DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
Rockville MD 20857

NDA 19-682/S-015, S-018

Abbott Laboratories
200 Abbott Park Road, D-389, J45-2
Abbott Park, IL 60064-6157

Attention: Mary Amiryaghoobi
Regulatory Specialist
Hospital Products Division

Dear Ms. Amiryaghoobi:

Please refer to your supplemental new drug applications dated April 4, 1997 (S-015), and August 21, 1998 (S-018) received April 8, 1997, and August 25, 1998, respectively, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Aminosyn II 3.5% M and 4.25% M in Dextrose Injection.

We acknowledge receipt of your submissions dated November 30, 1999 (S-015) and August 6, 2001 (S-018). Your submission of November 30, 1999, constituted a complete response to our November 19, 1997, action letter for supplement S-015.

Supplement S-015 provides for a revised **Pediatric Use** subsection of the **PRECAUTIONS** section.

Supplement S-018 provides for a revised **PRECAUTIONS** section. A **Geriatric use** subsection is added in accordance with 21CFR 201.57(f)(10).

We have completed the review of these supplemental applications, as amended, and have concluded that adequate information has been presented to demonstrate that the drug product is safe and effective for use as recommended in the agreed upon labeling text and with the minor editorial revisions listed below. Accordingly, the supplemental applications are approved effective on the date of this letter.

Revise the **Geriatric Use** subsection of the **PRECAUTIONS** section as follows.

> "Clinical Studies of Aminosyn II 3.5% M or 4.25% M in Dextrose Injection have not been performed to determine whether patients over 65 years of age respond differently from younger subjects. Other reported clinical experience has not identified differences in responses between elderly and younger patients. In general, dose selection for an elderly patient should be cautious, reflecting the greater frequency of decreased hepatic, renal, or cardiac function, and of concomitant disease or other drug therapy. This drug is known to be substantially excreted by kidney, and the risk for adverse reactions to this drug 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 function."

The final printed labeling (FPL) must be identical, and include the minor editorial revisions indicated, to the submitted draft labeling dated November 30, 1999 (S-015) and August 6, 2001(S-018). These revisions are terms of the approval of these applications.

Please submit the copies of final printed labeling (FPL) electronically according to the guidance for industry titled *Providing Regulatory Submissions in Electronic Format - NDA* (January 1999). Alternatively, you may submit 20 paper copies of the FPL as soon as it is available but no 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, this submission should be designated "FPL for approved supplements NDA 19-682/S-015, S-018." Approval of these submissions by FDA is not required before the labeling is used.

If a letter communicating important information about this drug product (i.e., a "Dear Health Care Professional" letter) is issued to physicians and others responsible for patient care, 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 the requirements for an approved NDA set forth under 21 CFR 314.80 and 314.81.

If you have any questions, call Ms. Victoria Kao, Regulatory Health Project Manager, at (301) 827-7410.

Sincerely,

{See appended electronic signature page}

Cynthia McCormick, M.D.
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/

Cynthia McCormick
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