DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

Amgen, Incorporated
Attention: Lisa Shamon-Taylor, Ph.D.
Senior Manager, Regulatory Affairs
One Amgen Center Drive
Thousand Oaks, CA 91320-1799

DEC 17 2007

Dear Dr. Shamon-Taylor:

We have received your supplement to your biologics license application (BLA) submitted under section 351 of the Public Health Service Act for Darbepoetin alfa/Aranesp to correct a typographical error in table 1 of the Warnings section of the package insert.

This supplement has been reviewed under submission tracking number STN BL 103951/5169 in accordance with 21 CFR 601.12(f)(2) and is approved effective this date.

We note your December 4, 2007, submission included final content of labeling [CFR 601.14(b)] in structured product labeling (SPL) format; we will transmit it to the National Library of Medicine for public dissemination. Within 21 days of the date of this letter, amend any pending supplement(s) for this BLA with content of labeling in SPL format to include the changes approved in this supplement.

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

Sincerely,

Patricia Keegan

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

Enclosures: Package Insert