

[Update: Reporting Thresholds in USP–NF Monographs](#)

Type of Notice: General Announcement

Posting Date: 23–Jul–2020; updated 12–Oct–2020*

This is an update for the [Reporting Threshold in USP–NF Monographs: Proposed Policy Change](#) Compendial Notice, posted on the USP website for public comments from August 13, 2019 to December 31, 2019. In order to facilitate further discussion, USP published [comments](#) received from 22 stakeholders who provided permission.

Based on the comments received, USP determined that removal of reporting thresholds from monographs needed further stakeholder engagement before any policy changes could be instituted. Thus, USP intends to host a virtual Roundtable in 2020 to continue the discussion on reporting thresholds and other impurities topics. USP looks forward to continued stakeholder engagement including from industry and U.S. Food and Drug Administration (FDA). Since this notice was originally posted, FDA has provided additional information and context related to reporting thresholds in [a letter](#) to USP.

In the interim, USP has taken the following actions:

- USP has forwarded previously deferred monographs with reporting thresholds to ballot so that the responsible Expert Committees can approve them for publication, thus ensuring quality updated standards for these substances and drug products.
- A new subsection was proposed for addition to the *General Notices and Requirements, 5.60.40. Impurities that are Unusually Toxic and/or Mutagenic*. The proposal was presented as a Proposed Interim Revision Announcement in *Pharmacopeial Forum* (PF) 46(3) [May-Jun 2020], which was open for public comment until July 31, 2020. The new subsection is intended to address potential safety concerns resulting from very toxic impurities not being controlled at appropriate levels in cases where a reporting threshold or disregard limit is included in official *USP–NF* monographs. Based on comments received, the proposal has been [deferred](#).
- General Chapters <476> *Control of Organic Impurities in Drug Substances and Drug Products* and <1086> *Impurities in Drug Substances and Drug Products* will be published in the *USP-NF* on November 1, 2020.

Should you have any questions or comments, please contact Elena Gonikberg, Ph.D., Principal Scientific Liaison, at EG@usp.org.

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*This Notice supersedes the previous Notice [posted here](#).