DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
Food and Drug Administration
Rockville, MD 20857

Our STN: BL 125268/28
BL 125268/36
BL 125268/2.0

March 23, 2010

Amgen
Attention: Anne Lauritzen, MBA, JD
Senior Manager, Regulatory Affairs
One Amgen Center Drive
Mail Stop 17-2-B
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 submissions dated March 31, 2009 (supplement 28) and June 19, 2009 (supplement 36) which contained REMS assessments and proposed modifications to the risk evaluation and mitigation strategy (REMS) for Nplate (romiplostim) which was originally 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 submission of assessments of the REMS.

We also refer to your August 26, 2008 submission in which you corrected a typographical error in the NEXUS Program Dose Calculator in the original REMS document.

Your proposed modifications include revisions to the Nplate NEXUS Program Patient Baseline Safety Data Form, the NEXUS Program Patient Enrollment form, the NEXUS Program Healthcare Provider Enrollment Form, and the NEXUS Program Institutional Enrollment Form and the NEXUS Program Dose Calculator.

We have completed our review of these supplemental biologics applications, as amended. Your proposed modified REMS, submitted on March 17, 2010 and appended to this letter, is approved.

The timetable for submission of assessments of the REMS will remain the same as that approved on August 22, 2008 with the original approval of Nplate (romiplostim)

We remind you that the requirements for assessments of an approved REMS under section 505-1(g)(3) include, in section 505-1(g)(3)(A), an assessment of the extent to which the elements to assure safe use are meeting the goal or goals to mitigate a specific serious risk listed in the labeling of the drug, or whether the goal or goals or such elements should be modified.

The requirements for assessments of an approved REMS also include, in section 505-1(g)(3)(B) and (C), information on the status of any postapproval 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 assessments provisions in 505-1(g) could result in enforcement action.

We remind you that in addition to the assessments submitted according to the timetable included in the approved REMS, you must submit a REMS assessment and may propose a modification to the approved REMS when you submit a supplemental application for a new indication for use as described in Section 505-1(g)(2)(A) of FDCA.

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

BLA 125268 REMS ASSESSMENT

NEW SUPPLEMENT FOR BLA 125268
PROPOSED REMS MODIFICATION
REMS ASSESSMENT

NEW SUPPLEMENT (NEW INDICATION FOR USE)
FOR BLA 125268
REMS ASSESSMENT
PROPOSED REMS MODIFICATION (if included)

If you do not submit electronically, please send 5 copies of REMS-related submissions.

We request that the revised labeling approved today be available on your website within 10 days of receipt of this letter.

This information will be included in your biologics license application file.

If you have any questions, call Diane Leaman, Safety Regulatory Project Manager, at (301) 796-1424.

Sincerely,

/Robert Kane/

Robert Kane, M.D.
Deputy Director for Safety
Division of Hematology Products
Office of Oncology Drug Products
Center for Drug Evaluation and Research