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MEMORANDUM

January 23, 2002

To: Mary C. Gross
Office of Drug Safety
Center for Drug Evaluation and Research
Food and Drug Administration
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grossm@cder.fda.gov and

Dockets Management Branch (HFA-305)
Food and Drug Administration
5630 Fishers Lane – Room 1061
Rockville, MD 20852
fdadockets@oc.fda.gov

Re: Comments for the Public Meeting to address Bar Code Labeling Requirements for Human Drug Products

Dear Ms. Gross:

In follow up to my previous request please find attached comments for the public meeting to address Bar Code Label Requirements for Human Drug Products.

Thank you for the opportunity to comment.

Sincerely,

Daniel M. Ashby, M.S., FASHP
Director of Pharmacy

OAN-0204

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**FDA Bar Code Label Requirements For
Human Drug Products**

July 26, 2002

A. General Questions Related to Drugs and Biologics:

1. Which medical products should carry a bar code? For example: should all prescription and over-the-counter drugs be bar coded?

Drug manufacturers should provide all prescription and over-the-counter drugs in bar coded packages down to the single unit dose or unit of use level. All drugs and all dosage forms would be included in the bar code labeling requirement (tablets, capsules, suppositories, ointments, creams, otics, ophthalmics and drugs for injection). The bar code should be present for each individual dose that goes to the patient.

Bar coding is needed in hospitals and health-systems for the following reasons:

- **Ensuring the accuracy of medication identification**
- **Ensuring the accuracy of the medication administration process**
- **Improving efficiencies within the medication distribution system in hospitals**
- **Reducing the number of medication errors**
- **Improving the efficiency of the supply system, including ordering, receipt, storage and dispensing, billing, administration documentation and tracking of drug products**

The most important benefit of bar code technology is the improvement of patient safety. These benefits will be obtained only when the bar code technology is utilized at the hospital or patient facility level.

In the hospital pharmacy, the availability of bar codes will assist with ordering, receipt, storage, dispensing and administration of drugs for patients.

2. What information should be contained in the bar code?

The following information should be included on the label:

- **National Drug Code (NDC)**
- **Drug name, strength and unit of measure**
- **Lot number (for recall purposes)**

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- **Expiration dates (to prevent the utilization of expired medications)**

What do you consider to be critical bar code information that will reduce medical product errors?

The critical bar code information that will reduce dispensing errors is the National Drug Code, drug name, strength and unit of measure to identify the product. The information such as lot number and expiration date is of limited value with respect to reducing dispensing errors.

It may be advisable to implement these recommendations in two stages. The first priority for patient safety would be to have the National Drug Code (NDC), drug name, strength and unit of measure. A second phase, possibly implemented in the future, would be to add the lot number and expiration date. These will have value for patient safety for the purposes of inventory control; supply chain management and the management of a complex recall process.

3. Considering current scanners and their ability to read certain symbologies, should the rule adopt a specific bar code symbology (e.g. RSS (reduced space symbology) and composite (2-dimensional) symbology)?

No comment.

Should we adopt one symbology over another, or should we allow for "machine readable" formats?

No comment.

What are the pros and cons of each approach?

4. Assuming that we require bar codes on all human drug products, where on the package should the bar codes be placed?

The bar codes for unit dose blister package should be placed on the drug label. The NDC bar code should be placed above or below the human readable NDC.

The bar code should be placed on the package that is ultimately used by the patient. Ointments, creams and containers for otic products, ophthalmic products, ampules and vials and inhalation products, that

are shipped in a box, must also have the bar code label on the container inside the box.

Are there benefits to placing bar codes on immediate containers, such as the bottles, tubes, foiled-wrapped tablets, and capsules, found inside prescription or OTC product cartons?

Yes, this is most important for hospitals, health systems and patient care facilities. The primary benefit will be patient safety. When a drug is issued to the patient external packaging is removed. Even if the product carton or box was provided to the patient care unit it can be lost or mixed up with other boxes or containers resulting in medical error. The final product such as the bottle, tube, foil-wrapped suppository, tablet and capsule, found inside prescription or over-the-counter product cartons must contain the bar code label.

The bar code should also be placed on the FDA approved selling unit (e.g. bottles or boxes of 100 tablets/capsules). There are numerous benefits such as improved traceability (i.e. tracking lot numbers and expiration dates for commercially available packages).

Is there a way to distinguish whether certain containers with a bar code will have a more significant effect on preventing errors than others?

Published literature supports that there is a reduction in medication errors when bar codes are used on product containers. It is believed that this would be demonstrated in all containers.

5. What products already contain bar codes?

Products of all types currently contain bar code labeling. This demonstrates that it is possible to provide the bar code labeling.

The difficulty for pharmacists and health care providers in hospitals and other health care facilities is that not all packages and drugs contain the bar code labeling. The percentage is very low. Products that come bar coded and ready to use for the AHI-RxOBOT™ dispensing system represent less than 15% of all of the doses dispensed.

As a result, it is necessary to take a perfectly adequate 'human-readable' unit dose package and repackage it to compensate for the lack of barcode labeling so that it may be read for dispensing in the hospital. This system is terribly inefficient and adds to the cost of health care while failing to fully capture the advantages of bar code technology.

Who (i.e., hospitals, nursing homes, outpatient clinics, retail pharmacies, etc.) uses these bar codes and how?

The utilization of drugs and drug packages with bar codes has increased substantially over the last 5 years. The value of this technology has been demonstrated in supermarkets and mail delivery. The current utilization is limited. The lack of bar code labeling is the major rate-limiting step at this time.

B. Medical Device Questions

Not applicable to my pharmacy practice environment. This issue is applicable to the Materials Management Department for The Johns Hopkins Hospital.

C. General Questions and Economic Impact Questions

1. Will bar code printing costs cause you to modify your packaging choices, such as reconsidering the use of blister packages or influencing future package choices? If so, how?

Not applicable to my practice environment.

2. Have you implemented bar code technology in your product line?

Not applicable to my practice environment.

If so, what elements and symbology are included in the bar code?

3. If you manufacture and bar code products, how do verification requirements for bar codes affect your ability to add bar codes?

Not applicable to my practice environment.

How much bar code verification is appropriate as part of the quality system?

The optimal level is 100% bar code verification.

4. Can bar codes be produced with a dose specific unique identifying number, lot number, and expiration date at your highest production line speeds?

Not applicable to my practice environment.

5. What equipment solutions are vendors offering to manufacturers for bar coding or scanning?

Not applicable to my practice environment.

How quickly can such systems run?

Not applicable to my practice environment.

What type of packaging line is equipment used for?

Not applicable to my practice environment.

6. What is the expected rate of technology acceptance in all health care sectors of machine-readable technologies?

The expected rate of technology acceptance is 100 percent as practitioners. The American Society of Health-System Pharmacists adopted at the June 2001 House of Delegates meeting the recommendation of the National Coordinating Council for Medication Error Reporting and Prevention recommending the implementation of uniform bar code standards in the medication use process.

Group Purchasing Organizations have for years established policies to require bar code labeling or stating that preference will be given to manufactures that offer bar code labeling. Voluntary compliance or even the potential of economic-market advantages have not been successful in achieving the desired outcome.

The end user will philosophically embrace the concept and technology. The adoption rate depends on the ability of the manufacturers and packagers to provide scannable bar codes for the end users and the capital funding available to the end user to purchase the machine-readable technology.

What are the major inhibiting factors to the current use of machine-readable technologies?

The major inhibiting factor is the lack of bar code labeling on drug products distributed in the United States.

What would be the expected benefit of using machine-readable technology in the delivery of health care services (including drug products)?

The primary benefit of using machine readable technology in the delivery of health care services (including drug products) is improved patient safety by the reduction of medication errors.

Additional benefits include increased efficiencies, a reduction of paperwork, improved audit trails and improved accuracy of medication identification.

What would be the expected benefit of machine-readable technology for other potential uses (e.g., reports, record keeping, inventory control, formulary setting, etc.)?

The other expected benefits of machine-readable technology for other potential uses are improvement of overall efficiencies in the supply system, including purchasing, storage, inventory control, record keeping, and distribution of drug products. The health care industry will realize the same benefits that are realized today by virtually every other industry.

7. Assuming a final rule is issued requiring bar coding, when should it become effective? For example, would some industries or products require more time than others to comply with a bar code requirement?

Unable to comment.

Would a certain compliance time sharply reduce costs of relabeling?

Yes. Health Systems are currently incurring costs to re-label drugs. The availability of bar code labeled products would offer cost advantages to hospitals and health-systems.