



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

Amgen, Incorporated
Attention: Neal Storm, M.S., M.B.A.
Manager, Regulatory Affairs
One Amgen Center Drive
Mail Stop 17-2-B
Thousand Oaks, CA 91320

DEC 17 2007

Dear Mr. Storm:

We have received your supplement to your biologics license application (BLA) submitted under section 351 of the Public Health Service Act for Epoetin alfa/Epogen; Procrit 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 103234/5163 in accordance with 21 CFR 601.12(f)(2) and is approved effective this date.

We note your December 7, 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,

A handwritten signature in cursive script that reads "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