Commentary

Interim Revision Announcements proposed in:
***Pharmacopeial Forum* 43(1) [Jan.–Feb. 2017]**

May 26, 2017

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

Monograph/Sections: Sulindac Tablets/Multiple Sections
Expert Committee: Chemical Medicine Monographs 2
No. of Commenters: 1

Comment Summary #1: The commenter recommended revising the impurity profile to be consistent with what has been approved by the FDA
Response: Comment not incorporated. The Expert Committee will consider future revisions to the monograph upon receipt of necessary supporting data.
Comment Summary #2: The commenter recommended adding the storage temperature –controlled room temperature in the *Package and Storage*
Response: Comment not incorporated. The Expert Committee will consider future revisions to the monograph.