



Our STN: BL 103951/0

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 STN BL 103951/5195 submitted on August 5, 2008 under section 351 of the Public Health Service Act (PHSA) for Aranesp (darbepoetin alfa) subsequently approved on November 19, 2008. Among other things, by approving this supplement, we approved a Medication Guide for Aranesp (darbepoetin 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 Aranesp is dispensed when Aranesp 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