

**Commentary – *Pharmacopeial Forum* 34(6) November- December 2008
Interim Revision Announcements to *USP 31-NF 26*
Revised October 31, 2008**

Revision proposals published in *Pharmacopeial Forum* often elicit public comments that are forwarded to the appropriate Expert Committee for review and response. In accordance with the Rules and Procedures of the 2005-2010 Council of Experts, revision proposals can advance to official status with minor modifications, as needed, without requiring further public review. In such cases a summary of comments received and the appropriate Expert Committee's responses are published in the *Commentary* section of the USP website at the time the revision becomes official. For those proposals that require further revision and republication in *Pharmacopeial Forum*, a summary of the comments and the Expert Committee's responses will be included in the briefing that accompanies each article.

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

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Monograph/Section(s): Estradiol and Norethindrone Acetate Tablets
Expert Committee(s): Monograph Development-Pulmonary and Steroids
No. of Commenter(s): 0
Content Summary: No comments received.
Reason for Revision #1: The impurity limits listed in the *Chromatographic purity* tests reflected release specifications rather than shelf life limits and were therefore revised to match the specifications in the approved FDA marketing application.
Reason for Revision #2: A test for *Uniformity of dosage units* was added.
Reason for Revision #3: The requirement for a photo-diode array detector for the Assay was replaced with a dual wavelength or equivalent detector.

Monograph/Section(s): Norgestimate and Ethinyl Estradiol Tablets
Expert Committee: Monograph Development-Pulmonary and Steroids
No. of Commenter(s): 0
Content Summary: No comments received.
Reason for Revision#1: The official *Assay preparation* procedure was replaced with a more rugged procedure.
Reason for Revision #2: The *Standard preparation* section and associated formulas were revised to correspond to the changes made in the *Assay preparation*.