



DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Rockville MD 20857

FILE COPY

October 16, 2002

Marcus Schabacker, MD, Ph.D.
B. Braun Medical Inc.
824 Twelfth Avenue
Bethlehem, PA 18018-0027

Dear Dr. Schabacker:

Your petition requesting the Food and Drug Administration to withhold approval of any abbreviated new drug application for amino acid solution drug products intended for use in infant patient populations which are packaged in polyvinyl chloride containers that have been plasticized with di(2-ethylhexyl)phthalate was received by this office on 10/16/02. It was assigned docket number 02P-0450/CP 1 and it was filed on 10/16/02. Please refer to this docket number in future correspondence on this subject with the Agency.

Please note that the acceptance of the petition for filing is a procedural matter in that it in no way reflects an agency decision on the substantive merits of the petition.

Sincerely,

Lyle D. Jaffe
Dockets Management Branch

02P-0450

ACK 1