

BLA 761274/S-008

SUPPLEMENT APPROVAL

Biocon Biologics Inc.
Attention: Scott D. Tomskey
Global Head of Regulatory Affairs
685 Route 202/206, Suite 204,
Bridgewater, NJ 08807

Dear Scott D. Tomskey:

Please refer to your supplemental biologics license application (sBLA) received February 23, 2026, and your amendments, submitted under section 351(k) of the Public Health Service Act for Yesafili (afibercept-jbv) injection.

This Prior Approval sBLA provides for the addition of a vial kit configuration (vial kit with 5-micron sterile filter needle only).

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 (Prescribing Information) and include the labeling changes proposed in any pending "Changes Being Effectuated" (CBE) supplements.

Information on submitting SPL files using eLIST may be found in 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 Effectuated" (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(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

We acknowledge your August 5, 2026, submission containing final printed carton and container labeling.

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 Nick Connis, Regulatory Project Manager, at Nick.Conniss@fda.hhs.gov or call (301) 796-0382.

Sincerely,

{See appended electronic signature page}

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

ENCLOSURES:

- Content of Labeling
 - o Prescribing Information
- Carton 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
08/20/2026 12:27:56 PM