

BLA 103951/S-5383

## **SUPPLEMENT APPROVAL**

Amgen Inc.  
Attention: Sharon Wu  
Senior Associate, Regulatory Affairs  
One Amgen Center Drive  
Thousand Oaks, CA 91320

Dear Sharon Wu:

Please refer to your supplemental biologics license application (sBLA), dated and received January 24, 2024, and your amendments, submitted under section 351(a) of the Public Health Service Act for Aranesp (darbepoetin alfa) injection.

We also refer to our letter Prior Approval Supplement Request letter dated October 31, 2023, informing you that the Prescribing Information (PI) and Medication guide for your product need updating to include information about drug abuse and dependence.

This Prior Approval supplemental biologics application provides for the following changes:

- A Drug Abuse and Dependence Section was added to the PI, and the Medication Guide was updated accordingly.
- The 300 mcg vial presentation was removed from the PI.
- Minor editorial revisions were made in some sections of the labeling.

### **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,<sup>1</sup> that is identical to the enclosed labeling (text for the Prescribing Information

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

and Medication Guide) and include the labeling changes proposed in any pending “Changes Being Effected” (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*.<sup>2</sup>

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).

## **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).

If you have any questions, contact Caden Brennen, Safety Regulatory Project Manager at 301-796-6591 or at Caden.Brennen@fda.hhs.gov.

Sincerely,

*{See appended electronic signature page}*

Rosanna Setse, MD, MPH, PhD.  
Deputy Director for Safety  
Division of Nonmalignant Hematology  
Office of Cardiology, Hematology,  
Endocrinology, and Nephrology  
Center for Drug Evaluation and Research

## ENCLOSURE(S):

- Content of Labeling
  - Prescribing Information
  - Medication Guide

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<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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**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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