**Commentary – *USP 34-NF 29,* General Chapter <1> *Injections***
**Section on *Labeling of Ferrules and Cap Overseals***
**August 4, 2010**

In accordance with USP's Rules and Procedures of the Council of Experts, USP publishes all proposed revisions to the *United States Pharmacopeia* and the *National Formulary (USP-NF)* for public review and comment in the *Pharmacopeial Forum* (*PF)*, USP's bimonthly journal for public notice and comment. After comments are considered and incorporated as the Expert Committee deems appropriate, the proposal may advance to official status or be republished in *PF* for further notice and comment, in accordance with the Rules and Procedures. In cases when proposals advance to official status without republication in *PF*, a summary of comments received and the appropriate Expert Committee's responses are published in the *Commentary* section of the USP Web site at the time the revision is published.

The *Commentary* presented below is a summary of comments received on this particular proposal, which has now been approved by the Expert Committee and is proceeding to official status. The *Commentary* is not part of the official text and is not intended to be enforceable by regulatory authorities. Rather, it explains the basis of the Expert Committee's response to public comments. If there is a difference between the contents of the *Commentary* and the official text, the official text prevails. In case of a dispute or question of interpretation, the language of the official text, alone and independent of the *Commentary*, shall prevail.

**General Chapter(s):** <1> *Injections*, section on Labeling of Ferrules and Cap Overseals
**Expert Committee(s):** Nomenclature
**No. of Commenters:** 6

**Comment Summary #1:** The commenter indicated that USP should seek and apply scientific concepts to this standard (e.g., human factors studies) and encouraged USP to test the final design standard on end-users to ensure its effectiveness in preventing medication errors and to maintain those data in support of the standard.
**Response:** The Expert Committee determined there was not sufficient reason to conduct or await any studies prior to the release of the standard. USP standards are in a process of continuous review and revision based upon new evidence, emerging public health concerns, and public requests for revision. The ongoing role of USP Expert Committees is to evaluate new data and to shape standards based upon the available evidence, public input and the Expert Committee's expertise. Such standards are always subject to further revision as additional evidence becomes available.

**Comment Summary #2:** The commenter suggested that the proposed USP standard may have unintended consequences. The commenter provided a commissioned, unpublished human factors engineering (HFE) evaluation of 20 healthcare practitioners (HCPs) handling injectable products in a variety of simulated scenarios. The authors of the HFE evaluation concluded that 1) HCPs are generally not used to viewing cap labels, 2) HCPs made many errors, with or without cap labels; 3) Some HCPs indicated that they did not notice the cap labels in the study; 4) When cap labels were noticed and used, HCP performance was better and faster, 5) When HCPs were trained to cross-check the vial label with the cap label, there was an increased benefit to drug selection accuracy and time. Post-interviews of HCP participants revealed a) belief that reducing the incidence of cap labels would

actually further reduce the likelihood of HCPs noticing any label that does exist, b) preference of HCPs towards having cap labels, c) concern that removing cap labels may increase medication errors, d) belief that cap labeling could be useful and improve patient safety if they were more common and HCPs were explicitly trained to make use of them. The results of the survey were presented to the Expert Committee for their review and consideration.

**Response:** The Expert Committee was not persuaded that the results of the HFE evaluation were in opposition of the proposed standard, as the experimental scenarios did not test the proposed standard. The Expert Committee did not agree with the commenter's suggestion that the results of the HFE evaluation warranted changes to the standard.

**Comment Summary #3:** Several commenters indicated that the proposed revision would increase risk to patients by forbidding the use of anticounterfeiting measures on the cap.
**Response:** Comments not incorporated. The Expert Committee determined that the proposed standard does not forbid the use of anticounterfeiting measures from appearing on the vial skirt, label, or cap and ferrule as long as it does not appear on the top (circle) surface of the vial and does not interfere with the cautionary statement.

**Comment Summary #4:** The commenter suggested minor wording changes to clarify the intent of the proposed revision. The suggestion was to add "cautionary statements" in place of "such statement" and add "free of nonessential information" in place of "clearly differentiated."
**Response:** Comment incorporated.

**Comment Summary #5:** The commenter suggested that the phrase "busy" healthcare practitioners implied that such practitioners are too busy to read labels. The commenter suggested removing the term "busy."
**Response:** Comment incorporated.

**Comment Summary #6:** The commenter indicated that additional examples such as "Not for Lock Flush" should be added to this section of the general chapter.
**Response:** Comment not incorporated. The two cautionary statements indicated in the general chapter are examples only.