NDA 17643/S-085 NDA 200656/S-024
NDA 18449/S-054 NDA 207648/S-013
NDA 19942/S-025 NDA 210589/S-005
NDA 20248/S-031

SUPPLEMENT APPROVAL

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

Dear Jennifer Gross,

Please refer to your supplemental new drug applications (sNDAs) dated and received June 12, 2025, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) the following:

Application	Supplement	Drug Product
NDA 017643	S-085	Intralipid (lipid injectable emulsion), 10%
NDA 018449	S-054	Intralipid (lipid injectable emulsion), 20%
NDA 019942	S-025	Intralipid (lipid injectable emulsion), 30%
NDA 020248	S-031	Intralipid (lipid injectable emulsion), 20%
NDA 200656	S-024	Kabiven and Perikabiven (amino acids, electrolytes, dextrose and lipid injectable emulsion)
NDA 207648	S-013	Smoflipid (lipid injectable emulsion), 20%
NDA 210589	S-005	Omegaven (fish oil triglycerides injectable emulsion)

We also refer to our letter dated May 15, 2025, notifying you, under Section 505(o)(4) of the FDCA, of new safety information that we have determined should be included in the labeling for intravenous lipid emulsions (IVLEs), including Intralipid, Kabiven and Perikabiven, SMOFlipid, and Omegaven. This information pertains to the risk of anaphylaxis.

These sNDAs provide for revisions to the labeling for Intralipid, Kabiven and Perikabiven, SMOFlipid, and Omegaven, consistent with our May 15, 2025 Safety Labeling Change (SLC) Notification letter.

Regarding Omegaven, the agreed upon change not included in the SLC Notification letter dated May 15, 2025 is described below:

- Subsection 6.2, Postmarketing Experience: revised the language describing the hemorrhage adverse reaction to align with FDA standard labeling practice

APPROVAL & LABELING

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

- For Intralipid, Kabiven, Perikabiven, and SMOFlipid: edited the revision date to the action month of July

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.

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).

[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.

PROMOTIONAL MATERIALS

You may request advisory comments on proposed introductory advertising and promotional labeling. For information about submitting promotional materials, see the final guidance for industry *Providing Regulatory Submissions in Electronic and Non-Electronic Format-Promotional Labeling and Advertising Materials for Human Prescription Drugs.*[3]

You must submit final promotional materials and Prescribing Information, accompanied by a Form FDA 2253, at the time of initial dissemination or publication [21 CFR 314.81(b)(3)(i)]. Form FDA 2253 is available at FDA.gov.[4] Information and Instructions for completing the form can be found at FDA.gov.[5]

The use of the term "new safety-related information" below includes new safety information (NSI) as described in section 505-1(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) (21 U.S.C. 355-1(b)) and other safety-related information unrelated to section 505(o)(4) of the FDCA.

All promotional materials that include representations about your drug product must be promptly revised to be consistent with the labeling changes approved in this supplement, including any new safety- related information [21 CFR 314.70(a)(4)]. The revisions in your promotional materials should include prominent disclosure of the important new safety-related information that appears in the revised labeling. Within 7 days of receipt of this letter, submit your statement of intent to comply with 21 CFR 314.70(a)(4).

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).

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[3] For the most recent version of a guidance, check the FDA guidance web page at https://www.fda.gov/media/128163/download.
[4] http://www.fda.gov/downloads/AboutFDA/ReportsManualsForms/Forms/UCM083570.pdf
[5] http://www.fda.gov/downloads/AboutFDA/ReportsManualsForms/Forms/UCM375154.pdf

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, Safety Regulatory 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

ENCLOSURE:

- 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
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