

***GASREGSINC***

**Gas Regs Incorporated**  
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Via FedEx and via fax (301) 827-6070

September 17, 2002

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

Dear Sir or Madam:

Gas Regs, Inc. is pleased to provide the following comments as they relate to the above referenced docket. Gas Regs, Inc., supports the initiative of the Secretary of Health and Human Services to reduce medication errors and the FDA's efforts to investigate the appropriate means and develop regulations to accomplish this initiative.

Gas Regs, Inc., is a Quality Assurance / Regulatory Affairs consulting firm dedicated to assisting companies who manufacture, fill, distribute and/or use medical or food grade 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); regional and single site cylinder filling operations, as well as medical gas container and equipment manufacturers. Gas Regs, Inc., has therefore limited its comments to the impact Bar Code Label Requirements will have on the use of medical gases and gas equipment, and the impact it will have on the industry that manufactures and distributes them. Gas Regs, Inc., welcomes the opportunity to engage in further dialogue on this subject with the FDA.

Medical gases, depending on their use, are classified either as prescription drugs (e.g., Oxygen, Nitrous Oxide, Medical Air) or as medical devices (e.g., Lung Diffusion mixtures, Blood Gas mixtures). 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 may be 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 connection specific 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

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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), or via oxygen concentrators (medical devices). 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.

The discussion at the July 26, 2002 public meeting addressed how bar coding, implemented by both manufacturers and users, would assure the five “rights”, “Right patient, right drug, right dose, right route of administration, and right time”. It was also stated that bar coding the unit-dose level product package would yield the greatest promise for patient safety improvement. Gas Regs, Inc. will address several of the questions posed by the agency in the Federal Register notice from this perspective as well.

Regarding the questions: **“Should all prescription and over-the-counter drugs be bar coded?”** and **“Should medical devices carry a bar code?”** and **“Can bar codes be produced with a dose specific unique identifying number?”**

Adding a bar code to drug or device medical gas package labels (high pressure cylinders or cryogenic vessels) or to medical gas wall outlets or other medical gas utilization equipment, is unlikely to prevent “wrong drug” medication errors. When the relatively few medical gas mix-ups have occurred, existing safety systems had been compromised. Either the medical gas manufacturer or the person installing the container on the utilization or distribution equipment, compromised the safety systems by removing or changing the connection(s) on the gas container or gas utilization equipment, or by using cross product adapters. Current regulations and regulatory initiatives already address the issues that have resulted in medical gas mix-ups.

While manufacturer or repackager bar coding of unit dose packaging may assist with the “right drug, right dose” aspect of many common pharmaceuticals, medical gases are not produced in unit dose packages. Bar coding would therefore not assist with the “right dose” right. High-pressure cylinders contain from several hundred to several thousand liters of gas, with liquid containers able to hold significantly more. Controlled by a gas flowmeter, “doses” of typically less than 1 liter to a few liters per minute are prescribed. A physician would not prescribe “one cylinder” of oxygen; rather prescribe oxygen at a specific flowrate for a specific duration.

It is Gas Regs, Inc.’s position that the FDA should not require medical gases (either those classified as drugs or devices) or medical gas equipment to be bar coded.

Regarding the questions: **“Assuming that FDA requires bar codes on all human drug products, where on the package should the bar codes be placed?”** and **“What information should be contained in the bar code?”** and **“Can bar codes be produced with a lot number, and expiration date at your highest production line speeds?”**

Typically, pharmaceutical unit dose packages are produced by a limited number of manufacturers or repackagers with nationwide or regional distribution. In contrast, medical gases are produced by a very large number of manufacturers/fillers, each with relatively limited geographical distribution. An NDC labeler code search on the trade name “OXYGEN” yields over one thousand NDC labeler codes, with a multitude of product and package codes. A similar search on “IBUPROFEN” yields less than 175 NDC labeler codes. 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.

Due to the material handling environments that medical gases containers are subjected to, product labels are considerably more durable than those found on typical pharmaceutical packages. Medical gas containers are typically refilled with the same product multiple times, without replacing the product label. Some medical gas product labels are placed under a protective coating and may not require replacement until the cylinder undergoes hydrostatic retest (every five years). If the agency disagrees with Gas Regs, Inc.’s position, and deems that medical gas containers should be labeled with a bar code, it is imperative that only the NDC label code (with product code) be required. If, and only if, a bar code will be required, it should be allowed to be included either (a) on the main product label or (b) on a separate bar code label for a period of up five years from the date the regulation becomes effective. After this five-year period, the NDC label code with product code could be required to be on the main product label only, if lot numbers and expiration dates are not included (see following paragraph for arguments against including lot number and expiration dates in the bar code for medical gases). For the reasons stated previously regarding unit doses, requiring a package code to be included would provide no additional “mix-up” prevention.

Medical gases, per current agency policy (as of the date of this letter), are not required to bear an expiration date. Medical gas lot numbers are typically identified on cylinders and liquid containers separately from the main product label. A high-pressure cylinder lot will typically not exceed 100 cylinders (and may even be as few as four or five cylinders) necessitating hand applied labeling. Typically, each medical gas liquid container filled is identified as a unique lot. The potential requirement to include lot numbers in the bar code label would be extremely burdensome, requiring each filling location, many of which are single site small business entities, to purchase and validate bar code printers and readers and implement extensive verification processes. If the agency rejects all of Gas Regs, Inc.’s previous arguments, deeming medical gas containers be bar coded with the NDC label code, product code, lot number and expiration date, the information should be on a separate bar code label not on the main product label.

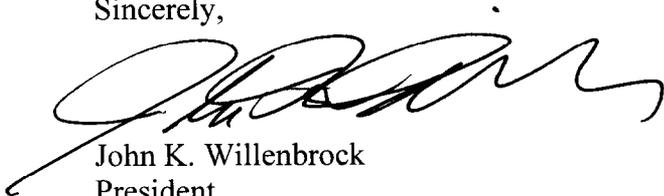
Regarding the questions: **“Assuming a final rule is issued requiring bar coding, when should it become effective?”** and **“Would a certain compliance time sharply reduce costs of relabeling?”**

If the agency allows bar codes (with only the NDC labeler and product code) to be included either (a) on the main product label or (b) on a separate bar code label for a period of up five years from the date the regulation becomes effective, an initial effective date two years from the

issue date should be acceptable. If the agency will not allow both (a) and (b) and requires the bar code to be on the main product label then the rule should become effective five years from the date issued. In both of these scenarios, the expectation is that only the NDC labeler and product code would be required. If lot number and expiration date would be required and would be allowed on a separate bar code label (not on the main product label) an initial effective date three to four years from the issue date may be acceptable to allow small entities to gear up for these requirements. If all potential components of the bar code (NDC labeler, product, and package codes with lot number and expiration date) are required on the main product label then an initial effective date five years from the issue date may be acceptable for larger medical gas firms. The potential of forcing smaller entities out of the medical gas business with these requirements is a distinct possibility. Gas Regs Inc. strongly recommends that prior to publishing and implementing bar coding regulations that would impact medical gas manufacturers, fillers and distributors, that the agency interact with trade associations such as the Compressed Gas Association, National Welding Supply Association, and the American Association for Homecare to assess the degree such regulations will impact this industry.

Gas Regs, Inc., appreciates the opportunity to comment on the Bar Code Label Requirements for Human Drug Products. If there are any questions regarding the positions presented, please do not hesitate to contact John K. Willenbrock, President, Gas Regs, Inc. via e-mail at [john.willenbrock@gasregs.com](mailto:john.willenbrock@gasregs.com), or via phone at 336-887-0510. Thank you for your consideration.

Sincerely,



John K. Willenbrock  
President  
Gas Regs, Inc.

Address, Ship Manager, 2001/12/05 12:00

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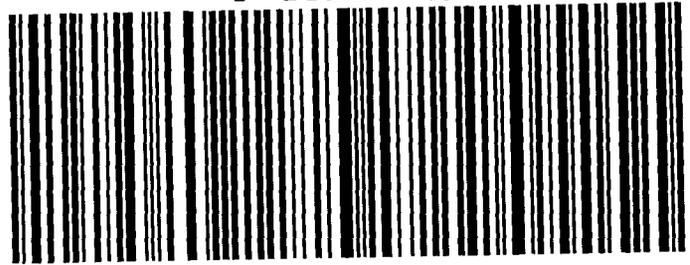
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