



BLA 125370/S-078

**SUPPLEMENT APPROVAL  
FULFILLMENT OF POSTMARKETING REQUIREMENT**

GlaxoSmithKline LLC  
1250 South Collegeville Road  
Collegeville, PA 19426

Attention: Wendy Valinski, MS  
Director Global Regulatory Affairs

Dear Ms. Valinski:

Please refer to your supplemental biologics license application (sBLA), dated and received January 26, 2022, and your amendments, submitted under section 351(a) of the Public Health Service Act for Benlysta (belimumab) for injection, for intravenous (IV) use.

This Prior Approval supplemental biologics license application provides for expansion of the approved indication of IV Benlysta for the treatment of patients with active lupus nephritis who are receiving standard therapy to now include patients 5 to 17 years of age.

**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 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 FDA.gov,<sup>1</sup> 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 Effectuated" (CBE) supplements.

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

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*.<sup>2</sup>

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 application, you are exempt from this requirement.

### **FULFILLMENT OF POSTMARKETING REQUIREMENT**

We have received your submission dated January 26, 2022, containing the final report(s) for the following postmarketing requirements listed in the December 16, 2020, approval letter for BLA 125370/S-073 and BLA 761043/S-013.

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|--------|---|
| 3994-1 | Provide an assessment of intravenous belimumab for the treatment of patients ages 5 to less than 18 years of age with lupus nephritis who are receiving standard therapy. |
|--------|---|

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

This completes all of your postmarketing requirements acknowledged in our December 16, 2020, letter for BLA 125370/S-073.

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<sup>2</sup> 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>.

## **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*.<sup>3</sup>

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 FDA.gov.<sup>4</sup> Information and Instructions for completing the form can be found at FDA.gov.<sup>5</sup>

## **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 Susan Rhee, Regulatory Project Manager, at 301-796-2402.

Sincerely,

*{See appended electronic signature page}*

Nikolay P. Nikolov, 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

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

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

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

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**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.**  
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/s/  
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