

# Pending Monograph Process

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## Pending Monographs

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 Compendial Notices section of the USP-NF website under [Notices of Intent to Revise: Pending Monograph Program](#).

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

**If you are interested in working with USP to develop or revise a monograph through the pending monograph process, please contact [pendingrevisions@usp.org](mailto:pendingrevisions@usp.org).**

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### Related Resources

- [Publication & Comment Schedule](#)
- [Compendial Tools](#)
- [Download Reference Standards Catalog](#)
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# Pending Monograph Process (PMP)

## Background

- ▶ New guideline posted June 2015
- ▶ New guideline includes processes for revisions (with and without the need for comment) and new monographs
- ▶ New requirement that application must have been submitted to FDA at time of request
- ▶ “Old” pending monographs removed from website on June 29, 2017 and website decommissioned



## Pending Monograph Guideline

### Background

Pending Monograph process allows for development of monographs or modifications 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 the request for Revision processes. Following publication in *PF*, these proposals remain in a pending status until FDA approval of the market application held by the donor. This 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 applicant. This process allows for review by FDA, and allows the new or revised monograph to become official monograph. It 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 revisions to their product and the existing monograph requirement by donating analytical methods, technology and reference standard bulk material as necessary to revise the monograph. The Pending Monograph process allows for development of these proposals in a number of 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 a pending status until FDA approval of the market application held by the donor.

In some of these situations – the proposal of a new monograph or the proposal of a revision to an existing monograph – the donor may choose to donate the necessary material to USP.

- ▶ 32 proposals have been initiated
  - 17 proposals have been submitted to PF and/or for posting as NITR
    - 12 new, 2 revision (comment required), 3 revision (comment not required) in process
      - 13 currently active
      - 2 reached official status
      - 2 cancelled
  - 12 are scheduled for publication in future PF
  - 3 were withdrawn/cancelled prior to action for various reasons

- ▶ 3 currently posted as NITR

## Notices of Intent to Revise: Pending Monograph Program

For more information please see the [Pending Monograph Program webpage](#)

- [Clomipramine Hydrochloride Capsules \(Pending\)](#) (posted 28-Jul-2017)
  - [Diltiazem Hydrochloride Extended-Release Capsules](#) (posted 29-Sep-2017)
  - [Metronidazole Gel \(Pending\)](#) (posted 26-May-2017; updated 25-Aug-2017 )
- Diltiazem HCl ER Capsules recently made official on October 10th



## FAQs: Pending Monograph Process

1. What is the objective of the Pending Monograph Process (PMP)? ⊕
2. How was the Pending Monograph Process (PMP) developed? ⊕
3. How does the Pending Monograph Process work? ⊕
4. What will happen if an application for a pending revision that does not require comment is approved by FDA before the posting of the Notice of Intent to Revise? ⊕
5. What will happen if an application for a pending revision that does require comment is approved by FDA before the posting of the Notice of Intent to Revise? ⊕
6. What if updates to a posted Notice of Intent to Revise (NITR) are required? ⊕
7. Can any stakeholders comment on these proposals? ⊕
8. Will the monograph portions of Notices of Intent to Revise (NITR) posted to USP's website be updated to include subsequent changes to that monograph that are unrelated to the pending revisions (e.g., routine revisions, Errata, reference changes)? ⊕
9. What will happen if the request to revise a monograph is canceled after the monograph is posted to USP's website as part of a Notice of Intent to Revise (NITR)? ⊕
10. Will monographs posted to USP's website under the former Pending Monograph guideline and that never reached official status be made available to the public? ⊕

- ▶ Continue to clarify process and communication flows (sponsor/applicant and FDA)
- ▶ Remain in alignment with FDA as they progress toward possible Guidance

**Guidance Agenda:  
New & Revised Draft Guidances CDER is  
Planning to Publish During  
Calendar Year 2017**

(See the Good Guidance Practices (GGPs) regulation on this Web page or 21 CFR 10.115 for details about the Guidance Agenda.)

**CATEGORY — Pharmaceutical Quality/CMC**

- CMC Postapproval Manufacturing Changes for Specified Biological Products to be Documented in Annual Reports
- Container Closure Systems for Packaging Human Drugs and Biologics; Revised Draft
- Drug Master Files; Revised Draft
- Drug Products, Including Biological Products, That Contain Nanomaterials
- Harmonizing Compendial Standards with Drug Application CMC Approval Requirements Using the USP Pending Monograph Process

# Questions



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# Thank You



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