



Consortium for the Advancement of Patient Safety

Report on Meeting with FDA Regarding USP <1>

CAPS and representatives of the FDA (Agency) met on March 26, 2009, to discuss USP <1>. Representing CAPS were Debbie Thomas and Solmaz Sedghi, joint chairs, and Fred Balboni, Executive Director.

The meeting was scheduled for two hours and, as a result of the discussion, the Agency extended it an additional 30 minutes. CAPS presented the same material used at the USP meeting on February 2, 2009. The conversation was quite interactive and both sides voiced their opinions and comments on USP <1>. As was the case with the USP meeting, CAPS is clearly being heard on this important issue.

There is agreement between the Agency and CAPS that current language in USP General Chapter <1> should be agreeable to all stakeholders.

The FDA understands industry's desire for using caps and ferrules in connection with anti-counterfeiting solutions and is willing to explore modifications in General Chapter <1> that would allow the use of anti-counterfeiting solutions provided they do not interfere with initiatives to improve the safe use of the drug product. There is also agreement to discuss the use of instructional use statements in relevant situations.

The FDA recommends industry conduct both risk analysis (e.g. FMEA) and human factor studies to help determine the types of statements and information most beneficial for patient safety. They feel these studies will bring value to industry in understanding how information is currently interpreted. Because space on caps and ferrules for messages is limited, the space should be used in the most effective and efficient manner with patient safety the primary interest. Additional efforts are needed to clarify when such a statement is needed and what constitutes an appropriate patient safety statement.

CAPS asked if the Agency would consider a small group of individuals from FDA, USP and CAPS to work jointly on the issue, with the goal of providing the USP with a proposal that would be agreeable to all parties. The Agency said it would consider this suggestion.

CAPS will plan a follow-up combined meeting with both FDA and USP.

CAPS members should check the USP website periodically in anticipation of an important message relative to USP General Chapter <1> revisions. The USP informed CAPS that they are still working on the statement.

A CAPS membership meeting will be scheduled soon. Please check your email for an announcement of the date, time, and call-in number.