U.S. Pharmacopeia
The Standard of Quality℠

June 9, 2003

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

Re: Bar Code Label Requirements For Human Drug Products and Blood

Dear Sir or Madam:

This letter provides the comments of the United States Pharmacopeia (USP) to the proposed rule "Bar Code Label Requirements For Human Drug Products and Blood," which appeared in the March 14, 2003 Federal Register.[1]

USP is a not-for-profit organization that promotes public health by the establishment of state of the art standards to ensure the quality of medicines and other health care technologies. USP also has public health programs that focus on promoting optimal health care, including the Dietary Supplement Verification Program, Health Care Information, and Patient Safety.

USP has worked for more than 30 years to improve drug product quality and has devoted specific attention for over a decade to prevent medication errors through voluntary reporting programs. Currently, USP has operated voluntary patient safety programs for health care professionals in an effort to reduce medication errors. USP operates two principal programs, the Medication Errors Reporting Program (MERP) and MEDMARX℠. MEDMARX is an Internet-accessible anonymous medication error reporting program for hospitals. MERP is a voluntary reporting program for practitioners. USP also is a founder of and serves as the secretariat to the National Coordinating Council for Medication Error Prevention, an independent body comprised of 24 national organizations that meet, collaborate, and cooperate to address the interdisciplinary causes of errors and to promote the safe use of medications.

USP supports the efforts of the Food and Drug Administration (FDA) to develop regulations for bar coding on medicines on human drug products and blood products. The bar coding proposal is an important part of a larger medication error prevention approach, which includes useful and clear names for ingredients and products, label simplification, standardized prescription ordering, and imprint codes. The presence of a bar code and the use of scanners are likely to result in greater accuracy in the delivery of medications to patients by ensuring the correct medicine in the correct dose and route of administration is given to the correct patient at the correct time.

12601 Twinbrook Parkway
Rockville, MD 20852

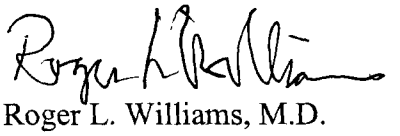
301-881-0666
www.usp.org

[1] 68 Fed. Reg. 12500 (March 14, 2003).

USP suggests that the bar codes contain, at a minimum, the product National Drug Code (NDC) number, lot number, and expiration date. This suggestion is contingent on FDA revision of the current NDC to provide greater accuracy and consistency to the codes. USP agrees and supports the FDA's position that bar codes should be standardized and should be present on the label and should be required for all drugs whether prescription or over-the-counter.

We trust that the FDA finds these comments useful. USP looks forward to working with FDA when the final rules are issued to assess the need to develop official USP standards or packaging, labeling, storage, and distribution requirements for compendial articles.

Sincerely,



Roger L. Williams, M.D.
Executive Vice President and Chief Executive Officer

cc: John T. Fowler
Joseph G. Valentino
Eric B. Sheinin
Diane D. Cousins