DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

Our STN: BL 103234/5164

MAR 07 2008

Amgen, Incorporated
Attention: Neal Storm, M.S., M.B.A.
Manager, Regulatory Affairs
One Amgen Center Drive
Mail Stop: 17-2-B
Thousand Oaks, CA 91320

Dear Mr. Storm:

Your request to supplement your biologics license application for epoetin alfa (Epogen/Procrit) to revise the Boxed Warnings and the Warnings section of the package insert to include information from the PREPARE/DE-2001-0033 study utilizing darbepoetin alfa and the GOG191 study utilizing epoetin alfa has been approved.

We also refer to STN BL 103234 the product correspondence to which the SAS transport files for GOG191 were submitted, to STN BL 103234 the product correspondence to which the clinical study report and dataset for GOG 191 was submitted, and to STN BL 103234 the product correspondence to which the revised addendum to the clinical study report was submitted. We also refer to STN BL 103951/5170 for information regarding study PREPARE/DE-2001-0033.

We acknowledge the statement in your February 29, 2008, letter that you will post a copy of the Dear Healthcare Provider Letter (DHCP) within 72 hours of receipt of this letter. In addition, we acknowledge your agreement to distribute the Dear Healthcare Provider Letter with the attached revised labeling within ten days from this approval (March 17, 2008).

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.

Within 21 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/oc/datacouncil/spl.html, that is identical in content to the enclosed labeling text. Upon receipt, we will transmit that version to the National Library of Medicine for public dissemination. For administrative purposes, please designate this submission "Product Correspondence – Final SPL for approved STN BL 103234/5164." In addition, 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.

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

Enclosure: Package Insert
Patient Package Insert Labeling