1

Financial Disclosures

Brenda Jensen declares that she has a current affiliation or financial arrangement as a consultant for Compounding Facilities within the past 24 months.

George Smith declares that he has a current affiliation or financial arrangement as a consultant for ARxIUM and Intelliguard within the past 24 months.

All of the other presenters declare that they do not have a current affiliation or financial arrangement with any ineligible companies that may have a direct interest in the subject matter of this continuing pharmacy education (CPE) activity within the past 24 months.

Additionally, NABP staff involved in the planning of this activity do not have a current affiliation or financial arrangement with any ineligible companies that may have a direct interest in the subject matter of NABP's CPE Program within the past 24 months.

All relevant financial disclosures have been mitigated.

NABP

2

NABP
National Association of Boards of Pharmacy

USP Standards Setting – How Pharmacy Can Engage

Gigi Davidson, BS Pharm, DICVP
CEO, VetPharm Consulting

Edmund J. Elder Jr, PhD, RPh
Emeritus Research Services
University of Wisconsin-Madison

Brenda Jensen, CPhT, CNMT, MBA
Owner and Consultant
Compounding Consultants, LLC

Jessica L. Hawkins, PharmD, BCPS, BCSCP
Pharmacy Program Manager – Sterile Compounding
Lexington VA Health Care System

Nicole Mercogliano, RPh, MS, BCSCP
Senior Scientist, United States Pharmacopeia

George R. Smith, PharmD, BCPS, BCSCP
System Sterile Compounding Services Specialist
Prisma Health

3

4

Learning Objectives:

1. Describe the USP standards-setting process, including how chapters and compounded preparation monographs (CPMs) are developed and revised.
2. Explain the evolution of key USP chapters (⟨795⟩, ⟨797⟩, and ⟨800⟩), including their historical development and major revisions.
3. Outline the current workplans of the USP Compounding Expert Committee
4. Identify how stakeholders can engage with USP.

5

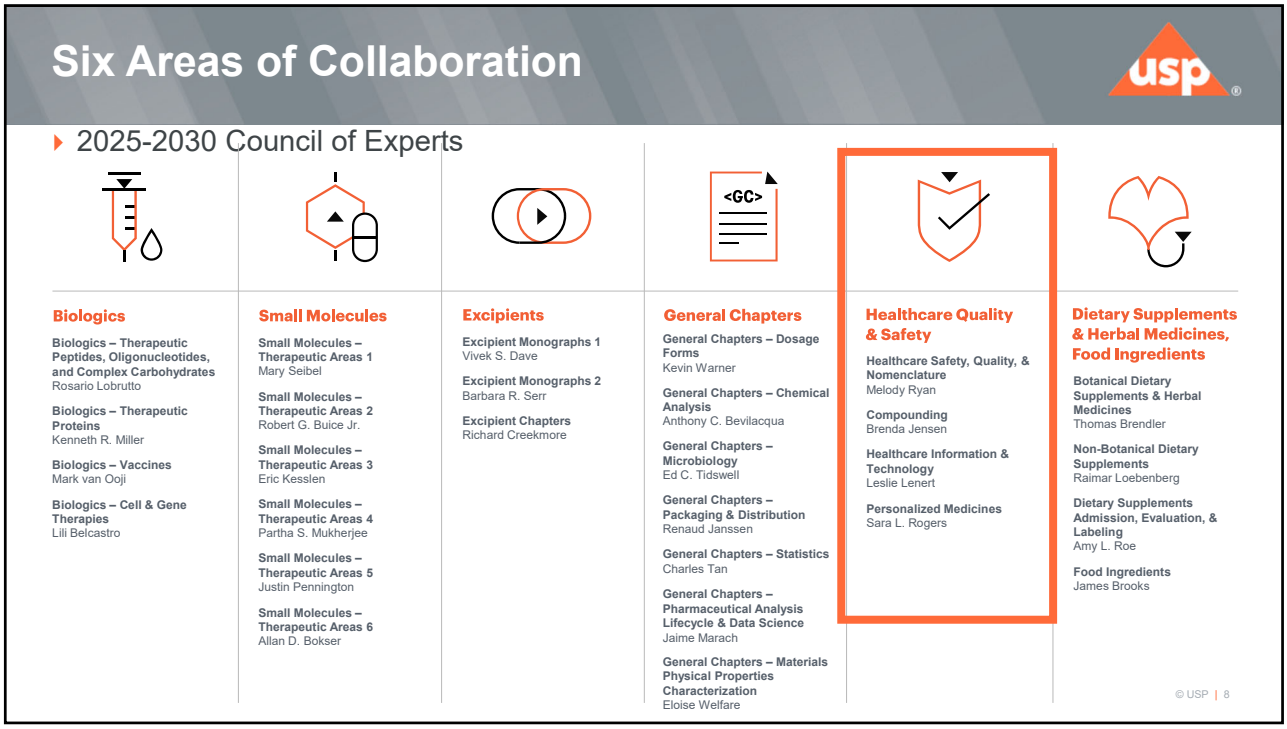
Outline:

1. How USP sets standards
2. History of ⟨795⟩
3. History of ⟨797⟩
4. History of ⟨800⟩
5. Subcommittee: ⟨1163⟩
6. Subcommittee: Technology
7. Subcommittee: Monograph Development
8. Final Thoughts
9. Q&A

6


1
How USP sets standards
Nicole Mercogliano, RPh, MS, BCSCP
USP Documentary Standards Scientist for Compounding Expert Committee
© USP | 7

7


Six Areas of Collaboration
2025-2030 Council of Experts
Biologics
Biologics – Therapeutic Peptides, Oligonucleotides, and Complex Carbohydrates
Rosario Lobrutto
Biologics – Therapeutic Proteins
Kenneth R. Miller
Biologics – Vaccines
Mark van Ooji
Biologics – Cell & Gene Therapies
Lili Belcastro
Small Molecules
Small Molecules – Therapeutic Areas 1
Mary Seibel
Small Molecules – Therapeutic Areas 2
Robert G. Buice Jr.
Small Molecules – Therapeutic Areas 3
Eric Kesslen
Small Molecules – Therapeutic Areas 4
Partha S. Mukherjee
Small Molecules – Therapeutic Areas 5
Justin Pennington
Small Molecules – Therapeutic Areas 6
Allan D. Bokser
Excipients
Excipient Monographs 1
Vivek S. Dave
Excipient Monographs 2
Barbara R. Serr
Excipient Chapters
Richard Creekmore
General Chapters
General Chapters – Dosage Forms
Kevin Warner
General Chapters – Chemical Analysis
Anthony C. Bevilacqua
General Chapters – Microbiology
Ed C. Tidswell
General Chapters – Packaging & Distribution
Renaud Janssen
General Chapters – Statistics
Charles Tan
General Chapters – Pharmaceutical Analysis Lifecycle & Data Science
Jaime Marach
General Chapters – Materials Physical Properties Characterization
Eloise Welfare
Healthcare Quality & Safety
Healthcare Safety, Quality, & Nomenclature
Melody Ryan
Compounding
Brenda Jensen
Healthcare Information & Technology
Leslie Lenert
Personalized Medicines
Sara L. Rogers
Dietary Supplements & Herbal Medicines, Food Ingredients
Botanical Dietary Supplements & Herbal Medicines
Thomas Brendler
Non-Botanical Dietary Supplements
Raimar Loebenberg
Dietary Supplements Admission, Evaluation, & Labeling
Amy L. Roe
Food Ingredients
James Brooks
© USP | 8

8

How We Work

Healthcare Quality & Safety Standard-Setting Process

9

USP Standards for Compounding

USP provides 3 types of public standards for compounding

USP General Chapters

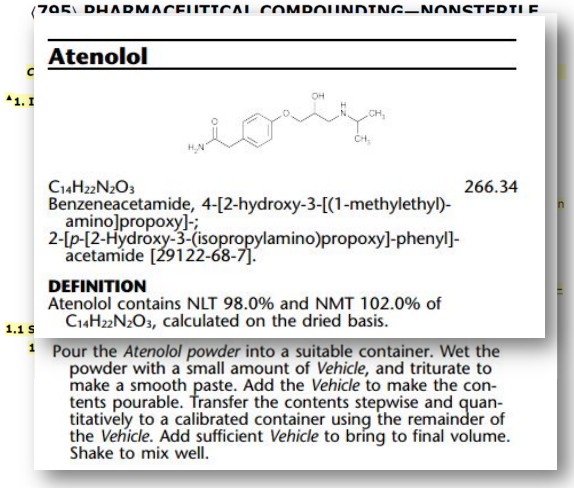
- Establish practice standards to help ensure the quality of compounded preparations

USP Compounded Preparation Monographs

- Contain formulations for specific preparations for which there is no suitable commercially available product

USP Monographs for Bulk Drug Substances and Other Ingredients

- Provide standards for identity, quality, purity, strength, packaging, and labeling for bulk substances and other ingredients that may be used in compounded preparations



⟨795⟩ PHARMACEUTICAL COMPOUNDING—NONSTERILE

Atenolol

$C_{14}H_{22}N_2O_3$ 266.34

Benzeneacetamide, 4-[2-hydroxy-3-[(1-methylethyl)-amino]propoxy]-;
2-[*p*-[2-Hydroxy-3-(isopropylamino)propoxy]-phenyl]-acetamide [29122-68-7].

DEFINITION

Atenolol contains NLT 98.0% and NMT 102.0% of $C_{14}H_{22}N_2O_3$, calculated on the dried basis.

Pour the *Atenolol powder* into a suitable container. Wet the powder with a small amount of *Vehicle*, and triturate to make a smooth paste. Add the *Vehicle* to make the contents pourable. Transfer the contents stepwise and quantitatively to a calibrated container using the remainder of the *Vehicle*. Add sufficient *Vehicle* to bring to final volume. Shake to mix well.

10

USP Standards for Compounding

USP standards help promote public health, protect patients and health care workers, and address public health challenges.

- ⟨795⟩ *Pharmaceutical Compounding—Nonsterile Preparations*
- ⟨797⟩ *Pharmaceutical Compounding—Sterile Preparations*
- ⟨800⟩ *Hazardous Drugs—Handling in Healthcare Settings*
- ⟨825⟩ *Radiopharmaceuticals—Preparation, Compounding, Dispensing, and Repackaging*
- ⟨1160⟩ *Pharmaceutical Calculations in Pharmacy Practice*
- ⟨1163⟩ *Quality Assurance in Pharmaceutical Compounding*
- ⟨1168⟩ *Compounding for Phase I Investigational Studies*
- ⟨1176⟩ *Prescription Balances and Volumetric Apparatus Used in Compounding*
- ⟨1191⟩ *Stability Considerations in Dispensing Practice*
- *Compounded Preparation Monographs (CPMs)*

11

Self-assessment Question #1

Which of the following best explains how the USP standards development process ensures that chapters such as ⟨795⟩ and ⟨797⟩ are scientifically sound, transparent, and broadly adopted?

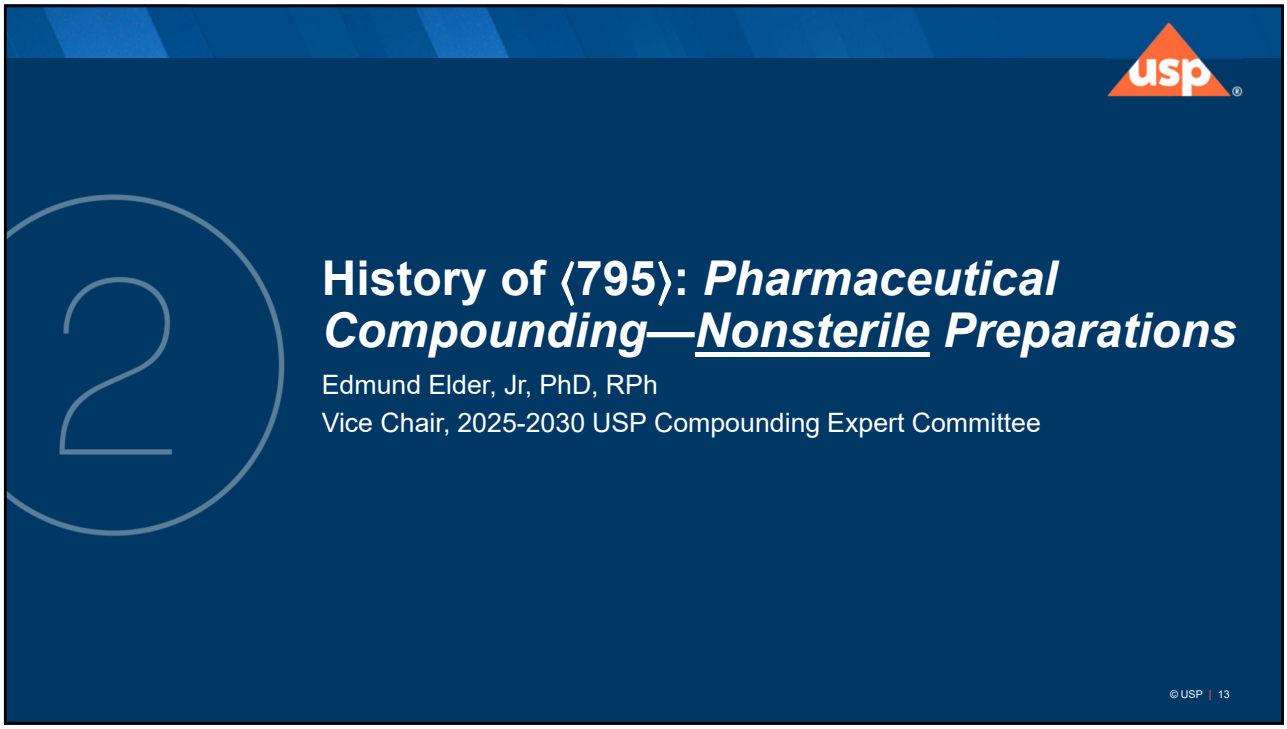
A. To ensure consistency, USP independently drafts and implements standards without stakeholder's feedback.

B. Expert Committees develop standards based on scientific evidence and practice, seek and incorporate public comment, and allow time for implementation before standards become official.

C. State boards of pharmacy create and enforce USP standards, while USP only publishes the final document.

D. Public comments are collected after standards become official and are used for future revisions.

12



13

History of ⟨795⟩

- First Nonsterile Compounding Standard
  - *USP* ⟨1161⟩ *Pharmacy Compounding Practices* **(1996)**
- **General Chapter ⟨795⟩**
  - Published in USP 24–NF 19 **(2000)**
  - Revised in USP 27–NF 22 **(2004)**
  - Revised in USP 34–NF 29 **(2011)**
    - Incorporated *USP* ⟨1075⟩ *Good Compounding Practices* (subsequently omitted)
  - Revision Bulletin **(2014)**
    - Clarified that the Beyond-use-dates (BUDs) in ⟨795⟩ are specific for nonsterile preparations
      - and do not apply to sterile preparations

14

History of ⟨795⟩

Current Revision

General Chapter ⟨795⟩

- Proposed Revision **(2018)**
  - >2000 comments
- Published Revision **(2019)**
  - Appealed and remanded back to Compounding EC
  - Additional stakeholder feedback obtained
- Proposed Revision **(2021)**
  - Addressed additional comments
- Published Revision **(2022)**
  - Became effective November 1, 2023
  - Only administrative revisions since then

Compounding EC Considerations

- Previous revisions including remanded revision served as a template
- Reflects current scientific considerations and best practices
- Responds to stakeholder input
- Clarifies topics frequently queried and misunderstood
- Aligns with ⟨800⟩ and ⟨797⟩

15

3

History of ⟨797⟩: *Pharmaceutical Compounding—Sterile Preparations*

Brenda Jensen, CPhT, CNMT, MBA
Chair, 2025-2030 USP Compounding Expert Committee

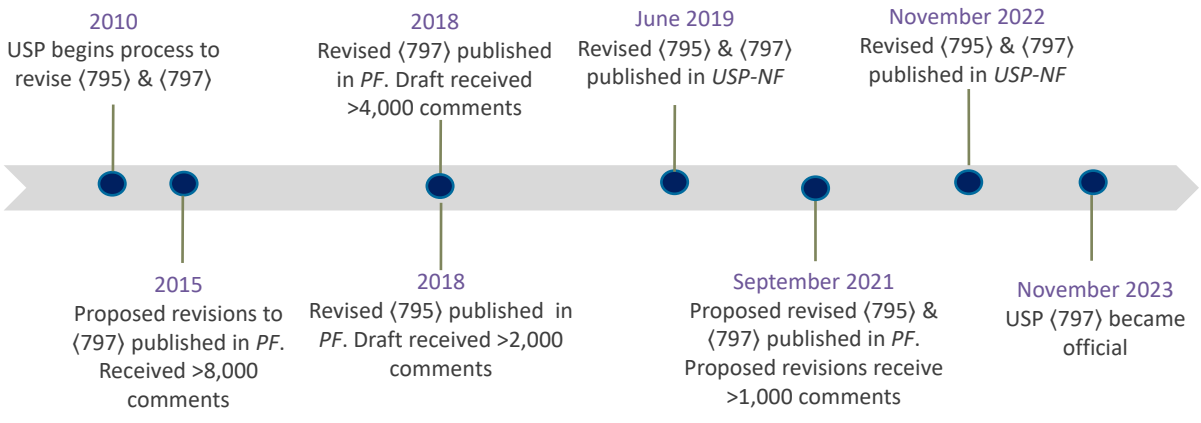
16

History of ⟨797⟩

- **First Sterile Compounding Standard**
  - ⟨1074⟩ *Dispensing Practices for Sterile Drug Products Intended for Home Use* **(1992)**
  - ⟨1206⟩ *Sterile Drug Products for Home Use* **(1995)**
- **General Chapter ⟨797⟩**
  - Published in USP27-NF22 **(2004)**
    - Incorporated ⟨1206⟩
    - Revised in USP USP31-NF26 2S **(2008)**

17

History of ⟨797⟩ Revisions



18

History of ⟨797⟩ Approach to Revisions

- **Stakeholder Engagement**
  - Reviewed feedback and public comments
  - Held stakeholder semi-structured interviews (May 2020)
  - Roundtable session (July 28, 2020)
  - Open forum (September 15, 2020)
- Identified key stakeholder engagement discussion topics as a framework
- Also had general considerations throughout the review process
  - Scientifically robust, risk-based approach to assigning BUDs
  - Physical and chemical stability considerations
  - Sterility assurance in ⟨797⟩
  - Operational implications
  - Balancing the need for patient access to cost-effective compounded preparations with rigorous quality standards
  - Implications on regulatory oversight and enforcement

 | 19

19

History of ⟨800⟩: *Hazardous Drugs—Handling in Healthcare Settings*

Gigi Davidson, BSPharm, DICVP
Member, 2025-2030 USP Compounding Expert Committee
Former Chair, 2010-2020 USP Compounding Expert Committee

 | 20

20

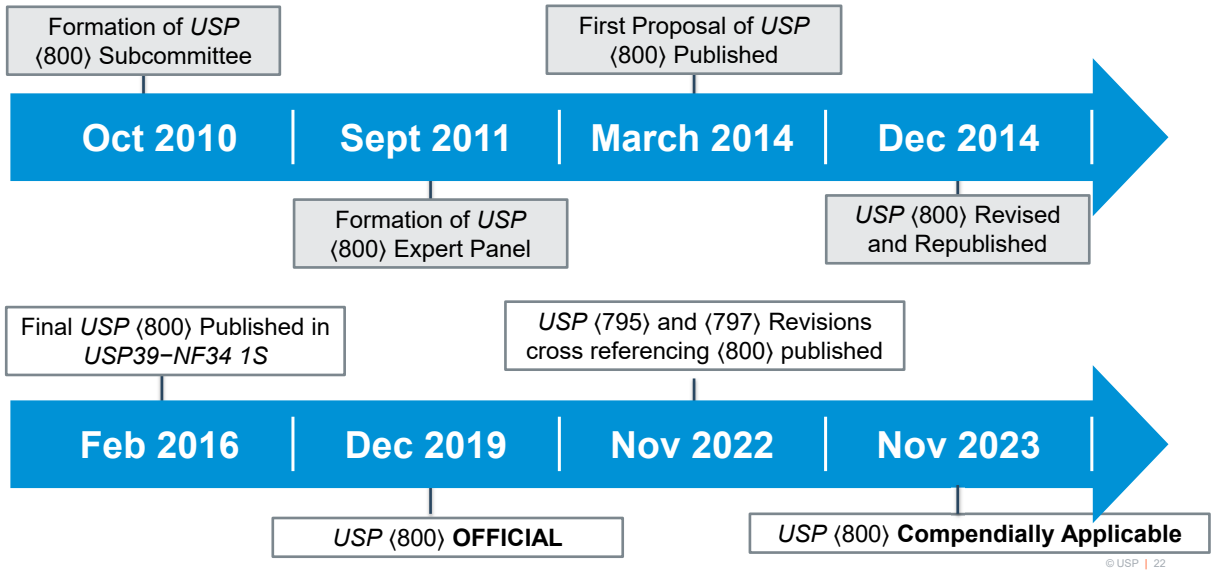
History of <800>

2008

- A veterinarian whose life had been interrupted by cancer wondered if unprotected exposure to cytotoxic agents was the cause
- He and his colleagues had never been cautioned to handle chemotherapeutic drugs with personal protection
- Took his concerns to USP leadership and planted the idea of developing national hazardous drug handling standards that would protect all health care workers, including veterinarians.
- USP executive leadership embraced the idea and placed the development of the standards on the workplan of the Compounding Expert Committee in 2010

21

History of ⟨800⟩



22

Self-assessment Question #2

What primary need led to the development of USP Chapters ⟨795⟩, ⟨797⟩, and ⟨800⟩,respectively?

A. To update practices based on advances in nonsterile compounding, strengthen enforcement of pharmacy regulations, and improve environmental sustainability in health care settings.

B. To establish quality standards for nonsterile compounding, create training requirements for sterile compounding personnel, and standardize hazardous drug disposal practices.

C. To standardize nonsterile compounding practices, address risks associated with sterile compounding, and protect health care workers from hazardous drug exposure.

D. To strengthen compounding quality standards, reduce variability in sterile preparation testing, and expand accreditation requirements for health care facilities.

23

5

Compounding Expert Committee Workplan: *⟨1163⟩ Subcommittee*

Jessica L. Hawkins, PharmD, BCPS, BCSCP
⟨1163⟩ SC Chair, 2025-2030 USP Compounding Expert Committee

24

⟨1163⟩ Subcommittee: History of ⟨1163⟩ Chapter

- **Originally developed in 2007**
  - Two compounding expert committees
  - Introduced the concept of quality assurance in compounding
- **2011 Revision**
  - Introduction expanded from 4 to 9 integrated components
  - New sections
    - Training
    - Cleaning, Disinfecting, & Safety
    - Containers, Packaging, Repackaging, Labeling, & Storage
    - Outsourcing
    - Responsible Personnel
  - Added guidance on physical testing of dosage units
  - Increased Standard Operating Procedures (SOPs) list from 13 to 21
  - Enhanced tables:
    - Testing methods and procedures
    - Testing methods for bulk substances and dosage forms

25

⟨1163⟩ Subcommittee: Workplan

2015 – 2020

- Prepared recommendations for improving the chapter and moving forward

2020 – 2025

- Compounding EC started working on the revision
- Draft work underway

2025 – 2030

- Notice of Intent to Revise published
- Goal is to publish the revision on this cycle

26

⟨1163⟩ Subcommittee: Notice of Intent to Revise

- **Goals of Revision**
  - Provide information framework for compounders adhering to USP ⟨795⟩, ⟨797⟩, and ⟨800⟩
- **Structural Changes**
  - Name change with a main chapter **⟨1163⟩** supported by a new subchapter **⟨1163.1⟩**
- **Timeline**
  - Proposed revision published for public comment: **Pharmacopeial Forum 53(5) – Sep/Oct 2027**
  - Public comment period closes: **November 30, 2027**
  - Expected official effective date: **December 1, 2028** (if no adverse comments)
- **Contact:** CompoundingSL@usp.org

27

Compounding Expert Committee Workplan: *Technology Subcommittee*

George R. Smith, PharmD BCPS, BCSCP
Technology SC Chair, 2025-2030 USP Compounding Expert Committee

28

Technology Subcommittee: Use of Technology

⟨795⟩ & ⟨800⟩ *Use of Technology*

- **Technology is not discussed in these chapters**
- However, alternative methods or procedures were discussed in ***USP General Notices and Requirements:***
  - **Section 6.30 Alternative and Harmonized Methods and Procedures:**

    "*. . .The alternative method or procedure must be fully validated (see Validation of Compendial Procedures ⟨1225⟩) and must produce comparable results to the compendial method or procedure within allowable limits established on a case-by-case basis.*"

⟨797⟩ *Use of Technology*

- ***USP* ⟨797⟩:** "The use of technologies, techniques, materials, and procedures other than those described in this chapter is not prohibited as long as they are noninferior to those described herein and validated for the intended purpose (eg, *Validation of Alternative Microbiological Methods* ⟨1223⟩ and *Validation of Compendial Procedures* ⟨1225⟩)."
- **Purpose:** ⟨797⟩ supports use of technology but guidance is needed to determine noninferiority and validation

29

Technology Subcommittee: Workplan

- Subcommittee of the 2020-2025 CMP EC began drafting the first *Stimuli* article on Technology
- The work continued into the 2025-2030 cycle for the *Stimuli* article
  - September 1, 2026, is the target publication in *Pharmacopeial Forum (PF)*
  - ***PF* Public Commentary Period** ends on November 30, 2026

30

Compounding Expert Committee Workplan:
Monograph Development Subcommittee

Edmund J. Elder Jr, PhD, RPh
Vice Chair, 2025-2030 USP Compounding Expert Committee

 | 31

31

MDSC: ⟨1191⟩ Revision Workplan

Stability Reference Document for Pharmaceutical Compounding[a]

Rebecca Lisa Diggs Ashworth[b], Phil Ayers[c], Gus Bassani[d], Brett Cordes[e], Gigi Davidson[f], Edmund J. Elder, Jr.[g], Blaine Groat[g], Kevin N. Hansen[h], Patricia Kienle[i], Brenda Jensen[k], Elizabeth Rebello[l], Rick Rhoads[m], Robert Shrewsbury[n], Connie Sullivan[o], Vanessa Pinheiro[g]
Correspondence should be addressed to: Blaine Groat, Senior Scientist II, US Pharmacopeia, 12601 Twinbrook Parkway, Rockville, MD 20852-1790; email: blaine.groat@usp.org.

ABSTRACT
This *Stimuli* article is intended to assist the compounder in understanding the 2023 revisions to *USP* general chapters:

- Pharmaceutical Compounding—Nonsterile Preparations ⟨795⟩
- Pharmaceutical Compounding—Sterile Preparations ⟨797⟩
- Hazardous Drugs—Handling in Healthcare Settings ⟨800⟩
- Radiopharmaceuticals—Preparation, Compounding, Dispensing, and Repackaging ⟨825⟩

This *Stimuli* article is not part of the referenced chapters, is not a comprehensive overview of the chapters, and is not intended to be used in place of chapters. It is a resource to help compounders further understand and perform stability studies used to establish or extend the Beyond-Use Dates (BUDs). The stability of a compounded preparation has several factors that must be evaluated by compounders utilizing or developing stability studies to determine the BUD. This does not reflect the opinions of the Compounding Expert Committee (CMP EC) on further revisions to the chapters. Please note that this article is not official United States Pharmacopeia (USP) and National Formulary (NF) text and is not intended to be enforceable by regulatory authorities. Users must refer to the *USP–NF* for official text. Questions may be sent to CompoundingSL@usp.org.

INTRODUCTION

Stability can be defined as the extent to which a compounded dosage form retains the same properties and characteristics that it possessed at the time of its compounding, within specified limits, and throughout its period of storage [i.e., beyond-use date (BUD)] and use. The stability of a compounded preparation therefore has many connotations: 1) The active pharmaceutical ingredient (API) must remain stable. That is, the API must be present in the intended form and concentration as indicated on the labeling; 2) is that the entire preparation remains stable; 3) The preparation remains stable during its use.

This *Stimuli* article details available references that detail types of instability (e.g., physical, chemical, or microbiological, etc.), and analytical methods are made available to determine the composition of preparations or the ingredients in a preparation.

Sections of *Pharmaceutical Compounding—Nonsterile Preparations ⟨795⟩* and *Pharmaceutical Compounding—Sterile Preparations ⟨797⟩* detail the stability limits that can be assigned to nonsterile and sterile preparations. There is information in those chapters about BUDs that can be assigned if instability documented by analytical methods is not available for a preparation. These BUDs were built using risk assessments of analytical information for the different classes of preparations.

Compounded preparation stability is a primary concern of any compounder. Therefore, the scope of this *Stimuli* article is to provide helpful insights about various aspects of stability and provide information about appropriate analytical methods and tests that can be used to assess

⟨1191⟩ Revision

- To assist compounders to further understand and perform stability studies used to establish or extend beyond-use dates
- Goal is to revise USP ⟨1191⟩ with principles from 3 Stimuli article:
  - *Formulation Development Reference Document for Pharmaceutical Compounding*
  - *Stability Reference Document for Pharmaceutical Compounding*
  - *Flavoring – Best Practices, Regulatory Considerations, and Innovative Approaches in Pharmaceutical Compounding*

32

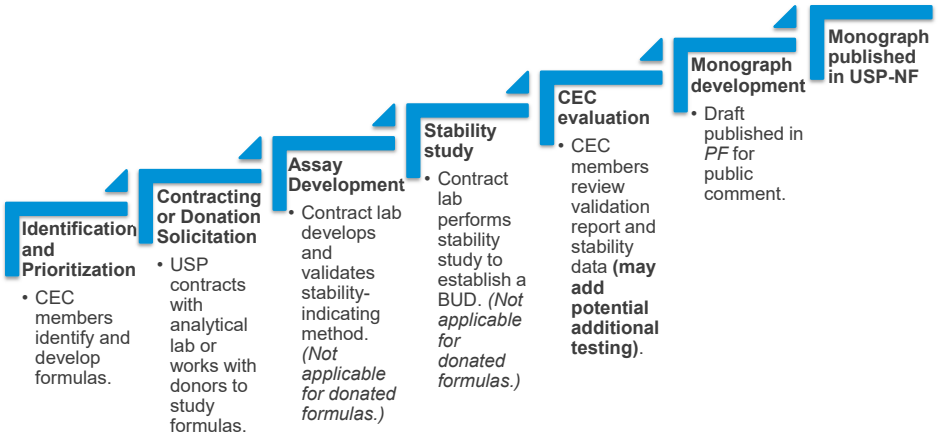
⟨1191⟩ Subcommittee: Notice of Intent to Revise

- **Aims of Revision**
  - Strengthen and clarify guidance for compounders on the design and application of stability studies when establishing or extending BUDs in ⟨795⟩ and ⟨797⟩.
- **Structural Changes**
  - The **⟨1191⟩** title may be updated to better reflect the expanded scope addressed in the revision.
  - The committee is also considering further structural enhancements to improve clarity and usability of the chapter that would be supported by two subchapters **⟨1191.1⟩ and ⟨1191.2⟩** to make material more accessible and enable more efficient future updates by allowing focused revisions to specific sections.
- **Proposed Timeline**
  - Proposed revision published for public comment: **Pharmacopeial Forum 53(5) – Sep/Oct 2027**
  - Public comment period closes: **November 30, 2027**
  - Expected official effective date: **December 1, 2028** (if no adverse comments)
- **Contact:** CompoundingSL@usp.org

33

MDSC: Compounded Preparation Monographs

How CPMs are developed



34


8
Final Thoughts
© USP | 35

35


Final Thoughts: Healthcare Quality and Safety (HQS)
2025-2030 Council of Experts
<GC>
Biologics
Biologics – Therapeutic Peptides, Oligonucleotides, and Complex Carbohydrates
Rosario Lobrutto
Biologics – Therapeutic Proteins
Kenneth R. Miller
Biologics – Vaccines
Mark van Ooji
Biologics – Cell & Gene Therapies
Lili Belcastro
Small Molecules
Small Molecules – Therapeutic Areas 1
Mary Seibel
Small Molecules – Therapeutic Areas 2
Robert G. Buice Jr.
Small Molecules – Therapeutic Areas 3
Eric Kesslen
Small Molecules – Therapeutic Areas 4
Partha S. Mukherjee
Small Molecules – Therapeutic Areas 5
Justin Pennington
Small Molecules – Therapeutic Areas 6
Allan D. Bokser
Excipients
Excipient Monographs 1
Vivek S. Dave
Excipient Monographs 2
Barbara R. Serr
Excipient Chapters
Richard Creekmore
General Chapters
General Chapters – Dosage Forms
Kevin Warner
General Chapters – Chemical Analysis
Anthony C. Bevilacqua
General Chapters – Microbiology
Ed C. Tidswell
General Chapters – Packaging & Distribution
Renaud Janssen
General Chapters – Statistics
Charles Tan
General Chapters – Pharmaceutical Analysis Lifecycle & Data Science
Jaime Marach
General Chapters – Materials Physical Properties Characterization
Eloise Welfare
Healthcare Quality & Safety
Healthcare Safety, Quality, & Nomenclature
Melody Ryan
Compounding
Brenda Jensen
Healthcare Information & Technology
Leslie Lenert
Personalized Medicines
Sara L. Rogers
Dietary Supplements & Herbal Medicines, Food Ingredients
Botanical Dietary Supplements & Herbal Medicines
Thomas Brendler
Non-Botanical Dietary Supplements
Raimar Loebenberg
Dietary Supplements Admission, Evaluation, & Labeling
Amy L. Roe
Food Ingredients
James Brooks
© USP | 36

36

37

Final Thoughts: Stay Connected!

- Sign up for updates to ⟨795⟩, ⟨797⟩, and other topics related to USP Healthcare Quality and Safety Standards
  - *https://www.usp.org/hqs-signup-form*
- Attend the Compounding Expert Committee's Official Meetings
  - *https://www.usp.org/search/events*
- Upcoming Events:
  - August 25: Ask the Expert: Compounding Query Webinar
  - October 26 and 27: USP 5th Annual Compounding Workshop

38

Self-assessment Question #3

Which of the following is the best way for stakeholders to engage with USP's workplans and contribute to future standards development?

A. Review proposed revisions and Stimuli articles in *Pharmacopeial Forum,* submit feedback during the public comment periods, and engage with USP through the provided communication channels.

B. Monitor the publication of official chapters and provide feedback after implementation to inform future revision cycles.

C. Participate primarily through professional organizations that may share feedback with USP during revisions.

D. Focus on implementing current standards, since Expert Committees play the primary role in developing and revising USP chapters.

 | 39

39

Thank you

Contact us at CompoundingSL@usp.org

The standard of trust

40

Q&A

You may use the Q&A tool on your screen to submit questions to the presenter.

Our host will read the questions out loud in the order they are received.

NABP

41

Submit Your CPE Claim

1. Claim your CPE credit by signing in to NABP's submission site: ***https://nabp.pharmacy/claimcpe*** (case-sensitive)
   If you do not have a login for NABP's CPE submission site, you will need to create an account.
2. Click on the "Live CPE" tab
3. Select the webinar from the Live Meetings and Conferences list
4. Enter the session code provided at the end of the webinar
5. Complete the course and speaker evaluations
6. Select the appropriate credit (pharmacist or pharmacy technician)
7. Enter your NABP e-Profile ID and date of birth and certify that the information is correct
8. Click the claim button

Claims must be submitted by noon on October 19, 2026.

NABP does not submit CPE credit claims on participants' behalf. Attendees must follow the steps above by October 19, 2026, in order for the credit to appear in CPE Monitor®.

ACPE

NABP® and NABP Foundation® are accredited by the Accreditation Council for Pharmacy Accreditation (ACPE) as providers of continuing pharmacy education (CPE). ACPE provider number: 0205.

1.5 contact hours (0.15 CEU)
0205-0000-26-088-L07-P
0205-0000-26-088-L07-T

The handout for today's presentation can be found at:
www.nabp.pharmacy/webinar

Questions about submitting your claim? Please contact CPE@nabp.pharmacy.

NABP

42