BLA 125268/S-170

SUPPLEMENT APPROVAL

Amgen, Inc.
Attention: Sahar Reka, MS
Manager, Regulatory Affairs
One Amgen Center Drive
Mail Stop 27-2-D
Thousand Oaks, CA 91320-1799

Dear Ms. Reka:

Please refer to your supplemental biologics license application (sBLA), dated and received November 17, 2020, submitted under section 351(a) of the Public Health Service Act for Nplate (romiplostim) 125 mcg, 250 mcg, 500 mcg for Injection.

This Prior Approval supplemental new drug application provides for proposed modification to the approved Nplate risk evaluation and mitigation strategy (REMS). This supplement is in response to our October 16, 2020, REMS Modification Notification letter.

We have completed our review of this supplemental application, as amended. It is approved effective on the date of this letter.

RISK EVALUATION AND MITIGATION STRATEGY (REMS) REQUIREMENTS

The REMS for Nplate was originally approved on August 22, 2008, and the most recent REMS modification was approved on December 6, 2011. The REMS consists of a communication plan, and a timetable for submission of assessments of the REMS. In order to minimize burden on the healthcare delivery system of complying with the REMS, we determined that you were required to make the REMS modifications outlined in our REMS Modification letter dated October 16, 2020.

Communication Plan: We have determined that the communication plan is no longer necessary as an element of the REMS to ensure the benefits of Nplate outweigh its risks because the communication plan has been completed and the most recent assessment demonstrates that the communication plan has met its goals. No further assessments are necessary to assess the current communication plan.

Therefore, because the communication plan is no longer necessary to ensure the benefits of the drug outweigh the risks, a REMS is no longer required for Nplate.

REPORTING REQUIREMENTS

We remind you that you must comply with reporting requirements for an approved BLA (in 21 CFR 600.80 and in 21 CFR 600.81).

If you have any questions, please call Lori Anne Wachter, RN, BSN, RAC, Acting Regulatory Project Manager for Safety, at 301 796-3975.

Sincerely,

{See appended electronic signature page}

Rosanna Setse, MD, PhD.
Acting Deputy Director for Safety
Division of Non-malignant Hematology
Office of Cardiology, Hematology, Endocrinology and Nephrology
Center for Drug Evaluation and Research

This is a representation of an electronic record that was signed electronically. Following this are manifestations of any and all electronic signatures for this electronic record.

/s/

ROSANNA W SETSE
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