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Ben Venue Laboratories

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May 29, 2007

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 Deferoxamine Mesylate for Injection, USP is suitable for submission as an Abbreviated New Drug Application (ANDA).

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#### A. Action Requested

This petition seeks a determination that an additional dosage of Deferoxamine Mesylate for Injection, USP is suitable for evaluation under an ANDA. The reference listed drug product upon which this petition is based is Desferal<sup>®</sup> deferoxamine mesylate for injection USP in glass vials.

#### B. Statement of Grounds

The reference listed drug, Desferal<sup>®</sup> deferoxamine mesylate for injection USP, by Novartis Pharmaceutical Corporation was approved prior to Jan 1, 1982 under NDA 16-267.

The proposed product is identical in indication, active ingredient and route of administration to the listed drug Desferal<sup>®</sup> deferoxamine mesylate for injection USP. The final dosage form contains only the active drug substance, Deferoxamine Mesylate USP, in sterile, lyophilized form. The concentration of the proposed product (1 gram) is bracketed by the current, existing dosage forms (500 milligram and 2 gram) as listed in the FDA approved labeling for Desferal<sup>®</sup> deferoxamine mesylate for injection USP. Please refer to Table I below.

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**Table I**  
**Comparison of the Reference Listed Drug and the Proposed Drug Product**

	Desferal <sup>®</sup>	Proposed Drug Product
Active Ingredient	Deferoxamine Mesylate, USP	Deferoxamine Mesylate, USP
Strength	500 mg 2 gram	1 gram
Dosage form	Lyophilized powder	Lyophilized powder
Route of Administration	Intramuscular, Subcutaneous, and Intravenous Administration	Intramuscular, Subcutaneous, and Intravenous Administration
Conditions of use	Indicated for the treatment of acute iron intoxication and of chronic iron overload due to transfusion-dependent anemias.	Indicated for the treatment of acute iron intoxication and of chronic iron overload due to transfusion-dependent anemias.

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

The need for a 1 gram dosage form of the Deferoxamine Mesylate for Injection, USP drug product is based on the suggested dosing outlined for all routes of administration listed (intramuscular, intravenous and subcutaneous). The Dosage and Administration section of the package insert for Desferal<sup>®</sup> deferoxamine mesylate for injection USP provides instruction for initial administration of 1000 mg (1 g) for intramuscular administration for all patients not in shock and initial intravenous infusion for patients in a state of cardiovascular collapse. A 1000 mg (1 g) dose is listed as the maximum recommended daily dose via intramuscular administration and is identified as the maximum total daily dose in the absence of transfusion. Further, the package insert states a 1000 mg (1 g) dose is the minimum daily dose to be administered by the subcutaneous route. A 1 gram presentation of Deferoxamine Mesylate for Injection, USP would allow for the specific dosing as stated in the insert.



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Please note that this product is labeled for single use only with instructions to discard the unused portion of the solution prepared. The proposed 1 gram presentation would reduce the amount of product that would be discarded from a preparation of the 2 gram dosage form and decrease the potential for multiple preparations of the 500 mg dosage, where only a 1000 mg (1 g) dose is recommended.

**Pediatric Patients:**

New or additional studies in pediatric patients are not necessary for the approval of this petition for an additional dosage form of Deferoxamine Mesylate for Injection, USP.

Desferal® product labeling already includes information for use in the pediatric population. The Pediatric Use section of the package insert states:

“Pediatric patients receiving deferoxamine mesylate should be monitored for body weight and growth every 3 months.

Safety and effectiveness in pediatric patients under the age of 3 years have not been established (see INDICATIONS AND USAGE, WARNINGS, PRECAUTIONS/Drug interactions/Vitamin C, and ADVERSE REACTIONS.”

The package insert provides information in all of the sections listed above concerning use of the product in the pediatric population and the dosing does not differ from that listed for adults. In addition, Desferal® is not listed under the “Written Request for Pediatric Studies” list as published by the FDA. A copy of the current list is provided in Attachment II for your reference.

Further, the addition of a 1 g size of Deferoxamine Mesylate for Injection will not produce a meaningful therapeutic benefit over the existing sizes as the indications, dosing and administration will remain unchanged. The additional size will provide convenience and advantages in the preparation of solutions for administration. In summary, studies in pediatric patients under the age of 3 years have not been requested from the Reference Listed Drug Product or any generic equivalents by the FDA, adequate information is provided in the package insert for pediatric use above the age of 3 years, and the subject of this petition does not represent a change in indication, active ingredient or dosing and administration from the currently approved strengths of deferoxamine mesylate. Therefore, pediatric studies should not be required for approval of this suitability petition.



C. Environmental 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,

A handwritten signature in black ink, appearing to read "Molly L. Rapp".

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