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Dockets Management Branch (HFA-305)
Food and Drug Administration
5630 Fishers Lane
Rockville, MD 20852

RE: Docket No. 02N-0204; Bar Code Label Requirements for Human Drug Products

The National Association of Chain Drug Stores (NACDS) is pleased to provide comments on the proposed bar code labeling requirements for human drug products and blood. NACDS supports the use of automated product identification technology, including bar codes, to help improve the quality of pharmacy care provided to patients, as well as create efficiencies in the provision of prescription services.

NACDS membership includes more than 200 chain companies that operate approximately 35,000 community retail pharmacies. Chain pharmacy is the single largest segment of pharmacy practice employing approximately 100,000 pharmacists. Chain community pharmacy fills about 70 percent of the 3 billion prescriptions provided to patients each year.

413 North Lee Street
P.O. Box 1417-D49
Alexandria, Virginia
22313-1480

Use of Current Automated Product Identification Technology in Retail Community Pharmacy

It is predicted that community pharmacy will fill about 4 billion prescriptions by the year 2004. More than seventy percent of these prescriptions will be filled by chain pharmacy. This fact, coupled with a continuing shortage of pharmacists will require that community pharmacy seek technological solutions to fill more prescriptions more efficiently. Automated dispensing devices that use bar codes to identify and verify prescription products have helped to achieve this goal.

Enhancements to those bar codes currently used could further improve patient care quality initiatives. By including certain information about the product, like the lot number and expiration date, quality of care in providing prescription services can continue to be improved. In addition, enhanced bar coding can assist the distribution system of product from a bioterrorism preparedness and counterfeit prevention perspective. The questions of who has product and how it can be moved from place to place could be asked and answered more efficiently with this information.

NACDS supports the use of bar codes as a way to complement the various programs that community pharmacies already have in place to enhance patient quality. By including relevant and specific drug product information in the RSS bar code, pharmacists can double check to assure that the prescription product being dispensed is consistent with the prescriber's order and that the product is not out of date.

Many automated dispensing systems in use today in community pharmacy incorporate bar code technology to enhance patient quality. One, in particular, allows the pharmacist to scan the bar code on the label of the completed prescription. This allows viewing of an image of the correct product. The pharmacist can compare and double check the image against what is in the pharmacy container before it is ultimately dispensed to the patient.

(703) 549-3001
Fax (703) 836-4869
www.nacds.org

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NACDS has reviewed the proposed rule, and is generally supportive of the direction that it takes. However, we do have some concerns and issues, which we address below.

Exclusion of Bar Code from Patient Prescription Package: NACDS supports the provision that exempts retail pharmacies from placing the bar code label on retail prescription products that are dispensed to patients. Some pharmacies place a barcode on the patient prescription package, and they should have this option. This bar code helps pharmacies refill prescriptions when the patient returns with the original container. In some cases, the package of the product that is ultimately dispensed to consumers will contain the bar code because it may be a unit of use prescription package. (The manufacturer would be required to place the bar code on such packages.) However, there is little value in requiring a bar code label be placed on prescription packaging, since consumers do not have the technology to read the bar code.

Bar Codes on Repackaged Products: Some NACDS members repackage pharmaceuticals that are purchased in bulk from manufacturers for later retail sale. These products are then supplied to individual stores in that chain's pharmacies and are used to fill prescriptions for retail customers. We recognize that these chains will have to place a bar code on the repacked prescription product similar to the bar code placed on an original manufacturer's package.

Bar Codes on Bulk Compounded Products: It is not clear how the proposed rule would treat pharmacy-compounded prescription products. Some pharmacies prepare compounded products in limited bulk in anticipation of receiving orders from local prescribers who regularly issue prescriptions for these compounded prescriptions in the course of their practice. The pre-compounding of these products enhances pharmacy efficiency and reduces patients' waiting time. Pharmacies should have the option of placing a bar code on the stock bottles in the pharmacies containing these compounded products, but since the preparation of these products is controlled by state laws, rather than FDA, they should be exempt from these bar code requirements.

Pharmaceutical Samples: NACDS believes that placing bar codes on samples can have useful patient care purposes. Many patients, especially those with low incomes, start their therapy with samples obtained through a physician's office or a hospital. Including a bar code on these samples could help a pharmacist identify the sample if a patient brings it into the pharmacy with a prescription for the remainder of the medication.

Lot Number and Expiration Dates: Including the lot number and expiration date on the bar code would substantially improve the current FDA recall system. In all recall situations, including Class I recalls, companies voluntarily contact every person who has received the drug to warn them of possible adverse reactions. This is necessary because there is no way of knowing which patients received the recalled lot number. By capturing the specific lot number, the targeted population is the affected population. This process would eliminate unnecessary alarm to those who may be taking a particular product, but who are not at risk of adverse events associated with the recall. Moreover, the company would be able to pull this unwanted stock expeditiously from the warehouse or distribution center.

The recent recall of certain counterfeit lots of the repackaged pharmaceutical Liptor is a good example of how a barcode system would help with a targeted recall of certain products without affecting all lot numbers of product that might have been distributed.

Issues Relating to Use of Linear Bar Code: We support the use of the EAN.UCC as the recognized standard setting body for pharmaceutical/prescription product identification. However, we do not believe that a final rule should be limited to linear bar code specifications, and suggest that this reference be deleted. The rule should simply indicate that the EAN.UCC standards are the accepted standards for bar code technology. This will allow for the use of the linear bar code today, but also potential new forms of product identification in the future without requiring a formal rule change. EAN.UCC has been involved in setting and maintaining standards for over 30 years. The retail industry and our suppliers have a great deal of confidence in the standards they set and the process they use to generate consensus.

Issues Relating to Use of GTIN on unit of use packaging: We are concerned about potential patient safety aspects of requiring that hospital-based OTC products contain a bar code number. While we believe that including bar codes on these products can enhance patient safety in the hospital environment, there are potential implications in the retail environment to how OTC manufacturers will respond to this requirement. We assume that manufacturers will place these bar codes on unit dose packaged OTC products, just as they do for prescription-packaged products. However, the vast majority of OTC medications are sold in retail outlets. As manufacturers try to become as efficient as possible in their packaging, we are concerned that they may create an OTC package that serves both the retail market as well as the hospital market.

This could cause a significant problem for retail consumers. Most OTC products have two layers of packaging. The secondary package is the outer package (which carries a bar code) and is often discarded by the consumer after the medication is opened. The primary package (or the internal package) is often either a bottle or a blister card. On the outside of these internal packages is important, human readable information.

First, manufacturers may switch from bottles to blister cards. This would raise the cost of the product for consumers and increase the amount of waste in our system. Second, if the individual unit dosage packages in the blister card have to include the bar code, there would not be any room for the human readable information important for the consumers to understand how to use the product. If the consumer disposes of the secondary (outer) package, they will be faced with a blister card with a bar code and little or no room for human readable information. This rule could have the unintended affect of causing harmful and misappropriate use of OTC medications at home.

Potential Changes to NDC Numbers: As the proposed rule states, the FDA is considering changes to the manner in which NDC numbers are assigned. We understand that the agency is considering a random numbering system for NDC numbers, or some other new scheme. This will create serious operational and administrative issues for the system, and well as result in significant costs.

The entire pharmaceutical and health care product distribution system – from the manufacturer to the wholesaler to the pharmacy to the payer – use the NDC number to order, track, warehouse, account, distribute, prescribe, dispense, bill, reconcile payment, and perform clinical functions on – prescription drugs and health care products.

There is a systematic rationality to the current NDC number code. While no system is perfect with the tens of thousands of products on the market, this NDC scheme is working well and has been programmed into the thousands of pharmacy-based computer systems in operation today.

Changes to the current NDC system would cost the industry tens of millions of dollars in reprogramming both central computer systems as well as the software that is used by individual pharmacies. State Medicaid programs as well as private payors would also incur significant costs to change their systems since both the Medicaid reimbursement and rebate system operate off the current NDC numbers. States can ill afford to absorb these costs. Changing the current rational basis of the NDC number would also compromise patient safety. Pharmacists use the current NDC numbers to reduce potential medical errors because NDC numbers help pharmacists to visually identify products, and are programmed into existing software systems to detect potential drug interactions. The Drug Enforcement Administration (DEA) also uses this system for various programs that help detect illegal controlled substance use.

Over time, pharmacists become familiar with the labeler code section of the NDC number, and are able to identify the manufacturers if the information is included on the actual pharmaceutical product. This patient safety check would be eliminated through a random-based NDC numbering system.

If the agency believes that the system is running out of NDC numbers, then they should adopt an alphanumeric system that would use both numbers and letters in the existing fields. For example, under a 5-3-2 NDC sequence, there are almost 99 package sizes available, more than enough for a single product. Under the 5-4-1 sequence, however, there are admittedly only nine potential package sizes. However, if letters were used once all the numbers were used in the package field, then that would give the manufacturer more than two dozen more potential package codes to use, given that bar code technology can read these letters as well. If the agency is concerned about the impact of a few errant NDC numbers on the use of bar coding technology, then the FDA should work with the industry to clean up any minor problems that exist in the market without resorting to massive changes in the system that will be costly and disruptive. Moreover, there are other existing technologies that can address the package size issues in the use of bar code technology that does not require a radical change in the system.

Conclusion

We appreciate the opportunity to respond to this proposed bar code regulation, and look forward to working with the FDA on the development of policy to improve the safety of prescription drugs through automated item identification.

Sincerely,



John M. Coster, Ph.D., R.Ph.
Vice President, Policy and Programs