, and
c) bar coding will not assist healthcare professionals with assuring the aforementioned five "rights"

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Gas Regs, Inc., welcomes the opportunity to engage in further dialogue with the FDA on this subject.

Overview of Medical Gases Packaging and Their Use in Healthcare Settings

Most medical gases are classified as prescription drugs (i.e., Oxygen USP, Nitrogen NF, Medical Air USP, Nitrous Oxide USP, Carbon Dioxide USP, and Helium USP as well as some mixtures of these gases). (Some medical gases, including most medical gas mixtures, are classified as medical devices and would not be subject to this proposed rule.) In emergency situations and when administered by properly trained personnel, Oxygen USP may be administered without a prescription. Medical gases, particularly oxygen are administered in various settings, from the institutional setting by nurses and respiratory therapists to normal day to day environs by ambulatory patients who self administer. Administration of medical gases to patients in hospitals, clinics or other institutional settings is typically via piping systems supplied by bulk storage tanks, large cryogenic vessels, and/or high pressure cylinders that are connected in remote areas, away from the pharmacy and patient use areas. The piping will end in the patient use and critical care areas with a labeled and gas specific connection wall outlet. Medical gases may also be administered in these environments via small (but still very large in comparison to unit dose packages) high-pressure cylinders or liquid containers. Medical gas container connections are also gas/gas property specific. Home respiratory care patients may obtain their oxygen via large stationary or small portable high-pressure cylinders, stationary and portable liquid vessels (with proprietary connections), directly via oxygen concentrators (medical devices), or via cylinders filled by concentrators in the home (to allow the concentrator patient mobility) . Physicians, dentists, and those involved in first aid/emergency care are also supplied with medical gases in labeled and color coded high pressure cylinders with gas specific connections.

In contrast to typical pharmaceutical packages, produced by a limited number of manufacturers or repackagers with nationwide or regional distribution, medical gases are produced by a very large number of manufacturers/fillers, each with relatively limited geographical distribution. Due to the modality of the gas provided, and the patient population served, medical gas manufactures and distributors often have significant overlap within limited geographical areas. An NDC labeler code search on the trade name "OXYGEN" yields well over a thousand NDC labeler codes, with a multitude of product and package codes. A similar search on "IBUPROFEN" yields less than 175 NDC labeler codes. Most medical gas manufacturers and private label distributors provide medical gases in two different modalities requiring two different NDC labeler codes for the same "gas" (due to differences in the safe handling and storage directions on the container label). For example, Oxygen USP may be provided in gaseous form in high pressure compressed gas cylinders with one label (and NDC code) and in cryogenic liquid form in cryogenic containers with a different label (and different NDC code) even though the Oxygen gas inhaled by the patient meet the same USP specifications. Home healthcare firms that provide Oxygen to patients at their residences fall under this proposed rule, as they are not exempt from the establishment registration and listing requirements (per section 510(g)(1) of the Act). The

agency considers filling liquid oxygen containers at a patient's residence, even though conducted in a retail capacity, a "manufacturing" activity. The rationale provided by the agency for omitting prescription drug samples from the proposed bar code requirement, "because patients would not have or be inclined to buy bar code scanners for their own use in the immediate future", should also apply to oxygen supplied to patients at their residence. Patients utilizing an oxygen concentrator (a device not requiring bar code) in their home, utilize high-pressure cylinders (drug product containers subject to the proposed rule) as their back-up source in case of power failure (if not using cylinder filled via the concentrator). Even though the oxygen strength differs between the output of a concentrator and that provided in the Oxygen, USP cylinder, the gases are therapeutically equivalent. One product would require a bar code and the other would not.

Gas Regs, Inc. questions the ability for hospitals and other health care entities to maintain a database that may require multiple thousands of NDC labeler and product code combinations just for medical gases and the software that will allow several NDC codes (that include company, product, and package code information) to be "scanned" for .the same drug. Gas Regs, Inc. also questions the risk-based justification to bar code medical oxygen cylinders and cryogenic containers used in the home healthcare environment. Bar coding medical gases will not assist in preventing medication errors in the healthcare facility or in the home as further discussed below with respect to the five "rights".

Why an NDC Labeler Code Bar Code on Medical Gases Will Not Assure "Right Drug" Right

Bar coding drug medical gas package labels (high pressure cylinders or cryogenic vessels) is unlikely to prevent "wrong drug" medication errors. When the relatively few medical gas mix-ups have occurred at healthcare facilities, existing safety systems were circumvented or compromised. Either the medical gas manufacturer or the person installing the container on the utilization or distribution equipment, compromised the safety systems by removing, changing, or modifying the gas property specific connection(s) on the gas container or gas utilization equipment, or by using cross product adapters. Current regulations and regulatory initiatives address the issues that have resulted in medical gas mix-ups. A bar code will not prevent a mix-up if the person supplying, connecting or administering the medical gas is willing to circumvent the physical safety systems provided

In addition, and as stated previously, medical gas containers are typically not in the patient care area, therefore they could not be scanned immediately prior to administration (as presented in the proposed rule discussion) to assure the "right drug" right.

Medical oxygen, in almost all instances, is the only medical gas prescribed for use in the home, therefore, no other medical gases are available to the patient. Even if a patient had more than one medical gas (and had a scanner), the inherent safety systems (different label, connection, and color code) would need to be circumvented in order to have a mix-up at the patient's home.

Why an NDC Labeler Code Bar Code on Medical Gases Will Not Assure "Right Dose" Right

While bar coding unit dose packaging may assist with the "right dose" aspect of many traditional pharmaceuticals, medical gases are not produced in unit dose packages nor can the labeling indicate the number of "doses" a container may contain. High-pressure cylinders contain from several hundred to several thousand liters of gas, with liquid containers able to hold significantly more (hundreds of thousands). Container size or net contents have no bearing on dose. "Doses" prescribed to a patient in a healthcare facility or at a patient's residence, are controlled by a pressure-regulator/gas flow meter (medical device), typically providing from less than 1 liter per minute to up to 10 liters per minute. A physician would not prescribe "one cylinder" of oxygen. Rather a physician would prescribe a specific flow rate for a specific duration (e.g., 2 liters per minute for 24 hours per day). For oxygen, the flow rate may change for the same patient over time based on the patient's blood oxygen level. Although one could calculate the duration (in minutes/hours) of "how long a cylinder would last", (by dividing the number of liters contained in the cylinder by the prescribed flow rate) this is typically not done. Bar coding labels on medical gas containers would therefore, not assist with the "right dose" right.

Single component medical drug gases (e.g., Oxygen USP, Nitrogen NF, Nitrous Oxide USP etc.) are filled to a uniform strength (irrespective of the net quantity per container). In healthcare facilities, single component medical gases (other than Oxygen USP), and medical gas drug mixtures, are usually mixed on-site (e.g. nitrous oxide and oxygen during some medical procedures) using a gas blender (medical device) per a doctor's order, to assure the proper percentage of each component is administered. The settings on the blending device assure the proper dose not a bar code on the single component or mixture label

Why an NDC Labeler Code Bar Code on Medical Gases Will Not Assure "Right Patient" Right

Medical gases are typically remote to the patient care area. Wall outlets at all patient bedsides and treatment areas typically provide for "oxygen", "medical air", (perhaps nitrous oxide in surgical areas), and "vacuum" and as stated previously, these outlets would not be bar coded. There may be a minimal positive effect in an institutional setting when the medical gas container is in close proximity to the patient and a proper patient bar code system is in place.

Unlike in institutional settings, homecare services are provided at the patient's home where patients do not wear identification wristbands and computer systems are not readily available. However, there currently are patient-identifiers inherent to the homecare setting that assure "right patient" such as, a delivery ticket that would include a unique address and patient identification number, and provider familiarity with the homecare patient.

Why an NDC Labeler Code Bar Code on Medical Gases Will Not Assure "Right Route of Administration" Right

Aside from the use of some cryogenic liquids in surgical applications and lab use (where again the containers utilize unique fittings to prevent mix-ups), medical gases have only one route of administration – inhalation. Basic training of medical staff and education of homecare patients assures administration of medical gases via the proper route. Medical gases are administered by inhalation via pressure reducing regulators or wall outlets with specific connections, and then via nasal cannula, mask, endotracheal or tracheostomy tube. 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 will not add value in assuring the "right route of administration".

Why an NDC Labeler Code Bar Code on Medical Gases Will Not Assure "Right Time" Right

Unlike traditional pharmaceuticals dispensed in discreet amounts at certain intervals, medical gases are not subject to right time errors (e.g., failing to provide the drug at the right time, providing the drug too many times within a specified period of time, etc.). Medical gases in a healthcare facility are either used for the duration of a procedure (e.g., nitrous oxide given with oxygen), or until a physician determines it is no longer necessary. Medical oxygen in a home care setting, like the institutional setting, is used for the duration prescribed by the physician (e.g., 24 hours per day, nocturnal, during exercise, etc.).

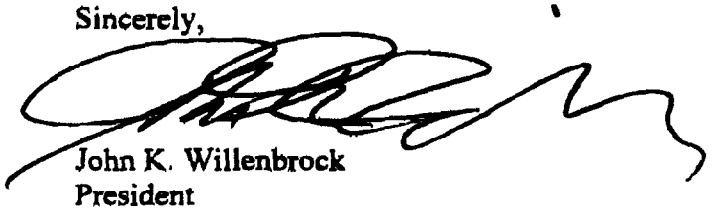
From our review of the studies sited in the Federal Register notice, it is evident that medical gases were not included in the medication error data (perhaps because there have been very few medical gas mix-ups when compared to other pharmaceutical medication errors). It also appears medical gases were not included in the economic impact data presented. Based on discussions with agency personnel, our understanding is that over fifty percent of all drug manufacturers registered with the agency are medical gas firms, and many of those would be classified as small business. The financial impact of this rule on these firms as well as larger regional and nationwide firms would be very significant if an exemption for this class of products is not granted. Contrary to the overall goal of trying to stem the increased cost of healthcare in the United States while increasing the overall safety of the healthcare system, this rule will significantly add cost to the manufacture, distribution, and even users of medical gases with minimal, or no, benefit.

Gas Regs, Inc. firmly believes the arguments it has put forth provide adequate rationale for the agency to exempt medical gases from the requirements of proposed 21 CFR 201.25. If the agency does not concur, we strongly recommend that prior to publishing this rule as a final rule, the agency meet with the trade associations that have medical gas firms as members (i.e., the Compressed Gas Association, the American Association for Homecare, and the Gases and

Welding Distributor's Association). The purpose of a meeting with these trade associations would be to discuss the degree this regulation will impact this industry and more importantly further discuss the minimal benefit, if any, that it will have on the administration of medical gases.

Gas Regs, Inc., appreciates the opportunity to comment on this proposed rule. If there are any questions regarding the request for exemption, please do not hesitate to contact John K. Willenbrock, President, Gas Regs, Inc. via e-mail at john.willenbrock@gasregs.com, or via phone at 336-887-0510. Thank you for your consideration.

Sincerely,



John K. Willenbrock
President
Gas Regs, Inc.