



U.S. Pharmacopeia  
The Standard of Quality<sup>SM</sup>

January 2, 2003

1142 02D-0254

Dockets Management Branch  
HFA-305  
Food and Drug Administration  
5600 Fishers Lane, Room 1061  
Rockville, Maryland 20857

Re: Docket # 02D-0254

Dear Sir/Madam:

We are sending this letter to document the continuing concerns of the USP Safe Medication Use Expert Committee (SMU EC) and 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.

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](mailto:scb@usp.org).

Sincerely,

Eric Sheinin, Vice President  
USP Information and Standards Development

cc: Yana Mille

02D-0254

C7

12601 Twinbrook Parkway  
Rockville, MD 20852

301-881-0666  
[www.usp.org](http://www.usp.org)