DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

Our STN: BL 125031/105 and 125031/91

NOV 14 2008

Amgen, Incorporated
Attention: Chanda Walton, Ph.D.
Senior Manager, Regulatory Affairs
One Amgen Center Drive, Mail Stop 17-2-C
Thousand Oaks, CA 91320-1799

Dear Dr. Walton:

Your request to supplement your biologics license application (BLA) for Neulasta (Pefilgrastim) to revise the CLINICAL PHARMACOLOGY, Special Populations section and to include pediatric information in the PRECAUTIONS, Pediatric Use section of the package insert has been approved.

Pursuant to 21 CFR 201.57(c)(18) and 201.80(f)(2), patient labeling must be reprinted immediately following the last section of labeling or, alternatively, accompany the prescription drug labeling.

We note your October 16, 2008, submission included final content of labeling [CFR 601.14(b)] in structured product labeling (SPL) format; we will transmit it to the National Library of Medicine for public dissemination. Within 21 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.

Marketing the product with labeling that is not identical to the approved labeling text may render the product misbranded and an unapproved new drug.

This fulfills your commitment as stated in postmarketing commitment (PMC) # 3 of the January 31, 2002 approval letter for your BLA, STN BL 125031/0:

PMC #3

- To submit results from an ongoing study to evaluate the pharmacokinetics (PK), safety and efficacy of Pegfilgrastim in pediatric patients. The protocol for study 990130 entitled "A Single Dose Per Cycle Filgrastim-SD/01 as an Adjunct to VadriaC/JE Chemotherapy in Pediatric Sarcoma Patients" was submitted to BB-IND 7110 on August 9, 1999 and the study was initiated in April 2000. Patient accrual will be completed by December 2004, the study completed (last patient exited) by September 2005, and the final clinical study report, with revised labeling if applicable, will be submitted to FDA by February 2006.

We note that the results from study 990130 were also submitted on August 24, 2007, as a PMC final study report assigned STN BL 125031/91. You are no longer required to report on this commitment.

Your supplement also contained a request for release from PMC # 4 identified in the January 31, 2002, approval letter for your BLA, STN BL 125031/0 as follows:

PMC # 4:

- To develop a pediatric dosage form based upon the data obtained from the pediatric study 990130 described in item 3. Formulation development will be completed by March 2006, six-month stability studies will be completed by September 2006, and a supplement with revised labeling will be submitted to FDA by November 2006.

You requested release from PMC # 4 because pediatric study 990130 did not provide sufficient data to enable extrapolation of efficacy to the pediatric population. We acknowledge your due diligence in pursuing this PMC and the difficulties in pediatric patient accrual. We agree that a similar difficulty in accrual is likely to occur with any future pediatric clinical studies and acknowledge that there currently is an approved and marketed alternative therapy for this indication. Therefore, you are released from PMC #4. You no longer have to report on this commitment.

Please refer to http://www.fda.gov/cder/biologics/default.htm for information regarding therapeutic biological products, including the addresses for submissions.

This information will be included in your biologics license application file.

Sincerely,

Patricia Keegan

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

Enclosures: Package Insert and Patient Package Insert Labeling