DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

BLA 103575 / 5126

SUPPLEMENT APPROVAL

Janssen Biotech, Inc.
Attention: Kimberly Shields-Tuttle, Senior Director
Global Regulatory Affairs, Immunology
Welsh & McKean Roads
P.O. Box 776
Spring House, PA 19477

Dear Ms. Shields-Tuttle:

Please refer to your Supplemental Biologics License Application (sBLA) dated December 19, 2012, received December 19, 2012, submitted under section 351(a) of the Public Health Service Act for ReoPro (abciximab).

This Prior Approval supplemental biologics application proposes changes to the existing bleeding events warning as well as additions to the adverse reactions section of the label. Those changes are as follows:

- To the **WARNINGS** section, **Bleeding Events** subsection, the following phrase was added when discussing the potential increase of bleeding events:

  "rarely including those with a fatal outcome"

- In the **ADVERSE REACTIONS** section, **Bleeding** subsection, the following sentence was added:

  "Cases of fatal bleeding have been reported rarely during post-marketing use of abciximab (see WARNINGS, Bleeding Events).

APPROVAL & LABELING

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

We note that your December 19, 2012, submission includes final printed labeling (FPL) for your package insert. We have not reviewed this FPL. You are responsible for assuring that the wording in this printed labeling is identical to that of the approved content of labeling in the structured product labeling (SPL) format.

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 http://www.fda.gov/ForIndustry/DataStandards/StructuredProductLabeling/default.htm, that is identical to the enclosed labeling (text for the package insert) 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 titled "SPL Standard for Content of Labeling Technical Qs and As" at http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM072392.pdf.

The SPL will be accessible via publicly available labeling repositories.

Also within 14 days, amend all pending supplemental applications that includes 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 MS Word format that includes the changes approved in this supplemental application.

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:

Alison Blaus, RAC
Regulatory Project Manager
(301) 796-1138

Sincerely,

{See appended electronic signature page}

Norman Stockbridge, M.D., Ph.D.
Director
Division of Cardiovascular & Renal Products
Office of Drug Evaluation I
Center for Drug Evaluation and Research

ENCLOSURE:
Content of Labeling

This is a representation of an electronic record that was signed electronically and this page is the manifestation of the electronic signature.

/s/

ALISON L BLAUS
11/25/2013

NORMAN L STOCKBRIDGE
11/25/2013