DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

Our STN: BL 103951/5195

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

Dear Dr. Shamon-Taylor:

This letter is in reference to your supplement submitted August 5, 2008, under section 351 of the Public Health Service Act for Aranesp (darbepoetin alfa).

This supplement provides for new labeling as described in our July 30, 2008, Complete Response and Safety Labeling Change Order letter issued to STN BL 103951/5189. The labeling changes include those agreed to during review of STN BL 103951/5189 and the additional changes ordered by FDA under the authority of section 505(o)(4)(E) of the Federal Food, Drug and Cosmetic Act (FDCA). The package insert includes revised Boxed Warning, Indications and Usage, Warnings, and Dosage and Administration sections. Also, the Patient Package Insert is replaced with a new Medication Guide and a new Patient Instructions for Use. Container and Carton labels were revised to reference the Medication Guide.

We remind you of your obligations under 21 CFR Part 208 regarding Medication Guides. Your approved Medication Guide will become part of the Risk Evaluation and Mitigation Strategy (REMS) in pending supplement STN BL103951/5197.

This CBE supplement containing a medication guide, patient instructions for use, revised container and carton labeling and revised package insert has been reviewed under submission tracking number STN BL 103951/5195 in accordance with 21 CFR 601.12(f)(2) and is approved effective this date.

Upon receipt of this supplement implementing the changes described in our July 30, 2008, letter, your supplement STN BL 103951/5189 is considered withdrawn.

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

We acknowledge that the revised labeling approved today was posted on your website on August 7, 2008. We further acknowledge that the revised labeling was provided as an enclosure to the Dear Healthcare Provider letter mailing distributed to oncologists, hematologists, hematology/oncology specialists, radiation oncologists, nephrologists, and infectious disease

specialists and to healthcare practitioners who wrote at least one prescription for an erythropoiesis-stimulating agent (ESA) between December 1, 2007 and May 31, 2008, and that the dissemination of that letter to the above mentioned list of healthcare practitioners was completed by August 20, 2008.

We also acknowledge your plan, as outlined in your letter of September 5, 2008, for inclusion of the revised labeling in packaged product as follows:

- Amgen commits to assembling packaging configurations associated with particular stock keeping units (SKUs) using the revised container and carton packaging and labeling components for all production runs scheduled to begin on or after October 1, 2008 for the 15 Aranesp products on a staggered basis as inventory is depleted.

- Amgen commits to introducing 13 of the 15 Aranesp SKUs into distribution with the revised container and carton packaging and labeling components on a rolling basis, to be completed within 6-months from FDA approval of the pending labeling supplement on a staggered basis as inventory is depleted.

- For the remaining two Aranesp SKUs, 1 SKU will be introduced into distribution within 7 months with the revised container and carton packaging and labeling components, and the last 1 SKU within 9 months with the revised container and carton packaging and labeling components. We acknowledge your statements that it will take longer to use up inventory for these SKUs because of the lower demand for these presentations.

Failure to make these changes under the timeframes described above could make your product misbranded under Sections 201(n) and 502(a) of FDCA.

CONTENT OF LABELING

Within 7 days of the date of this letter, please amend any pending supplement(s) with revised labeling in MS word format to include the changes approved in this supplement.

Submit all final printed carton and container labels that are identical to the enclosed draft labels as soon as they are available but no more than 30 days after they are printed. Please submit these labels electronically according to the guidance for industry titled *Providing Regulatory Submissions in Electronic Format – Human Pharmaceutical Product Applications and Related Submissions Using the eCTD Specifications (October 2005)*. Alternatively, you may submit 12 paper copies, with 6 of the copies individually mounted on heavy-weight paper or similar material. For administrative purposes, designate this submission "Product Correspondence – Final Printed Carton and Container Labels for approved STN BL 103951/5195." Approval of this submission by FDA is not required before the labeling is used.

If you have any questions, call Monica Hughes, M.S., Lead Regulatory Health Project Manager, at (301) 796-2320.

Sincerely,

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

Enclosures: Package Insert
Medication Guide
Patients Instructions for Use
Carton and Vial Labeling