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November 30, 2006

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

Amendment to Citizen Petition Docket Number 2006P-0403/CP-1

On September 29, 2006 B. Braun Medical submitted a Citizen Petition in accord with 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) could be filed against the listed drug Novamine® 15%, manufactured by Hospira under NDA 17-957. At this time B. Braun Medical would like to amend this petition to include additional information for your consideration.

B. Braun Medical would like to file an ANDA against the drug Novamine 15% manufactured by Hospira and in addition package the finished product in a 2L glass bottle (PBP). Hospira's Novamine 15% is currently approved for a 500 mL glass bottle (PBP). Although Hospria'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).

B. Braun Medical Inc., hereby 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 using NDA 17-957 Novamine® 15% manufactured by Hospira as the Refereneed Listed Drug but package the formulation in a different container size than Hospira's Novamine 15% product. B. Braun would like to package the proposed product in a 2L glass bottle (PBP) rather than a 500 mL glass bottle (PBP).

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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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