



Summary of CAPS Presentation at June 29 USP Nomenclature Expert Committee Meeting

This will summarize the CAPS presentation on June 29 at the USP Nomenclature (NOM) Expert Committee (EC) concerning General Chapter <1> Labeling on Ferrules and Cap Overseals.

The meeting was well attended, with more than 20 committee members present. USP Vice President and CEO Dr. Roger Williams and USP General Counsel, Susan DeMars, were also present. A large contingent from the FDA attended and several people participated by teleconference.

CAPS was scheduled to present for 10 minutes because of time limitations as a result of the many agenda items to be addressed by the EC. Our presentation lasted approximately 10 minutes. The questions and discussion that followed extended our participation to more than one hour.

While strong opinions were expressed endorsing restrictive language, those comments were generally confined to approximately five members of the Committee. While there was an unusually strong presence from the FDA (both Committee members and observers), no one from the Agency weighed in during the discussion. Overall, it appeared the group understood the value of using printing technology for anti-counterfeiting. It appears that the "cautionary statements" that have been at the focal point of the discussions may become mandatory.

Toward the end our discussion, Dr. Williams addressed the EC and emphasized the benefit of the mandatory printing in Chapter <1> for Potassium Chloride. He also generally supported various aspects of the CAPS presentation, more specifically, the anti-counterfeiting technology.

At the conclusion of our agenda item, the Committee deliberated Chapter <1> in a closed session for about 45 minutes. Our USP contacts indicated that they expect the USP's decision to be published in the next several weeks.

We remain cautiously optimistic that USP will adopt many, if not all, of the CAPS suggestions and we look forward to USP's final determination on the matter.