DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20852

Our STN: BL 103951/5096

Amgen, Incorporated
Attention: Wayne Frost, Ph.D.
Director, Regulatory Affairs
One Amgen Center Drive
Thousand Oaks, CA 91320-1799

OCT 26 2005

Dear Dr. Frost:

Your request to supplement your biologics license application for Darbepoetin 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 are the possible or reasonably likely side effects of Aranesp®" section of the patient package insert has also been approved.

We acknowledge your written agreement to disseminate the revised package insert and patient 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 letter, the approved package insert, and the approved patient 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

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