



DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Rockville MD 20857

APR -8 2003

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

Re: Docket No. 02P-0450/CP1

Dear Dr. Schabacker:

I am writing to inform you that the Food and Drug Administration (FDA) has not yet resolved the issues raised in your petition dated October 15, 2002, requesting that the FDA withhold approval of any and all pending or future abbreviated new drug applications (ANDAs) for amino acid solutions that are packaged in DEHP-plasticized PVC and are intended for use in infant patient populations.

FDA has been unable to reach a decision on your petition because it raises issues that require additional review and analysis by the Agency. This interim response is provided in accordance with FDA regulations on citizen petitions (21 CFR 10.30(e)(2)). We will respond to your petition as soon as we have reached a decision on your request.

Sincerely yours,

Janet Woodcock, M.D.
Director
Center for Drug Evaluation and Research

02P-0450

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