**DEPARTMENT OF HEALTH & HUMAN SERVICES**

Public Health Service

Food and Drug Administration
Rockville, MD 20857

Our STNs: BL 103234/5195 and BL 103234/5196

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

Dear Mr. Storm:

This letter is in reference to your supplements submitted August 5, 2008 and August 7, 2008, under section 351 of the Public Health Service Act for Epogen/Procrit (epoetin alfa).

Supplement STN BL 103234/5195 provides for new labeling as described in our July 30, 2008, Complete Response and Safety Labeling Change Order letter issued to STN BL 103234/5190. The labeling changes include those agreed to during review of STN BL 103234/5190 and the additional changes ordered by FDA under the authority of section 505(o)(4)(E) of the Federal Food, Drug and Cosmetic Act (FDCA). The package insert includes revised Boxed Warning, Indications and Usage, Warnings, and Dosage and Administration sections. Also, the Patient Package Insert is replaced with a new Medication Guide and a new Patient Instructions for Use. Container and Carton labels were revised to reference the Medication Guide. This supplement, submitted as a "Special Labeling Supplement – Changes Being Effected" as described under 21 CFR 601.12(f)(2), has been approved.

We remind you of your obligations under 21 CFR Part 208 regarding Medication Guides. Your approved Medication Guide will become part of the Risk Evaluation and Mitigation Strategy (REMS) in pending supplement STN BL103234/5199.

Supplement STN BL 103234/5196 proposes additional revisions to the carton and container labeling. This "Prior Approval Supplement" as described under 21 CFR 601.12(b), has also been approved.

Upon receipt of supplement BL 103234/5195 implementing the changes described in our July 30, 2008, letter, your supplement STN BL 103234/5190 is considered withdrawn.

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

We acknowledge that the revised labeling approved today was posted on your website on August 7, 2008. We further acknowledge that the revised labeling was provided as an enclosure to the Dear Healthcare Provider letter mailing distributed to oncologists, hematologists, hematology/oncology specialists, radiation oncologists, nephrologists, and infectious disease specialists and to healthcare practitioners who wrote at least one prescription for an erythropoiesis-stimulating agent (ESA) between December 1, 2007 and May 31, 2008, and that the dissemination of this letter to the above mentioned list of healthcare practitioners was completed by August 20, 2008.

We also acknowledge your plan, as outlined in your letter of September 9, 2008, for inclusion of the revised labeling in packaged product as follows:

- Amgen commits to assembling packing configurations associated with particular stock keeping units (SKUs) using the revised packaging and labeling components for all production runs scheduled to begin on or after October 1, 2008, for the 7 Epogen and 11 Procrit products on a staggered basis as inventory is depleted.

- Amgen commits to introducing 6 of the 7 Epogen and 11 of the 11 Procrit SKUs into distribution with the revised packaging and labeling components on a rolling basis, to be completed within 6-months from FDA approval of the pending labeling supplement on a staggered basis as inventory is depleted.

- The 1 remaining Epogen SKU will be introduced into distribution within 7 months. We acknowledge your statements that it will take longer to use up inventory for this SKU because of the lower demand for this presentation.

Failure to make these changes promptly could make your product misbranded under Sections 201(n) and 502(a) of FDCA.

**CONTENT OF LABELING**

Within 7 days of the date of this letter, amend any pending supplement(s) with revised labeling in MS word format to include the changes approved in this supplement.

Submit all final printed carton and container labels that are identical to the enclosed draft labels as soon as they are available but no more than 30 days after they are printed. Please submit these labels electronically according to the guidance for industry titled *Providing Regulatory Submissions in Electronic Format – Human Pharmaceutical Product Applications and Related Submissions Using the eCTD Specifications (October 2005)*. Alternatively, you may submit 12 paper copies, with 6 of the copies individually mounted on heavy-weight paper or similar material. For administrative purposes, designate this submission "Product Correspondence – Final Printed Carton and Container Labels for approved STN BL 103234/5195." Approval of this submission by FDA is not required before the labeling is used.

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

If you have any questions, call Monica Hughes, M.S., Lead Regulatory Health Project Manager, at (301) 796-2320.

Sincerely,

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

Enclosures: Package Insert for Epogen/Procrit
Medication Guide for Epogen/Procrit
Patients Instructions for Use for Epogen/Procrit
Carton and Vial Labeling for Epogen/Procrit