



NDA 18-991/S-025  
NDA 18-997/S-026

Abbott Laboratories  
Hospital Products Division  
D-389, Building AP30  
200 Abbott Park Road  
Abbott Park, Illinois 60064-6157

Attention: Nichol R. Wilding  
Regulatory Specialist, Hospital Products Division

Dear Ms. Wilding:

Please refer to your supplemental new drug applications dated October 14, 2002, received October 15, 2002, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Liposyn® II 20% (I.V. Fat Emulsion) and Liposyn® II 10% (I.V. Fat Emulsion).

We acknowledge receipt of your submissions dated December 5, 2002.

These "Changes Being Effected" supplemental new drug applications provide for revised package inserts per the requirements of 21 CFR 201.323, revised stability protocols and revised release specifications, which include a test for aluminum determination with the acceptance criterion of "NMT 25 mcg/L of aluminum."

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

If you issue a letter communicating important information about any of these drug products (i.e., a "Dear Health Care Professional" letter), we request that you submit a copy of the letter to the respective 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).

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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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