



**Compounding Expert Committee (CMP EC)
September 20, 2016
USP–U.S., Rockville, MD**

Executive Summary

A quorum was present and Ms. Gigi Davidson, Chair, presided over the Compounding Expert Committee (CMP EC) face-to-face meeting. She noted that this was an information gathering session and emphasized that the Expert Committee (EC) had made no conclusions on General Chapter <797> and the standards were still in review and revision. The following is a summary of the actions and key discussion topics that impacted the work of the CMP EC, grouped by topic.

1. **<797> Pharmaceutical Compounding—Sterile Preparations:** The Chair provided a high level overview of more than 8,000 public comments received on revisions to <797> published in *Pharmacopeial Forum (PF)*. EC members and Government Liaisons are reviewing the comments and proposed responses, section by section, in weekly teleconferences. USP will convene roundtables with allergists and radiopharmacists to supplement the public comment process.
2. **<795> Pharmaceutical Compounding—Nonsterile Preparations:** The EC discussed key changes proposed by the Subcommittee.
3. **<1168> Compounding for Phase 1 Investigational Studies:** The EC discussed this proposed new General Chapter that the <1168> Subcommittee is preparing for republication in *PF*.
4. **<800> Hazardous Drugs—Handling in Healthcare Settings:** The EC discussed the <800> Frequently Asked Questions posted on USP.org and the cost of retrofitting facilities to comply with the proposed <800> requirements.
5. **<1163> Quality Assurance in Pharmaceutical Compounding:** The EC provided feedback on proposed revisions to this General Chapter.
6. **Monograph Development:** Fiscal Year (FY) 2016 stability studies are in progress for 15 compounded preparation monographs (CPMs), and USP is planning FY 2017 studies to continue development of CPMs. The EC provided feedback on a CPM donation program to create donation processes and recognize and reward donors.
7. **Monographs Published in *PF*:** Following successful completion of stability studies, monographs for the following were published in *PF* 42(5) [Sep.-Oct. 2016]:
 - Ascorbic Acid Compounded Oral Solution
 - Dexamethasone Sodium Phosphate Compounded Injection
 - Estriol Compounded Vaginal Cream
 - Fentanyl Citrate and Bupivacaine Hydrochloride Compounded Injection
 - Fentanyl Citrate and Ropivacaine Hydrochloride Compounded Injection
 - Fentanyl Citrate Compounded Injection
 - Folic Acid Compounded Oral Solution
 - Morphine Sulfate Compounded Injection
 - Ondansetron Compounded Topical Gel
 - Potassium Phosphates Compounded Injection
 - Sodium Bicarbonate Compounded Injection
 - Sodium Phosphates Compounded Injection

- 8. Modern Microbiological Methods Expert Panel:** The EC received a report on the work of this Expert Panel, which is making recommendations on user requirements and potential technologies for modern sterility tests (i.e., rapid sterility tests).
- 9. USP Compounding Managed Services:** USP is designing resources for healthcare entities related to <795>, <797>, and <800>. E-learning modules on <800> are targeted for release in December 2016 or January 2017.