



Our STN: BL 103234/5093

Amgen, Incorporated
Attention: Douglas Hunt
Director, Regulatory Affairs
One Amgen Center Drive
Thousand Oaks, CA 91320-1799

OCT 26 2005

Dear Mr. Hunt:

Your request to supplement your biologics license application for Epoetin alfa to revise the Warnings: Pure Red Cell Aplasia, Adverse Reactions: Immunogenicity, and Dosage and Administration: Chronic Renal Failure sections of the package insert has been approved. Your request to revise the "What is the Most Important Information I Should Know about EPOGEN and Chronic Renal Failure" section of the patient package insert has also been approved.

We acknowledge your written agreement to disseminate the revised package insert as an attachment to a Dear Health Care Provider Letter, as described in your letter of October 24, 2005, and as outlined below:

To reach agreement regarding the content of the Dear Health Care Provider letter with the Agency by November 4, 2005. Amgen will begin to disseminate the final, signed Dear Health Care Provider letter and the approved package insert to the oncology and hematology medical communities in coordination with other erythropoiesis-stimulating protein products in the same class by December 10, 2005.

Pursuant to 21 CFR 201.57(f)(2), patient labeling must be reprinted at the end of the package insert.

Please submit all final printed labeling at the time of use and include implementation information on FDA Form 356h. Please provide a PDF-format electronic copy of the signed Dear Health Care Provider Letter, package inset, and patient package insert, as well as original paper copies (ten for circulars and five for other labels).

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

Effective August 29, 2005, the new address for all submissions to this application is:

Food and Drug Administration
Center for Drug Evaluation and Research
Therapeutic Biological Products Document Room
5901-B Ammendale Road
Beltsville, MD 20705-1266

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

Sincerely,



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

Enclosures: Package Insert and Patient Package Insert