DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

Our STN: 125268/26

8/14/2009

Amgen
Attention: Anne Lauritzen, MBA, JD
Senior Manager, Regulatory Affairs
One Amgen Center Drive
Thousand Oaks, CA 91320-1799

Dear Ms. Lauritzen:

Please refer to your Biologic License Application (BLA) submitted under section 351 of the Public Health Service Act for Nplate (romiplostim) for subcutaneous injection.

We also refer to your March 24, 2009 submission, received on March 25, 2009, which proposes a modification to the Risk Evaluation and Mitigation Strategy (REMS) for Nplate (romiplostim) that was approved on August 22, 2008. Your approved REMS contains a Medication Guide, communication plan, elements to assure safe use, an implementation system, and a timetable for assessments of the REMS. Your proposed modification would add to the Nplate NEXUS website the Nplate NEXUS Program risk-specific safety questionnaires.

We completed our review of this application containing the proposed modifications to the REMS. Your proposed modifications, as incorporated in the REMS appended to this letter, are approved, effective on the date of this letter. The timetable for submission of assessments will remain the same as that approved on August 22, 2008, with the original approval of Nplate.

The requirements for assessments of an approved REMS under section 505-1(g)(3) include, in section 505-1(g)(3)(B) and (C), requirements for information on the status of any post-approval study or clinical trial required under section 505(o) or otherwise undertaken to investigate a safety issue. You can satisfy these requirements in your REMS assessments by referring to relevant information included in the most recent annual report required under section 506B and 21 CFR 601.70 and including any updates to the status information since the annual report was prepared. Failure to comply with the REMS assessment provisions in 505-1(g) could result in enforcement action.

Prominently identify future amendments containing the REMS assessments or proposed modifications with the following wording in bold capital letters at the top of the first page of the submission:

STN 125268 REMS ASSESSMENT
NEW SUPPLEMENT FOR STN 125268 REMS ASSESSMENT
PROPOSED REMS MODIFICATION

If you have any questions, call Hyon-Zu Lee, Pharm.D., Regulatory Project Manager, at (301) 796-2192

Sincerely,

/Ira Krefting/
Ira Krefting, M.D.
Deputy Director for Safety
Division of Medical Imaging and Hematology Products
Office of Oncology Drug Products
Center for Drug Evaluation and Research

Enclosure: Modified REMS