DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

BLA 125031/S-189
BLA 125031/S-191

SUPPLEMENT APPROVAL

Amgen Inc.
Attention: Naomi Kozlowski, PharmD
Manager, Regulatory Affairs
One Amgen Center Drive, Mail Stop: 17-1-C
Thousand Oaks, CA 91320-1799

Dear Dr. Kozlowski:

Please refer to your Supplemental Biologics License Applications (sBLA) for Supplement 189, dated June 29, 2017, received June 29, 2017, and Supplement 191, dated October 4, 2017, received October 4, 2017, and your amendments, submitted under section 351(a) of the Public Health Service Act for Neulasta® (pegfilgrastim), 6 mg per 0.6 mL.

The "Changes Being Effected" supplemental biologics application 189 provides for revisions to the Healthcare Provider Instructions for Use related to changes made in 2016 to the on-body injector.

The Prior Approval supplemental biologics application 191 provides for revisions to the United States Prescribing Information with the addition of a new subsection Potential Device Failures in Section 5: Warnings and Precautions.

APPROVAL & LABELING

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

WAIVER OF HIGHLIGHTS SECTION

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, 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 http://www.fda.gov/ForIndustry/DataStandards/StructuredProductLabeling/default.htm, that is identical to the enclosed labeling (text for the prescribing information and healthcare provider instructions for use) 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 titled "*SPL Standard for Content of Labeling Technical Qs and As*" at http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM072392.pdf.

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 MS Word format that includes the changes approved in this supplemental application.

REQUIRED PEDIATRIC ASSESSMENTS

Under the Pediatric Research Equity Act (PREA) (21 U.S.C. 355c), all applications for new active ingredients, new indications, new dosage forms, new dosing regimens, or new routes of administration are required to contain an assessment of the safety and effectiveness of the product for the claimed indication(s) in pediatric patients unless this requirement is waived, deferred, or inapplicable.

Because none of these criteria apply to your application, you are exempt from this requirement.

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, please contact Jennifer Lee, Regulatory Project Manager, at (240) 402-4622.

Sincerely,

{See appended electronic signature page}

Barry W. Miller
Acting Deputy Director for Safety
Division of Hematology Products
Office of Hematology and Oncology Products
Center for Drug Evaluation and Research

ENCLOSURE:
Content of Labeling

This is a representation of an electronic record that was signed electronically and this page is the manifestation of the electronic signature.

/s/

BARRY W MILLER
12/09/2017