



January 4, 2005

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 Bumetanide Injection, USP 10 mg/40 mL, 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 Bumetanide Injection, USP 10 mg/40 mL, is suitable for evaluation under an ANDA. The reference listed drug product upon which this petition is based is Bumex® 0.25 mg/mL in 2 mL, 4 mL, and 10 mL vials.

#### B. Statement of Grounds

The reference listed drug, Bumex®, (Bumetanide Injection, 0.25 mg/mL in 2 mL, 4 mL, and 10 mL vials) by Roche was approved on February 28, 1983 under NDA 18-226

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

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

Ingredient	Amount per mL	
	Bumex®	Proposed Drug Product
Bumetanide	0.25 mg	0.25 mg
Sodium Chloride	8.5 mg	8.5 mg
Ammonium Acetate	4 mg	4 mg
Edetate Disodium	0.1 mg	0.1 mg
Benzyl Alcohol	10 mg	10 mg
Sodium Hydroxide	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**

	Bumex®	Proposed Drug Product
Active Ingredient	Bumetanide	Bumetanide
Strength	0.25 mg/mL	0.25 mg/mL
Dosage form	Injection	Injection
Route of Administration	Intravenous or intramuscular	Intravenous or intramuscular
Conditions of use	Indicated for the treatment of edema associated with congestive heart failure, hepatic and renal disease, including nephrotic syndrome	Indicated for the treatment of edema associated with congestive heart failure, hepatic and renal disease, including nephrotic syndrome

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



The need for a 40 mL dosage of bumetanide is based on the total allowable daily dosage contained in the package insert. The Dosage and Administration section of the package insert allows for an initial dose of 0.5 to 1 mg (2 to 4 mL) and subsequent doses every two to three hours if needed, but should not exceed a daily dosage of 10 mg (40 mL).

Providing a 10 mg/40 mL size of Bumetanide Injeciton, USP would provide for the dosing listed in the insert while significantly reducing the need for the use of multiple vials of the smaller dosages.

Bumex® is not listed under the “Written Request for Pediatric Studies” list as published by the FDA. It has been on the market since 1983 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.. 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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