



Commentary

Interim Revision Announcements proposed in: *Pharmacopeial Forum* 40(5) [Sep.–Oct. 2014]

January 30, 2015

In accordance with USP's Rules and Procedures of the 2010-2015 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.

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Comments were received for the following IRA, when it was proposed in the *Pharmacopeial Forum*:

General Chapter/Sections: <121> Insulin Assays
Expert Committee(s): Monographs – Biologics and Biotechnology 1
No. of Commenters: 1

Comment Summary #1: The commenter indicated that the word “qualitative” should be changed to “quantitative” in sentence 5 of the *Introduction* which states, “Thus, a qualitative test in rabbits is included in this chapter, and its use is called for in the appropriate monographs.”

Response: Comment partially incorporated. The Expert Committee changed the word “qualitative” to “bioidentity” to refer to this procedure as a bioidentity test and to distinguish this procedure from the procedure for Rabbit Blood Sugar Method–Quantitative.

No comments received for the following IRAs, when they were proposed in *Pharmacopeial Forum*:

Ganoderma Lucidum Fruiting Body

Ganoderma Lucidum Fruiting Body Powder