DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20852

Our STN: BL 103234/5104

MAY 11 2006

Amgen, Inc.
Attention: Mei Ling Chang-Lok, Ph.D., RAC
Manager, Regulatory Affairs
One Amgen Center Drive
Thousand Oaks, CA 91320-1799

Dear Dr. Chang-Lok:

Your request to supplement your biologics license application for Epoetin Alfa (Epogen®) to revise the physician and patient package inserts has been approved.

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 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.

If you have any questions, please contact the Regulatory Project Manager, Florence O. Moore, M.S., at (301) 796-2050.

Sincerely,

George Q. Mills, M.D., M.B.A.
Director
Division of Medical Imaging and Hematology Products
Office of Oncology Drug Product
Center for Drug Evaluation and Research