Levalbuterol Inhalation Solution

Type of Posting: Notice of Intent to Revise

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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 Inhalation Solution monograph as follows:

- Definition and the Assay calculation are revised to be consistent with the FDA-approved package insert.
- Under Organic Impurities test, a Table identifying process impurities and degradants, along with their relative retention times and appropriate relative response factors, is being added.
- Enantiomeric Purity and Chiral Identity test is being revised to add clarity to the monograph.
- Color test referencing <631> is deleted. The acceptance criteria in this test are expressed in APHA platinum cobalt units which are not defined in <631>.

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 rr@usp.org).