American Pharmacists Association
Improving medication use. Advancing patient care.
APhA

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

Dear Sir/Madam:

Thank you for the opportunity to comment on the proposed rule to require bar codes on the labels of certain human drug products and biological products. The American Pharmacists Association, founded in 1852 as the American Pharmaceutical Association, represents more than 50,000 practicing pharmacists, pharmaceutical scientists, student pharmacists, and pharmacy technicians. APhA is the first-established and largest national association of pharmacists. APhA is also an active member of the National Coordinating Council for Medication Error Reporting and Prevention (NCC MERP), a group of 24 national organizations dedicated to medication error prevention and increased patient safety.

The proposed rule is an important step in decreasing medication errors. Medication errors are a serious public health threat. As the Food and Drug Administration (FDA) outlines in the March 14, 2003 *Federal Register* Notice, medication errors and other medical mistakes have been identified as the cause of death or serious injury for thousands of Americans each year. According to the landmark 1999 Institute of Medicine (IOM) report "To Err is Human: Building a Safer Health System," which focused on medical errors in the hospital setting, between 44,000 and 98,000 Americans die annually because of medical mistakes – many of which are preventable.[1] The IOM report further suggested that the use of bar codes could help prevent many of the medication-related errors.[2] APhA supports the IOM's recommendation on bar coding and the subsequent NCC MERP 2001 recommendation to the FDA and the U.S. Pharmacopeia (USP) to establish and implement uniform bar code standards for all medication packages and containers.

The Association appreciates the FDA's action to require bar codes in an effort to decrease medication errors and increase patient safety. If implemented, the proposed changes will represent an important technological advancement in the ordering, dispensing, and administration of drug products. However, it is critical to note that bar codes and other uses of technology are just one tool in the arsenal to prevent

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medical errors. The use of technology to prevent medication errors must be viewed as part of the much larger medication use process – a process in which medication errors can occur at any point. Bar codes can supplement health care professionals' efforts to enhance patient safety throughout the process, but technology cannot supplant the role of health care professionals and their ability and responsibility to make sure that the right medication is selected, prepared, and correctly administered to the patient.

Use of Bar Codes in Hospital and Retail Pharmacy Settings

The use of bar codes in the general retail environment is widespread. From grocery stores and department stores to libraries and video stores, retailers use bar codes to maintain product and pricing information and to track product inventory. The use of bar code technology in health care institutional settings is less common. According to a 2002 survey by the American Society of Health-System Pharmacists, only 1.5% of hospitals utilized bar code technology, a slight increase from 1.1% in 1999.[3] While the low number of health care institutions currently utilizing bar code technology is discouraging, APhA urges the Agency and other stakeholders to proceed with the implementation of this regulation. Health care institutions that have implemented a bar coding system have demonstrated dramatic results in decreased medication errors. When the Veterans Health Administration (VA) implemented a drug dispensing system called Bar Code Medication Administration (BCMA), VA hospitals experienced "a drastic reduction in the number of its medication errors and adverse events."[4] Once the bar code requirement is implemented and all prescription drug products contain a standardized bar code, institutions will have an increased incentive to obtain bar code scanning devices and computer databases.

Bar codes can also be of use in community pharmacy environments. A number of community pharmacies are already using automated prescriptions technologies to make more efficient and appropriate use of pharmacists' time by freeing them from manual dispensing functions. Automated prescription technologies such as the robotic counting of capsules and tablets make use of bar codes throughout the dispensing process to assure that the drug dispensed matches the information entered into the pharmacy's computer system. However, manufacturers of automated prescription technologies have expressed concern that many drug products arrive at pharmacies without usable bar codes on the product packaging or container.[5] As with hospitals, the inclusion of standardized bar codes on all drug products will increase the feasibility of such systems for community pharmacies.

Bar Code Design and Placement

APhA offers the following recommendations regarding bar code design and placement.

APhA supports the proposed requirement that all bar codes contain, at a minimum, the drug product's National Drug Code (NDC) number.[6] The NDC number contains identifying information on the drug product's manufacturer or labeler, the product's strength and dosage form, and the package size. The information contained in the NDC number – particularly information on the drug, its strength and dosage form – is necessary to determine if the correct product has been selected for dispensing or

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[1] Institute of Medicine Report "To Err is Human: Building a Safer Health System," 1999: Pg. 27.
[2] Ibid., Pgs. 37, 175, 188, 189, 195-196.
[3] American Journal of Health-Systems Pharmacists. "ASHP National Survey of Pharmacy Practice in Hospital Settings: Dispensing and Administration—2002," January 2003: 52-58.
[4] Drug Topics. "Drug Firms Scramble to Roll Out Bar-Code Products," September 2, 2002: 16.
[5] Michael Coughlin, ScriptPro. "Statement on Bar Code Label Requirements for Human Drug Products," July 26, 2002.
[6] 68 FR at 12,506.

administration to the patient. The NDC number is also one of the most commonly used identifiers in hospital and community pharmacy today. The NDC number is commonly used in pharmacy dispensing and billing software, and many pharmacies use the NDC number to track and order drug product inventory. Pharmacies with automated dispensing systems also use a bar-coded NDC number to verify that the right product has been dispensed. By mandating the use of the NDC number in bar codes, the Agency would not only be adopting an identification system health care professionals are already familiar with, it would also allow pharmacies that currently possess scanners capable of reading linear NDC numbers to continue to use the same equipment.

APhA also supports the Agency's recommendation that bar codes be placed on all prescription drug products, biological products, and vaccines down to the unit-of-use dosage size.[7] To achieve the greatest safety benefit from bar coding, every product, regardless of its packaging size, must contain a scannable bar code. As an advocate of unit-of-use packaging, the APhA House of Delegates, the policy-making body of the Association adopted policy in 2001 encouraging "the continued development, distribution, and use of unit-of-use packaging to enhance patient safety, patient compliance, and efficiencies in drug distribution."[8] And again in 2003, the Association adopted policy advocating for "the adoption of 'unit of use' packaging as the industry standard to enhance patient safety, patient compliance, and efficiencies in drug distribution."[9] As the number of products available in unit-of-use packaging continues to grow, the need to bar code these products will also increase.

We are disappointed that the proposed regulation does not include a requirement that bar codes contain information on product lot number and expiration dating. Inclusion of lot number and expiration dating information would provide additional identifier information, and would allow for easier identification of expired or recalled drug products. While the FDA acknowledges these benefits, the Agency choose not to require them because it "neither found nor received data to show that the benefits of bar coding lot number and expiration date information would exceed the costs of putting that information in the bar code."[10] The Agency further explains that while it agrees that bar codes "may be useful outside the medication error context [the] rule focuses on the use of bar codes to prevent medication errors."[11] We disagree that the inclusion of lot number and expiration dating falls outside of the Agency's immediate purpose of this regulation. If a recalled drug product is dispensed or administered to a patient, a medication error has occurred. With 97 Class 1 recalls between 1997 and 2002, the potential for death or serious harm upon use of these products is great.[12] Bar-coded lot numbers and expiration dating would allow for quick identification of recalled products and decrease the chance for medication errors. The additional benefits of these elements should not be ignored.

APhA recommends that the Agency reconsider its position and strongly encourage, if not require, the inclusion of lot number and expiration dating in bar codes. The benefits of including these elements in bar codes have been recognized by many in the industry. For example, in January 2003 pharmaceutical manufacturer Pfizer Inc. announced that it would begin including bar codes that contain the NDC number, lot number, and expiration date on unit-of-use products.[13] APhA applauded Pfizer's actions

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[7] 68 FR at 12,504.
[8] JAPhA NS(5) Supp 1.1:S10. September/October, 2001.
[9] 2003 Action of the House of Delegates. American Pharmacists Association.
[10] 68 FR at 12, 507.
[11] Ibid.
[12] Ibid.
[13] Press Release. "Pfizer to Implement New Product Bar Coding to Help Reduce Medical Errors in Hospitals and Pharmacies," January 15, 2003.

and encourages other manufacturers to follow suit. However, without uniform standards for the inclusion of lot number and expiration, each manufacturer or labeler could incorporate the information in a bar code in a different manner. This could result in hundreds of different bar coding methodologies not easily read. APhA recommends that the Agency include a uniform standard for bar-coded lot numbers and expiration dating in the final regulation – even if the Agency does not mandate their use. By setting a standard for these elements now, manufacturers and labelers that elect to include these elements can do so in a similar manner.

Over-the-Counter Products

The FDA has proposed that bar codes be placed on over-the-counter (OTC) products that are dispensed pursuant to an order and are commonly used in hospitals. According to the *Federal Register* Notice, OTC products administered in hospitals are included because bar codes would allow health care professionals to verify that they are administering or providing the right OTC medication in a hospital setting.[14] Bar codes would not be required on OTC products available outside of the hospital setting, "because it is unlikely that putting bar codes on all OTC drugs would have a significant impact on reducing medication errors."[15] Although the Agency is likely correct in its assumption that the majority of bar-coded OTC products in a retail setting would not be scanned to detect medical errors, there are some circumstances in which bar coding OTC products would be very useful. For instance, physicians often prescribe or recommend a particular OTC product to a patient. Pharmacists could scan the OTC product and record the information in the patient profile. This creates a more complete record of all the drugs the patient is taking, and facilitates checking for potential interactions.

In conclusion, APhA fully supports the intent of the proposed regulation. Measures to decrease medication errors and increase patient safety are a priority for this Association and its members. Again, we encourage the Agency to move forward with this regulation, however, we ask the Agency to revise and amend its position on including lot numbers and expiration dating. Expanding the bar code to include this information would decrease medication errors and help pharmacists fulfill their role of improving medication use to advance patient care.

Thank you for your consideration of the views of the nation's pharmacists. Please contact Susan C. Winckler, APhA's Vice President, Policy and Communications, at 202-429-7533 or SWinckler@APhAnet.org, or Susan K. Bishop, APhA's Senior Manager of Regulatory Affairs and Political Action, at 202-429-7538 or SBishop@APhAnet.org with any questions.

Sincerely,

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Executive Vice President

cc: Susan C. Winckler, RPh, JD, Vice President, Policy and Communications and Staff Counsel
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[14] 68 FR at 12,505.
[15] Ibid.