Commentary

Interim Revision Announcements proposed in:
***Pharmacopeial Forum* 42(3) [May.–Jun. 2016]**

November 1, 2016

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/Section: Insulin Glargine/Product Related Substances and Impurity
Expert Committee: Biologics Monographs 1—Peptides
No. of Commenters: 1
Comment Summary #1: The commenter recommended revising the acceptance criteria for *Total insulin glargine related substances* to be consistent with what has been approved by the agency.
Response: Comment is not incorporated. The acceptance criteria referred by the commenter was based on a method that is different from the one currently described in the monograph. Because the method for the test *Product-Related Substances* was not changed, the acceptance criteria remained the same. In addition, the use of alternative methods is covered in *General Notices* 6.30. *Alternative and Harmonized Methods and Procedures*.

Monograph/Section: Pimozide/Impurities
Expert Committee: Chemical Medicines Monographs 4
No. of Commenters: 1
Comment Summary # 1: The commenter indicated that the limit for *Total Impurities* is not consistent with what has been approved by the FDA.
Response: Comment incorporated. The acceptance criteria for the *Total Impurities* is revised form NMT 0.75% to NMT 1.0%.

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

Insulin Glargine Injection
Pimozide Tablets