DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

BLA 125031/130

SUPPLEMENT BLA APPROVAL
June 03, 2011

Amgen, Inc.
Attention: Monica Sandberg, Ph.D., RAC
Manager, Regulatory Affairs
One Amgen Center Drive
Thousand Oaks, CA 91320-1799

Dear Dr. Sandberg:

Please refer to your Supplemental Biologics License Application (sBLA), dated February 7, 2011, received February 8, 2011, submitted under section 351 of the Public Health Service Act for Neulasta (pegfilgrastim).

We acknowledge receipt of your amendment dated May 17, 2011.

This "Changes Being Effected" labeling supplement to your biologics license application proposes to update the Adverse Reactions, Postmarketing Experience subsection of the package insert to include a new system organ class entitled, "Hypersensitivity Reactions" and to add cutaneous vasculitis to skin and subcutaneous tissue disorders.

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

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 package insert, 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 titled "SPL Standard for Content of Labeling Technical Qs and As" at http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM072392.pdf. For administrative purposes, please designate this submission "**Product Correspondence – Final SPL for approved BLA STN 125031/130**."

Also within 14 days, amend all pending supplemental applications 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.

The SPL will be accessible via publicly available labeling repositories.

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, call me, Regulatory Project Manager, at (301) 796-0704.

Sincerely,

/Jeffery Summers, M.D./
Jeffery Summers, M.D.
Deputy Director of Safety
Division of Biologic Oncology Products
Office of Oncology Drug Products
Center for Drug Evaluation and Research
Center for Drug Evaluation and Research

ENCLOSURE:
Content of Labeling