USP Revises its Request for Revision Guideline

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USP has updated the previous "Introduction" and "Glossary" sections of the USP Guideline for Submitting Requests for Revision, into a more informative and combined "General Information For All Submissions" section. USP also has updated the Monograph Submission Templates so they are in the redesigned monograph format. The intent of this update is to provide clarity on monograph submission policies and to provide user–friendly resources for submitting new monographs or revisions to existing monographs.

Specific updates, most of which are in the new "General Information" section, include:

- **New Monograph Submission Templates** for each class of compendial article. Templates facilitate preparation of *USP–NF* submissions.
- **Clarification of USP's Standards Acquisition Policy** that indicates USP will work with pioneer manufacturers during the period leading up to approximately five years before patent expiration/generic entry, after which USP may begin working with potential generic applicants under the "Pending Monograph" approach to source priority compendial standards.
- **Basis for standards** that requires Sponsors to certify that proposed tests, methods and specifications are consistent with, and no more stringent than, those contained in sponsor applications or supplements submitted to and approved by FDA, and that any standards more stringent than those previously approved by FDA are clearly identified and explained to USP.
- **Role of reference materials** and the sponsor's role in submitting such materials in a timely manner.
- **USP's intellectual property (IP) policy** that emphasizes that USP respects IP rights and applicable laws. Because USP's public compendial standards are for the use and benefit of all parties, USP requests Sponsors disclose in their Request for Revision whether any portion of the methods or procedures submitted are subject to patent or other IP rights.
- **Confidentiality policy** that requests that Sponsors indicate in their RFR whether any of the submitted documents or other information should be treated as confidential. Documents not clearly marked confidential will be subject to disclosure under the USP Document Disclosure Policy.

Other components of the Request for Revision Guideline will be updated in the near future.

For further information about the revisions to the USP Submission Guideline, please contact Mario Sindaco, Director, Compendial Affairs and Executive Secretariat (301-816-8246 or mys@usp.org).