

B|BRAUN

0012 6 001-3 00:15

September 29, 2006

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

Citizen Petition

The undersigned submits this petition under 21 CFR 10.25(a) and 21 CFR 10.30 to request the Commissioner of the Food and Drug Administration to determine whether an Abbreviated New Drug Application (ANDA) can be filed against the listed drug Novamine[®] 15%, manufactured by Hospira under NDA 17-957.

A. Action Requested

The petitioner (B. Braun Medical Inc.) requests that the Commissioner of the Food and Drug Administration determine if B. Braun Medical can file an ANDA for a 15% Amino Acid solution and use NDA 17-957 Novamine[®] 15% manufactured by Hospira as the Referenced Listed Drug.

B. Statement of Grounds

The Food and Drug Administration's electronic Orange Book, updated July 2006 does not contain a Reference Listed Drug for a 15% amino acid product. Currently, the Orange Book lists two 15% amino acid products, Novamine 15% (NDA 17-957) and Clinisol (ANDA 20-512); neither is listed as the Reference Listed Drug. Copies of the Orange Book references are enclosed as **Attachment 1**.

B Braun Medical's proposed formulation is based on Hospira's Novamine 15% product. Please find in **Attachment 2** a chart comparing the formulations of Novamine 15% and B Braun Medical's proposed formulation. B. Braun Medical Inc. petitions FDA to determine that an ANDA can be filed against the NDA 17-957 for Novamine 15% despite the fact that it has not been designated as the Reference Listed Drug in the Orange Book.

C. Environmental Impact

A claim for categorical exclusion of the requirement for submission of an environmental assessment or environmental impact statement is made pursuant to 21 CFR 25.31.

2006P-0403

CP1

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

B. Braun Medical Inc.

901 Marcon Boulevard

Allentown, PA 18109

Telephone: 610-596-2517

Fax: 610-266-4962

Email: susan.olinger@bbraun.com