NDA 019942/S-022

SUPPLEMENT APPROVAL

Fresenius Kabi Deutschland GmbH
c/o Fresenius Kabi USA, LLC
Attention: Peter Baer
Senior Regulatory Specialist
Three Corporate Drive
Lake Zurich, IL 60047

Dear Peter Baer:

Please refer to your supplemental new drug application (sNDA) dated and received August 22, 2023, and your amendments, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Intralipid 30% (lipid injectable emulsion), for intravenous use.

This Prior Approval sNDA provides for the conversion of the Prescribing Information to Physician Labeling Rule (PLR) format and compliance with the Pregnancy and Lactation Labeling Rule (PLLR) content and format requirements.

APPROVAL & LABELING

We have completed our review of this application, as amended. It is approved, effective on the date of this letter, for use as recommended in the enclosed agreed-upon labeling with minor editorial revisions listed below and reflected in the enclosed labeling.

- In the **HIGHLIGHTS OF PRESCRIBING INFORMATION**
  - In **DOSAGE AND ADMINISTRATION** section, subsection numbers updated to the following:
    - Admixtures containing Intralipid 30% are prepared by a healthcare provider. (2.1)
    - Intralipid 30% must be combined with other PN fluids so that the resulting admixture has a final lipid concentration of no more than 20% (0.2 g lipid per mL of admixture). (2.1, 2.2)

- In the **FULL PRESCRIBING INFORMATION**
  - In subsection 2.3 Recommended Dosage and Administration, the statement in the first bullet was revised:
    - The recommended nutritional requirements of lipid and recommended dosages of Intralipid to be administered to meet those requirements for adults and pediatric patients are provided in Table 1.
  - Updates to Table 1 in subsection 2.3 Recommended Dosage and Administration:
    - Minor edit to Table 1 title: **Recommended Pediatric and Adult Dosage for Intralipid Concentrations of 20% or less in an Admixture**
    - Removal of an extra asterisk (*) at Nutritional Requirements for Pediatrics patients 2 to < 12 years of age: Initial 1 to 2 g/kg/day not to exceed 2.5 g/kg/day**

WAIVER OF ½ PAGE LENGTH REQUIREMENT FOR HIGHLIGHTS

We are waiving the requirements of 21 CFR 201.57(d)(8) regarding the length of Highlights of Prescribing Information. This waiver applies to all future supplements containing revised labeling unless we notify you otherwise.

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.[1] 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*.[2]

The SPL will be accessible from publicly available labeling repositories.

[1] http://www.fda.gov/ForIndustry/DataStandards/StructuredProductLabeling/default.htm
[2] 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.

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).

PATENT LISTING REQUIREMENTS

Pursuant to 21 CFR 314.53(d)(2) and 314.70(f), certain changes to an approved NDA submitted in a supplement require you to submit patent information for listing in the Orange Book upon approval of the supplement. You must submit the patent information required by 21 CFR 314.53(d)(2)(i)(A) through (C) and 314.53(d)(2)(ii)(A) and (C), as applicable, to FDA on Form FDA 3542 within 30 days after the date of approval of the supplement for the patent information to be timely filed (see 21 CFR 314.53(c)(2)(ii)). You also must ensure that any changes to your approved NDA that require the submission of a request to remove patent information from the Orange Book are submitted to FDA at the time of approval of the supplement pursuant to 21 CFR 314.53(d)(2)(ii)(B) and 314.53(f)(2)(iv).

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 Chinedu Ebonine, Regulatory Project Manager, at (240) 402-3448.

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

ENCLOSURE(S):

- Content of Labeling
  - 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/

JUDITH A RACOOSIN
02/22/2024 03:17:42 PM