Comment Lifecycle

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Where does my comment go?

Agenda

- What happens to my comment after I press send?
- When can I expect a response to my comments?
  - Timing based on Pharmacopeial Forum cycles
- What will that response be and where can I find it?
- Resources
What happens to my comment after I press send?

Review by staff and Volunteers

- Comments go to the responsible Scientific Liaison (SL)
- Commenter receives an initial receipt letter (FDA exempt)
- SL compiles and summarizes comments
- Expert Committee (EC) reviews comments
- SL and Expert Committee decide whether and how to move forward with the proposal based on comments
  - If it doesn’t move forward it will either be deferred or canceled
Expert Committee Comment Review

- The responsible Expert Committee reviews all comments received and decides whether to incorporate each
  - 7.05 (c) Consideration of Comments. After the comment period expires, the Expert Committee and Scientific Liaison review and consider the comments, and revise the proposal as needed. A proposal is not republished in PF if the changes made to the proposal are in response to comments received and do not create new compendial requirements that were not contained in the initial PF.
Commentary Rules

- 7.05 (d) Comment Summary.
  - Where a proposal appears in the PF and is approved for publication in the USP-NF, a summary or abstract of each significant type of comment received and a succinct response to the comment from the Expert Committee or CoE Chairperson shall be posted on USP’s website.

- Comment summary is known as Commentary and publishes on the website the same day as the publication.
  - Commentary for USP 42 will publish November 1, 2018.
Commentary notes

‘Comment to Commentary’ timing depends on a number of factors

- According to the rules, commentary is only published for comments received on the PF proposal directly prior to publication in the USP–NF
  - If you comment on the first PF publication and it goes to USP–NF after a second PF publication, your comments will be taken into account in the republication in PF and will not appear in commentary
    - Briefings of subsequent proposals may serve as a communication route for comments received

Timing from ‘Comment to Commentary’

- Assuming that the proposal moves forward after one PF publication, with no deferrals, commentary is posted 7-9 months after the close of the comment period
  - In that timing the EC is review comments, balloting, and the Publications department is preparing the publication
- Because two issues of PF feed into each publication and there three publications per year, the time between comment period close and commentary varies

Comments on sections not being revised

- According to the Rules and Procedures, comments made to sections of a proposal that are not under review are generally not included in the commentary unless the comment results in a change to the text
Comment lifecycle examples

- Single PF publication
  - PF 43(6) Nov/Dec 2017
  - Comment period closed January 31, 2018
  - Comments reviewed through late Spring
  - Balloting in early Summer with PF 44(1) proposals
  - Publication of USP42–NF37 and commentary November 1, 2018
    - Total time from comment close to commentary: 9 months
    - A comment submitted to PF 44(1) ballots at the same time and would have a 7 month lifecycle

- More than one PF publication
  - Comment period closes
  - Decision to defer initial proposal and publish in a later PF
    - Minimum 4 months elapse between initial and subsequent PF publication
    - Time between initial and subsequent PF publication varies based on time required to develop revisions
  - Comments to the initial proposal are generally reflected in the subsequent proposal and/or briefing
  - If the subsequent proposal moves forward to ballot, comments to that proposal will follow the 7-9 month timeline, above
    - Only comments to the most recent proposal are published in commentary
  - Minimum 11 months from close of the first comment period to publication of commentary when two rounds of PF publication are needed
    - And comments to the initial proposal will not appear in that commentary
Resources

Newsletter and websites

- Subscribe to Compendial Updates to receive notification of Commentary posting, Accelerated Revision postings, and other compendial topics

- Find commentary for each USP–NF publication
  - [https://www.uspnf.com/official-text/proposal-statuscommentary](https://www.uspnf.com/official-text/proposal-statuscommentary)
  - This page also has lists of what is moving forward into the coming publication and what is not under each: Revisions, Deferrals, and Cancelations
  - Cumulative List also found here

- More resources on the PF landing page
  - Login at uspnf.com

Welcome to the Pharmacopeial Forum (PF) Online

These pages contain proposed revisions and additions to the USP–NF as well as Stimuli articles for which USP is seeking public comments. Your comments about these proposed changes provide essential public input to help shape future USP–NF chapters and monographs, ensuring that all users have access to the most current, relevant, and validated data. We encourage you to review all articles of interest and provide your comments for improvement.

For the following information previously published in PF, please click here:

- Policies and Announcements
- Interim Revision Announcements
- IAP Reference Standard Information
- Errata
- Previous PF Proposals RNS Landing
- Cancelled Proposals
- POG Harmonization Process and Harmonized Standards (Stage B)

Note that POG proposals from the European and Japanese Pharmacopoeias may be found at

- [Pharmacopoeia Online](https://www.usp.org/newsletter-and-information)
- [Japanese Pharmacopoeial Forum](https://www.usp.org/newsletter-and-information)

Nomenclature will be updated through the annual USAN publication and will not be included on the USP website

- Chromatographic Column

If you are a first time user of the PF, please see “How to Use PF.”

If you are interested in submitting a Stimuli article, please see the Conflict of Interest Disclosure Form for Stimuli Authors.

For additional information regarding the USP Reagent Linking Project, click here.
USP 41-NF 36

Supplement 1

IRAs in PF 43(3)
- No IRAs were published for comment in PF 43(3)

IRAs in PF 43(2)
- Deferrals: Valine, and Levocetirizine Dihydrochloride
- Cancellations: None
- Commentary: PF 43(2)

USP 41-NF 36

- Revisions (posted 28-Jul-2017)
- Deferrals (posted 28-Jul-2017)
- Cancellations (posted 28-Jul-2017)
- Index (posted 01-Nov-2017)

IRAs in PF 43(1)
- Deferrals: None
- Cancellations: None
- Commentary: PF 43(1)

IRAs in PF 42(6)
- Deferrals: None
- Cancellations: None
- Commentary: PF 42(6)

USP 40-NF 35

Supplement 2

- Approvals (posted 28-Apr-2017)
- Deferrals (posted 28-Apr-2017)
- Cancellations (posted 28-Apr-2017)
- Commentary (posted 01-Jun-2017)
- Index (posted 01-Jun-2017)
Coming changes to PF

Pharmacopeial Forum (PF)

The PF Online will soon be moving to a new online platform!

USP will be moving the Pharmacopeial Forum (PF), starting with PF45(1), to the new electronic platform, similar to the new USP-NF Online.

As a result, you will experience the same benefits of the new USP-NF Online including:

- Customized dashboard
- Improved search with real-time filtering
- Optimized navigation
- Personalized bookmarks
- E-mail alerts

The new PF Online will contain that same content that you would expect such as Stimuli Articles, In-Process Revisions, and Proposed Interim Revision Announcements.

Want to help shape the next generation of PF Online?

Click here to share your input and help USP create a better experience for you as you find content and submit your comments!

Click here for Frequently Asked Questions (FAQs) on the new USP-NF Online including features, how to gain access, and
Thank You

Empowering a healthy tomorrow