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July 30, 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 Inc. to package a 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 Inc. to package a 15% Amino Acid Injection product in a package size not covered under the Reference Listed Drug's (RLD) 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<sup>®</sup> (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 Inc. is proposing to package a 15% Amino Acid formulation, which is identical to the RLD, in a 1L glass bottle (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).

**C. Environmental Impact**

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

2007P-0300

CPI

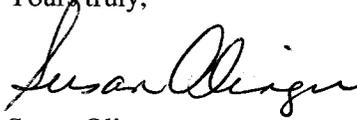
**D. Economic Impact**

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  
Corporate Vice President, Regulatory Affairs

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Enclosures

# Electronic Orange Book

## Approved Drug Products with Therapeutic Equivalence Evaluations

Current through June 2007\*\*

\*\* In order to provide timely consumer information on generic drugs, the Electronic Orange Book will be updated daily as new generic approvals occur. Refer to [FAQ](#) for additional information. **New!!**

### Annual Edition

### FAQ

[Search by Active Ingredient](#)    [Search by Applicant Holder](#)

[Search by Proprietary Name](#)    [Search by Application Number](#)

[Search by Patent](#)

The products in this list have been approved under section 505 of the Federal Food, Drug, and Cosmetic Act.

Drug questions email: [DRUGINFO@CDER.FDA.GOV](mailto:DRUGINFO@CDER.FDA.GOV)

U.S. Department of Health and Human Services  
Food and Drug Administration  
Center for Drug Evaluation and Research  
Office of Pharmaceutical Science  
Office of Generic Drugs

## Proprietary Name Search Results from "OB\_Rx" table for query on "Novamine."

Appl No	TE Code	RLD Active Ingredient	Dosage Form; Route	Strength	Proprietary Name	Applicant
<u>017957</u>		Yes AMINO ACIDS	INJECTABLE; INJECTION	11.4% (11.4GM/100ML)	NOVAMINE 11.4%	HOSPIRA
<u>017957</u>		Yes AMINO ACIDS	INJECTABLE; INJECTION	15% (15GM/100ML)	NOVAMINE 15%	HOSPIRA

[Return to Electronic Orange Book Home Page](#)

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FDA/Center for Drug Evaluation and Research

Office of Generic Drugs

Division of Labeling and Program Support

Update Frequency:

Orange Book Data - **Monthly**

Generic Drug Product Information & Patent Information - **Daily**

Orange Book Data Updated Through June, 2007

Patent and Generic Drug Product Data Last Updated: July 27, 2007

Active Ingredient: AMINO ACIDS  
Dosage Form;Route: INJECTABLE; INJECTION  
Proprietary Name: NOVAMINE 15%  
Applicant: HOSPIRA  
Strength: 15% (15GM/100ML)  
Application Number: 017957  
Product Number: 004  
Approval Date: Nov 28, 1986  
Reference Listed Drug: Yes  
RX/OTC/DISCN: RX  
TE Code:  
Patent and Exclusivity Info for this product: [View](#)