DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

NDA 17643/S-078
NDA 18449/S-045
NDA 19942/S-016
NDA 20248/S-022

SUPPLEMENT APPROVAL

Fresenius Kabi USA, LLC
Attention: Jennifer Gross
Regulatory Affairs Specialist
Three Corporate Drive
Lake Zurich, IL 60047

Dear Ms. Gross:

Please refer to your Supplemental New Drug Application (sNDA) dated and received on, October 11, 2016, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for the following:

Application	Supplement	Drug Product
NDA 017643	S-078	Intralipid 10% I.V. Fat Emulsion
NDA 018449	S-045	Intralipid 20% I.V. Fat Emulsion
NDA 019942	S-016	Intralipid 30% (Pharmacy Bulk Pack) I.V. Fat Emulsion
NDA 020248	S-022	Intralipid 20% (Pharmacy Bulk Pack) I.V. Fat Emulsion

This "Changes Being Effected" supplemental new drug application provides for minor changes to the instructions for use section of the Prescribing Information (PI) for Intralipid in Biofine® packaging system. The revised instruction for use is to provide clarity to the providers.

We have completed our review of this supplemental application, as amended. It is approved, effective on the date of this letter, for use as recommended in the enclosed, agreed-upon labeling text.

CONTENT OF LABELING

As soon as possible, but no later than 14 days from the date of this letter, submit the content of labeling [21 CFR 314.50(l)] in structured product labeling (SPL) format using the FDA automated drug registration and listing system (eLIST), as described at http://www.fda.gov/ForIndustry/DataStandards/StructuredProductLabeling/default.htm.

Content of labeling must be identical to the enclosed labeling (package insert), with the addition of any labeling changes in pending "Changes Being Effected" (CBE) supplements, as well as annual reportable changes not included in the enclosed labeling.

Information on submitting SPL files using eList may be found in the guidance for industry titled "SPL Standard for Content of Labeling Technical Qs and As at http://www.fda.gov/downloads/DrugsGuidanceComplianceRegulatoryInformation/Guidances/UCM072392.pdf

The SPL will be accessible from publicly available labeling repositories.

Also within 14 days, amend all pending supplemental applications that include labeling changes for this NDA, including CBE supplements for which FDA has not yet issued an action letter, with the content of labeling [21 CFR 314.50(l)(1)(i)] in MS Word format, that includes the changes approved in this supplemental application, as well as annual reportable changes and annotate each change. To facilitate review of your submission, provide a highlighted or marked-up copy that shows all changes, as well as a clean Microsoft Word version. The marked-up copy should provide appropriate annotations, including supplement number(s) and annual report date(s).

REPORTING REQUIREMENTS

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 Thao Vu, Regulatory Project Manager, at (240) 402-2690.

Sincerely,

{See appended electronic signature page}

Joyce Korvick, M.D., M.P.H.
Deputy Director for Safety
Division of Gastroenterology and Inborn Errors Products
Office of Drug Evaluation III
Center for Drug Evaluation and Research

ENCLOSURE(S):
Prescribing Information

This is a representation of an electronic record that was signed electronically. Following this are manifestations of any and all electronic signatures for this electronic record.

/s/

JOYCE A KORVICK
07/25/2018