



November 18, 2004

Ben Venue Laboratories, Inc.

Dockets Management Branch
Food and Drug Administration
HFA-305, Room 1061
5630 Fishers lane
Rockville, MD 20852

ANDA Suitability Petition

The undersigned submits this petition under section 505(j)(2)(C) of the Federal Food Drug, and Cosmetic Act and 21 CFR 314.93, and 10.30 to request the Commissioner of Food and Drugs to seek a determination that an additional dosage of Terbutaline Sulfate Injection, USP 1 mg/mL 25 mL Pharmacy Bulk, is suitable for submission as an Abbreviated New Drug Application (ANDA).

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A. Action Required

This petition seeks a determination that an additional dosage of Terbutaline Sulfate Injection, USP 1 mg/mL 25 mL Pharmacy Bulk, is suitable for evaluation under an ANDA. The reference listed drug product upon which this petition is based is Brethine® 1 mg/1 mL single dose vials.

B. Statement of Grounds

The reference listed drug, Brethine® 1 mg/1 mL single dose vials by AAI Pharma was approved on November 20, 1981 under NDA 18-571.

The proposed product is identical in indication, active ingredient and route of administration to the listed drug Brethine®, and the concentration of the proposed product is in accordance with the FDA approved labeling for Brethine®. Please refer to Tables I and II below.

2004P-0518

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Table 1.
Formulation of the Reference Listed Drug and the Proposed Drug Product

Ingredient	Amount per mL	
	Brethine®	Proposed Drug Product
Terbutaline Sulfate	1 mg	1 mg
Sodium Chloride	Isotonicity	Isotonicity
Hydrochloric Acid	To adjust pH	To adjust pH
Water for Injection,	q.s. to 1.0 mL	q.s. to 1.0 mL

Table 2
Comparison of the Reference Listed Drug and the Proposed Drug Product

	Brethine®	Proposed Drug Product
Active Ingredient	Terbutaline Sulfate	Terbutaline Sulfate
Strength	1 mg/mL	1 mg/mL
Dosage form	Injection	Injection
Route of Administration	Subcutaneous	Subcutaneous
Conditions of use	Indicated for the prevention and reversal of bronchospasm in patients 12 years of age and older with asthma and reversible bronchospasm associated with bronchitis and emphysema	Indicated for the prevention and reversal of bronchospasm in patients 12 years of age and older with asthma and reversible bronchospasm associated with bronchitis and emphysema

The labeling for reference listed drug and the proposed dosage are provided in Attachment I.

A Pharmacy bulk would provide the pharmacist with the ability to prepare multiple single doses at one time from one container without the time and



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resources needed to prepare the same number of doses from single individual vials.

Brethine is not listed under the "Written Request for Pediatric Studies" list as published by the FDA. It has been on the market since 1981 and the FDA has not deemed it as a critical product to pediatric care. A copy of the current list is provided in as Attachment II for your reference. In addition, the currently approved labeling for Brethine, the Reference Listed Drug, states that it is for use in patients above 12 years of age. Because these studies have not been requested from the Reference Listed Drug Product or any generic equivalents by the FDA, and because the subject of this petition does not represent a change in indication, active ingredient, concentration or dosing and administration, pediatric studies should not be required.

C. Environment Impact

Action on an ANDA is categorically excluded from the requirements of an environmental assessment or impact statement under 21 CFR 25.31 (a).

D. Economic Impact

Not Applicable

E. Certification

The undersigned certifies that to the best knowledge and belief of the undersigned, this petition includes all the information and views on which the petition relies, and that it includes representative data and information known to the petitioner, which are unfavorable to the petition.

Sincerely,

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