



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
Food and Drug Administration
Rockville, MD 20857

STN: BL 103951/5211

October 13, 2009

Amgen
Attention: Ravi Magavi
Senior Manager, Regulatory Affairs
One Amgen Center Drive
Thousand Oaks, CA 91320-1799

Dear Ms. Dang:

Your request to supplement your biologics license application for Darbepoetin alfa (Aranesp) to modify the WARNINGS section of the Package Insert to describe the potential for pure red cell aplasia (PRCA) in the specific clinical setting of hepatitis C virus (HCV) therapy with ribavirin and interferon has been approved.

We acknowledge your written commitments to disseminate a Dear Health Care Provider Letter to gastrointestinal (GI) and infectious disease (ID) physicians identified through the American Medical Association sub-specialty registry.

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 103951/5211." 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,

/Rafel Dwaine Rieves/
Rafel Dwaine Rieves, M.D.
Director
Division of Medical Imaging and Hematology Products
Office of Oncology Drug Products
Center for Drug Evaluation and Research