U.S. Pharmacopeia
The Standard of Quality℠

October 28, 2002

Yana Ruth Mille, Chief
FDA Compendial Operations Staff, HFD-354
Office of Pharmaceutical Science
Center for Drug Evaluation & Research
Parklawn Bldg. (WOC II, Room 3070)
5600 Fishers Lane
Rockville, Maryland 20857

Re: Plastic Ampul Labeling

Dear Ms. Mille:

On behalf of the USP Safe Medication Use Expert Committee (SMU EC), I am sending this letter to inform you of the continuing concerns of the Committee and also healthcare practitioners regarding the inability to identify drug products in plastic ampuls that is secondary to inadequate labeling.

Plastic ampul packaging has been frequently used for respiratory therapy drugs. The ampuls often do not bear labels but are labeled by debossing/embossing the actual plastic container. This imprinting is perceived by healthcare practitioners reporting to the USP Medication Errors Reporting Program as being difficult to read and sometimes illegible. In response to these perceptions, the FDA reported that the glue used to attach labels on plastic ampuls was leaching into the drug. Additionally, inks used to print directly on the plastic were also found to leach. To solve the leaching problem, manufacturers typically emboss imprinting into the plastic ampuls and/or flange. Because these are now being used not only for respiratory therapy drugs, but also for injectable and oral solutions, it is imperative that labels be readily readable. The enclosed case studies and pictures are taken from the USP Medication Errors Reporting Program and will attest to the nature of the problem.

The Safe Medication Use Expert Committee unanimously voted to encourage the FDA to establish an alternate method of labeling these plastic ampuls, so that these products are clearly identifiable. The SMU EC also suggests that the FDA cease approving products in these containers because their use continues to be the subject of numerous medication errors.

12601 Twinbrook Parkway
Rockville, MD 20852

301-881-0666
www.usp.org

Thank you for your attention in this matter. If you have questions please call Shawn C. Becker, B.S.N., R.N., USP Liaison to the USP SMU EC at 301-816-8216 or e-mail to **scb@usp.org**.

Sincerely,

Eric Sheinin, Vice President
USP Information and Standards
Development