DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 18-895/S-013

Abbott Laboratories
200 Abbott Park Road
D-0389, J-45/2
Attention: Ms. Nicohl R. Wilding
Regulatory Specialist

Dear Ms. Wilding:

Please refer to your supplemental new drug application dated October 15, 2002, received October 16, 2002, submitted under section 505 (b) of the Federal Food, Drug, and Cosmetic Act for TPN Electrolytes in Plastic Vials.

We acknowledge receipt of your submission dated February 19, 2003.

This "Changes Being Effected" supplemental new drug application provides for a revised package insert per the requirements of 21 CFR 201. 323 and revised release and stability specifications, which include a test for aluminum determination with the acceptance criterion of "NMT 600 mcg/L of aluminum."

We have completed our review of this application, as amended, and it is approved, effective on the date of this letter, with the changes listed below which were approved in supplement S-009.

Insert the following text for "geriatric use" subsection under the PRECAUTIONS heading.

> **Geriatric Use:** An evaluation of current literature revealed no clinical experience identifying differences in response between elderly and younger patients. In general, dose selection for an elderly patient should be cautious, usually starting at the low end of the dosing range, reflecting the greater frequency of decreased hepatic, renal, or cardiac function, and of concomitant disease or other drug therapy.
>
> Sodium ions and phosphorus are known to be substantially secreted by the kidney, and the risk of toxic reactions may be greater in patients with impaired renal function. Because elderly patients are more likely to have decreased renal function, care should be taken in dose selection, and it may be useful to monitor renal functions.

The final printed labeling (FPL) must be identical, and include the minor editorial revisions indicated, to the submitted labeling (package insert submitted October 15, 2002, immediate container submitted October 15, 2002). These revisions are terms of the approval of this application.

Please submit the FPL electronically according to the guidance for industry titled Providing Regulatory Submissions in Electronic Format – NDA. Alternatively, you may submit 20 paper copies of the FPL as soon as it is available, in no case more than 30 days after it is printed. Please individually mount ten of the copies on heavy-weight paper or similar material. For administrative purposes, these submissions should be designated "FPL for approved supplement NDA 18-895/S-013." Approval of this submission by FDA is not required before the labeling is used.

If you issue a letter communicating important information about this drug product (i.e., a "Dear Health Care Professional" letter), we request that you submit a copy of the letter to this NDA and a copy to the following address:

MEDWATCH, HF-2
FDA
5600 Fishers Lane
Rockville, MD 20857

We remind you that you must comply with reporting requirements for an approved NDA (21 CFR 314.80 and 314.81).

If you have any questions, call Victoria Kao, Regulatory Project Manager, at (301) 827-7416.

Sincerely,

{See appended electronic signature page}

Bob Rappaport, M.D.
Acting Director
Division of Anesthetic, Critical Care,
And Addiction Drug Products
Office of Drug Evaluation II
Center for Drug Evaluation and Research

This is a representation of an electronic record that was signed electronically and this page is the manifestation of the electronic signature.

/s/

Bob Rappaport

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