

NDA 17643/S-082  
 NDA 18449/S-049  
 NDA 19942/S-020  
 NDA 20248/S-026

**SUPPLEMENT APPROVAL**

Fresenius Kabi USA, LLC  
 Attention: Peter Baer  
 Senior Regulatory Specialist  
 Three Corporate Drive  
 Lake Zurich, IL 60047

Dear Mr. Baer,

Please refer to your supplemental new drug applications (sNDAs) submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for the following:

Application	Supplement	Drug Product	Submission Date	Receipt Date
NDA 017643	S-082	Intralipid 10% I.V. Fat Emulsion	7/1/2021	7/1/2021
NDA 018449	S-049	Intralipid 20% I.V. Fat Emulsion	7/1/2021	7/1/2021
NDA 019942	S-020	Intralipid 30% (Pharmacy Bulk Pack) I.V. Fat Emulsion	7/1/2021	7/1/2021
NDA 020248	S-026	Intralipid 20% (Pharmacy Bulk Pack) I.V. Fat Emulsion	7/1/2021	7/1/2021

These Prior Approval sNDAs provide for the following changes to the Prescribing Information (PI):

- Add to the stability and storage information in the MIXING GUIDELINES AND LIMITATIONS section a statement to protect the admixed parenteral nutrition solution from light.
- Add to the CONTRAINDICATIONS section a statement regarding known hypersensitivity to egg, soybean, or peanut protein, or to any of the active ingredients or excipients.
- Remove the pregnancy category from the PRECAUTIONS section in accordance with Pregnancy and Lactation Labeling Rule (PLLR).

- Add to the WARNINGS section a statement regarding the risk of Parenteral Nutrition Associated Liver Disease (PNALD), also known as Intestinal Failure Associated Liver Disease (IFALD), presenting as cholestasis or steatohepatitis in patients, especially preterm infants, who received parenteral nutrition for greater than two weeks. Add minor related revisions in other parts of labeling (e.g., PRECAUTIONS, DOSAGE AND ADMINISTRATION/Pediatric Patients).

## **APPROVAL & LABELING**

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

## **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 FDA.gov.<sup>1</sup> Content of labeling must be identical to the enclosed labeling (text for the Prescribing Information), 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 *SPL Standard for Content of Labeling Technical Qs and As*.<sup>2</sup>

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 Microsoft Word format, that includes the changes approved in this supplemental application, as well as annual reportable changes. To facilitate review of your submission(s), 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).

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<sup>1</sup> <http://www.fda.gov/ForIndustry/DataStandards/StructuredProductLabeling/default.htm>

<sup>2</sup> We update guidances periodically. For the most recent version of a guidance, check the FDA Guidance Documents Database <https://www.fda.gov/RegulatoryInformation/Guidances/default.htm>.

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## **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, Sr. Regulatory Health Project Manager, at (240) 402-2690.

Sincerely,

*{See appended electronic signature page}*

Judith A. Racoosin, M.D., M.P.H.  
Deputy Director for Safety  
Division of Hepatology and Nutrition  
Office of Immunology and Inflammation  
Office of New Drugs  
Center for Drug Evaluation and Research

### ENCLOSURES:

- Content of Labeling
  - Prescribing Information

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**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.**  
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/s/  
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JUDITH A RACOOSIN  
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