DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

Our STN: BL 103353/5127

APPROVAL
March 2, 2010

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

Dear Dr. Sandberg:

Please refer to your supplement to your biologics license application (BLA), dated August 31, 2009, received September 1, 2009, submitted under section 351 of the Public Health Service Act for Neupogen (filgrastim).

We acknowledge receipt of your amendments dated September 25, 2010, January 27, 2010, and February 25, 2010.

Your request to supplement your BLA for Neupogen (filgrastim) to update the PRECAUTIONS, Pregnancy Category C, section of the package insert with information regarding a voluntary pregnancy surveillance program has been approved.

Within 14 days of the date of this letter, submit 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 in content to the enclosed labeling text. The content of labeling should be submitted by updating your applications by referencing the SPL file submitted to the drug establishment registration and drug listing system. To do this, place a link in your application submissions that directs FDA to your SPL file. For administrative purposes, please designate this submission "Product Correspondence – Final SPL for approved BLA STN 103353/5127." In addition, within 14 days of the date of this letter, amend any pending supplement(s) for this BLA with content of labeling in SPL format to include the changes approved in this supplement. For additional information on submitting labeling to drug establishment registration and drug listing and to applications, see the FDA guidances at http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/ucm072339.pdf and http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM072392.pdf.

If you have any questions, please contact the Senior Regulatory Health Project Manager, Erik Laughner, at (301) 796-1393.

Sincerely,

/ Patricia Keegan /
Patricia Keegan, M.D.
Director
Division of Biologic Oncology Products
Office of Oncology Drug Products
Center for Drug Evaluation and Researc