

Welcome



Empowering a healthy tomorrow

Overview of USP activities and how to get involved

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SNMMI
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Topics

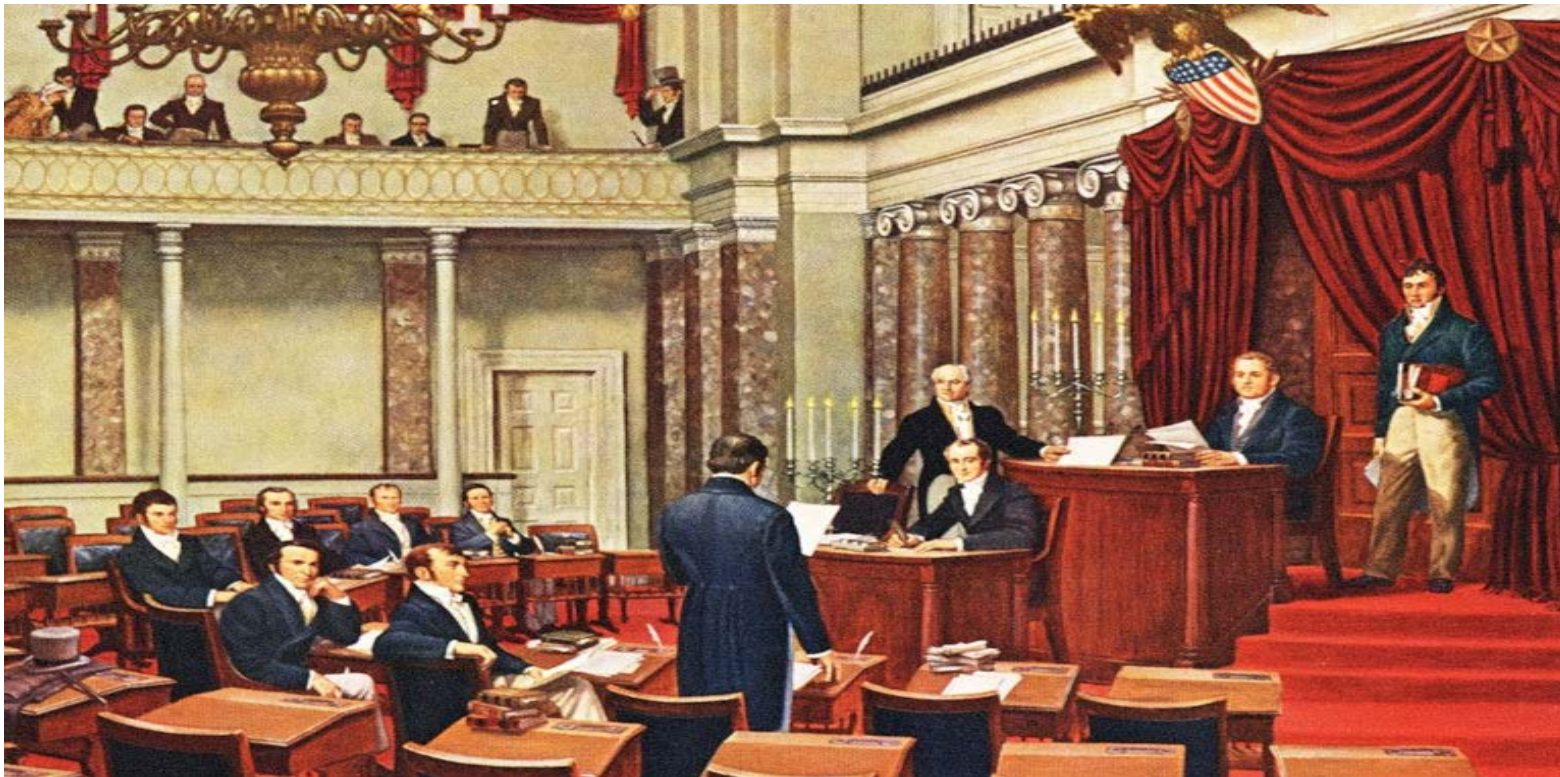


- ▶ USP history
 - USP Mission
 - Legal Recognition
 - USP Council of Experts
- ▶ USP standard-setting process
- ▶ How to get involved

USP history



- ▶ Dr. Lyman Spalding surveyed physicians nationwide between 1817 and 1819
- ▶ Spalding and 10 fellow physicians met in the US Capitol, January 1-7, 1820 and laid the groundwork for establishing the first *Pharmacopeia of the United States of America*





Mission

To improve global health through public standards and related programs that help ensure the quality, safety and benefit of medicines and foods



USP facts



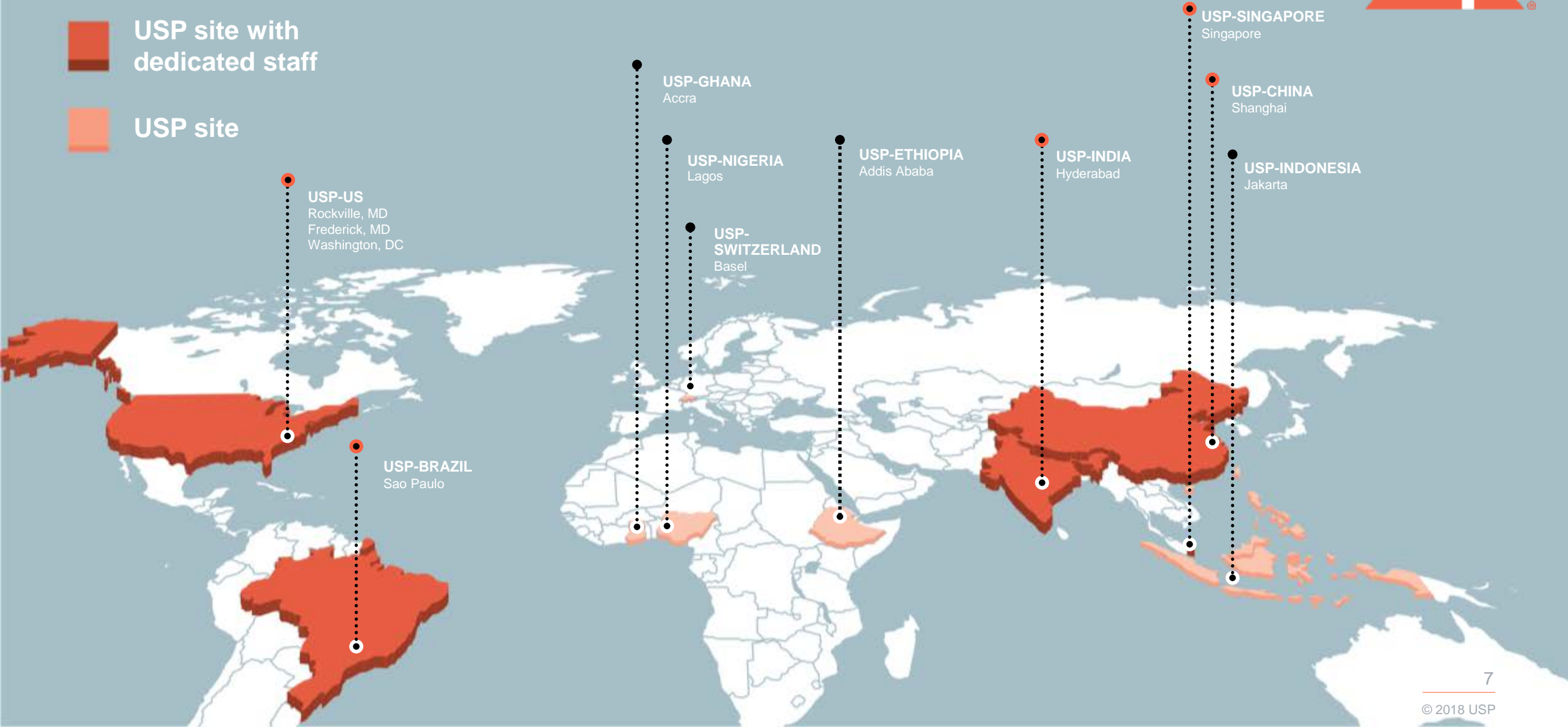
- ▶ **Established in 1820**
- ▶ **Mission is to protect public health by establishing public standards**
- ▶ **Non-Profit private organization**
- ▶ **Volunteer-based**
- ▶ **Convention meets every five years in Washington, D.C. (2020)**
- ▶ **Headquartered in Rockville, MD**
- ▶ **Global presence**

We work globally



 USP site with dedicated staff

 USP site



The *USP–NF*: What is it?



Legally enforceable documentary standards governing the quality, strength and purity of articles of commerce (drug substances, drug products and other components used in the formulations) in the United States.



Role of USP drug quality standards and law

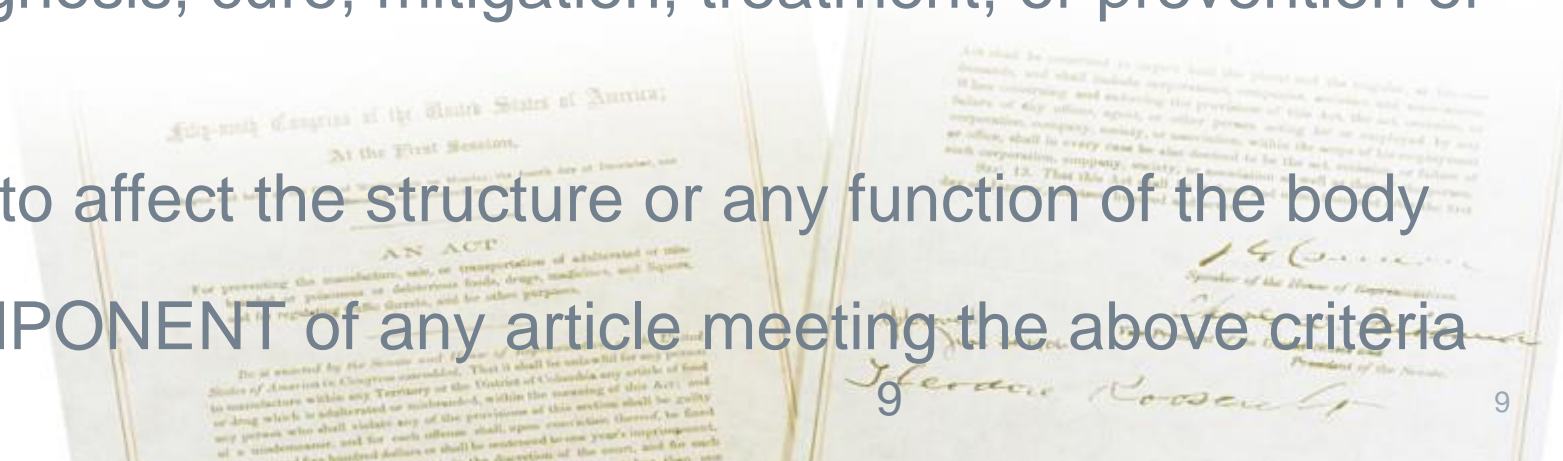


Under FD&C Act

21 U.S.C. § 321 Section 201(g)(1)

The term “drug” means articles:

- ▶ recognized in an official US compendium: United States Pharmacopeia, Homoeopathic Pharmacopoeia, or National Formulary
- ▶ intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease
- ▶ (other than food) intended to affect the structure or any function of the body
- ▶ intended for use as a **COMPONENT** of any article meeting the above criteria

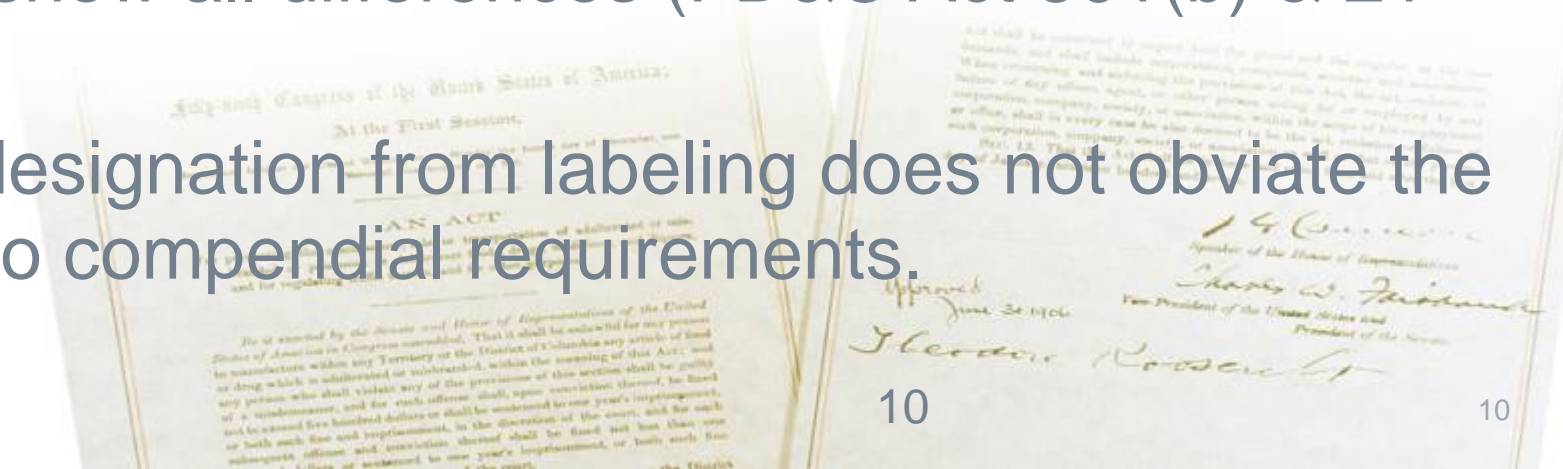


Role of USP drug quality standards and law



Under the relevant FD&C Act provisions:

- ▶ A drug with a name recognized in USP-NF must comply with compendial identity standards or be deemed adulterated, misbranded, or both (FD&C Act 501(b) & 502(e)(3)(b)).**Cannot label away from identity!**
- ▶ Must also comply with compendial standards for strength, quality, and purity, unless labeled to show all differences (FD&C Act 501(b) & 21 CFR 299.5).
- ▶ Removing the USP-NF designation from labeling does not obviate the requirement to conform to compendial requirements.



United States Pharmacopeia – National Formulary



A combined compendium of internationally recognized standards for drug substances, dosage forms, compounded preparations, excipients, and dietary supplements.

It contains:

- More than 4,500 monographs with specifications for identity, purity, quality, and strength.
- More than 320 General Chapters
- Official Standards in USP are FDA-enforceable for drugs manufactured or marketed in the U.S.





▶ USP: Private not-for-profit organization

- ▶ Engaged in the development and revision of compendial standards for drugs (and other products)
- ▶ Public standards related to identity, strength, purity, quality, packaging, labeling

▶ US FDA: Government agency

- ▶ Engaged in the promulgation and enforcement of drug (and other product) regulatory requirements
- ▶ Safety, Efficacy, NDA (private license) approvals for marketing, manufacturing processes, etc.

USP is the only major non-governmental pharmacopeia in the world.

Shared goals ... but challenging to balance



FDA

- Public Safety (maximize)
- Unambiguous enforceable specifications
- Referee method(s)
- U.S. scope, participate globally



- USP Public Standard (minimum)
- Align with FDA as much as possible
- Broad scope
- Work globally

- Industry / Professional groups
- Commerce
- Practical, meaningful, balanced
- Requirement clarity, but flexibility
- U.S. focused, but global scope

FDA engagement goes beyond enforcing USP standards

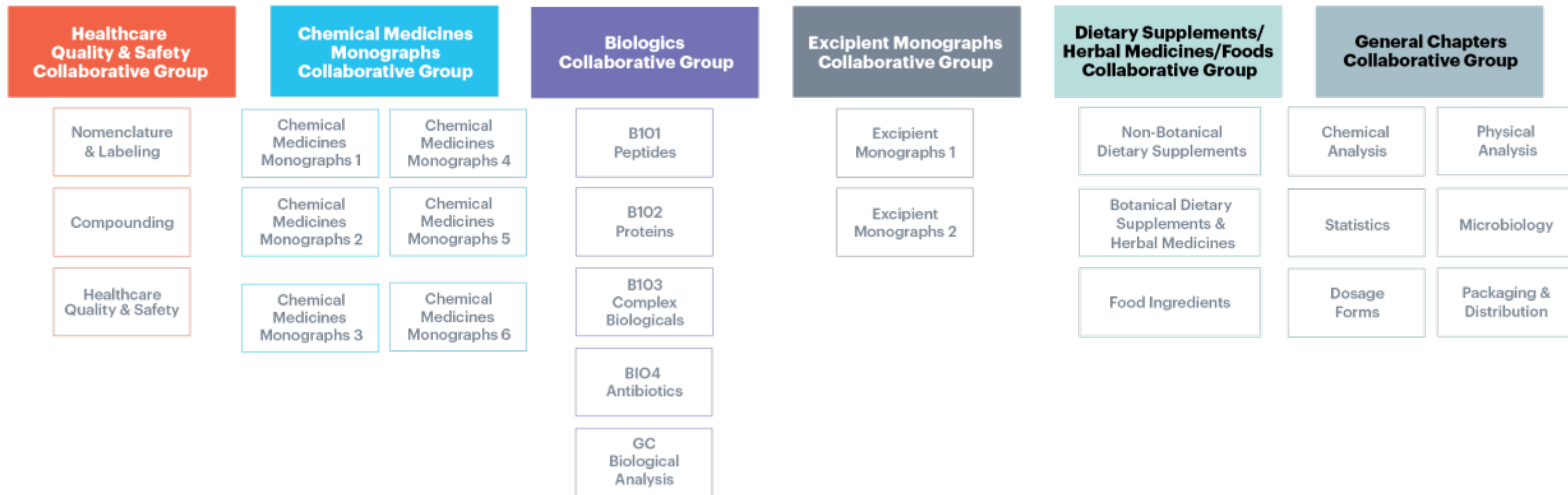


- ▶ FDA reviews proposed standards in *Pharmacopeial Forum* and provides comments
- ▶ Participates as delegates, provides resolutions, provides members to the council of the Convention and other Convention committees
- ▶ Provides FDA liaisons to USP's expert committees
- ▶ Participates in workshops and stakeholder forums
- ▶ Works with USP through cooperative research and development agreements
- ▶ Collaborates with USP through quarterly meetings, pharmacopeial discussion group and special topics such as OTC monograph modernization, compounding, structured product labeling, pharmacologic classes

Areas our standards address



2015–2020 Council of Experts



USP–NF publication & official dates



- ▶ **USP –NF Main Edition** published every November 1st, official May 1st of the following year
- ▶ *1st Supplement published February 1st, official August 1st same year*
- ▶ *2nd Supplement published June 1st, official December 1st same year*



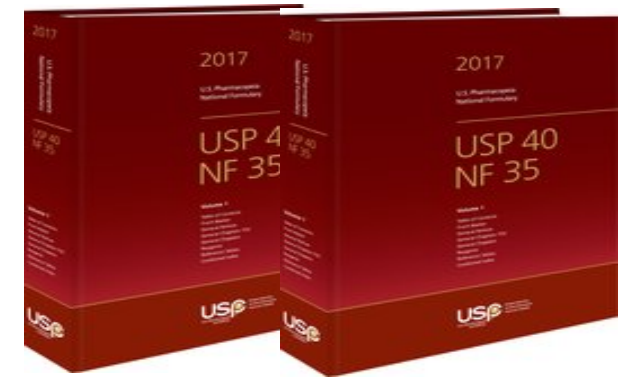
Currently Official:

- ▶ *USP 41–NF 36 Published Nov 1, 2017, Official since: May 1, 2018*

Supplements available:

- ▶ *USP 41–NF 36, **Supplement 1***

Published Feb 1, 2018, Becomes official August 1, 2018





- **General Notices** contain requirements applicable throughout *USP–NF* unless superseded by a monograph
- **General Chapters** contain requirements relevant to monographs to which they apply
- **Monograph** requirements are specific to the monograph in which they appear - Monograph requirements supersede General Notice and General Chapter requirements in case of conflict

How we work



USP Monograph Development Process



Expert Panels for radioactive articles



▶ Radioactive Drugs Expert Panel

- Members of the panel review the submissions
- Recommend to the Chemical Medicines 4 Expert Committee the draft for public comment
- Review the public comments and recommend go-no go decisions to the EC

▶ <825> Radiopharmaceuticals – Preparation, Compounding, Dispensing and Repackaging

- Members of the panel develop the chapter
- Recommend to the Chemical Medicines 4 Expert Committee the draft for public comment
- Review the public comments and recommend go-no go decisions to the EC

Standards for radioactive articles



▶ General Chapters

- <821> RADIOACTIVITY
- <823> POSITRON EMISSION TOMOGRAPHY DRUGS FOR COMPOUNDING, INVESTIGATIONAL, AND RESEARCH USES
- <1821> RADIOACTIVITY — THEORY AND PRACTICE
- <1823> POSITRON EMISSION TOMOGRAPHY DRUGS — INFORMATION

▶ Monographs:

- 4 PET drug monographs
 - Fludeoxyglucose F18 Injection – PF 43(3)
 - Ammonia N13 Injection - PF 43(3)
- 60+ monographs – all need to be revised

Current and future activities



- Revise 2 existing PET drug monographs
 - Sodium Fluoride F18 Injection
 - Rubidium Chloride Rb82 Injection
- Revise all the existing SPECT monographs
- Develop new monographs for articles (PET & SPECT) approved by FDA
- Develop additional general chapters as appropriate

Challenges in developing and revising monographs



- Need submissions from FDA approved applicants to ensure proposed specifications are appropriate
- Getting timely cooperation from sponsors
- Multiple manufacturers for drug products
- Active participation in the compendial process by stakeholders
- Ensuring the availability of necessary reference standards

How can the stakeholders help?



- Provide submissions for monographs not included in USP
- Provide supporting data for modernizing the old monographs
- Actively participate in the public comment process
- Volunteer to serve on the expert committees and panels

Call for Candidates: 2020-2025 Council of Experts



- ▶ The Call for Candidates for the 2020-2025 cycle begins July 2018
- ▶ We are seeking technical and scientific experts in the pharmaceutical, biologics, and food industries, academia, regulatory and government sectors to volunteer for USP's Council of Experts and Expert Committees
- ▶ Join with fellow committed professionals that are helping to develop standards of quality for medicines, dietary supplements and foods
- ▶ To receive updates on the Expert Committee requirements and responsibilities, email USPVolunteers@usp.org



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<http://www.usp.org/>



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Questions



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Thank You



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