Diphenhydramine Hydrochloride and Phenylephrine Hydrochloride Monographs

Type of Posting: Notice of Intent to Revise

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Expert Committee: Chemical Medicines Monographs 6

In accordance with section 7.04 (c) of the 2015–2020 Rules and Procedures of the Council of Experts, this is to provide notice that the Chemical Medicines Monographs 6 Expert Committee intends to postpone the *Organic Impurities* section in the following monographs:

- Diphenhydramine Hydrochloride
- Phenylephrine Hydrochloride
- Diphenhydramine and Phenylephrine Hydrochloride Tablets,
- Phenylephrine Hydrochloride Tablets

Comments were received regarding the inclusion of limits for unspecified impurities, which are scheduled to become official on May 01, 2016. Postponing these sections will allow time for further consideration by the Expert Committee.

In the previous version of this notice, posted on February 26, 2016, USP had indicated that the Chemical Medicines Monographs 5 and 6 Expert Committees were considering a revision to the Diphenhydramine and Phenylephrine Hydrochloride Tablets, Phenylephrine Hydrochloride Tablets, and Diphenhydramine Hydrochloride Injection monographs, similar to the revision proposed for the Diphenhydramine Hydrochloride Capsules, and Diphenhydramine Hydrochloride Oral Solution monographs. The purpose of this revised notice is to confirm that the Chemical Medicines 6 Expert Committee does intend to revise the *Organic Impurities* section of the Diphenhydramine and Phenylephrine Hydrochloride Tablets and

Phenylephrine Hydrochloride Tablets monographs. It is anticipated that Revision Bulletins for these proposed revisions will be published on the USP website on March 25, 2016 and become official on May 1, 2016.

A similar revision of the Diphenhydramine Hydrochloride Injection monograph is no longer being considered.

Should you have any questions, please contact Clydewyn M. Anthony, Ph.D., Scientific Liaison to the Chemical Medicines Monographs 6 Expert Committee (301-816-8139 or cma@usp.org).