U.S. Pharmacopeia
The Standard of Quality℠

August 2008

To: Pharmaceutical Industry Representatives

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

Re: General Chapter <1> *Injections* on "Labeling on Ferrules and Cap Overseals"

USP wishes to thank representatives of the pharmaceutical industry for the discussion held on June 27, 2008, on the "Labeling on Ferrules and Cap Overseals." section of General Chapter <1> *Injections*. The notes of this meeting are attached to this memo.

Due to industry's concerns about implementation issues of this section of the General Chapter, the Parenteral Products Industrial Expert Committee has granted—and I have approved—a postponement of the official date of the General Chapter <1> *Injections* section on "Labeling on Ferrules and Cap Overseals" to **May 1, 2010.** This postponement is in accordance with the Section 9.08 of the Rules and Procedures of the 2005-2010 Council of Experts, and extends the official date of the General Chapter by 15 months from its original date of February 1, 2009.

USP also currently is working with FDA and industry to attempt to resolve other industry concerns related to the cautionary statements, including industry's expressed need for additional clarity as to what constitutes a cautionary statement. During this meeting, industry was 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 develop a general list of cautionary statements that will assist industry in implementing the standard. USP believes that this activity can be accomplished expeditiously and should provide industry with the clarification it needs.

If you wish to submit cap statement data to assist in this effort, please submit it by **September 30, 2008** to Larry Ouderkirk at FDA (Ouderkirk@cder.fda.gov) and Angela Long at USP (agl@usp.org).

With regard to concerns raised about the anti-counterfeiting measures associated with ferrules and caps overseals, we refer industry to USP's *Anti-Counterfeiting Measures and USP Standards* policy, which can be found at (http://www.usp.org/USPNF/notices/antiCountMeasuresStandards.html). USP's policy indicates that anti-counterfeiting 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.

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.

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

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