



BLA 125370/S-081

SUPPLEMENT APPROVAL

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), dated and received August 4, 2023, and your amendments, submitted under section 351(a) of the Public Health Service Act for Benlysta (belimumab) for injection, for intravenous (IV) use, in vials containing 120 mg and 400 mg lyophilized powder for reconstitution.

This Prior Approval supplemental biologics application provides for alignment of the common prescribing information for the two routes of administration of Benlysta, incorporating changes of Benlysta approval for subcutaneous administration in pediatric patients 5 years and older with systemic lupus erythematosus (BLA 761043/S-027).

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.

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, 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.

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>.

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.

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, contact Saharat Patanavanich, Regulatory Project Manager, at (240) 402-0139 or Saharat.patanavanich@fda.hhs.gov.

Sincerely,

{See appended electronic signature page}

Ozlem Belen, MD, MPH
Deputy Division 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
- Patient Package Insert or 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/

OZLEM A BELEN
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