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VIA FACSIMILE (301) 827-6870
and email to www.fda.gov/dockets/ecomments
Original to Follow via U.S. Mail

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

Re: Docket No. 02N-0204
Bar Code Label Requirements for Human Drug Products and Blood

Dear Sir or Madam:

Lincare Inc. ("Lincare") 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 (the "Notice"), for the reasons set forth herein, Lincare proposes the Food and Drug Administration ("FDA") exempt medical oxygen distributed to home care patients from the proposed rule (21CFR §201.25 "Bar code label requirements").

Lincare is a home respiratory company that principally provides medical oxygen to patients in their homes. Accordingly, Lincare limits its comments to medical oxygen used in the home care setting.

Medical oxygen, or Oxygen USP, is a drug within the meaning of Section 201(g)(1) of the Federal Food, Drug, and Cosmetic Act (the "FDC Act") and pursuant to Section 503(b)(1)(A) of the FDC Act is required to be dispensed by prescription. However, in emergency situations and when administered by properly trained personnel, Oxygen USP may be administered without a prescription.

As detailed in this letter, Lincare believes bar-coding Oxygen USP for home care use is unnecessary and warrants an exemption, given:

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a) All medical gases, including Oxygen USP, are uniquely packaged and used; and
b) Bar coding medical gases, including Oxygen USP, will not reduce medication errors in the home care setting.

Application of the Proposed Rule to Home Respiratory Companies

Transfilling oxygen cylinders (gas to gas or liquid to gas) is considered a "manufacturing" activity under Section 501(g)(1) of the FDC Act. In addition, filling liquid oxygen containers at a patient's residence (curbside fill) is also considered a "manufacturing" activity under Section 501(g)(1) of the FDC Act. As a consequence, home respiratory companies that engage in these activities would be subject to the proposed rule, as currently written, since they are not exempt from the establishment registration and listing requirements.

Typically, transfilling by home respiratory companies is a low-tech, small production operation used only to fill cylinders for the home care company's customers in a limited geographic area -- not for wholesale to other suppliers or for mass distribution. These are not the type of large-scale, national or regional manufacturing operations contemplated to be affected by the proposed rule.

In the case of curbside liquid fills, there is no true manufacturing operation at all. Rather, one delivery truck makes multiple stops to refill patients' in-home liquid reservoirs. Nevertheless, this process is regulated as "manufacturing/packaging" by the FDC Act and, as written, the proposed rule would require bar code printers on each and every delivery truck. Home respiratory companies generally receive the same reimbursement for providing gaseous oxygen (which has lower operating, capital and regulatory costs) as for higher-cost liquid oxygen. Given the limited reimbursement, many home care providers no longer supply liquid oxygen. Consequently, access to liquid oxygen is already limited in certain geographic regions. Application of the proposed rule to curbside fill operations of home oxygen suppliers will further increase the cost thereof, which is likely to further reduce the number of liquid oxygen suppliers in home care.

Overview of Oxygen Use in Home Care Settings

Home respiratory patients typically self-administer their prescribed oxygen via various modalities, including:

a) large stationary or small portable high-pressure cylinders;
b) stationary and portable liquid vessels (with proprietary connections); and/or
c) oxygen concentrators (medical devices that do not require bar coding under the proposed rule).

Many patients utilizing an oxygen concentrator in their home merely use high pressure cylinders as their back-up source in case of power failure. Ambulatory patients may use an oxygen

concentrator while at home and liquid oxygen or high pressure cylinders for portability. Even though the oxygen strength differs between the output of a concentrator and that provided in the cylinder or liquid unit, the gases are therapeutically equivalent. The oxygen cylinder or liquid unit would require a bar code under the proposed rule, whereas the oxygen concentrator would not. Such a result demonstrates the inapplicability of the bar coding to medical oxygen supplied in the home.

The Exemptions Proposed for Physician Samples and Certain OTC Drugs Should Apply to Medical Oxygen

Under the proposed rule, prescription drug samples are exempt from the bar code requirement "because physicians or patients would not have or be inclined to buy bar code scanners for their own use in the immediate future." Similarly, the proposed rule exempts OTC drugs outside the hospital setting because "it is unlikely that individual consumers would buy, use or have access to bar code scanners or use such scanners before taking an OTC drug." Given the lack of access to bar code scanners for the end-user patient, even the proposed rule recognizes that the impact of bar coding such drugs would be minimal. This logic applies equally to medical oxygen used in the home setting. Home care patients would derive no benefit from bar coding because they would typically not have access to scanners.

Existing Procedures in Home Oxygen Delivery Intercept Medication Errors Without the Need for Bar Coding

The primary focus of the proposed rule is to "help reduce the number of medication errors occurring in hospitals...". Oxygen USP used in home care is outside of the hospital setting and thus, is not the focus of the proposed rule. In addition, in quantifying errors to be prevented by the proposed rule, the FDA has "assumed that bar code systems would produce no reduction in prescribing and transcribing errors but that its use would intercept [an assumed percentage of] preventable [medication errors] in the dispensing and administration stages of the medication process." In light of the mode of delivery of home oxygen compared to traditional prescription drugs, the concerns of dispensing and administration are not applicable concerns in delivery of oxygen in the home care setting, as more fully explained below.

The Notice states that bar coding will reduce medication errors by allowing healthcare professionals to use bar code scanning equipment to verify that:

1. the right drug in
2. the right dose and
3. the right route of administration is being given to
4. the right patient at
5. the right time

It is Lincare's opinion that bar coding medical oxygen will not reduce medication errors in the home with respect to these five "rights".

1. Bar Coding Medical Oxygen Will Not Facilitate the Application of the "Right Drug"

Bar coding drug Oxygen USP packaging (high pressure cylinders or cryogenic vessels) is unlikely to prevent "wrong drug" medication errors in the home.[1] 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. In the unlikely event a patient had more than one medical gas, all the safety systems inherent in home care (*e.g.*, one on one patient education, color-coded cylinders, gas property-specific connections and labeling) would need to be circumvented in order to have a mix-up at the patient's home. In the event a patient was determined to ignore or evade all of these safety precautions, it is a virtual certainty that a bar code (even if the patient had access to a bar code scanner) would be ignored as well.

2. Bar Coding Medical Oxygen Will Not Facilitate the Application of the "Right Dose"

While bar coding may assist with the "right dose" aspect of many traditional prescription drugs, such is not the case with Oxygen USP. Labels on oxygen packaging (high pressure cylinders or cryogenic vessels) cannot indicate the number of "doses" therein contained. High-pressure cylinders contain from less than one hundred up to several thousand liters of gas. Liquid containers are capable of holding significantly more (hundreds of thousands of liters of gas). However, container size or net contents have no bearing on dose in the case of Oxygen USP. "Doses" of Oxygen USP prescribed by a physician for a patient 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 of time (*e.g.*, 2 liters/minute for 24 hours per day). The patient would then self-administer the oxygen (whether from an oxygen concentrator, high pressure cylinder or liquid unit) at the prescribed flow-rate for the prescribed duration. Depending on a patient's prescription (and whether the physician has also prescribed a conserving device in the case of cylinders), a cylinder may last from only a few hours or to several hours. Given the peculiarities of medical oxygen compared to other prescription drugs, bar coding labels on Oxygen USP containers will not facilitate proper dosing.

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[1] While there have been certain high-profile medical gas mix-ups, these have occurred at health care facilities or institutions where existing safety systems were compromised. As such, these situations are inapplicable to the home care setting. In each of these cases, 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 industry standards, regulations and regulatory initiatives address the issues that have resulted in these medical gas mix-ups. For example, a cylinder of medical oxygen is color-coded green and has a CGA 870 or CGA 540 valve that is incompatible with the connections of other medical (or industrial) gases.

3. Bar Coding Medical Oxygen Will Not Enhance the Application of the "Right Route of Administration"

Oxygen USP has only one route of administration – inhalation. It is unnecessary to rely on a bar coded label on a high pressure cylinder or cryogenic vessel to assure proper administration.

4. Bar Coding Medical Oxygen Will Not Facilitate Application to the "Right Patient"

Unlike in institutional settings, home care services are provided to a single patient in the patient's home, where a computer database would not be readily available to immediately confirm the patient's identity via bar code. Home care patients do not wear bar coded identification wristbands that are commonly found in the acute and sub-acute care setting. Rather, there are existing patient-identifiers inherent to the home care setting that assure the "right patient" is being seen. For example, a delivery ticket would include a unique address and patient identification number. Moreover, home care providers become familiar with their home care patients, identifying them with particular residences through repeated oxygen delivery visits.

5. Bar Coding Medical Oxygen Will Not Facilitate "Right Time" Dosing

Unlike traditional prescription drugs which are dispensed at certain intervals, "right time" medication administration errors (e.g., failing to provide the drug at the right time or providing it at multiple times) do not apply to Oxygen USP. Medical oxygen in the home care setting is self-administered by the patient for the prescribed duration (e.g., 24 hours per day, nocturnal, during exercise, etc.). See Item 2 above.

The Notice Fails to Consider the Impact of the Proposed Rule on Home Respiratory Companies

The Notice fails to consider home oxygen providers (typically, NAICS 621610 or NAICS 621999) in its discussion of affected sectors even though same are deemed manufacturers or packagers of Oxygen USP under the FDC Act. In fact, Lincare understands that over fifty percent (50%) of all drug manufacturers registered with the FDA are medical gas firms and it is likely that a large portion of these are home respiratory companies. It is inappropriate for the FDA to ignore such a large "affected sector" in promulgating the proposed rule.

Conclusion

Lincare believes the reasoning herein provides adequate rationale for the FDA to exempt medical oxygen distributed to home care patients from the requirements of proposed 21 CFR 201.25. If the FDA is not inclined to grant this request to exempt Oxygen USP for home use from the

proposed rule, Lincare requests that, prior to publishing a final rule, the FDA meet with the American Association for Homecare and members of the industry to discuss the degree this regulation will impact the home care industry and the minimal potential health benefit that the regulation will have on the administration of medical oxygen in the home care setting.

Lincare appreciates the opportunity to comment on this proposed rule. Thank you for your consideration.

Sincerely,

Mike Daly
Lincare Inc.
Regulatory Compliance Analyst