Commentary

Interim Revision Announcements proposed in:
***Pharmacopeial Forum* 42(4) [Jul.–Aug. 2016]**

Posted, December 1, 2016; updated January 27, 2017[1]

In accordance with USP's Rules and Procedures of the 2015-2020 Council of Experts ("Rules") and except as provided in Section 7.02 Accelerated Revision Processes, USP publishes proposed revisions to the *United States Pharmacopeia and the National Formulary* (*USP–NF*) for public review and comment in the *Pharmacopeial Forum (PF),* USP's free bimonthly journal for public notice and comment. After comments are considered and incorporated as the Expert Committee deems appropriate, the proposal may advance to official status or be republished in *PF* for further notice and comment, in accordance with the Rules. In cases when proposals advance to official status without republication in *PF,* a summary of comments received and the appropriate Expert Committee's responses are published in the Revisions and Commentary section of the USP Web site at the time the official revision is published.

The *Commentary* is not part of the official text and is not intended to be enforceable by regulatory authorities. Rather, it explains the basis of Expert Committees' responses to public comments on proposed revisions. If there is a difference between the contents of the Commentary and the official text, the official text prevails. In case of a dispute or question of interpretation, the language of the official text, alone and independent of the Commentary, shall prevail.

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[1] The PF 42(4) IRA Commentary was updated on January 27, 2017 to include information on the previously deferred IRA for Doxorubicin Hydrochloride Injection. The Naproxen Sodium Tablets IRA is still deferred and comments on this proposal will be posted when this revision is published on the USP Website.

Comments were received for the following IRAs, when they were proposed in *Pharmacopeial Forum*:

Monograph/Section: Acitretin Capsules/Multiple Sections
Expert Committee: Chemical Medicines Monographs 3
No. of Commenters: 1
Comment Summary #1: The commenter recommended adding an identification test using Infrared Absorption in the *Identification* section.
Response: Comment not incorporated. The Expert Committee determined that the tests for identification in the monograph are acceptable.
Comment Summary #2: The commenter recommended tightening the limit for any unspecified impurity in the test for *Organic impurities*.
Response: Comment not incorporated. The unspecified impurity limit in the monograph is consistent with the FDA-approved requirement.

Monograph/Section: Doxorubicin Hydrochloride Injection/Impurities
Expert Committee: Chemical Medicines Monographs 1
No. of Commenters: 1
Comment Summary #1: The commenter indicated that the Acceptance criteria for Any other individual degradation product is different from what has been approved by FDA.
Response: Comment not incorporated. The acceptance criteria in the proposal are consistent with FDA-approved requirements.

Monograph/Section: Octyldodecanol/Impurities
Expert Committee: Excipient Monographs 2
No. of Commenters: 1
Comment Summary #1: The commenter indicated that in *Table* 4 the footnote for "2-Octyl-1-tetradecanol or 2-decyl-1-dodecanol" should reference footnote "a," rather than footnote "b."
Response: Comment incorporated.

No comments were received on the following when they were proposed in Pharmacopeial Forum:

Aspirin Boluses
Aspirin Delayed-Release Capsules
Aspirin Tablets
Buffered Aspirin Tablets
Aspirin Delayed-Release Tablets
Aspirin Effervescent Tablets for Oral Solution
Aspirin Extended-Release Tablets
Aspirin, Alumina, and Magnesia Tablets
Eprinomectin

Deferred Items:

Naproxen Sodium Tablets