BLA 103575/S-5318

SUPPLEMENT APPROVAL

Janssen Biotech, Inc.
Attention: Kelly Rudnick, MSPH
Associate Director, Global Regulatory Affairs
1400 McKean Road
Spring House, PA 19477

Dear Ms. Rudnick:

Please refer to your supplemental biologics license application (sBLA), dated and received March 1, 2019, and your amendments, submitted under section 351(a)/351(k) of the Public Health Service Act for Reopro (abciximab) 2 mg/mL for Intravenous Use.

This Prior Approval supplemental biologics application provides for the following revisions to the Precautions section:

Under **PRECAUTIONS, Thrombocypenia**, the following text was added (additions are shown as underlined text):

> **Thrombocytopenia-** Thrombocytopenia, including severe thrombocytopenia, has been observed with Abciximab administration (*see ADVERSE REACTIONS: Thrombocytopenia*). Platelet counts should be monitored prior to, during, and after treatment with Abciximab *(see PRECAUTIONS: Laboratory Tests*). Acute decreases in platelet count should be differentiated between true thrombocytopenia and pseudothrombocytopenia (*see PRECAUTIONS: Laboratory Tests*). If true thrombocytopenia is verified, Abciximab should be immediately discontinued and the condition appropriately monitored and treated.
>
> In clinical trials, patients who developed thrombocytopenia were followed with daily platelet counts until their platelet count returned to normal. Heparin and aspirin were discontinued for platelet counts below 60,000 cells/mL and platelets were transfused for a platelet count below 50,000 cells/mL. Most cases of severe thrombocytopenia (< 50,000 cells/mL) occurred within the first 24 hours of Abciximab administration, but some cases have been reported up to 2 weeks after administration.

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.

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
Regulatory Project Manager for Safety
301 796-3975

Sincerely,

{See appended electronic signature page}

Mary Ross Southworth, PharmD.
Deputy Director for Safety
Office of Drug Evaluation I
Center for Drug Evaluation and Research

ENCLOSURE(S):
- Content of Labeling

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

[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/

MARY R SOUTHWORTH
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