
[Pending Monograph Program](#)

The USP Pending Monograph process allows for development of monographs or monograph revisions for articles awaiting approval by FDA, and permits publication of these proposals in the Pharmacopeial Forum (PF) for notice and comment where required in accordance with USP's typical Request for Revision processes. Following publication in PF, these proposals remain in an unofficial status until FDA approval of the market application held by the donor. The Pending Monograph process is available where USP does not yet have a monograph for a drug, or where there is an existing monograph with requirements that are not met by a potential product under review by FDA, and allows the new or revised monograph to become official more rapidly than would be possible if development began only after final FDA approval. In cases where there is an existing monograph, it is common for the application holder to propose reconciliation between their product and the existing monograph requirement by donating analytical methodology and reference standard bulk material as necessary to revise the monograph. The USP Pending Monograph process allows for development of these proposals in a number of different ways, depending on the type of change that is needed and the amount of time available before the anticipated approval. In any case, these proposals remain in an unofficial status until FDA approval of the market application held by the donor.

Pending monographs are published for comment in the in-process revision section of the Pharmacopeial Forum. Pending Revisions which have been approved for potential adoption are published on the [Pending Monographs page](#).

Details of the approach are described in the [Pending Monographs Guideline \(originally effective June 1, 2015, updated November 30, 2017\)](#).

[Additional information can be found at: FAQs Pending Monograph Process](#)

If you are interested in working with USP to develop or revise a monograph through the pending monograph process, please contact pendingrevisions@usp.org.