Proposal Status/Commentary

After a standard is proposed in *Pharmacopeial Forum* (*PF*) for public comment, the assigned Expert Committee reviews the comments and determines whether to approve the standard as a Revision, defer or cancel the standard. USP posts the lists of Revisions, Deferrals, Cancellations, and Commentary for each Issue of *USP–NF*.

- Revisions are items that have been proposed in *PF*, were approved by the assigned Expert Committee, and will appear in the noted publication. These items will have corresponding Commentary (see below).
- Deferrals are items that have been proposed in *PF* but are not yet approved by an Expert Committee. Items that have been deferred can be approved and published in a subsequent Issue of *USP–NF*. Some deferrals are later canceled.
- Cancellations are items that have been proposed in *PF* but will not move forward to ballot and subsequent publication. Canceled items may be re-proposed in a future *PF*.

Commentary is a summary of comments received and the assigned Expert Committee's responses. Commentary is published for Revisions only. In cases where proposals have been re-published in *PF*, only comments from the most recent *PF* publication are included in Commentary. Revisions, Deferrals, and Cancellations generally are posted prior to publication in *USP–NF Online*. Commentary is posted the same day the official text is published in *USP–NF Online*.

2020-2024 Cumulative List of USP-NF Revisions (updated 30-Aug-2024)

The Cumulative List of USP–NF Revisions provides updated information on all items approved, deferred, or cancelled during the 2020-2025 Cycle. Cumulative List from 2015-2020 cycle can be found <u>here</u>.

USP-NF 2025, Issue 1

• Deferrals (posted 23-Jul-2024)

- Cancellations (posted 23-Jul-2024)
- <u>Revisions</u> (posted 23-Jul-2024)

USP-NF 2024, Issue 3

- <u>Deferrals</u> (posted 26-Apr-2024)
- Cancellations (posted 26-Apr-2024)
- <u>Revisions</u> (posted 26-Apr-2024)
- Commentary (posted 03-Jun-2024)

USP-NF 2024, Issue 2 (currently official)

- Deferrals (posted 27-Dec-2023)
- Cancellations (posted 27-Dec-2023)
- <u>Revisions</u> (posted 27-Dec-2023)
- Commentary (posted 01-Feb-2024)

USP-NF 2024, Issue 1

- Deferrals (posted 29-Sep-2023)
- Cancellations (posted 29-Sep-2023)
- Revisions (posted 29-Sep-2023)
- Commentary (posted 01-Nov-2023; updated 26-Dec-2023)
- Monographs appearing in redesign format (posted 27-Dec-2023)

USP-NF 2023, Issue 3

- Deferrals (posted 28-Apr-2023)
- Cancellations (posted 28-Apr-2023)
- Revisions (posted 28-Apr-2023)
- Commentary (posted 01-Jun-2023)

Previous USP-NF Issues

Expand/collapse list

<u>USP-NF 2023</u>

<u>USP-NF 2022</u>

<u>USP-NF 2021</u>

<u>USP 43–NF 38</u>

<u>USP 42–NF 37</u>

<u>USP 41–NF 36</u>

<u>USP 40–NF 35</u>

<u>USP 39–NF 34</u>

<u>USP 38–NF 33</u>

<u>USP 37–NF 32</u>

<u>USP 36–NF 31</u>

<u>USP 35–NF 30</u>

<u>USP 34–NF 29</u>

USP 33-NF 28

<u>USP 32–NF 27</u>

USP 31-NF 26

USP 30-NF 25

Interim Revision Announcements

IRAs published in 50(4)

- Dimethyl Fumarate Delayed-Release Capsules
- Protriptyline Hydrochloride

IRAs published in 50 (3)

• Methylprednisolone Acetate Injectable Suspension

IRAs published in 50(2)

No comments were received when the following proposals were published

• Gadopentetate Dimeglumine Injection

The following proposal have comments under consideration

• Fexofenadine Hydrochloride and Pseudoephedrine Hydrochloride Extended-Release Tablets

IRAs published in 50(1)

- Commentary (posted 28-Jun-2024)
 - Clonidine Transdermal System
 - Norgestimate

IRAs published in 49(6)

- Commentary (posted 26-Apr-2024)
 - Acyclovir

- Zinc Acetate
- Zinc Chloride
- Zinc Sulfate

IRAs published in 49(5)

- Commentary (posted 26-Jan-2024)
 - o <64> Probiotic Tests
 - Lactobacillus acidophilus
 - Ligilactobacillus salivarius
- Commentary (posted 23-Feb-2024)
 - Sitigliptan Tablets

IRAs published in 49(4)

- Commentary (posted 26-Jan-2024)
 - Fosfomycin Tromethamine

IRAs published in 49(3)

No IRA proposals were published in PF 49(3)

- <u>Commentary</u> (posted 25-Aug-2023)
 - <660> Containers- Glass
 - <661.2> Plastic Packaging System for Pharmaceutical Use
- Commentary (posted 29-Sep-2023)
 - Phenoxybenzamine Hydrochloride

IRAs published in 49(2)

No comments were received when the following item was published:

• Bicalutamide Tablets

IRAs published in 49(1)

No IRA proposals were published in PF 49(1)

<u>Commentary</u> (posted 26-May-2023)
 · Ziprasidone Hydrochloride

Previous PF Issues

Expand/collapse list

Pharmacopeial Forum 48, Issues 1-6

Pharmacopeial Forum 47, Issues 1-6

Pharmacopeial Forum 46, Issues 1-6

Pharmacopeial Forum 45, Issues 1-6