



NDA 19-437/S-014

Abbott Laboratories  
200 Abbott Park Road  
D-389, J45-2  
Abbott Park, IL 60064-6133

Attention: Maryam Amiryaghoobi  
Specialist, Regulatory Affairs

Dear Ms. Amiryaghoobi:

Please refer to your supplemental new drug application dated August 21, 1998, received August 25, 1998, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Aminosyn II w/ Electrolytes (amino acid injection with electrolytes).

We acknowledge receipt of your submissions dated September 6, 2002, and March 11, 2003.

Your submission of March 11, 2003, constituted a complete response to our November 14, 2001, action letter.

This supplement proposes labeling changes in response to the August 27, 1997, Federal Register Notice entitled, "Specific Requirements on content and Format of Labeling for Human Prescription Drugs; Addition of 'Geriatric Use' Subsection in the Labeling."

We have completed our review of this supplemental new drug 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, 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 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

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/s/

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Bob Rappaport  
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