BLA 761274/S-001

SUPPLEMENT APPROVAL

Biocon Biologics Inc.
Attention: Raja Sekhar Vanga
Vice President - Regulatory Affairs
245 Main St., 2nd Floor
Cambridge, MA 02142

Dear Mr. Vanga:

Please refer to your supplemental biologics license application (sBLA) dated and received November 25, 2024, and your amendments, submitted under section 351(k) of the Public Health Service Act for Yesafili (aflibercept-jbvf) injection.

This Prior Approval sBLA seeks licensure as follows:

- Yesafili (aflibercept-jbvf) injection 2 mg (0.05 mL of 40 mg/mL) for intravitreal use in a single-dose pre-filled syringe (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, and

- Yesafili (aflibercept-jbvf) injection 2 mg (0.05 mL of 40 mg/mL) for intravitreal use in a PFS as biosimilar to US-Eylea (aflibercept) injection 2 mg (0.05 mL of 40 mg/mL) for intravitreal use in a single-dose vial kit (vial kit).

Yesafili (aflibercept-jbvf) is licensed for the following indications:

- Neovascular (wet) age-related macular degeneration (AMD),
- Macular edema following retinal vein occlusion (RVO),
- Diabetic macular edema (DME), and
- Diabetic retinopathy (DR).

For administrative purposes, we have split the sBLA 761274/S-001 into the following supplements:

- sBLA 761274/S001:

- Yesafili (aflibercept-jbvf) injection 2 mg (0.05 mL of 40 mg/mL) for intravitreal use in a PFS seeking biosimilarity with US-Eylea (aflibercept) injection 2 mg (0.05 mL of 40 mg/mL) for intravitreal use in a PFS, and

- Yesafili (aflibercept-jbvf) injection 2 mg (0.05 mL of 40 mg/mL) for intravitreal use in a PFS seeking biosimilarity with US-Eylea (aflibercept) injection 2 mg (0.05 mL of 40 mg/mL) for intravitreal use in a vial kit.

- (b) (4)

The subject of this correspondence is sBLA 761274/S-001. (b) (4)

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

[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.

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 761274/S-001**." Approval of this submission by FDA is not required before the labeling is used.

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]

All promotional materials that include representations about your drug product must be promptly revised to be consistent with the labeling changes approved in this supplement, including any new safety information [21 CFR 314.70(a)(4)]. The revisions in your promotional materials should include prominent disclosure of the important new safety 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 314.70(a)(4).

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[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

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, we have determined that no pediatric studies will be required under PREA for your sBLA.

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, call Nick Connis, Regulatory Project Manager, at (301) 796-0382 or via e-mail at nick.connis@fda.hhs.gov.

Sincerely,

{See appended electronic signature page}

William 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
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