BLA 761122/S-011
BLA 125526/S-021

CORRECTED
SUPPLEMENT APPROVAL

GlaxoSmithKline
14200 Shady Grove Road
Rockville, MD, 20850

Attention: Surulikka Di Marino
Director, Global Regulatory Affairs,
Specialty Therapeutic Group

Dear Ms. Di Marino:

Please refer to your supplemental biologics license application (sBLA), dated September 9, 2022, received September 9, 2022, and your amendments, submitted under section 351(a) of the Public Health Service Act for Nucala (mepolizumab) for Subcutaneous Injection and Lyophilized Powder for Subcutaneous Injection.

We also refer to our approval letter dated March 8,2023, which contained the following errors:

1. In the HIGHLIGHTS OF PRESCRIBING INFORMATION, Nucala is referenced incorrectly as “coNucala.”

2. In the HIGHLIGHTS OF PRESCRIBING INFORMATION, the revision date is corrected to reflect 3/2023.

3. In Section 14.1 under the Severe Asthma subsection: it should say “Oral Corticosteroid reduction”. Instead, this section is missing “Oral Corticosteroid in front of reduction.

This corrected action letter incorporates the correction of the error. The effective action date will remain March 8, 2023, the date of the original letter.

These Prior Approval supplemental biologics license applications provide Labeling revisions to remove the Pregnancy Exposure Registry text in Section 8.1 and Section 17 and the reference to the registry in the Patient Information leaflet.

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.

WAIVER OF HIGHLIGHTS ½ PAGE LENGTH REQUIREMENT FOR HIGHLIGHTS

Please note that we have previously granted a waiver of the requirements of 21 CFR 201.57(d)(8) regarding the length of Highlights of Prescribing Information.

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, Instruction for use and Patient Information Leaflet) 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.

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[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.

Because none of these criteria apply to your application, you are exempt from this requirement.

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]

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

All promotional materials for your drug product that include representations about your drug product must be promptly revised to make it consistent with the labeling changes approved in this supplement, including any new safety-related information [21 CFR 601.12(a)(4)]. The revisions to your promotional materials should include prominent disclosure of the important new safety-related information that appears in the revised labeling. Within 7 days of receipt of this letter, submit your statement of intent to comply with 21 CFR 601.12(a)(4).

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 Julianne Lee, Regulatory Project Manager, at 240-402-5130.

Sincerely,

{See appended electronic signature page}

Robert Lim, M.D.
Deputy Director for Safety
Division of Pulmonology, Allergy, and Critical Care
Office of Immunology and Inflammation (OII)

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

Center for Drug Evaluation and Research

ENCLOSURE(S):

- Content of Labeling
    - Prescribing Information
    - Patient Information Leaflet
    - Instruction 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/

ROBERT H LIM
03/15/2023 09:14:43 AM