



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration  
Rockville, MD 20857

Our STN: BL 103951/5164

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

**NOV 08 2007**

Dear Dr. Shamon-Taylor:

Your request to supplement your biologics license application for darbepoetin alfa (Aranesp<sup>®</sup>) to revise the Boxed Warnings, DESCRIPTION, CLINICAL STUDIES, INDICATIONS AND USAGE, WARNINGS, PRECAUTIONS, DOSAGE AND ADMINISTRATION, and HOW SUPPLIED sections of the package insert (PI) and to revise the patient package insert (PPI) has been approved.

Pursuant to 21 CFR 201.57(c)(18) and 201.80(f)(2), patient labeling must be reprinted immediately following the last section of labeling or, alternatively, accompany the prescription drug labeling.

We acknowledge the statement in your November 6, 2007, letter that you will distribute a Dear Healthcare Provider Letter with the attached revised labeling within 2 weeks from approval (November 8, 2007).

Within 21 days of the date of this letter, submit content of labeling [21 CFR 601.14(b)] in structured product labeling (SPL) format, as described at <http://www.fda.gov/oc/datacouncil/spl.html>, that is identical in content to the enclosed labeling text. Upon receipt, we will transmit that version to the National Library of Medicine for public dissemination. For administrative purposes, please designate this submission "Product Correspondence – Final SPL for approved STN BL 103951/5164." In addition, 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.

Marketing the product with labeling that is not identical to the approved labeling text may render the product misbranded and an unapproved new drug.

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

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