

Albuterol Inhalation Solution

Type of PostingRevision BulletinPosting Date30-Apr-2021Official Date1-Nov-2023

Expert Committee Small Molecules 5

In accordance with the Rules and Procedures of the Council of Experts, the Small Molecules 5 Expert Committee has revised the Albuterol Inhalation Solution monograph. The purpose for the revision is to provide an additional 30-month implementation period for the Albuterol Inhalation Solution monograph, and to change its official date from May 1, 2021 to November 1, 2023.

Comments were received that the marketed Albuterol Inhalation Solution products are using the name "Albuterol Sulfate Inhalation Solution," and an extended implementation time may be required for the marketed product nomenclature to be revised. The approved title "Albuterol Inhalation Solution" is consistent with <1121> Nomenclature and with the Monograph Naming Policy for Salt Drug Substances in Drug Products. The additional 30-month implementation period, as described in <1121> Nomenclature, is provided to facilitate adoption of the monograph and changing the name of the marketed products to "Albuterol Inhalation Solution."

The Albuterol Inhalation Solution Revision Bulletin will supersede the monograph becoming official on May 1, 2021.

Should you have any questions, please contact Shankari Shivaprasad, Principal Scientist (301-230-7426 or sns@usp.org).