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

Re: Bar Code Label Requirement For Human Drug Products and Blood, Proposed Rule; [Docket No. 02N-0204]

The American Society of Consultant Pharmacists (ASCP) is pleased to submit comments in response to the March 14, 2003 *Federal Register* notice, "Bar Code Label Requirement for Human Drug Products and Blood" (68(50); Fed. Reg. 12500-12534). ASCP represents approximately 7,000 consultant pharmacists who provide medication management and distribution services to improve the quality of life of seniors who reside in a variety of settings, including their homes and long-term care facilities. ASCP appreciates the Food and Drug Administration's (FDA) effort to reduce medication errors in hospitals and other health care settings by requiring bar codes on drug products commonly used in hospital settings.

ASCP supports this proposal as a long-awaited next step towards ensuring appropriate safeguards for accurate administration of medications to patients. Our comments regarding this proposal are listed below:

1. Information Requirements
   According to the proposed rule, it "would require the bar code to contain, at the minimum, the drug's NDC number." ASCP supports this notion because the NDC number will become a unique identifying number for each medication, which health care professionals can then readily verify as the right drug for the right patient.

ASCP supports FDA's decision to not require inclusion of the drug product expiration date and lot number in the bar code at this time. However, we believe that inclusion of the lot number and expiration date at some time in the future is a highly desirable goal. This would facilitate efficiency and accuracy in the use of automated dispensing systems, and facilitate tracking of recalled medications. ASCP suggests that the FDA final rule on bar coding include a requirement for incorporation of the drug product expiration date and lot number in the bar code, but provide an extended time period for implementation of this requirement. Since the initial bar coding requirement has a three-year window for implementation, we suggest that an additional 3 years be provided for implementation of the lot number and expiration date requirement.

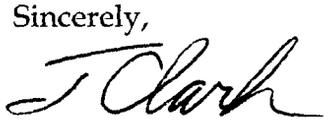
2. Normal Conditions of Use
   The proposed rule requires that, "the bar code be surrounded by sufficient blank space so that the bar code can be scanned correctly and remain intact under normal conditions of use." ASCP supports the inclusion of the phrase "normal conditions of use."

3. Utilization of Bar Coding for Vaccines
   The proposed rule would require biologicals (including vaccines) to carry a bar code. If such a bar coding requirement creates a potential for disruption of the fragile vaccine supply, the burden imposed would certainly not be worth the benefit. Only a very small proportion of vaccines are administered in hospitals, and those are primarily given in emergency rooms and ambulatory clinics, where bar code scanning technology is less likely to be used than in inpatient units. Most vaccines are administered in settings where bar code scanning is not as likely to be used, such as physician offices, health departments, and vaccine "clinics" offered by mass immunizers in grocery stores, shopping malls, and other settings.

Overall, ASCP supports the implementation of the proposed rule for bar coding as it will ultimately enhance the ability of health care professionals, including our members, to reduce the expense and impact of medication errors.

Again, ASCP appreciates the opportunity to comment on the FDA bar coding proposed rule and we thank you in advance for your consideration of these comments. If you have any further comments or questions regarding this document, please contact Tom Clark by phone at 703/739-1316, ext. 123 or by email at tclark@ascp.com.

Sincerely,



Tom Clark
Director of Professional Affairs