BLA 761378/S-001

SUPPLEMENT APPROVAL

Formycon AG
Attention: Scott Oglesby, PhD
Principal Consultant
6518 Green Rise Road
Hillsborough, NC 27278

Dear Dr. Oglesby:

Please refer to your supplemental biologics license application (sBLA) dated and received December 17, 2024, and your amendments, submitted 351(k) of the Public Health Service Act for Ahzantive (aflibercept-mrbb) injection.

This Prior Approval sBLA seeks licensure of:

- Ahzantive (aflibercept-mrbb) injection 2 mg (0.05 mL of 40 mg/mL) for intravitreal use in a single-dose pre-filled syringe (PFS) as biosimilar to US-Eylea (aflibercept) injection 2 mg (0.05 mL of 40 mg/mL) for intravitreal use in a vial kit, and

- Ahzantive (aflibercept-mrbb) injection 2 mg (0.05 mL of 40 mg/mL) for intravitreal use in a PFS as biosimilar to (b) (4) US-Eylea (aflibercept) injection 2 mg (0.05 mL of 40 mg/mL) for intravitreal use in a PFS.

For administrative purposes, we have split sBLA 761378/Supplement 001 into the following supplements:

- sBLA 761378/Supplement 001 – Ahzantive (aflibercept-mrbb):

    - Ahzantive injection 2 mg (0.05 mL of 40 mg/mL) for intravitreal use in a PFS seeking biosimilarity to US-Eylea injection 2 mg (0.05 mL of 40 mg/mL) for intravitreal use in a vial kit and PFS.

(b) (4)

The subject of this correspondence is sBLA 761378/Supplement 001. (b) (4)
(b) (4)

All future submissions to the BLA should specify the sBLA number to which each submission pertains.

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 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 761378/ S-001**." Approval of this submission by FDA is not required before the labeling is used.

---

[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.

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

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

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.

At this time, no pediatric assessments are required under PREA for this supplemental BLA.

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).

Your product is a Part 3 combination product (21 CFR 3.2(e)); therefore, you must also comply with postmarketing safety reporting requirements for an approved combination product (21 CFR 4, Subpart B). Additional information on combination product postmarketing safety reporting is available at FDA.gov.

If you have any questions, contact Lois.Almoza@fda.hhs.gov, Senior, Regulatory Health Project Manager, at (240) 402-5146 or Lois.Almoza@fda.hhs.gov.

Sincerely,

{See appended electronic signature page}

William M. Boyd, MD
Deputy Director
Division of Ophthalmology
Office of Specialty Medicine
Office of New Drugs
Center for Drug Evaluation and Research

ENCLOSURES:

- Content of Labeling
  - Prescribing Information
- Carton and Container Labeling

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/

WILLIAM M BOYD
04/17/2025 03:30:33 PM