DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 17-643/S-070
NDA 18-449/S-037
NDA 19-942/S-010

Fresenius Kabi
8484 US 70 West
Clayton, NC 27520-0597

Attention: Janet B. Sherrod, R.A.C.
Senior Regulatory Associate

Dear Ms. Sherrod:

Please refer to your supplemental new drug applications dated October 16, 2003, received October 20, 2003, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for the following:

Name of Drug Product	NDA Number	Supplement number
Intralipid 10% I.V. Fat Emulsion	17-643	S-070
Intralipid 20% I.V. Fat Emulsion	18-449	S-037
Intralipid 30% I.V. Fat Emulsion	19-942	S-010

We acknowledge receipt of your submissions dated January 22, 2004.

These "Changes Being Effected" supplemental new drug applications provide for revised **PRECAUTIONS** and **WARNINGS** sections of the package insert, and revised release specification and stability protocol containing a test for aluminum determination with a validated analytical method and an acceptance criterion of NMT 25 mcg/L of aluminum in accordance with the requirements of 21 CFR 201.323.

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

The final printed labeling (FPL) must be identical to the labeling submitted October 16, 2003.

Please submit the FPL electronically according to the guidance for industry titled Providing Regulatory Submissions in Electronic Format – NDA. Alternatively, you may submit 20 paper copies of the FPL as soon as it is available, in no case more than 30 days after it is printed. Please individually mount 15 of the copies on heavy-weight paper or similar material. For administrative purposes, these submissions should be designated "FPL for approved supplement NDA 17-643/S-070, NDA 18-4469/S-037 and NDA 19-942/S-010." Approval of these submissions by FDA is not required before the labeling is used.

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 Sara E. Stradley, Regulatory Project Manager, at (301) 827-7430.

Sincerely,

{See appended electronic signature page}

Bob 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

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