

BLA 761122/S-008
BLA 125526/S-019

SUPPLEMENT APPROVAL

GlaxoSmithKline
1250 S. Collegeville Road
Collegeville, PA 19426

Attention: Thomas Kline
Regulatory Executive, Global Regulatory Affairs

Dear Mr. Kline:

Please refer to your supplemental biologics license applications (sBLA) dated September 24, 2021, received September 24, 2021, submitted under section 351(a) of the Public Health Service Act for Nucala (mepolizumab); Liquid Formulation, Safety Syringe Device (SSD), 40 mg/0.4 mL; and Lyophilized Powder for Subcutaneous Injection, 100 mg to provide:

1. BLA 761122/S-008: New strength: 40 mg/0.4 mL liquid formulation packaged in a Safety Syringe Device (SSD)
2. BLA 125526/S-019: Labeling changes to align and harmonize the prescribing information between the two BLAs

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.

Additionally, language “Rx Only” was added to the container labels for the 100mg/mL Autoinjector and the 100 mg/mL SSD

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

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

Information, Patient Package Insert, Instructions for Use) 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, 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 “**Product Correspondence – Final Printed Carton and Container Labeling for approved BLA 761122/ S-008 and BLA 125526-S-019.**” Approval of this submission by FDA is not required before the labeling is used.

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

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 For the most recent version of a guidance, check the FDA guidance web page at <https://www.fda.gov/media/128163/download>.
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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 314.81(b)(3)(i)]. Form FDA 2253 is available at FDA.gov.⁴ Information and Instructions for completing the form can be found at FDA.gov.⁵

This information will be included in your biologics license application file.

If you have any questions, call Ji Hyun LaRose, Regulatory Project Manager, at (301) 796-9017.

Sincerely,

{See appended electronic signature page}

Sally Seymour, MD
Director
Division of Pulmonology, Allergy, and Critical Care
Office of Immunology and Inflammation (OII)
Center for Drug Evaluation and Research

ENCLOSURE(S):

- Content of Labeling
 - Prescribing Information
 - Patient Package Insert
 - Instructions for Use
- Carton and Container Labeling

U.S. Food and Drug Administration
Silver Spring, MD 20993
www.fda.gov

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/

KELLY D STONE

01/22/2022 06:59:59 AM

Signing with the delegated authority of Dr. Sally Seymour, Director, DPACC