DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20852

DEC 16 2004

Our STN: BL 103951/5069

Amgen, Incorporated
Attention: Randy Steiner
Regulatory Affairs
One Amgen Center Drive
Thousand Oaks CA 91320-1799

Dear Mr. Steiner:

Your request to supplement your biologics license application for Darbepoetin alfa to revise the Warnings and Precautions sections to include information regarding thrombotic events and the risk of tumor promotion has been approved.

Pursuant to 21 CFR 201.57(f)(2), patient labeling must be reprinted at the end of the package insert. We request that the text of information distributed to patients be printed in a minimum of 10 point font.

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).

We acknowledge your written commitment to disseminate the agreed upon Dear Health Care Professional Letter within three weeks of the approval date of this supplement.

Please refer to http://www.fda.gov/cder biologics/default.htm for important information regarding therapeutic biological products, including the address for submissions Effective October 4, 2004, the new address for all submissions to this application is:

CDER Therapeutic Biological Products Document Room
Center for Drug Evaluation and Research
Food and Drug Administration
12229 Wilkins Avenue
Rockville, Maryland 20852

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

Sincerely,

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

Enclosure: Package Insert