



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

Our STN: BL 125031/72

OCT 25 2006

Amgen, Incorporated
Attention: Chanda Walton, Ph.D.
Manager
One Amgen Center Drive
Thousand Oaks, CA 91320-1799

Dear Dr. Walton:

Your request to supplement your biologics license application for Pegfilgrastim to include bone imaging changes in the Precautions section, and a statement in the How Supplied section of the package insert and in the patient package insert regarding the presence of dry natural rubber in the pre-filled syringe needle cover 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. The final printed labeling (FPL) must be identical to the enclosed labeling text dated October 25, 2006. Marketing product with FPL that is not identical to the approved labeling may render the product misbranded and an unapproved new drug. 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, Maryland 20705-1266

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

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