## <u>Levalbuterol Hydrochloride</u>

Type of Posting: Notice of Intent to Revise

Posting Date: 29-Jul-2011

Targeted Official Date: Interim Revision Announcement, 01–May–2012

Expert Committee: Monographs—Small Molecules 4

In accordance with section 7.05(c) of the 2010–2015 Rules and Procedures of the Council of Experts, this is to provide notice that the USP Monographs—Small Molecules 4 Expert Committee intends to revise the Levalbuterol Hydrochloride monograph as follows:

- Under Organic Impurities test, the limit of total unspecified impurities is being deleted.
- Enantiomeric Purity and Chiral Identity test is being revised to add clarity to the monograph.
- Identification section is strengthened by adding a second test based on retention time agreement between Standard and Sample solutions in the Enantiomeric Purity and Chiral Identity test.

It is anticipated that the revision will be published as a Proposed Interim Revision Announcement in PF 37(6) [Nov.–Dec. 2011] pursuant to section 7.02 of the Rules and Procedures.

Should you have questions, please contact Ravi Ravichandran, Ph.D., Principal Scientific Liaison to the Monographs—Small Molecules 4 Expert Committee (301-816-8330 or <a href="mailto:rr@usp.org">rr@usp.org</a>).