



September 20, 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 Fluconazole Injection, 100 mg/50 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 Fluconazole Injection, 100 mg/50 mL, is suitable for evaluation under an ANDA. The reference listed drug product upon which this petition is based is Diflucan® 200 mg/100 mL and 400 mg/200 mL in glass vials.

B. Statement of Grounds

The reference listed drug, Diflucan®, (Fluconazole Injection, 200 mg/100 mL and 400 mg/200 mL) by Pfizer was approved on January 29, 1990 under NDA 019950.

The proposed product is identical in indication, active ingredient and route of administration to the listed drug Diflucan®, and the concentration of the proposed product is in accordance with the FDA approved labeling for Diflucan®. 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	
	Diflucan®	Proposed Drug Product
Fluconazole	2 mg	2 mg
Sodium Chloride	9 mg	9 mg
Water for Injection, USP	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

	Diflucan®	Proposed Drug Product
Active Ingredient	Fluconazole	Fluconazole
Strength	2 mg/mL	2 mg/mL
Dosage form	Injection	Injection
Route of Administration	Intravenous	Intravenous
Conditions of use	Used in the treatment of Oropharyngeal and esophageal candidiasis and cryptococcal meningitis	Used in the treatment of Oropharyngeal and esophageal candidiasis and cryptococcal meningitis

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

The need for a 50 mL dosage of fluconazole is based on the needs of pediatric patients, patients with renal impairment, and the daily dose suggested for normal patients. The Dosage and Administration section of the package insert of Diflucan® allows for reduced dosing in pediatric and really impaired patients and provides calculations for determining the dose. In really impaired patients with creatinine clearances ≤ 50 with no dialysis, the loading dose is 50-400 mg with daily doses of 50% of that used for non-really impaired patients. In addition, the daily dose of fluconazole (given after the first day loading



dose) in normal adult patients is 100 mg for oropharyngeal candidiasis and esophageal candidiasis. Urinary tract infections and peritonitis dosing states that doses of 50 to 200 mg have been used in noncomparative studies of small numbers of patients.

Providing a 100 mg/50 mL size of Fluconazole Injection would provide for the specialized dosing listed in the insert while significantly reducing the amount of product which would be discarded, as compared with the larger currently marketed sizes.

Pediatric Exclusivity was granted to Diflucan[®], extending the patent life from January 29, 2004 to July 29, 2004, therefore, the data submitted was in accordance with the Agency's written request for pediatric studies (Refer to Attachment II). Because these studies have already been completed by Pfizer for fluconazole and the subject of this petition does not represent a change in indication, active ingredient, concentration or dosing and administration, the pediatric assessment required under the Pediatric Research Equity Act of 2003 has been completed.

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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