Revision to USP Pending Monographs Guideline

Type of Posting: General Announcement

Posting Date: 03–Jul–2010

USP has revised the Pending Monographs Guideline to include manufacturers who have filed or intend to file with FDA a Biosimilar or Interchangeable Biologics License Application (a Public Health Service Act 351(k) BLA) within six months. This change reflects enactment of healthcare reform legislation which includes establishment of a new approval pathway for biosimilar and interchangeable biologics (Public Law 111–148, signed by President Obama March 23, 2010). A clarification was also made to the Requirements section of the Guideline indicating that the timing of a Pending Monograph submission should be consistent with USP's general timeline for working with potential generic applicants.

This version updates and replaces USP Pending Monographs Guideline Version 2.5 as of August 1, 2010.