DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

Our STN: BL 103234/0

Amgen, Incorporated
Attention: Neal Storm, M.S., M.B.A
Senior Manager, Regulatory Affairs
One Amgen Center Drive
Mail Stop: 17-2-B
Thousand Oaks, CA 91320

Dear Mr. Storm:

This letter is in reference to your supplements (STN BL 103234/5195 and STN BL 103234/5196) submitted on August 5, 2008 and August 7, 2008, respectively under section 351 of the Public Health Service Act (PHSA) for Epogen/Procrit (epoetin alfa) both were subsequently approved on November 19, 2008. Among other things, by approving those supplements, we approved Medication Guides for Epogen/Procrit (epoetin alfa).

Section 208.24(e) of our regulations (21 CFR 208.24(e)) provides, in pertinent part, that "[e]ach authorized dispenser of a prescription drug product for which a Medication Guide is required under this part shall, when the product is dispensed to a patient (or to a patient's agent), provide a Medication Guide directly to each patient (or to the patient's agent)…."

FDA has determined it is not necessary that a patient receive the Medication Guide each time Epogen/Procrit is dispensed when Epogen/Procrit is administered to patients by a healthcare provider, (e.g., in a physician's office, clinic, hospital inpatient setting, or dialysis center). Therefore, in these instances, we intend to exercise enforcement discretion with respect to the requirements of 208.24(e) as long as the drug's Medication Guide is provided to each patient or patient caregiver at the initiation of therapy and then at least once a month to each patient or patient caregiver for as long as treatment continues. If the Medication Guide is materially revised or updated, it should be provided to the patient or patient caregiver at that time, and at least monthly from that time on.

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

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

Sincerely,

Michael M. Levy, Jr., Esq.
Director
Division of New Drugs and Labeling Compliance
Office of Compliance
Center for Drug Evaluation and Research