



BLA 761061/S-028
BLA 761061/S-029

**SUPPLEMENT APPROVAL
POSTMARKETING REQUIREMENT
NOT FULFILLED**

Janssen Biotech, Inc.
Attention: Matthew Phillips
Associate Director, Global Regulatory Affairs
Welsh and McKean Roads
P.O. Box 776
Spring House, PA 19477-7709

Dear Matthew Phillips:

Please refer to your supplemental biologics license applications (sBLAs) received November 27, 2024 and your amendments, submitted under section 351(a) of the Public Health Service Act for Tremfya (guselkumab), injection.

These Prior Approval supplemental biologics license applications extend the indications to:

- S-028: Pediatric patients 6 years and older who also weigh at least 40 kg with moderate-to-severe plaque psoriasis and who are candidates for systemic therapy or phototherapy
- S-029: Pediatric patients 6 years and older who also weigh at least 40 kg with active psoriatic arthritis

APPROVAL & LABELING

We have completed our review of these 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,

¹ <http://www.fda.gov/ForIndustry/DataStandards/StructuredProductLabeling/default.htm>

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 *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).

CARTON AND CONTAINER LABELING

Submit final printed carton and container labeling that are identical to the enclosed carton and container labeling, 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 *Providing Regulatory Submissions in Electronic Format — Certain Human Pharmaceutical Product Applications and Related Submissions Using the eCTD Specifications*. For administrative purposes, designate this submission “**Final Printed Carton and Container Labeling for approved BLA 761061/S-028 and BLA 761061/S-029.**” 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.

We are waiving the pediatric study requirement for the treatment of juvenile psoriatic arthritis in children ages 5 to less than 6 years of age because necessary studies are impossible or highly impractical due to the rarity of the diagnosis in this age group.

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>.

As discussed further below, we note that pediatric study requirements (PMR 3225-1 and PMR 3899-1) for these applications are partially fulfilled.

FULFILLMENT OF POSTMARKETING REQUIREMENT(S)

We have received your submissions dated November 27, 2024, containing the final reports for the following postmarketing requirements listed in the July 13, 2017, and July 13, 2020, Approval letters. We note that you have partially fulfilled the pediatric study requirements PMR 3225-1 and 3899-1 below.

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|--------|--|
| 3225-1 | Conduct a Pharmacokinetics (PK), Safety and Efficacy Study in pediatric subjects 6 years to less than 18 years of age with moderate to severe plaque psoriasis (with a duration of exposure to guselkumab of at least one year). |
| 3899-1 | Provide PK and safety information to support the pediatric assessment of guselkumab for the treatment of juvenile psoriatic arthritis (jPsA) in children 5 to 17 years of age. |

We remind you of your ongoing obligation to complete your pediatric assessments with respect to pediatric patients who are 6 years and older with moderate to severe plaque psoriasis and juvenile psoriatic arthritis who weigh less than 40 kg, using an appropriate formulation to adequately assess safety and effectiveness and support dosing and administration (e.g., appropriate strength and presentation) in this pediatric subpopulation.

We also remind you that there are other postmarketing requirements listed in the July 13, 2017, approval letter that are still open.

PROMOTIONAL MATERIALS

You may request advisory comments on proposed introductory advertising and promotional labeling. For information about submitting promotional materials, see the final guidance for industry *Providing Regulatory Submissions in Electronic and Non-Electronic Format-Promotional Labeling and Advertising Materials for Human Prescription Drugs*.³

³ For the most recent version of a guidance, check the FDA guidance web page at <https://www.fda.gov/media/128163/download>.

You must submit final promotional materials and Prescribing Information, accompanied by a Form FDA 2253, at the time of initial dissemination or publication [21 CFR 601.12(f)(4)]. Form FDA 2253 is available at FDA.gov.⁴ Information and Instructions for completing the form can be found at FDA.gov.⁵

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).

Your product is a Part 3 combination product (21 CFR 3.2(e)); therefore, you must also comply with postmarketing safety reporting requirements for an approved combination product (21 CFR 4, Subpart B). Additional information on combination product postmarketing safety reporting is available at FDA.gov.

If you have any questions, contact Kimberle Searcy, Regulatory Project Manager, at 240-402-4454.

Sincerely,

{See appended electronic signature page}

Gordana Diglisic, MD
Associate Director for Therapeutic Review
Division of Dermatology and Dentistry
Office of Immunology and Inflammation
Office of New Drugs
Center for Drug Evaluation and Research

Raj Nair, MD
Director
Division of Rheumatology and Transplant Medicine
Office of Immunology and Inflammation
Office of New Drugs
Center for Drug Evaluation and Research

ENCLOSURE(S):

- Content of Labeling
 - Prescribing Information
 - Medication Guide
 - Instructions for Use
- Carton Labeling

⁴ <http://www.fda.gov/downloads/AboutFDA/ReportsManualsForms/Forms/UCM083570.pdf>

⁵ <http://www.fda.gov/downloads/AboutFDA/ReportsManualsForms/Forms/UCM375154.pdf>

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/

RAJ NAIR
09/26/2025 05:13:00 PM

GORDANA DIGLISIC
09/26/2025 05:22:53 PM