BLA 761077/S-014

SUPPLEMENT APPROVAL

Amgen Inc.
Attention: Jennifer Rowland
Manager, Regulatory Affairs
One Amgen Center Drive
Mail-Stop: 38-5-A
Thousand Oaks, CA 91320-1799

Dear Ms. Rowland:

Please refer to your Supplemental Biologics License Application (sBLA) dated September 17, 2021, received September 17, 2021, submitted under section 351(a) of the Public Health Service Act for Aimovig (erenumab-aooe) injection.

We also refer to our approval letter dated March 4, 2022, which contained the following error: The approval letter issued on March 4, 2022, was missing autoinjector pen presentation language. The autoinjector pen presentation language has been added to the corrected approval letter for this supplement.

This replacement approval letter incorporates the correction of the error. The effective approval date will remain March 4, 2022, the date of the original approval letter.

This "Changes Being Effected in 30 days" sBLA replaces the (b) (4) needle shield containing dry natural rubber for the Aimovig drug product presentations which include the stand-alone prefilled syringe (PFS) and autoinjector pen presentations of 70 mg/mL and 140 mg/mL, with a similar (b) (4) needle shield without natural rubber. It also changes the needle for the stand-alone prefilled syringe (b) (4) .

APPROVAL

We have completed our review of this sBLA. This supplement is approved.

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

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}

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

Gibbes Johnson

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