Commentary – *Pharmacopeial Forum 35(3) May-June* 2009
Interim Revision Announcements to *USP 32-NF 27*
Revised April 15, 2009

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): Amantadine Hydrochloride Capsules/Dissolution
Expert Committee(s): Biopharmaceutics
No. of Commenter(s): 0
Content Summary: No comments received.
Reason for Revision #1: The Monograph was revised to include a *Dissolution test 2* for a generic version of this product recently approved by the U.S. Food and Drug Association. The chromatographic procedure in this test was validated using the RTX-1 or DB-1 brand of G1 phase. The retention times for naphthalene and amantadine hydrochloride are approximately 6 and 7 minutes, respectively.

Monograph/Section(s): Bupropion Hydrochloride Extended-Release Tablets/Dissolution
Expert Committee(s): Biopharmaceutics
No. of Commenter(s): 0
Content Summary: No comments received.
Reason for Revision #1: The Monograph was revised to include a *Dissolution test 8 f*or a product recently approved by U.S. Food and Drug Association.