BLA 761077/S-017

CORRECTED SUPPLEMENT APPROVAL

Amgen Inc.
Attention: Pavithra Arunachalam, PharmD
Manager, Regulatory Affairs
One Amgen Center Drive
Mail Stop 38-5-B
Thousand Oaks, CA 91320-1799

Dear Dr. Arunachalam:

Please refer to your supplemental biologics license application (sBLA) dated and received March 25, 2022, submitted under section 351(a) of the Public Health Service Act for Aimovig (erenumab-aooe) injection.

We also refer to our approval letter dated September 22, 2022, which contained the following error(s): Missing updated carton and container labels, Autoinjector 70 mg Dispensing Carton, 1ct (Latex-Free), Autoinjector 70 mg Dispensing Carton, 1ct Not for Sale (Latex-Free), Autoinjector 140 mg Dispensing Carton, 1ct (Latex-Free), Autoinjector 140 mg Carton, 1ct Not For Sale (Latex-Free), Pre-filled Syringe 140 mg Carton 1ct (Latex-Free), Pre-filled Syringe 70 mg Carton 1ct (Latex-Free), Pre-filled Syringe 70 mg Carton, 1ct Not For Sale (Latex-Free), Pre-filled Syringe 140 mg Carton 1ct, Not for Sale (Latex-Free).

This corrected action letter incorporates the correction of the error. The effective action date will remain September 22, 2022, the date of the original letter.

This Prior Approval sBLA proposes modifications to the Aimovig US labeling documents to reflect the transition to non-dry-natural rubber (non-DNR) syringe needle shield for Aimovig prefilled syringes (PFS) and prefilled autoinjector pens (AI/Pen) presentations. Aimovig PFS and AI/Pen are no longer made with natural rubber latex.

APPROVAL & LABELING

We have completed our review of this sBLA. 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,

text for the patient package insert, and 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 titled *SPL Standard for Content of Labeling Technical Qs and As* at http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM072392.pdf.

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 MS Word format that includes the changes approved in this supplemental application.

CARTON AND CONTAINER LABELS

Submit final printed carton and container labels that are identical to enclosed carton and container labels, as soon as they are available, but no more than 30 days after they are printed. Please submit these labels 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 Labels for approved BLA 761077/S-017.**" Approval of this submission by FDA is not required before the labeling is used.

REQUIRED PEDIATRIC ASSESSMENTS

Under the Pediatric Research Equity Act (PREA) (21 U.S.C. 355c), all applications for new active ingredients, 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, please contact Erica Keafer, Regulatory Business Process Manager, at erica.keafer@fda.hhs.gov.

Sincerely,

{See appended electronic signature page}

Gerald Feldman, Ph.D., Lab Chief
On behalf of Gibbes Johnson, Ph.D., Director
Division of Biotechnology Review and Research IV
Office of Biotechnology Products
Office of Pharmaceutical Quality
Center for Drug Evaluation and Research

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/

GERALD M FELDMAN
09/23/2022 10:58:43 AM