BLA 103772/S-5389
BLA 103772/S-5391
BLA 103772/S-5394

SUPPLEMENT APPROVAL
FULFILLMENT OF POSTMARKETING COMMITMENT

Janssen Biotech, Inc.
800/850 Ridgeview Drive
Horsham, PA 19044

Attention: Richard Lee, PharmD
Manager, Global Regulatory Affairs

Dear Dr. Lee:

Please refer to the following supplemental biologics license application(s) (sBLA), and your amendments, submitted under section 351(a) of the Public Health Service Act for Remicade (infliximab) for injection.

S-5389: dated and received March 5, 2018,
S-5391: dated and received August 29, 2018
S-5394: dated and received December 20, 2018

These Prior Approval supplemental biologics applications provide for revisions to the U.S. Prescribing Information (USPI) as specified below:

S-5389: following sections and any corresponding changes to the Medication Guide:

- Dosage and Administration, section 2.11 for preparing larger volumes for administration,
- Warnings and Precautions section for revised vaccination recommendation pertaining to all patients,
- Adverse Reactions, Postmarketing Experience section adding linear immunoglobulin A bullous dermatosis and (b) (4) (b) (4).

S-5391: inclusion of acute generalized exanthematous pustulosis (AGEP) in the Adverse Reactions, Postmarketing Experience section, and Medication Guide.

S-5394: Pregnancy and Lactation Labeling Rule (PLLR) conversion and addition of lichenoid reactions to the Adverse Reactions section.

In addition, we have received your submission to IND 005947 dated December 21, 2016, containing the final report for the following postmarketing commitment listed in the May 13, 2005, approval letter for BLA 103772/S-5089. We also refer to the subsequent revised milestone dates as noted in the March 6, 2013, letter for BLA 103772/5349 submitted October 15, 2012.

2598-1 To conduct a prospective, observational registry study of women with Crohn's disease, rheumatoid arthritis, and psoriatic arthritis exposed to infliximab during pregnancy. This study will assess the pregnancy outcomes in women who were exposed to infliximab during pregnancy relative to background risk in similar patients not exposed to infliximab.

We have reviewed your submission and conclude that the above commitment was fulfilled.

APPROVAL & LABELING

We have completed our review of these supplemental applications, as amended. They are 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 Medication Guide) 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

[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.

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).

REQUIRED PEDIATRIC ASSESSMENTS

Under the Pediatric Research Equity Act (PREA) (21 U.S.C. 355c), all applications for new active ingredients (which includes new salts and new fixed combinations), new indications, new dosage forms, new dosing regimens, or new routes of administration are required to contain an assessment of the safety and effectiveness of the product for the claimed indication(s) in pediatric patients unless this requirement is waived, deferred, or inapplicable.

Because none of these criteria apply to your application, you are exempt from this requirement.

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, call Christine Ford, Regulatory Project Manager, at (301) 796-3420.

Sincerely,

{See appended electronic signature page}

Nikolay Nikolov, MD
Director (Acting)
Division of Rheumatology and Transplant Medicine
Office of Immunology and Inflammation
Center for Drug Evaluation and Research

ENCLOSURE(S):
Content of Labeling
- Prescribing Information
- Medication Guide

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/

NIKOLAY P NIKOLOV
05/14/2020 06:18:02 PM