Changes to Pending Monographs Program

Type of Posting: General Announcement

Posting Date: 29–May–2015

USP has developed a new version of its Pending Monograph Guideline, which reflects substantial changes to eliminate the use of a separate web-based process for Pending Monographs. Instead, monograph proposals pending FDA approval will utilize the standard *USP–NF* revision processes.

The Pending Monograph approach was implemented in 2007 to allow USP to develop new monographs or monograph revisions while a sponsor was awaiting FDA approval. The process was intended to enable new monographs or monograph revisions to become official shortly after they receive FDA approval, rather than waiting until after approval to begin the monograph development process. Under the original approach, the Pending Monograph proposals were published on the USP website for notice and comment. Following balloting by the relevant Expert Committee, the monograph or monograph revision was posted on the website as an Authorized Pending Monograph, and moved to official status following FDA approval.

While the Pending Monograph program has enabled the successful development of numerous monographs, the use of a separate web-based process is cumbersome for USP staff and challenging for stakeholders attempting to monitor the status of these proposals. The approach specified in the revised guideline is designed to allow Pending Monographs to utilize the same Pharmacopeial Forum (PF) notice and comment process as other USP monograph proposals, rather than this separate web-based process.

USP will be reevaluating all of the Draft Monographs and Authorized Pending Monographs that are currently posted on the Pending Monograph webpage, with input from their sponsors. If no longer relevant, these monographs will be eliminated. Where there is a desire to move these monographs forward to official status, they will be developed, balloted, and published in accordance with the revised Pending Monograph Guideline, including publication in PF where required under the Guideline. This process is expected to take several months. Beginning June 26, 2015, the tables of pending proposals currently posted on the Pending Monograph webpage will be updated monthly to indicate which monographs were removed from the website and whether they were eliminated or proposed in PF.

The revised Pending Monograph Guideline will be effective on June 1, 2015. It is anticipated that USP will begin publishing proposals for new pending monograph and pending revisions in PF 41(5) [Sep.–Oct. 2015]. The pending proposals will be published in the In-Process Revision section of PF, and distinguished from regular PF proposals by a note in the monograph briefings indicating that they are pending FDA approval. USP may revise the Pending Monograph Guideline further to address issues that arise after the initial implementation of the new process.

Should you have any questions, please contact Elizabeth Besteder, Supervisor, Executive Secretariat Administration (301-816-8383, edb@usp.org).