General Chapters–Dosage Forms Expert Committee
Bethesda North Marriott Hotel and Conference Center
Wednesday, July 22, 2015
North Bethesda, MD

Executive Summary

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A quorum was present and Dr. James De Muth, Chair, presided over the General Chapters–Dosage Forms Expert Committee (GCDF EC) meeting. The Chair selected Dr. Raymond Skwierczynski to serve as Vice Chair for at least a 1-year term. The following is a summary of the actions and key discussion topics that impacted the work of the GCDF EC, grouped by topic.

1. **Prednisone Tablets Reference Standard:** The Expert Committee (EC) discussed the withdrawal of Prednisone Tablets Reference Standard (RS) Lot R001B0 and USP's response to the incident. The EC asked the Performance Verification Test (PVT) Subcommittee to explore the benefits of a PVT and issues related to the manufacture and formulation of the RS.

2. **Capsule Shell Monographs:** The EC agreed to re-publish in *Pharmacopeial Forum* (*PF*) the Hard Gelatin Capsule Shell monograph proposal which was substantially re-written in response to public comments. The Combined Liquid-filled Capsules/Use of Enzymes in the Dissolution Test of Gelatin Capsules Expert Panel plans to develop a hydroxypropyl methylcellulose capsule shell monograph.

3. **March 2016 Veterinary Drugs Workshop:** The EC is seeking experts to present at the Workshop on *In Vitro* Testing for Meeting Future Challenges for Veterinary Dosage Forms (March 14–15, 2016, at USP–U.S.).

4. **Subcommittees:** The EC formed the following Subcommittees:
    - Subcommittee A: Performance Verification Testing (PVT)
    - Subcommittee B: <2040> *Disintegration and Dissolution of Dietary Supplements*
    - Subcommittee C: <1151> *Pharmaceutical Dosage Forms*
    - Subcommittee D: <1004> *Mucosal Products–Product Performance Tests*
    - Subcommittee E: <3> *Topical and Transdermal Drug Products: Quality Tests* and <603> *Topical Aerosols*
    - Subcommittee F: <788> *Particulate Matter in Injections*
    - Subcommittee G: <909> *Uniformity of Dose from Oral Suspensions in Multi-Unit Containers*
    - Subcommittee H: <1090> *Assessment of Drug Product Performance–Bioavailability, Bioequivalence, and Dissolution*
    - Subcommittee I: Aerosols
        - <601> *Inhalation and Nasal Drug Products–Performance Quality Tests*
        - Nasal Sprays
        - Metered-Dose Inhalers
        - Dry Powder Inhalers
        - Data Analysis for Orally Inhaled and Nasal Products
        - Good Cascade Impactor Practices
        - <604> *Leak Rate*

    - <5> *Inhalation and Nasal Drug Products–General Information and Product Quality Tests*
- Subcommittee J: Pharmaceutical Foams

5. Expert Panels: The EC received reports on the continued work of the following Expert Panels:

- Ophthalmic Products Expert Panel
- Solubility Criteria for Veterinary Drugs Expert Panel
- Visible Inspection of Injectables Expert Panel
- Liquid-filled Capsules Expert Panel
- Use of Enzymes in the Dissolution Test of Gelatin Capsules Expert Panel

6. Joint Subcommittees: The EC began forming Joint Subcommittees with other ECs on the following topics:

- <905> *Uniformity of Dosage Units* Joint Subcommittee
- Viscosity and Rheology Joint Subcommittee
- Nanotechnology Joint Subcommittee
- <785> Osmolality and Osmolarity Joint Subcommittee