BLA125268/S-169

GENERAL ADVICE

Amgen
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) submitted under section 351(a) of the Public Health Service Act for Nplate (romiplostim) 125 mcg, 250 mcg and 500 mcg vial for Injection.

We also refer to our approval letter dated November 23, 2020, which contained an error.

The 125 mcg dose was inadvertently omitted from the November 23, 2020 Approval letter.

This General Advice letter acknowledges the error described above and incorporates the correction of the error. The effective approval date will remain November 23, 2020, the date of the original approval letter.

If you have any questions, please call Lori Anne Wachter, RN, BSN, RAC (US), 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 Nonmalignant 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
11/24/2020 04:41:43 PM

BLA 125268/S-169

SUPPLEMENT APPROVAL

Amgen
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 October 20, 2020, and your amendments, submitted under section 351(a) of the Public Health Service Act for Nplate (romiplostim) Injection, 250 mcg, 500 mcg vial (500 mcg/mL).

We also refer to our August 18, 2020 Safety-Related Labeling Supplement Request letter requesting revisions to the Adverse Reactions section of the approved labeling to add language regarding anaphylaxis.

This supplemental biologics application provides for revisions consistent with our August 18, 2020 letter.

APPROVAL & LABELING

We have completed our review of this application, as amended. It is approved, effective on the date of this letter, for use as recommended in the enclosed agreed-upon labeling.

CONTENT OF LABELING

As soon as possible, but no later than 14 days from the date of this letter, submit, via the FDA automated drug registration and listing system (eLIST), the content of labeling [21 CFR 601.14(b)] in structured product labeling (SPL) format, as described at FDA.gov,[1] that is identical to the enclosed labeling (text for the Prescribing Information) and include the labeling changes proposed in any pending "Changes Being Effected" (CBE) supplements.

[1] http://www.fda.gov/ForIndustry/DataStandards/StructuredProductLabeling/default.htm

Information on submitting SPL files using eLIST may be found in the guidance for industry *SPL Standard for Content of Labeling Technical Qs and As*.[2]

The SPL will be accessible via publicly available labeling repositories.

Also within 14 days, amend all pending supplemental applications that include labeling changes for this BLA, including pending "Changes Being Effected" (CBE) supplements, for which FDA has not yet issued an action letter, with the content of labeling [21 CFR 601.12(f)] in Microsoft Word format that includes the changes approved in this supplemental application, as well as annual reportable changes. To facilitate review of your submission(s), provide a highlighted or marked-up copy that shows all changes, as well as a clean Microsoft Word version. The marked-up copy should provide appropriate annotations, including supplement number(s) and annual report date(s).

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 (US), 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 Nonmalignant Hematology
Office of Cardiology, Hematology, Endocrinology and Nephrology
Center for Drug Evaluation and Research

ENCLOSURE(S):

- Content of Labeling
    - Prescribing Information

[2] We update guidances periodically. For the most recent version of a guidance, check the FDA Guidance Documents Database https://www.fda.gov/RegulatoryInformation/Guidances/default.htm.

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
11/23/2020 11:27:50 AM