U.S. Pharmacopeia
The Standard of Quality℠

July 21, 2008

Alice B. Till, Ph.D.
Vice President, Science Policy and Technical Affairs
Pharmaceutical Research and Manufacturers of America
950 F. Street, NW
Washington, DC 20004

Dear Dr. Till:

Thank you for your letter of June 30, 2008, requesting an appeal to indefinitely postpone the section in General Chapter <1> *Injections* on "Labeling on Ferrules and Cap Overseals." I am responding to you in my role as Chair, Council of Experts.

In accordance with section 9.10(d) of the Rules and Procedures of the 2005-2010 Council of Experts, as Chair of the Council of Experts, I have determined not to grant PhRMA's appeal. USP has already decided to postpone the official date of the standard until May 1, 2010, and is currently working with FDA and industry to resolve many of the concerns you raise, which we believe can be accomplished prior to the new official date. Thus, we have determined that PhRMA's appeal should be denied. To respond specifically to the points raised in your June 30, 2008 letter:

- Regulatory Timeline. Again, we have acknowledged the difficulties the February 1, 2009 official date posed for industry, and have addressed the need for a longer implementation period through the 15 month postponement.

- Lack of Clarity About Cautionary Statements. As you will see from the attached notes of the June 27, 2008 USP-FDA-Industry web meeting on this topic, industry has been asked by FDA to provide specific data about the existing cap statements to USP and FDA. Once submitted, USP will work with FDA, and then later with industry to try to identify a general list of cautionary statements. USP believes that this activity can be accomplished expeditiously and will provide industry with the clarity it needs.

- Potential Consequences to Anti-Counterfeiting Strategies. We fully understand the significant public health issues created by counterfeit drugs. As stated in USP's Anti-Counterfeiting Measures and USP Standards policy, (see http://www.usp.org/USPNF/notices/antiCountMeasuresStandards.html) USP works with many parties throughout the world to support anti-counterfeiting efforts. However, USP's policy also states that such efforts shall not "interrupt or otherwise distort or disturb labeling and other standards created by the Council of Experts that reflect usual and customary communications between providers and patients/consumers" in achieving access to and appropriate use of high quality, safe drugs. In this case, there is a strong public health interest in restricting cap and overseal printing to only cautionary statements, as the health care practitioner is more likely to see and read the cautionary statement when there is one. As the notes of the June 27, 2008 meeting reflect, this view is shared by FDA, which supports the principle behind the new standard.

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- Regulatory Impact. As noted above, FDA has expressed its support for the new standard. USP is aware of the potential impact of this standard, as is FDA, and USP is committed to working with FDA and manufacturers on a case-by-case basis if necessary to identify the appropriate solutions.

Finally, I would note that denial of PhRMA's appeal at this time does not prejudice PhRMA's ability to re-file an appeal and request for postponement at a later date if, as the May 1, 2010 official date approaches, it believes that its implementation issues still have not been resolved.

Please let me know if you have any further questions. We look forward to working with industry on this topic.

Sincerely yours,

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

Attachment 1: Meeting Notes of the June 27, 2008 Labeling Meeting