



Biologics Monographs 2–Proteins Expert Committee (BIO2 EC)
February 9–10, 2016
USP–U.S.
Rockville, MD

Executive Summary

A quorum was present and Dr. Michael Mulkerrin, Chair, presided over the Biologics Monographs 2–Proteins Expert Committee (BIO2 EC) face-to-face meeting. The following is a summary of the actions and key discussion topics that impacted the work of the BIO2 EC, grouped by topic.

1. Monographs

To be published in *USP 39–NF 34, First Supplement*:

- **Somatropin** monograph revision
- **Somatropin for Injection** monograph revision

Comments Reviewed: During closed session, the EC reviewed public comments on the following:

- **Epoetin Monograph:** USP staff will revise the monograph based on review of public comments and prepare it for balloting once the Reference Standard (RS) is approved.
- **Interferon Beta-1A and Interferon Beta-1A Injection Monographs:** The EC determined that significant changes were needed in response to public comments and decided to cancel the current monograph proposals. The EC will prepare new proposals for publication in a future issue of *Pharmacopeial Forum (PF)*

In Development/Ongoing Revisions

- **Pegfilgrastim and Filgrastim Monographs:** The Pegfilgrastim Subcommittee is developing the Pegfilgrastim monograph and revising the Filgrastim monograph. USP is developing a Pegfilgrastim RS and a Filgrastim RS replacement lot.
- **Enzyme Monographs:** The EC formed an Enzyme Expert Panel that will revise the Pancreatin monograph, Trypsin monograph, and Chymotrypsin monograph.

2. General Chapters

- **For Public Comment—<126> *Somatropin Bioidentity Tests*:** The EC reviewed proposed revisions and approved its publication in *PF 42(3)* [May–Jun. 2016].
- **Comments Reviewed—<89.1> *Collagenase I* and <89.2> *Collagenase II*:** During closed session, the EC reviewed public comments. USP staff will revise the General Chapters based on the comments and prepare them for ballot once the RSs are available.
- **In Development—Fc-Binding Assays:** The EC recommended the formation of an Fc-Function Assay Expert Panel to develop a general chapter describing assays to assess Fc-function.

3. Work Plan Updates: USP aims to improve and modernize protein monographs, including using orthogonal identification methods, giving cell-based assays preference over animal-based assays, using multiple RSs to support a single monograph, including RSs that are traceable to the International Standard, and including more system suitability RSs.

- 4. FDA Proposed Guidance and Rule on Biologics Naming:** The EC received an overview of USP comments on the U.S. Food and Drug Administration's (FDA's) proposed rule and guidance on biologics naming. If the rule becomes law, USP would need to revise *USP–NF* accordingly and the Filgrastim monograph may require accelerated revision. USP will continue to communicate with FDA on this issue and keep the EC informed.