BLA 761304/S-008

SUPPLEMENT APPROVAL

argenx BV
Attention: Purve Patel, RPh
Head of US Regulatory Affairs
33 Arch Street, 32nd Floor
Boston, MA 02110

Dear Purve Patel:

Please refer to your supplemental biologics license application (sBLA) received June 10, 2024, submitted under section 351(a) of the Public Health Service Act for Vyvgart Hytrulo (efgartigimod alfa and hyaluronidase-qvfc) injection.

This Prior Approval supplemental biologics license application provides for the following: new drug substance (DS) and drug product (DP) formulation with dosing change; new container closure system: prefilled syringe (PFS) with corresponding labeling changes (revisions to the Prescribing Information, a new Instructions for Use, and a new Patient Information); new manufacturing and QC testing facility for drug substance; and new manufacturing and QC testing facility for drug product.

The chemistry, manufacturing, and controls changes are detailed as follows:

1. Introduction of a new drug product (DP) presentation in PFS manufactured at [redacted] (b) (4)
2. Addition of a new drug substance (DS) and drug product (DP) formulation [redacted] (b) (4) [redacted] (b) (4) respectively with dosing change with the recommended dosage form and strength: single-dose pre-filled syringe: 1,000 mg efgartigimod alfa and 10,000 units hyaluronidase per 5 mL (200 mg and 2,000 units per mL);
3. Addition of [redacted] (b) (4) [redacted] (b) (4) as a new DS manufacturing and DS release and stability testing site;
4. Introduction of a new DP presentation in prefilled syringe (PFS) manufactured at [redacted] (b) (4)
5. Addition of [redacted] (b) (4) PFS DP release and stability testing site [redacted] (b) (4)

[redacted]

6. Addition of [redacted] a PFS DP release and stability testing site [redacted]

7. Addition of [redacted] as a PFS DP release and stability testing site [redacted]

8. Addition of [redacted] as a PFS DP release and stability testing site for [redacted]

9. Implementation of 18-month shelf-life from the date of manufacture for PFS DP manufactured at [redacted] when stored at 2-8°C with date of manufacture defined as the date of final sterile filtration;

10. Implementation of a comparability protocol [redacted]

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, Patient Information, and Instructions for Use) and include the labeling changes proposed in any pending "Changes Being Effected" (CBE) supplements.

[1] http://www.fda.gov/ForIndustry/DataStandards/StructuredProductLabeling/default.htm

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).

CARTON AND CONTAINER LABELING

Submit final printed carton and container labeling that are identical to the carton and container labeling submitted on April 4, 2025, 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 "**Final Printed Carton and Container Labeling for approved BLA 761304/S-008**." 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 (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 this drug product for this indication has an orphan drug designation, you are exempt from this requirement.

[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.

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]

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 601.12(f)(4)]. Form FDA 2253 is available at FDA.gov.[4] Information and Instructions for completing the form can be found at FDA.gov.[5]

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 Jemini Patel, Regulatory Project Manager, at jemini.patel@fda.hhs.gov.

Sincerely,

{See appended electronic signature page}

Laura Jawidzik, MD
Deputy Director
Division of Neurology 1
Office of Neuroscience
Center for Drug Evaluation and Research

ENCLOSURE(S):

- Content of Labeling
  - Prescribing Information
  - Patient Information
  - Instructions for Use

[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

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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/

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