



U.S. PHARMACOPEIA
The Standard of QualitySM




Isranalytica Conference

David InterContinental Hotel
Tel Aviv, Israel
8 February 2011

USP Monograph Initiatives

Karen A. Russo, Ph.D.
Vice President, Small Molecules

Quality Standards for Medicines | Dietary Supplements | Food Ingredients



Topics

Quality Standards for Medicines, Dietary Supplements, and Food Ingredients

- ▶ **USP Overview**
- ▶ Monograph Modernization
- ▶ Flexible Monographs
- ▶ USP Pending Monographs



USP Convention Headquarters Rockville, MD USA

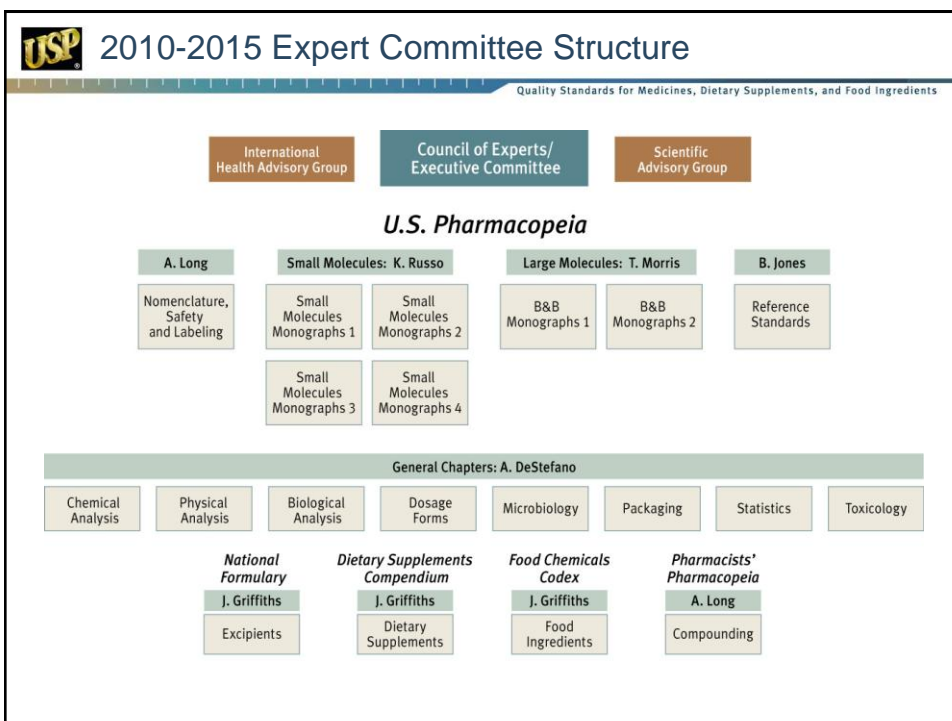
Quality Standards for Medicines, Dietary Supplements, and Food Ingredients



USP—An Overview

Quality Standards for Medicines, Dietary Supplements, and Food Ingredients

- ▶ Since 1820, nonprofit, private, independent, and self-funded
- ▶ Establishes public standards and related programs that help ensure the quality, safety, and benefit of medicines and foods
- ▶ Expert volunteers are scientific decision-makers
- ▶ Headquartered in Rockville, MD; 600+ employees; facilities in India, China, Switzerland, Brazil





2010-2015 Council of Experts - Demographics

Quality Standards for Medicines, Dietary Supplements, and Food Ingredients

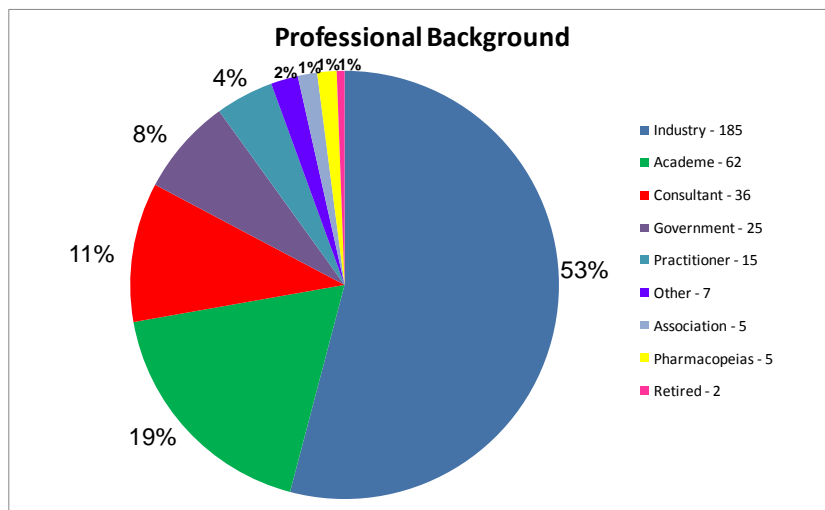
- 332 expert volunteers serving on 20 Expert Committees
 - 75 international experts from 22 countries:

• Argentina	1	• Jordan	1
• Australia	2	• Netherlands	2
• Austria	1	• Portugal	2
• Belgium	1	• Saudi Arabia	1
• Brazil	3	• South Korea	1
• Canada	15	• Spain	1
• China	8	• Sweden	1
• Denmark	3	• Switzerland	2
• France	2	• Taiwan	1
• Germany	6	• United Kingdom	12
• India	7		
• Israel	2		



2010-2015 Council of Experts - Demographics

Quality Standards for Medicines, Dietary Supplements, and Food Ingredients

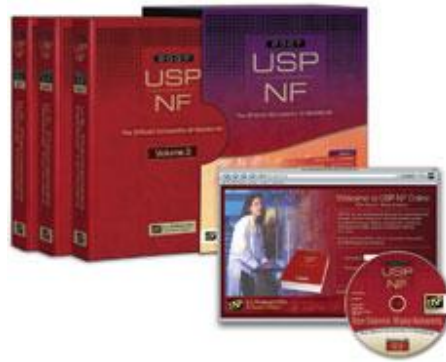




USP-NF

Quality Standards for Medicines, Dietary Supplements, and Food Ingredients

- Official authority—***FDA-enforceable standards***
- Time-tested, international resource
- More than 4,500 monographs
- Drug products and substances, excipients, dietary supplements, veterinary, biologics
- Continuously updated



Pharmacopeial Forum

Quality Standards for Medicines, Dietary Supplements, and Food Ingredients

- ▶ ***Free, online only as of 3 January 2011***
- ▶ To broaden participation in the public review process
- ▶ Beginning with PF 37(1) [Jan-Feb 2011]
- ▶ Includes an archive back to PF 28 (2002)
- ▶ Contains only proposals for which USP is seeking public comments
 - In process revisions (new and revised monographs and general chapters)
 - Stimuli Articles
 - PDG Harmonization Stage 4 proposals
 - Proposed Interim Revision Announcements (i.e., an accelerated revision)
- ▶ One-time registration is required

USP Pharmacopeial Forum
Quality Standards for Medicines, Dietary Supplements, and Food Ingredients

ENGLISH ESPAÑOL 中文 PORTUGUÊS

SEARCH All of USP.org

LOG-IN USP Store

Home > USP-NF > Pharmacopeial Forum

NEW OFFICIAL TEXT GET INVOLVED PHARMACOPEIAL FORUM BUY USP-NF

Pharmacopeial Forum (PF)

PF is the bimonthly online journal through which USP develops and revises standards for the **United States Pharmacopeia and the National Formulary (USP-NF)** by a process of public review and comment. Changes and additions to USP-NF standards are first proposed in PF to invite public comment.

Now a Free, Online-only Resource
To encourage and broaden participation in the standards-setting process, USP transitioned PF from a subscription-based print and online publication to a free, online-only resource with the release of PF 37 (1) on January 3, 2011.

New issues are posted online every two months and the comment period is 90-days and ends on the last day of the month ([View current PF Publication and Comment Schedule](#)).

Information Featured in PF
To make it easier for users to identify and respond to proposed changes to USP-NF standards, PF now contains only proposals for which USP is seeking public comment and information, including:

- In-Process Revisions
- Proposed Interim Revision Announcements (IRAs)
- PDG Harmonization Proposals (Stage 4)
- Stimuli Articles

What's New

PHARMACOPEIAL FORUM
FREE In 2011
[Click here for details](#)

[New Pending Monographs](#) (01/28/11)

[Revisions for FCC Seventh Edition, Second Supplement](#) (01/28/11)

[Six new Revision Bulletins](#) (01/28/11)

[Propofol Injectable Emulsion: Notice of Intent to Revise](#) (01/28/11)

[Tazobactam: Notice of Intent to Revise](#) (01/28/11)

Information For: Manufacturers

ACCESS PF NOW

USP Topics
Quality Standards for Medicines, Dietary Supplements, and Food Ingredients

ENGLISH ESPAÑOL 中文 PORTUGUÊS

SEARCH All of USP.org

LOG-IN USP Store

Home > USP-NF > Topics

NEW OFFICIAL TEXT GET INVOLVED PHARMACOPEIAL FORUM BUY USP-NF

Topics

- USP Overview
- Monograph Modernization**
- Flexible Monographs
- USP Pending Monographs



Monograph Modernization

Quality Standards for Medicines, Dietary Supplements, and Food Ingredients


- ▶ *Replacing* outdated technology and methodology with more current procedures
- ▶ *Adding* critical tests to the monograph
- ▶ *Deleting* non-value added tests, as needed (e.g., odor test, melting point)
- ▶ Follows the USP standards-setting process (i.e., with publication in PF for 90-day comment period)
- ▶ Considerations
 - Use procedures from other pharmacopeias (e.g, EP, BP)
 - Will the same limits apply?
 - May need RS materials
 - Revising the monograph “family”, as needed




Monograph Modernization Needs: Major Categories

Quality Standards for Medicines, Dietary Supplements, and Food Ingredients

- ▶ *No impurity test*
- ▶ Non-specific Identification procedures
- ▶ Non-specific Assay procedures
- ▶ Packed column GC procedures
- ▶ Safety-related concerns (e.g., chlorinated solvents).
- ▶ TLC (particularly <466> Ordinary Impurities), UV, or wet chemistry test for impurities

 Monograph Modernization: Recent Examples		
Quality Standards for Medicines, Dietary Supplements, and Food Ingredients		
Monograph	PF Citation	Modernization
Alclometasone Dipropionate	PF 36(5) [Sep-Oct 2010]	Replace Ordinary Impurities by TLC with HPLC
Glycopyrrolate	PF 37(1) [Jan-Feb 2011]	Replace titration Assay with HPLC; replace Ordinary Impurities by TLC with HPLC; delete Melting Range or Temperature test; add test for Limit of Erythro Isomer by HPLC
Glycopyrrolate Tablets	PF 37(1) [Jan-Feb 2011]	Replace UV-based Assay and Dissolution procedure with HPLC; added impurities test
Spironolactone	PF 37(1) [Jan-Feb 2011]	Replace chloroform with alcohol in Specific Rotation test; replace <197S> using chloroform with <197K
Temazepam	PF 36(6) [Nov-Dec 2010]	Replace TLC-based impurities procedure with HPLC procedures; removed use of Internal Standard from the Assay

 Monograph Modernization	
Quality Standards for Medicines, Dietary Supplements, and Food Ingredients	
<ul style="list-style-type: none"> ▶ Significant focus for USP ▶ USP labs used to generate data to support revisions ▶ Submissions from manufacturers encouraged <ul style="list-style-type: none"> – See <i>USP Fact Sheet on Donor Recognition</i> ▶ USP Monograph Modernization Web Page <ul style="list-style-type: none"> – Launched in May 2010 – Includes spreadsheet with top 200 small molecule monographs and 96 excipient monographs in need of modernization – Monthly status updates (last Friday of the month, adjusted for holidays) – Each month's status changes are highlighted in yellow – http://www.usp.org/USPNF/submitMonograph/improveMon.html 	

USP **USP Monograph Modernization Web Page**
Quality Standards for Medicines, Dietary Supplements, and Food Ingredients

Monograph modernization - Windows Internet Explorer
http://www.usp.org/USP/USP/Monograph/Propose/Prop.html

NEW OFFICIAL TEXT GET INVOLVED PP HIGHLIGHTS/STIMULI BUY NOW

USP Seeks Submission of Proposals for Monograph Modernization

May 28, 2010

The USP is actively engaged in efforts to modernize official USP-NF monographs for small molecules and excipients that utilize outdated technology (e.g. use of packed gas chromatography columns), have safety/environmental concerns (e.g. chlorinated solvents, etc) or are missing procedures for key aspects such as impurities. For excipients, a major modernization goal is to replace generally non-specific identification procedures with specific procedures (e.g. IR spectroscopy). To facilitate the modernization efforts, USP has identified and prioritized monographs in need of modernization and is seeking proposals to replace the current procedures or add procedures, as needed.

Monographs in need of modernization are presented in a downloadable spreadsheet that includes information on what procedure needs modernization and the current status of the modernization (separate tabs for small molecules and excipients). Some monographs have more than 200 small molecule monographs and 44 excipient monographs. There are more monographs in need of modernization and they will be added to the spreadsheet periodically as work progresses. Submissions for monograph modernizations that are not listed are also encouraged and can be submitted at anytime. The spreadsheet will be updated and posted on the USP web site on a monthly basis on the last Friday of each month.

In order for USP to maintain consistency with FDA-approved control strategies, USP prefers to receive submissions from manufacturers of FDA-approved products (including drug substances and excipients that are listed in FDA-approved products) or manufacturers intending to seek FDA approval. The latter category of submissions will be initially considered for publication as a Pending standard (see USP Pending Monograph Guidelines). Submissions, especially new research procedures, from other sources (e.g. contract laboratories, academic institutions, analytical instrumentation equipment manufacturers) can be accepted on a case-by-case basis and should follow ICH Q3 guidelines. All submissions should include data and other information recommended in the USP Guideline for Submission of Request for Revision to USP-NF. Please review the USP Submission Checklist for data and information that should be included in the submission. Some modernization proposals may generate new USP Reference Standards and USP invites the sponsor of the proposal to donate the necessary bulk reference materials. For more information, please review the USP Guideline for Suppliers of Reference Standard Materials.

Electronic submissions (e.g., pdf, access to ftp site) are preferred and can be submitted to Mr. Michael Goede for Small Molecules at mgo@usp.org or to Mr. Jay Pearson for Excipients at jp@usp.org. USP also accepts hard copies and they can be sent accordingly to the following address:

Mr. Michael Goede or Mr. Jay Pearson
Manager, Standards Acquisition
United States Pharmacopeia
12601 Twinbrook Parkway
Rockville, MD 20852

If your organization would like a list of company-specific modernization proposals needed, please contact Mr. Randy Kiser at rwk@usp.org.

What's New

PHARMACOPEIA FORUM
FREE IN BDT1
See us to learn

First Prescription/Over-the-counter Stakeholder Forum for 2010-2011 Cycle Expires Earlier Participation 10-16-10

October New Official Text, Revision Revision Bulletins 09-30-10

Cyclophosphamide Hydrofluoride: Notice of Intent to Revise (Proposed) 09-24-10

Small Molecules and Excipients Monographs Needing Modernization list updated 09-24-10

USP Has Revised New General Chapter <3> Topical and Transdermal Drug Products, Quality Tests, To Be Republished in FF 2010 09-20-10

Renew Your USP-NF Subscription Today! 08-19-10

FF 24(1), September/October 2010: HAs, Emph, Highlights, and Stimuli Articles 08-31-10

Related Resources

- Subscribe to Updates
- Notices
- Education Courses
- USP Catalog

Information For:

- Manufacturers
- Regulators
- Healthcare Providers
- Consumers
- Members/Volunteers

Search USP Careers

Attend a USP Event

USP **USP Monograph Modernization Web Page**
Quality Standards for Medicines, Dietary Supplements, and Food Ingredients

Providers

Consumers

Members/Volunteers

Search USP Careers

Attend a USP Event

Electronic submissions (e.g., pdf, access to ftp site) are preferred and can be submitted to Mr. Michael Goede for Small Molecules at mgo@usp.org or to Mr. Jay Pearson for Excipients at jp@usp.org. USP also accepts hard copies and they can be sent accordingly to the following address:

Mr. Michael Goede or Mr. Jay Pearson
Manager, Standards Acquisition
United States Pharmacopeia
12601 Twinbrook Parkway
Rockville, MD 20852

If your organization would like a list of company-specific modernization proposals needed, please contact Mr. Randy Kiser at rwk@usp.org.

For general information, please contact:

Karen A. Russo, Ph.D.
Vice President, Small Molecules
kar@usp.org 301-816-8379

Catherine Sheehan, M.S.
Director, Excipients
cxs@usp.org 301-816-8262

Small Molecules and Excipients Monographs Needing Modernization
Posting Date: October 29, 2010

Download the Monograph Modernization list (151KB) (updated October 22, 2010)

Next Posting Date: November 29, 2010

USP Small Molecules Monograph Modernization List

Quality Standards for Medicines, Dietary Supplements, and Food Ingredients

USP Monographs in Need of Modernization (Last Updated 22-October-2010)

Monograph Name	Monograph Family	Date Added to List	Date of Last Status Change	Status	Publication	Monograph Type	Monograph Test	Procedure	Replace or Add Test	Replacement Procedures	Liaison	Comments
DEXBROMPHENIRAMINE MALEATE	DEXBROMPHENIRAMINE MALEATE	24-May 2010 (Initial posting)		Submission Needed		Drug Substance	Assay	Titration	Replace	Stability Indicating Assay	Domenick Vicchio dvw@usp.org	
DEXCHLORPHENIRAMINE MALEATE	DEXCHLORPHENIRAMINE MALEATE	24-May 2010 (Initial posting)	22-Oct-2010	Submission Committed		Drug Substance	Related Compounds	GC - Packed Column	Replace	Modern Procedure	Domenick Vicchio dvw@usp.org	
DEXCHLORPHENIRAMINE MALEATE	DEXCHLORPHENIRAMINE MALEATE	24-May 2010 (Initial posting)	22-Oct-2010	Submission Committed		Drug Substance	Assay	Titration	Replace	Stability Indicating Assay	Domenick Vicchio dvw@usp.org	
DIFLUNISAL	DIFLUNISAL	24-May 2010 (Initial posting)		Submission Needed		Drug Substance	Chromatographic Purity	TLC	Replace	Modern Procedure	Clydewyn Anthony cma@usp.org	
DIHYDROCODEINE BITARTRATE	DIHYDROCODEINE BITARTRATE	24-May 2010 (Initial posting)		Submission Needed		Drug Substance	Ordinary Impurities	TLC	Replace	Modern Procedure	Clydewyn Anthony cma@usp.org	
DIPHENHYDRAMINE CITRATE	DIPHENHYDRAMINE CITRATE	24-May 2010 (Initial posting)		Submission Needed		Drug Substance	Assay	Titration	Replace	Stability Indicating Assay	Domenick Vicchio dvw@usp.org	
DIPHENHYDRAMINE CITRATE	DIPHENHYDRAMINE CITRATE	24-May 2010 (Initial posting)		Submission Needed		Drug Substance	Impurities	Missing	Add	Quantitative stability indicating procedure	Domenick Vicchio dvw@usp.org	
DIPHENHYDRAMINE HYDROCHLORIDE	DIPHENHYDRAMINE HYDROCHLORIDE	24-May 2010 (Initial posting)		Submission Needed		Drug Substance	Impurities	Missing	Add	Quantitative stability indicating procedure	Domenick Vicchio dvw@usp.org	
DIPHENHYDRAMINE HYDROCHLORIDE CAPSULES	DIPHENHYDRAMINE HYDROCHLORIDE	24-May 2010 (Initial posting)		Submission Needed		Drug Product	Impurities	Missing	Add	Quantitative stability indicating procedure	Domenick Vicchio dvw@usp.org	
DIPHENHYDRAMINE HYDROCHLORIDE INJECTION	DIPHENHYDRAMINE HYDROCHLORIDE	24-May 2010 (Initial posting)		Submission Needed		Drug Product	Impurities	Missing	Add	Quantitative stability indicating procedure	Domenick Vicchio dvw@usp.org	
DIPHENHYDRAMINE HYDROCHLORIDE ORAL SOLUTION	DIPHENHYDRAMINE HYDROCHLORIDE	24-May 2010 (Initial posting)		Submission Needed		Drug Product	Impurities	Missing	Add	Quantitative stability indicating procedure	Domenick Vicchio dvw@usp.org	

Small Molecules Small Molecules Archive Excipients Excipients Archive

USP Topics

Quality Standards for Medicines, Dietary Supplements, and Food Ingredients

- ▶ USP Overview
- ▶ Monograph Modernization
- ▶ **Flexible Monographs**
- ▶ USP Pending Monographs



Flexible Monograph Approach

Quality Standards for Medicines, Dietary Supplements, and Food Ingredients

- ▶ **Need-based** flexibility to account for different routes of synthesis, hydrates, solvates, polymorphs, or formulations
- ▶ Enables multiple procedures, preparations, and/or acceptance criteria within a single monograph
- ▶ Uses of the flexible approach
 - multiple formulation-specific dissolution procedures
 - multiple organic impurity procedures based on different impurity profiles
 - hydrate-specific water limits/ranges
 - polymorph-specific crystallinity requirement
- ▶ May need procedure-specific USP Reference Standards



Flexible Monographs: Examples

Quality Standards for Medicines, Dietary Supplements, and Food Ingredients

- ▶ Ethinyl Estradiol
- ▶ Loratadine
- ▶ Meloxicam
- ▶ Paclitaxel
- ▶ Paroxetine Hydrochloride
- ▶ Potassium Chloride Extended-Release Tablets
- ▶ Theophylline Extended-Release Capsules



Flexible Monograph Example: Paclitaxel

Quality Standards for Medicines, Dietary Supplements, and Food Ingredients

Labeling—The labeling indicates the type of process used to produce the material and the Related compounds test with which the material complies.

Related compounds—

Test 1 (for material labeled as isolated from natural sources)—If the material complies with this test, the labeling indicates that it meets USP Related compounds Test 1.

Test 2 (for material labeled as produced by a semi-synthetic process)—If the material complies with this test, the labeling indicates that it meets USP Related compounds Test 2

Test 3 (for material labeled as produced by a plant cell fermentation process)—If the material complies with this test, the labeling indicates that it meets USP Related compounds Test 3.



Paroxetine Hydrochloride

Quality Standards for Medicines, Dietary Supplements, and Food Ingredients

Water, Method I <921>: not more than 1.5% for the anhydrous form and between 2.2% and 2.8% for the hemihydrate form.

Chromatographic purity—[note—On the basis of the synthetic route, perform either Test 1 or Test 2. Test 2 is recommended if paroxetine related compound F or paroxetine related compound G is a potential related compound.]

Test 1— ...

Test 2 — ...



Topics

Quality Standards for Medicines, Dietary Supplements, and Food Ingredients

- ▶ USP Overview
- ▶ Monograph Modernization
- ▶ Flexible Monographs
- ▶ **USP Pending Monographs**



USP Pending Monographs

Quality Standards for Medicines, Dietary Supplements, and Food Ingredients

- ▶ Initiated in February 2007
- ▶ Web-based publication of monographs
- ▶ Enables monograph development and publication before FDA approval has been granted to a generic manufacturer
- ▶ Ultimate purpose is to have an official *USP-NF* monograph ready as soon as possible after FDA approval of an application (i.e., ANDA)
- ▶ Not legally enforceable



USP Pending Monographs: Requirements

Quality Standards for Medicines, Dietary Supplements, and Food Ingredients

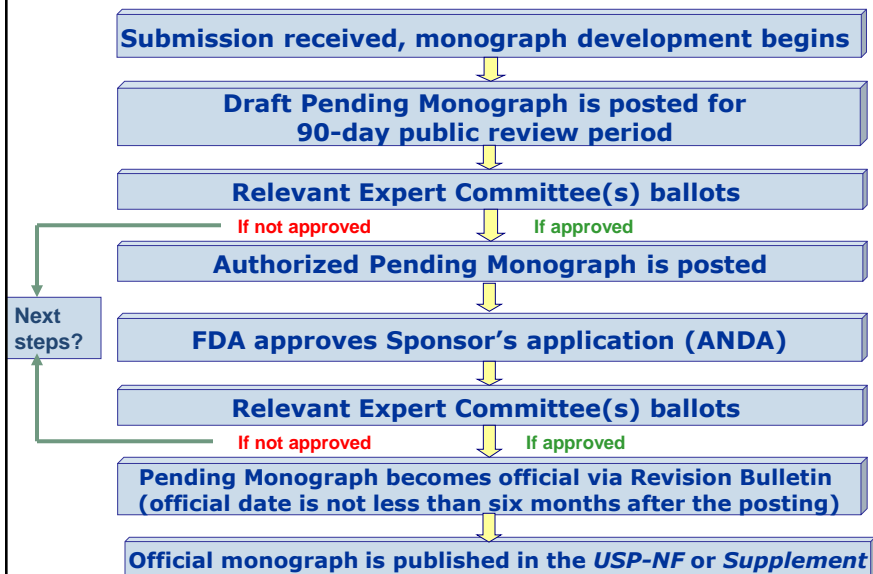
Sponsors

- Who have filed or intend to file with FDA an Abbreviated New Drug Application (ANDA) or Abbreviated New Animal Drug Application (ANADA) within six months; or
- 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; or
- Who have submitted a Drug Master File (DMF) for an article to FDA; or
- Whose substance is or will be the subject of a Time and Extent Application or citizen petition to amend an FDA OTC drug monograph.



USP Pending Monographs Process

Quality Standards for Medicines, Dietary Supplements, and Food Ingredients





USP Pending Monographs: Current Status

Quality Standards for Medicines, Dietary Supplements, and Food Ingredients

- ▶ Pending Monographs Advancing to USP–NF
 - 12 monographs have received full FDA approval and advanced to official USP text (in their entirety or specific sections)
- ▶ Authorized Pending Monographs
 - 48 Authorized monographs posted; sponsors waiting for full FDA approval
- ▶ Draft Pending Monographs
 - 15 Draft monographs posted for public comment



USP Pending Monographs Web Page

Quality Standards for Medicines, Dietary Supplements, and Food Ingredients

- ▶ USP Pending Monographs are posted on the USP web site at www.usp.org/standards/pending/
- ▶ Guideline is available on the web site
- ▶ Updated monthly (last Friday of the month, adjusted for holidays)

USP Pending Monographs

USP provides Pending Monographs for certain drug products, drug substances, and excipients that have been submitted or are intended to be submitted to the U.S. Food and Drug Administration (FDA) for approval to be marketed in the United States, but have not yet received such approval. Under this approach, sponsors of Requests for Revision such as manufacturers of generic or over-the-counter (OTC) products and others can work with USP to create a Pending Monograph as authorized text. Once FDA approval is granted, USP then works with the sponsor to move that monograph into official USP-NF status, along with an official USP Reference Standard where appropriate. Details of the approach are described in the Pending Monographs Guideline, Version 2.6

As new and revised Pending Monographs become available, they will be posted on the USP Web site on a monthly basis on the last Friday of each month. Monographs posted in draft for comment will also indicate the deadline for submitting comments and the e-mail address of the USP staff person to whom comments should be directed. Following review of comments and approval by the relevant Expert Committee, the Authorized Pending Standard will be posted to this web site.

Download a Power Point presentation on the Pending Monographs Guideline.

For additional information, contact Karen A. Russo, Ph.D., kar@usp.org

Draft Monographs – New Postings
Posting Date: October 29, 2010 – No New Postings

Monograph	Date Posted	Status	Liaison	History
Next Posting Date: November 24, 2010				
Draft Monographs – Previous Postings				
Monograph	Date Posted	Status	Liaison	History
Adipalene (13194)	Apr. 30, 2010	Draft 1, Comment period ended Jul. 31, 2010. Awaiting Expert Committee approval.	Feiwen Mao (fm@usp.org)	--
Alprostadil (13204)	Apr. 30, 2010	Draft 1, Comment period ended Jul. 31, 2010. Awaiting Expert Committee approval.	Hari Ramanathan (hr@usp.org)	--
Chromolauretole Trihydroxide (13189)	Aug. 27, 2010	Draft 1, Comment period ends Nov. 30, 2010	Feiwen Mao (fm@usp.org)	--
Etrimecibine (13248)	May. 28, 2010	Draft 1, comment period ended Aug. 31, 2010. Awaiting Expert Committee approval.	Leonel Santos (ls@usp.org)	--
Etrimecibine Capsules (13249)	May. 28, 2010	Draft 1, comment period ended Aug. 31, 2010. Awaiting Expert Committee approval.	Leonel Santos (ls@usp.org)	--
Exemestane (13441)	Apr. 30, 2010	Draft 1, comment period ended Jul. 31, 2010. Awaiting Expert Committee approval.	Feiwen Mao (fm@usp.org)	--
Esomeprazole Magnesium (13248)	Apr. 30, 2010	Draft 2, Comment period ended Jul. 31, 2010. Awaiting Expert Committee approval.	Elena Gonikberg (eg@usp.org)	Esomeprazole Magnesium, Draft 1 (13184)
Ictant (13248)	Aug. 27, 2010	Draft 1, Comment period ends Nov. 30, 2010	Feiwen Mao (fm@usp.org)	--
Iron Sucrose Injection	N/A	Withdrawn at sponsor's request.	Sujatha Ramakrishna (sar@usp.org)	--
Lamivudine and Zidovudine Tablets (13179)	Aug. 27, 2010	Draft 1, Comment period ends Nov. 30, 2010	Leonel Santos (ls@usp.org)	--
Lamivudine and Zidovudine Tablets (13179)	Aug. 27, 2010	Draft 1, Comment period ends Nov. 30, 2010	Leonel Santos (ls@usp.org)	--
Minoxidilum (13194)	Feb. 26, 2010	Draft 1, Comment period ended May, 31, 2010. Awaiting Expert Committee Approval.	Hari Ramanathan (hr@usp.org)	--
Phenylephrine Hydrochloride (13194)	Aug. 31, 2010	Draft 1, comment period ended Aug. 31, 2010.	Feiwen Mao (fm@usp.org)	--

Parallel Submissions

Quality Standards for Medicines, Dietary Supplements, and Food Ingredients

- ▶ May have Pending and USP submissions for the same monograph
- ▶ “First official” becomes Test/Procedure 1
- ▶ Not easy to predict outcome--depends on timing of submissions, FDA approval, etc



Comments and Commentary

Quality Standards for Medicines, Dietary Supplements, and Food Ingredients

- ▶ Interested parties may comment on any posted monograph at any time; deadlines observed for balloting purposes
- ▶ Regulatory status of commenter affects how the comments are handled
- ▶ Comments from Pending Manufacturer
 - Draft and Authorized Pending monographs may be revised, flexible approach possible
- ▶ Comments from FDA-approved manufacturer
 - Comments may be incorporated into the Pending monograph when it advances to official status
 - Commenter may opt to submit a parallel submission



Contact Information

Quality Standards for Medicines, Dietary Supplements, and Food Ingredients

Karen A. Russo, Ph.D
Vice President, Small Molecules
kar@usp.org

 U.S. PHARMACOPEIA
The Standard of QualitySM

Thank You

Quality Standards for Medicines | Dietary Supplements | Food Ingredients