DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 17-673/S-069

Abbott Laboratories
D-389, Bldg. J45-2
200 Abbott Park Road
Abbott Park, Illinois 60064-6133

Attention: Jean Kirkeleit Davis
Manager, Regulatory Affairs

Dear Ms. Davis:

Please refer to your supplemental new drug application dated September 12, 2003, received September 15, 2003, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Aminosyn 5%, 7%, 8.5%, 8.5% w/Electrolytes, 10% and Cysteine Hydrochloride.

Reference is also made to your submission dated February 11, 2004.

This "Changes Being Effected in 30 days" supplemental new drug application provides for a new vial injector assembly to be used with Cysteine Hydrochlride Injection, USP.

We have completed our review of this application as amended, and it is approved, effective on the date of this letter.

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, HFD-410
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 Pratibha Rana, Regulatory Project Manager, at (301) 827-7431.

Sincerely,

{See appended electronic signature page}

Bob A. Rappaport, 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/

Bob Rappaport

3/9/04 01:59:16 PM