



BLA 761173/S-013

SUPPLEMENT APPROVAL

Fresenius Kabi USA, LLC
Attention: Navayath Shobana, PhD
Senior Director, Regulatory Affairs Lead
Three Corporate Drive
Lake Zurich, IL 60047

Dear Navayath Shobana:

Please refer to your supplemental biologics license application (sBLA) dated and received July 16, 2025, and your amendments, submitted under section 351(k) of the Public Health Service Act for Stimufend (pegfilgrastim-fpgk) injection.

This “Changes Being Effectuated” supplemental biologics license application provides for the addition of a private labeler for Stimufend (pegfilgrastim-fpgk) Pre-Filled Syringe (6 mg/0.6 mL).

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.

CONTENT OF LABELING

As soon as possible, but no later than 14 days from the date of this letter, submit, via the FDA automated drug registration and listing system (eLIST), the content of labeling [21 CFR 601.14(b)] in structured product labeling (SPL) format, as described at [FDA.gov](http://www.fda.gov),¹ that is identical to the enclosed labeling (text for the Prescribing Information, Patient Package Insert, and Instructions for Use) and include the labeling changes proposed in any pending “Changes Being Effectuated” (CBE) supplements.

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

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>.



The SPL will be accessible via publicly available labeling repositories.

Also within 14 days, amend all pending supplemental applications that include labeling changes for this BLA, including pending “Changes Being Effected” (CBE) supplements, for which FDA has not yet issued an action letter, with the content of labeling [21 CFR 601.12(f)] 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).

CARTON AND CONTAINER LABELING

Submit final printed carton and container labels that are identical to the enclosed carton and container labeling, as soon as they are available, but no more than 30 days after they are printed. Please submit these labels electronically according to the guidance for industry *Providing Regulatory Submissions in Electronic Format – Certain Human Pharmaceutical Product Applications and Related Submissions Using the eCTD Specifications*. For administrative purposes, designate this submission “**Final Printed Carton and Container Labeling for approved BLA 761173/S-013.**” Approval of this submission by FDA is not required before the labeling is used.

REPORTING REQUIREMENTS

We remind you that you must comply with reporting requirements for an approved BLA (in 21 CFR 600.80 and in 21 CFR 600.81).

Your product is a Part 3 combination product (21 CFR 3.2(e)); therefore, you must also comply with postmarketing safety reporting requirements for an approved combination product (21 CFR 4, Subpart B). Additional information on combination product postmarketing safety reporting is available at FDA.gov.

If you have any questions, contact Hannah Lee, Regulatory Business Process Manager, at (301) 796 – 9644 or Hannah.Lee@fda.hhs.gov.

Sincerely,

{See appended electronic signature page}

Ashutosh Rao, Ph.D.
Director
Division of Product Quality Assessment XIV
Office of Product Quality Assessment III
Office of Pharmaceutical Quality
Center for Drug Evaluation and Research

ENCLOSURES:

- Content of Labeling
 - Prescribing Information
 - Patient Package Insert
 - Instructions for Use
- Carton and Container Labeling



Ashutosh
Rao

Digitally signed by Ashutosh Rao

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