Overview of the Public Commenting Open Forum Held March 29, 2022

Jessica Simpson, MPH

April 11, 2022





Main theme: stakeholder input



- Discussed where stakeholder feedback has been received, what was heard, and how it's been implemented thus far
- Reviewed standard setting process and opportunities for engagement throughout
- Mural session to gather more feedback and prioritize ideas we've heard
- Reviewed upcoming comment form and asked for further input
- USP hears stakeholder feedback and is continuing to act on it



Stakeholder input



- Compendial Process Improvement Project Team has provided recommendations to USP throughout its history
- Multiple surveys
 - USP customers, PNP attendees, PF users, USP-NF users
- FDA Quarterly meetings
- Customer Advisory Board
- Prescription/Non-Prescription Stakeholder Forum
 - Industry presentations
 - Breakouts
- User interviews

Stakeholder input

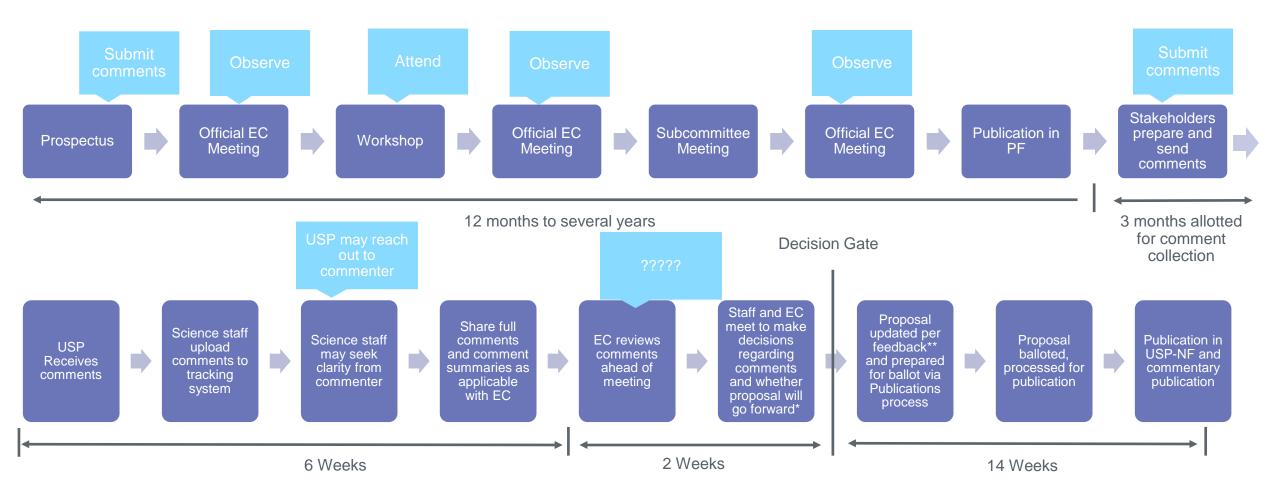


- How to have an impact on standards—early in the process and during PF
- Want to know more about commenting
 - How to comment effectively
 - Understand the comment process
 - Dispensation of comments
- Desire for transparency in the standards-setting process
- Implement a standardized comment form
- Incorporate line numbers in PF
- Want more opportunities to communicate with Expert Committees and more feedback on comments

Comprehensive engagement example and timelines



Example standard goes through one PF publication, moves to ballot, and is approved at ballot



^{*}these decisions are made following Robert's Rules

^{**}changes must adhere to Rules and Procedures of the CoE

Mural session outcome





Current/Future of Public Comments Process

Intent to Revise.)

Our Goal is to identify best solutions to improving public commenting for both USP and Stakeholders



Mural session outcome



Question #2: What could the USP do to get Stakeholders to utilize more fully the current opportunities for engagement/comments-sharing regarding standards development?

Distinguish level of impact the revisions presents to help stakeholders understand implications early on.

Industry has to process multiple changes. Having to engage multiple times on each topic is not effective and is not needed in with other pharmacopoeies. One or a limited number of effective opportunities should a surjicient.

Comments that any go against stiff may be proporing trend to be requisit highlighted during Open discussions by LS Staff as to what LSP may want to use that discussions is a weight or indeed of wang public discussions to verigit paint LSP straking.

If USP could increase the frequency with which it responds to comments from individual stakeholders, it would go a long way to reinforcing the benefit of commenting.

home page and/or in

official USP-NF

USP should definitely bring up new proposals for things that will have brand industry impact at a workshop or Open Forum BEFORS stating to work on connecting to make our ethal industry seed whee in thinking a chandled or in what the proposals is about or in what the proposals is about. Smaller companies are not able to test proposed methods if they do not have the equipment from the method previously first table to the transition of the including equipment. It will allow all companies to test methods and comment or methods and companies to test methods.

Pour EC meeting classes with enough time for observers to spilly to observe- for example, the Biological Monographic 3 convenience met today, but that meeting was not posted on the calendar with enough time to allow for observers. Attending selevant EC meetings it helpful to know allows upcoming revisions and when comment periods will Engage the manufactures if using their samples for standardsetting If USP ong is call used as the primary tool for announcing resistors, they deserve more presence and violatity on USP ong its home page. This seems like it would be the primary dauge of rariffs to the size too. Meaning, the home page should reflect USP's standards earting work more standards earting work more than dead earting earting than dead earting earting than dead ea

resources are limited, reduce change for the sake of change. USP should do more to understand the impact of proposals and changes on industry. More engagement with manufacturers and users is needed. Be your question about only enquipment. There seem to be more proposal intraced by USI soften that is closely about the Charges. These changes are no always recentury from a technic analytical perspective, cloner improve patient safely, inclusive apparent experiment for requirement and experiment that require acting resources and consenter to the tool the second.

Engage earlier

Frequency of Commentary Increased, make informatin more accessible and timely

Make sure to engage on right topics in the right

Themes:

Engage to understand impact to industry

Suggest including a link to "Events and Training" and "Get Involved" on USP-NF home page and/or in help drop down on the official USP-NF Themes:
Engage to understand impact to Industry

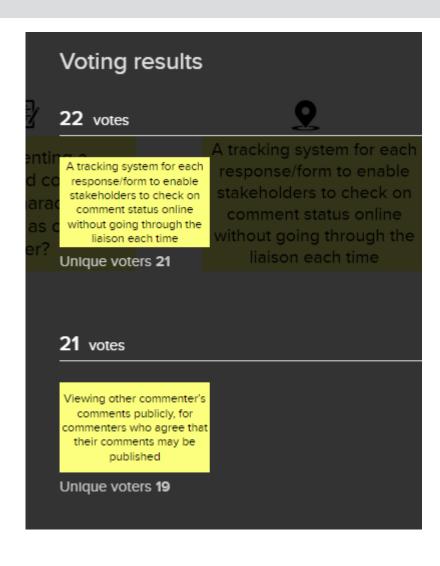
Engage earlier

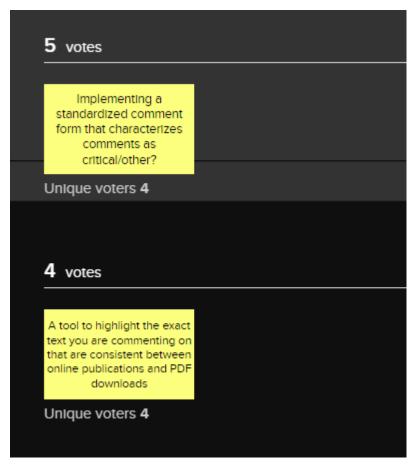
Frequency of Commentary increased, make information more accessible and timely

Make sure to engage on right topics in the right time

Mural session outcomes





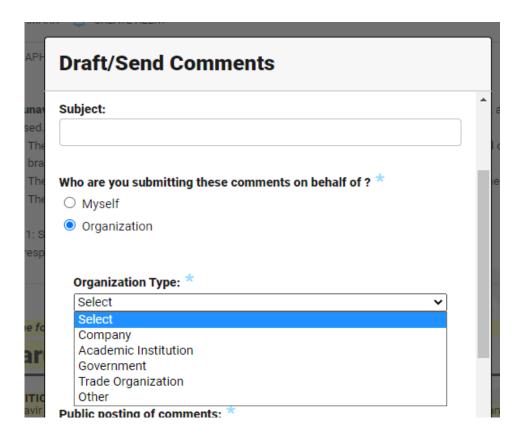


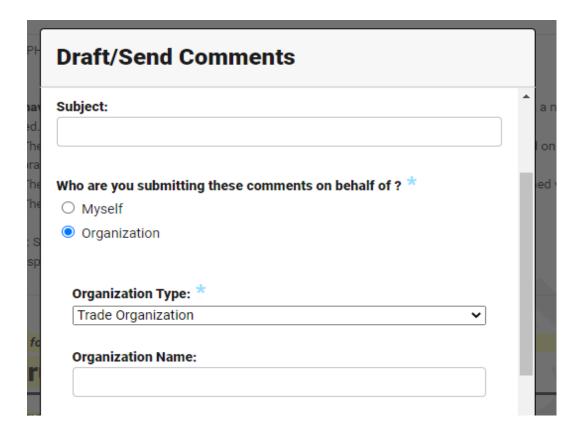
Asked stakeholders to use
 2 votes to prioritize 4
 previously submitted ideas

Comment form updates launching June 2022



Launching June 2022





Saving draft and accessing past comments



Launching June 2022

My Resources

MY VIEWING ACTIVITY BOOKMARKS COMMENTS					
DOCUMENT \$	COMMENTING STATUS	COMMENTING DATE \$	PUBLICATION \$	SUBMISSION STATUS \updownarrow	LAST MODIFIED \$
Bromelain PF 47(6)	Commenting Open	01-Nov-2021 to 31-Jan- 2022	PF 47(6)	Draft	28-Mar-2022
Norflurane PF 47(6)	Commenting Open	01-Nov-2021 to 31-Jan- 2022	PF 47(6)	Draft	28-Mar-202
Bromelain PF 47(6)	Commenting Open	01-Nov-2021 to 31-Jan- 2022	PF 47(6)	Draft	28-Mar-2022
Polyethylene Glycol 30 Dipolyhydroxystearate 5 PF 47(6)	Commenting Open	01-Nov-2021 to 31-Jan- 2022	PF 47(6)	Submitted	24-Mar-2022
Bromelain PF 47(6)	Commenting Open	01-Nov-2021 to 31-Jan- 2022	PF 47(6)	Draft	24-Mar-2022
⟨1604⟩ Presentation of Aerodynamic Particle Size Distribution (APSD) Measurement Data for Orally Inhaled Drug Products PF 48(1)	Commenting Open	03-Jan-2022 to 31-Mar- 2022	PF 48(1)	Draft	01-Mar-2022
⟨1604⟩ Data					

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Resources



- Rules and Procedures of the Council of Experts
- Request for Revision information and guidelines
 - Stakeholders are welcome to submit information and recommendations for developing new monographs or revising proposed or existing official monographs. Revisions may be to an entire monograph or specific monograph tests, procedures, and/or acceptance criteria. USP also welcomes proposed revisions to general chapters.
- Commentary location and schedules
- Overview of the USP-NF training webinar (free, 49 minutes)
- Accelerated Revision Process and Guideline
 - The Rules and Procedures of USP's Council of Experts specify processes that can be used to make revisions to the USP–NF official more quickly than through USP's standard revision process. These accelerated processes include Errata, Interim Revision Announcements (IRAs), and Revision Bulletins.

Thank You



Empowering a healthy tomorrow