BLA 761043/S-034

**SUPPLEMENT APPROVAL**
**FULFILLMENT OF POSTMARKETING REQUIREMENT**

GlaxoSmithKline (GSK) LLC
Attention: Stephanie Kim, PharmD
Associate Director, Global Regulatory Affairs
2929 Walnut St., Suite 1700
Philadelphia, PA 19104

Dear Dr. Kim:

Please refer to your supplemental biologics license application (sBLA) received August 21, 2024, and your amendments, submitted under section 351(a) of the Public Health Service Act for Benlysta (belimumab) injection, for subcutaneous use.

This Prior Approval supplemental biologics license application provides for an expansion of the use of Benlysta for subcutaneous administration via the autoinjector to include treatment of pediatric patients down to 5 years of age with active lupus nephritis who are receiving standard therapy.

## 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.

Benlysta (belimumab) injection, for subcutaneous use is also approved for use in pediatric patients 5 years of age and older for the treatment of active lupus nephritis who are receiving standard therapy. This supplement provides for pediatric labeling text pursuant to the Pediatric Research Equity Act (PREA). This approval is in response to a PREA PMR.

## 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).

## 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 supplement application, you are exempt from this requirement.

## FULFILLMENT OF POSTMARKETING REQUIREMENT(S)

We have received your submission dated November 29, 2023, containing the final report for the following postmarketing requirement listed in the December 16, 2020, approval letter for BLA 125370/S-073 and BLA 761043/S-013.

| | |
|---|---|
| 4021-1[3] | Provide an assessment of subcutaneous belimumab for the treatment of patients ages 5 to less than 18 years of age with lupus nephritis who are receiving standard therapy.<br><br>Final Report Submission: 11/2023 |

[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.
[3] PMR 4021-1 was initially issued as PMR 3994-2

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

This closes all of your postmarketing requirements and postmarketing commitments acknowledged in our December 16, 2020, letter. You are not required to report on the status of closed (released or fulfilled) PMRs/PMC in your annual report required under 21 CFR 601.70.

## 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.*[4]

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.[5] Information and Instructions for completing the form can be found at FDA.gov.[6]

## 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).

[4] For the most recent version of a guidance, check the FDA guidance web page at https://www.fda.gov/media/128163/download.
[5] http://www.fda.gov/downloads/AboutFDA/ReportsManualsForms/Forms/UCM083570.pdf
[6] http://www.fda.gov/downloads/AboutFDA/ReportsManualsForms/Forms/UCM375154.pdf

If you have any questions, contact Suprat Saely, Regulatory Project Manager at suprat.saely@fda.hhs.gov or 240-402-1604.

Sincerely,

*{See appended electronic signature page}*

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

---

**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/

---

HYON J KWON
06/20/2025 10:43:45 AM
Signing on behalf of Raj Nair