DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

Our STN: BL 103234/5158

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

NOV 0 8 2007

Dear Mr. Storm:

Your request to supplement your biologics license application for epoetin alfa (EPOGEN®/Procrit®) to revise the Boxed Warnings, INDICATIONS AND USAGE, CLINICAL EXPERIENCE: RESPONSE TO EPOGEN®/Procrit®, WARNINGS, PRECAUTIONS, DOSAGE AND ADMINISTRATION and REFERENCES sections of the package insert (PI) and to revise the patient package insert (PPI) 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 acknowledge the statement in your November 6, 2007, letter that you will distribute a Dear Healthcare Provider Letter with the attached revised labeling within 2 weeks from approval (November 8, 2007).

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 for EPOGEN® and which contains the same changes for Procrit® labeling. Product labeling for both EPOGEN® and Procrit®, in SPL format, should be contained in the same submission and revised labeling should be implemented simultaneously. 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 103234/5158." 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