

## REVISION HISTORY

### General Information For All Submissions, Version 5 January 2011 Summary of Changes Made From Version 4 July 2009

#### INTRODUCTION

- Clarified existing policy of FDA and USP, that biologics are considered a subset of drugs.
- Clarified that USP standards acquisition policy is to seek to actively collaborate with pioneer Sponsors until approximately five years prior to potential generic entry, at which time USP will seek alternative Sponsors.
- Added footnote clarifying that in assessing potential generic entry, USP as a general rule focuses on drug substance patents listed in the FDA Orange Book, and in the case of multiple listed drug substance patents USP will generally focus on the patent with the later expiration date, although where sources are available to identify an earlier expiring patent as likely being key to generic entry USP may use such earlier date.

#### REFERENCE MATERIALS

- Clarified existing USP policy that any reference materials likely to be required for use with (as a component of) a *USP* or *NF* standard should either accompany a Sponsor's submission or be a part of an overall monograph development commitment.

### Version 4 July 2009 Summary of Changes Made From Version 3.1 April 2007

#### INTRODUCTION

- Retitled "General Information For All Submissions." Introductory material reorganized to provide a resource for those planning to make submissions.
- Clarification of USP standards acquisition policy was added.
- Provision is made for a free-standing Submission Guideline for each class of compendial articles, including dietary supplements (new).
- Explanation added regarding the basis for USP standards, as well as the relation of standards to FDA-approved specifications.
- Explanation added regarding the role of reference materials, as well as provision for sponsors undertaking to provide all suitable reference materials, and agreeing to USP sourcing such materials elsewhere if necessary.
- Explanation added regarding USP policy regarding intellectual property.

**USP Guideline for Submitting Requests for Revision to USP-NF**  
**V5 January 2011**

- Explanation added regarding USP confidentiality policy, and policy regarding sponsor identification.
- Glossary moved to end of this section.

**GLOSSARY**

- Moved to new “General Information” section.

**CHAPTERS ONE – FIVE**

- Existing Submission Guideline chapters replaced by four free-standing Submission Guidelines, to facilitate continuous updating as appropriate. Submission Guidelines effectively expanded from five to six, and now include: (1) Small Molecule. (2) Excipients. (3) Biologics/Biotechnology, including (3A) General; (3B) Vaccines; and (3C) Blood, Blood Components and Blood Products. (4) Dietary Supplements (new).

**TEMPLATES**

- Updated Templates provided to facilitate preparation of submissions for selected types of articles.

**Version 3.1 April 2007**  
**Summary Of Changes Made From Version 3 January 2007**

**TEMPLATES**

- A new template for Metered Dose Inhalers was added.

**Version 3 January 2007**  
**Summary of Changes Made from Version 2 September 2005**

**INTRODUCTION**

- Reference to the *Rules and Procedures of the 2005-2010 Council of Experts* was added
- Reference to the USP Intellectual Property Policy was added
- Explanation of SAPFA (Standards for Articles Pending FDA Approval) monographs was added
- Explanation of the USP Flexible Monograph policy was added

**GLOSSARY**

- Minor changes were made to some of the terms

## CHAPTER TITLES

- “Noncomplex” was replaced by “Small Molecules” throughout the Guideline
- “Biologicals/Biotechnologicals” was replaced by “Biologics and Biotechnology” throughout the Guideline

## CHAPTER 1 SMALL MOLECULES SUBSTANCES AND PRODUCTS

The following major revisions were made and apply to both drug substances and drug products:

### **Labeling**

- New information regarding the flexible monograph policy was added

### **Impurities**

- ICH reporting format (e.g., the number of decimal places) and terminology were added

### **Organic Impurities**

- A reference to the USP policy of Relative Response Factors was added
- Possible inclusion of a Quantitative Limit Solution was added

### **Residual Solvents**

- An explanation that all drug substances and products are subject to the relevant control of residual solvents even when no test is specified in the monograph was added.

## New Monographs for a Drug Product

### Official Title

- An explanation that the title of a dosage form formulated with the salt of an acid or base shall be the same as that used in the expressing the strength of the article in the *Assay* was added.

### Microbial Limits Test

- A reference to ICH Q6A was added

## TEMPLATES

### Revised Templates

- The templates for Drug Substance, Excipient, and Tablet and Capsule monographs were revised to include tables for gradient elution and presentation of data for impurities such as relative retention time and relative response factors. Minor editorial changes were made.

### New Templates

- Cream and Ointment
- Injection and For Injection
- Oral Solution and Suspension
- Topical Lotion and Suspension
- Transdermal Delivery System