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March 23, 2007

Division of Dockets Management
Food and Drug Administration
Department of Health and Human Services
5630 Fishers Lane, Room 1061
Rockville, MD 20852

Suitability Petition

The undersigned submits this petition under 21 CFR 10.20 and 21 CFR 10.30 as provided for in 21 CFR 314.93 and Section 505(j)(2)(c) of the Federal Food, Drug and Cosmetic Act or the Public Health Service Act or any other statutory provision for which authority has been delegated to the Commissioner of Food and Drugs under 21 CFR 5.10, to request the Commissioner of the Food and Drug Administration to determine if it is suitable for B Braun Medical to package their 15% Amino Acid Injection product in a package size not covered under the Reference Listed Drug's application.

A. Action Requested

The petitioner (B. Braun Medical Inc.) requests that the Commissioner of the Food and Drug Administration determine that it is suitable for B Braun Medical to package a 15% Amino Acid Injection product in a package size not covered under the Reference Listed Drug's application.

B. Statement of Grounds

B. Braun Medical plans to submit an Abbreviated New Drug Application (ANDA) under 21 CFR 314.92 against the RLD Novamine[®] (15% Amino Acid Injection) manufactured by Hospira, Inc. Hospira's Novamine 15% is currently approved under NDA# 17-957 for a 500 mL glass bottle (PBP). B. Braun Medical is proposing to package a 15% Amino Acid formulation, which is identical to the RLD, in a 2L glass bottle (PBP). Although Hospira's Novamine 15% is not packaged in a 2L container, Clinisol (ANDA# 20-512) – another 15% Amino Acid solution produced by Baxter Healthcare is produced in a 2L plastic container (PBP).

In support of this petition please see the enclosed pages of the electronic Orange Book referencing NDA# 17-957 Novamine (15% Amino Acid Injection) as well as the electronic Orange Book pages referencing ANDA# 20-512 for Clinisol.

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C. Environmental Impact

An environmental assessment report on the action requested in this petition is not required under 21 CFR 25.31.

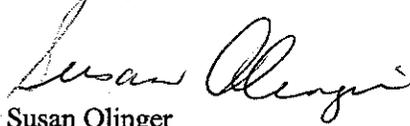
D. Economic Impact

In accordance with 21 CFR 10.30(b), economic impact information is to be submitted only when requested by the Commissioner following review of the petition. B. Braun Medical Inc. hereby commits to promptly provide this information, if so requested.

E. Certification

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

Yours truly,



Susan Olinger
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Enclosures