DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
Rockville MD 20857

NDA 17-673/S-066
NDA 17-789/S-052
NDA 18-429/S-019
NDA 19-374/S-015
NDA 19-398/S-016
NDA 19-437/S-015
NDA 19-438/S-014
NDA 19-492/S-016

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

Attention: Lisa K. Zboril, R.Ph.
Associate Director, Regulatory Affairs

Dear Ms. Zboril:

Please refer to your supplemental new drug applications dated June 24, 2002, received June 25, 2002, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for the following products:

NDA 17-673/S-066	Aminosyn® 5%, 7%, 8.5%, 8.5% w/Electrolytes & 10%
NDA 17-789/S-052	Aminosyn® 3.5%, 3.5% M and 7% w/ Electrolytes
NDA 18-429/S-019	Aminosyn®-RF 5.2%
NDA 19-374/S-015	Aminosyn®-HBC 7%
NDA 19-398/S-016	Aminosyn®-PF 7%
NDA 19-437/S-015	Aminosyn®-II w/Electrolytes
NDA 19-438/S-014	Aminosyn® II
NDA 19-492/S-016	Aminosyn®-PF 10%

We acknowledge receipt of your submissions dated June 25 and August 23, 2002.

These supplemental new drug applications provide for:

1. A change from glass to plastic containers;

2. A new manufacturing facility;

3. Reformulations to the drug product(s), including deletion of (b)----------

4. Revisions to the release and stability specifications, including addition of new analytical methods for the determination and identification of amino acids; and

5. Revised package insert and immediate container labelings, which include changes regarding (b)-------- content supported by data generated using a new analytical method for (b)--------- determination.

We have completed the review of these supplemental applications, as amended, and they are approved effective on the date of this letter.

The final printed labeling (FPL) must be identical to the submitted draft labeling (package insert and immediate container and carton labels submitted June 24, 2002).

Please submit the copies of final printed labeling (FPL) electronically to each application 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, these submissions should be designated "FPL for approved supplement NDA 17673/S-066, 17789/S-052, 18429/S-019, 19374/S-015, 19398/S-016, 19437/S-015, 19438/S-014, 19-492/016." Approval of these submissions by FDA is not required before the labeling is used.

In addition, all previous revisions as reflected in the most recently approved labeling must be included. To facilitate review of your submission, please provide a highlighted or marked-up copy that shows the changes that are being made.

If additional information relating to the safety or effectiveness of this drug becomes available, revision of the labeling may be required.

In addition, submit three copies of the introductory promotional materials that you propose to use for this/these product(s). Submit all proposed materials in draft or mock-up form, not final print. Send one copy to this division and two copies of both the promotional materials and the package insert(s) directly to:

Division of Drug Marketing, Advertising, and Communications, HFD-42
Food and Drug Administration
5600 Fishers Lane
Rockville, MD 20857

If a letter communicating important information about these drug products (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 appropriate NDA and a copy to the following address:

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

We have not completed validation of the regulatory methods. However, we expect your continued cooperation to resolve any problems that may be identified.

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}

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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