American Society of
Health-System Pharmacists®

7272 Wisconsin Avenue
Bethesda, Maryland 20814
301-657-3000
Fax: 301-652-8278
www.ashp.org

June 11, 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 for Human Drug Products and Blood

TO WHOM IT MAY CONCERN:

The American Society of Health-System Pharmacists (ASHP) is pleased to provide comments on the Food and Drug Administration's (FDA's) March 14, 2003, *Federal Register* notice requesting comments on the agency's proposed rule that would require manufacturers to place bar codes on drug products and blood. ASHP is the 30,000-member national professional and scientific association that represents pharmacists who practice in hospitals (including outpatient services), health maintenance organizations, long-term care facilities, home care agencies, and other components of health systems.

For the most part, ASHP supports the March 14, 2003, proposed rule and commends the FDA for the amount of work the agency has done in developing the proposal. The FDA's stated goal in requiring manufacturers to place bar codes on drug products is "to help reduce the number of medication errors in hospitals." ASHP has long supported the use of this technology to help prevent patient harm, and we consider this to be one of the most significant regulatory proposals associated with patient safety and medication-error reduction that the FDA has ever issued. Health-system pharmacists work diligently to put checks and balances in place to prevent patient harm. Bar coding on drug products will significantly advance this process.

Drug manufacturers have an obligation and responsibility to provide the safest form of their drug products possible. Given the proven benefits of bar-code bedside verification of medications, manufacturers should be required by FDA regulation to include bar codes on their product packages, including unit dose packages. As ASHP's representative stated at the public meeting the FDA held on bar coding on July 26, 2002, bar coding technology is entrenched throughout America in all types of venues -- grocery stores, department stores, libraries. It is something everyone expects and is found everywhere, except where it can do the greatest good -- saving lives, by preventing medication errors. This is a high urgency, public health and safety issue and the action on this initiative is long overdue.

In its proposed rule, the FDA asked for comments on specific issues. ASHP's responses are as follows:

Whether the FDA should require bar codes on prescription drug samples, and the costs and benefits associated with such bar codes

The FDA's proposal to exclude prescription drug samples from the bar code requirement should be carefully considered. While the addition of a bar code to drug samples may not add the same safety benefits as it would for unit dose packages, it would offer other potential benefits associated with sample use. Some ASHP members believe that bar codes should be required on drug samples, because some institutional sites accept samples into their facility, and the Joint Commission on Accreditation of Healthcare Organizations (JCAHO) requires that these facilities exert some control over all medications. A simple bar code would assist in using automation to help track samples at these sites.

ASHP suggests that, if the final rule excludes drug samples from the bar code requirement, the FDA conduct a study to clarify how samples are actually used in institutional settings nationwide to determine whether drug samples should be included in future rulemaking.

The risks and benefits of including vaccines in a bar code rule

It is imperative that bar codes that include the NDC number, lot number, and expiration date be required for vaccines. ASHP believes that there would be no risks involved by including vaccines in the bar code requirement. Benefits include accurate identification of product, as well as rapid and accurate transcription of vaccine lot number and expiration date into an electronic medical record. This data must now be recorded manually, and as such is not searchable and is difficult to store and retrieve.

What terms the FDA should use to describe OTC drugs that should be subject to the bar code requirement

ASHP endorses the idea of requiring bar codes on OTC products commonly used in hospitals, but the problem is in defining what that means. Bar codes currently on OTC drug packages meant for retail sales are generally used for inventory and sales purposes, and to require additional bar coding for these products would probably not increase patient safety. However, from a hospital inpatient perspective, drug products are not differentiated in regard to prescription or OTC status – they are either on a patient's medication profile or not. To extend the FDA's proposal for bar codes that include NDC numbers, lot numbers, and expiration dates to "all unit dose packages of drugs intended

for hospital inpatient use" would increase patient safety in the same way that it would for any other drug. ASHP also recommends defining the term "commonly used in hospitals" as "packaged for hospital use, labeled for hospital use, or marketed, promoted, or sold to hospitals."

Information on the costs and benefits associated with putting lot number and expiration date information in the bar code

ASHP realizes that there are widely divergent opinions regarding the usefulness of including lot numbers and expiration dates on drug-product bar codes. ASHP appreciates that the FDA does not go so far as to prohibit manufacturers from including these elements on the bar code. However, our members believe strongly that lot number and expiration date should be included in the mandated bar coding. The ASHP House of Delegates voted earlier this month to urge the FDA "to mandate that pharmaceutical manufacturers place standardized machine-readable coding, which includes National Drug Code, lot number, and expiration date, on all manufacturers' unit dose, unit of use, and injectable drug packaging."

In its proposed rule, the FDA has taken the position that, while lot number and expiration date information in a product's bar code would make it easier to identify drugs that had been recalled or were expired, the agency has received no explicit data to indicate that the benefits of adding lot numbers and expiration dates would exceed the costs of putting that information in the bar code.

The National Drug Code, lot number, and expiration date establish a "triad of safety." These patient-safety data elements, as a package, should all be required in the final rule. For patient safety reasons, lot number and expiration date are now required elements on drug products in human-readable form and, therefore, should be included in a machine-readable format.

The fact that the FDA cannot quantify the safety benefit of including lot number and expiration date in a bar code is not surprising. There is a paucity of data directly correlating expired drugs and recalled lots to patient harm. These elements are not part of bar codes now, so there are no quantifiable means to point out the potential benefits of including them in drug product bar codes. However, there is no evidence to the contrary – little data exist to suggest that patients are not being harmed by out-of-date and recalled drug products – either. It is, simply, a basic, common-sense patient safety issue. As Dr. John Combes of the American Hospital Association pointed out at the FDA's July 26,

2002, public meeting on bar coding, in relation to the FDA's goal of ensuring that the right dose of the right drug gets to the right patient by the right route of administration at the right time, "if you're giving an expired drug or a recalled drug to somebody, then you're not giving the right drug any more." Nurses should be alerted if the medication they are about to administer to a patient is from a recalled lot.

Hospitals need a mechanism to effectively and efficiently track patients by name and lot number. There are things that pharmacists cannot do at present that would be facilitated by having the lot number and expiration date in the bar code. Currently, when there is a drug-product recall, pharmacies have no way of knowing which patients may have received a specific lot of a product. Manually recording and accessing such information is impractical. As soon as the lot number is part of the bar code, appropriate tracking systems can evolve in the pharmacy dispensing process. This is especially important for Class I recalls. Having the ability to correlate a specific patient with a specific lot number in a database would facilitate the identification of patients for contact when a recall is announced.

When a product is recalled because of a serious threat to patients, the best that pharmacies can do at present is to inspect shelf packages – and possibly shipping records – to discover whether the pharmacy ever had any of the product. Then, if so, the pharmacy would have to contact every patient to whom the drug might have been dispensed or administered. The patient fear provoked by that action could be profound. Without the lot number in the bar coding, there is no reliable, efficient way to track patients who may have received a recalled product.

Expiration dates are, similarly, difficult to monitor manually, but expired drugs given to patients can cause harm, and they should be identifiable through machine-readable coding. Medication-use processes in hospitals are complex. In hospitals and similar settings where unit doses of medication are used, individual doses are disseminated throughout the institution, may be moved around in the facility, and they might even be recycled through stock. Inspecting stock to detect specific expired doses is labor-intensive and resource-prohibitive. If an expired dose is identified just before administration, patient therapy must be delayed, with the potential for suffering and suboptimal care, while an unexpired package is found. If the expiration date were part of the bar code, expired drugs could be electronically identified before dispensing, appropriate tracking and detecting systems would evolve in pharmacy computer systems, and patient safety would be significantly enhanced.

To give the industry sufficient time to re-tool production lines, ASHP suggests that drug manufacturers be given four years from the date of the final rule to include lot number and expiration date in machine-readable format on all unit-dose packages, including single dose ampules.

Whether the rule should refer instead to linear bar codes without mentioning any particular standard or refer to UCC/EAN and HIBCC standards

We do not fault the FDA from wanting to identify a particular standard for the proposed bar code. Our concern is not with the standard itself, but we suggest that the FDA reconsider whether the agency needs to dictate a standard, or even insist on a linear bar code. This unnecessarily narrows the field of possibilities and limits innovation in the industry.

The final rule should not specify any specific symbology. Patients will be best served by requiring a machine-readable code that fits on any given package size, including unit-dose, with NDC, lot number, and expiration date. This can be achieved by using 2-D symbologies that are currently available. Emphasis should be placed on the use of "open standards" and standardized data structures for representing the necessary data elements. The FDA should trust the market – let the technology evolve.

Additional information regarding bar code scanning technology and the ability of bar code scanners to read different symbologies

We discourage the FDA from setting a standard for a specific symbology. As noted above, technology in this field is evolving, and standardizing one specific technology for all time is not a realistic approach. Innovations and advancements in machine-readable codes should be encouraged, not stifled, by the FDA. Drug manufacturers should reach out to health professionals in hospitals to determine the best standard for machine-readable coding symbologies that meet the needs of patients and health care organizations. This will not happen if the FDA sets a specific scanning technology standard.

Whether any specific product or class of products should be exempt from a bar code requirement and the reasons why an exemption is considered to be necessary

ASHP believes that waivers could be considered for some OTC products that are not classified as drugs (such as toothpaste and shaving cream). To avoid making this issue too complex, the FDA should consider, as suggested above, using the term "non-

prescription drugs" that is commonly used in hospitals to eliminate the confusion over which specific OTC products are required to contain machine-readable codes with NDC number, lot number, and expiration date. Emphasis must be placed on requiring machine-readable codes on drugs, not on every over-the-counter product that does not meet the definition of a drug.

Whether the implementation period for a final rule can and should be shortened from 3 years to some other specific time period

ASHP has always insisted that the sooner action is taken on this issue, the sooner practitioners will have better tools to improve patient safety. We recognize, however, that manufacturers may require time and resources not currently available to meet the demands of the regulation when it is finalized. ASHP believes that because some drug manufacturers are already including machine-readable coding on their products, the requirements can be met by the industry within two years of the final rule. Lot numbers and expiration dates should be required within four years of the final rule.

How the proposed rule might affect hospitals where patients receive blood or blood components, particularly with respect to a hospital's decision to purchase a machine reader (e.g., scanner) that can properly identify the intended recipient of the blood or blood component, the machine readable information encoded on the blood or blood component label, and perhaps the linear bar codes appearing on drugs and OTC drugs that are dispensed pursuant to an order and commonly used in the hospital

The technology that is required has been in existence for a number of years. Most – if not all – hospitals have become computerized. The necessity of purchasing bar code scanners by hospitals would have to be determined by each facility. The FDA's requirement for manufacturers to place bar codes on product labels will enable those sites that choose to purchase the appropriate technology the ability to do so, using a universal standard to enable reading and recording via product bar codes.

Additional Consideration

ASHP is aware of another concern that is related to the bar coding issue. The FDA has already made the connection between requiring bar coding on drug product labels and the availability of unit dose packaging. In the December 3, 2001, *Federal Register* announcement in the Department of Health and Human Services' Unified Regulatory Agenda, the FDA recognized that there is a risk that drug manufacturers, if they were required to bar could individual unit-dose packages, might stop producing these smaller

packages and only supply products in bulk containers in order to reduce production costs. If there is a significant decline in the availability of unit dose packages, hospital pharmacies will be required to routinely repackage products without the benefit of large-scale quality control such as the manufacturers have. This potential introduction of new errors will diminish the safety gains of the bar code rule, and from a patient safety perspective, this would be unacceptable.

Our members report a disturbing general trend whereby fewer and fewer pharmaceutical manufacturers are producing products in unit-dose packages, requiring individual hospitals to repackage medications. Repackaging introduces new opportunities for mistakes to be made. This is a fundamental concern among our members, and from a limited review of comments already submitted to this docket, it is a concern among other health care providers as well.

For bar coding to be effective in hospitals and health systems, products in unit-dose packages should be made available by pharmaceutical manufacturers, and bar codes should be required on all pharmaceutical product packages, including the unit-dose, single unit level.

While ASHP recognizes that it would be inadvisable, at this point, to suggest that the FDA mandate unit dose packaging, in the interest of enhancing patient safety, ASHP advocates for the inclusion of bar codes on all pharmaceutical product packages, and for pharmaceutical manufacturers to make all products available in unit-dose form.

ASHP appreciates this opportunity to present its comments on this important patient-safety issue to the FDA. Feel free to contact me if you have any questions regarding our comments.

Sincerely,

Gary C. Stein, Ph.D.
Director, Federal Regulatory Affairs

Q:\Regs\FDA\barcodecomments.doc