DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Silver Spring, MD 20993

Our STN: BLA 103951

March 12, 2010

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

Dear Dr. Shamon-Taylor:

This letter is in reference to the Risk Evaluation and Mitigation Strategy (REMS) approved on February 16, 2010 under Section 505-1 of Federal Food, Drug, and Cosmetic Act (FDCA) for BLA 103951 (Aranesp). Aranesp is one of a class of drugs collectively referred to as Erythropoeisis Stimulating Agents, or "ESAs". One element of the approved REMS for the ESAs requires the distribution of a Medication Guide in accordance with the requirements of Part 208 of our regulations (21 CFR. Part 208).

FDA approved Medication Guides for the ESA products on November 19, 2008. On December 18, 2008, we issued a letter which indicated our intent to exercise enforcement discretion with respect to the frequency of the distribution of the Medication Guides in physicians' offices, and in certain inpatient or clinical settings, under specified conditions.

Since the Medication Guide has now been approved as part of a REMS under section 505-1 of the FDCA, we want to clarify that we intend to continue the enforcement approach outlined in our letter dated December 18, 2008, when evaluating compliance with the Medication Guide distribution requirements of the approved REMS. Specifically, when ESAs are administered to patients by a healthcare provider (e.g., in a physician's office, clinic, hospital inpatient setting, or dialysis center), we intend to exercise enforcement discretion with respect to the requirements of 21 CFR 208.24(e) as long as the Medication Guide is provided to each patient or patient caregiver at the initiation of therapy and then at least once a month for as long as treatment continues. In addition, if the Medication Guide is materially revised or updated, it should be given to the patient or patient caregiver at that time, and at least monthly thereafter. Amgen remains obligated to ensure that healthcare providers, clinics, and hospitals are notified and provided with updated Medication Guides if they are materially revised.

Please be advised that the policy reflected in this letter may be revoked at any time upon appropriate notice, and may also be superseded in the event FDA subsequently promulgates regulations or issues guidance relating to the issues addressed.

If you have questions, contact Suzanne Barone, Ph.D., Team Leader in the Division of Compliance Risk Management and Surveillance at 301/796-3224.

Sincerely,

/H. Gregg Claycamp, Ph.D./
H. Gregg Claycamp, Ph.D
Director
Division of Compliance Risk Management and Surveillance
Office of Compliance
Center for Drug Evaluation and Research