DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

BLA 761061/S-001

SUPPLEMENT APPROVAL

Janssen Biotech, Inc.
Attention: Manomi Tennakoon, PhD
Director, Global Regulatory Affairs, Immunology
920, Route 202 South
Raritan, NJ 08869

Dear Dr. Tennakoon:

Please refer to your Supplemental Biologics License Application (sBLA), dated and received March 29, 2018, and your amendments, submitted under section 351(a) of the Public Health Service Act for TREMFYA® (guselkumab) injection, for subcutaneous use.

We also refer to our approval letter dated January 28, 2019 which contained the following error: the sample and trade container labels for the Single-dose 100 mg/mL One-Press patient-controlled injector were not attached to the approval letter.

This replacement approval letter incorporates the correction of the error. The effective approval date will remain January 28, 2019, the date of the original approval letter.

This Prior Approval supplemental biologics application provides for registration of Single-dose 100 mg/mL One-Press patient-controlled injector.

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.

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 Prescribing Information, Instructions for Use, 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 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 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).

CARTON AND CONTAINER LABELING

The supplemental new drug application proposes to include "inspirational text" statements on the interior of the TREMFYA One-Press injector carton, which will be placed on the interior of the front panel and will be visible only after opening the carton. We have completed our review of this supplemental application. It is approved, effective on the date of this letter.

Your submission asserts that the proposed statements "are intended to be inspirational and are not intended to convey claims of benefit from treatment with TREMFYA." We agree that the proposed "inspirational text" statements are general in nature and, as presented, do not make representations about the TREMFYA One-Press injector. Your submission further states that the proposed statements are "intended to enhance the experience of those patients suffering from psoriasis who are about to receive a dose of TREMFYA" and that "[p]roviding inspirational messaging in the moment may help patients prepare and build confidence prior to injection." You have not submitted any evidence regarding the effect of the proposed inspirational statements on patient confidence or experience, and FDA has not made an independent determination that the proposed inspirational statements build patient confidence or otherwise enhance the patient experience in any way. Nonetheless, FDA has determined that the proposed inspirational statements, in their proposed placement on the interior of the Tremfya One-Press injector carton, do not interfere with the required content of the labeling.

Submit final printed carton and container labeling that are identical to the enclosed carton and container labeling and carton and container labeling submitted on January 7, 2019, as soon as they are available, but no more than 30 days after they are printed. Please submit these labeling electronically according to the guidance for industry titled *Providing Regulatory Submissions in Electronic Format — Certain Human Pharmaceutical Product Applications and Related Submissions Using the eCTD Specifications (April 2018, Revision 5).* For administrative purposes, designate this submission "**Final Printed Carton and Container Labeling for**

approved BLA 761061/S-001." Approval of this submission by FDA is not required before the labeling is used.

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.

PROMOTIONAL MATERIALS

You may request advisory comments on proposed introductory advertising and promotional labeling. To do so, submit, in triplicate, a cover letter requesting advisory comments, the proposed materials in draft or mock-up form with annotated references, and the Prescribing Information to:

OPDP Regulatory Project Manager
Food and Drug Administration
Center for Drug Evaluation and Research
Office of Prescription Drug Promotion
5901-B Ammendale Road
Beltsville, MD 20705-1266

Alternatively, you may submit a request for advisory comments electronically in eCTD format. For more information about submitting promotional materials in eCTD format, see the draft Guidance for Industry (available at: http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM443702.pdf).

As required under 21 CFR 601.12(f)(4), you must submit final promotional materials, and the Prescribing Information, at the time of initial dissemination or publication, accompanied by a Form FDA 2253. Form FDA 2253 is available at http://www.fda.gov/downloads/AboutFDA/ReportsManualsForms/Forms/UCM083570.pdf. Information and Instructions for completing the form can be found at http://www.fda.gov/downloads/AboutFDA/ReportsManualsForms/Forms/UCM375154.pdf. For more information about submission of promotional materials to the Office of Prescription Drug Promotion (OPDP), see http://www.fda.gov/AboutFDA/CentersOffices/CDER/ucm090142.htm.

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 Matthew White, Senior Regulatory Project Manager, at (301) 796-4997.

Sincerely,

{See appended electronic signature page}

Kendall A. Marcus, MD
Director
Division of Dermatology and Dental Products
Office of Drug Evaluation III
Center for Drug Evaluation and Research

ENCLOSURE(S):
- Content of Labeling
  - Prescribing Information
  - Medication Guide
  - Instructions for Use
- Carton and Container Labeling

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/

KENDALL A MARCUS
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