CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

761274Orig1s000

OTHER ACTION LETTERS

BLA 761274

PROVISIONAL DETERMINATION

Biocon Biologics Inc.
Attention: Paul V. Thomas
Global Head Portfolio and Program Management
245 Main St., 2nd Floor
Cambridge, MA 02142

Dear Paul V. Thomas:

Please refer to your biologics license application (BLA) dated and received October 29, 2021, and your amendments, submitted under section 351(k) of the Public Health Service (PHS) Act for Yesafili (aflibercept-jbvf) injection, 2 mg/0.05 mL for intravitreal use. The corresponding reference product is US-licensed Eylea (aflibercept) injection 2 mg/0.05 mL for intravitreal use.

This BLA proposes the use of Yesafili (aflibercept-jbvf) injection, 2 mg/0.05 mL for intravitreal use for neovascular (wet) age-related macular degeneration, macular edema following retinal vein occlusion, diabetic macular edema, and diabetic retinopathy.

We have completed a provisional review of this application, as amended. A final determination that your application meets the standards for biosimilarity and interchangeability to the corresponding presentation of US-licensed Eylea (aflibercept) injection, 2 mg/0.05 mL for intravitreal use under sections 351(i) and 351(k) of the PHS Act is currently subject to an unexpired period of reference product exclusivity, to which an additional period of pediatric exclusivity has attached, and thus may not be made before the period of pediatric exclusivity has expired. See sections 351(k)(7) and 351(m) of the PHS Act. We have not identified any deficiencies that would justify a complete response action at this time; however, we also cannot approve your application because of the unexpired period of exclusivity. We have therefore provisionally determined that your 351(k) application meets the biosimilarity and interchangeability criteria under sections 351(i) and 351(k) of the PHS Act.

This provisional determination is based upon information available to the Agency at this time (i.e., information in your application and that the manufacturing of the biological product complies with the standards established in the BLA as well as the requirements in applicable regulations). This determination is subject to change on the basis of new information that may come to our attention.

To obtain approval of this application, submit an amendment no more than six months prior to the date you believe that your BLA will be eligible for approval. In your cover letter, clearly identify your amendment as **"REQUEST FOR APPROVAL"**. This amendment should provide the legal/regulatory basis for your request for final approval and should include a copy of any relevant supporting documentation, as appropriate. In addition to a safety update, the amendment should also identify changes, if any, in the application, i.e., updated labeling; chemistry, manufacturing, and controls data; and risk evaluation and mitigation strategy (REMS). If there are no changes, clearly state so in your cover letter. Any changes require our review before approval and the goal date for our review will be set accordingly.

This biological product is not approved and cannot be legally marketed unless and until you have been notified in writing that this BLA is approved after any necessary additional review of the BLA. Enclosed are the currently agreed upon labeling (text for the Prescribing Information, carton and container labeling) with minor editorial revisions reflected in the enclosed labeling. The use of the enclosed currently agreed upon labeling is not permitted for marketing of this biological product. If you believe that there are grounds for issuing the approval letter before the expiration of the exclusivity period, you should amend your application accordingly.

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

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 in pediatric patients unless this requirement is waived, deferred, or inapplicable. At this time, we have determined that, with respect to neovascular (wet) age-related macular degeneration, macular edema following retinal vein occlusion, diabetic macular edema, and diabetic retinopathy indications, no pediatric studies will be required under PREA for your BLA. You have provided a pediatric assessment for the retinopathy of prematurity indication, and nothing further is required at this time.

If you have any questions, contact Diana Willard, Chief, Project Management Staff, at diana.willard@fda.hhs.gov or 301-796-0833.

Sincerely,

{See appended electronic signature page}

Wiley A. Chambers, MD
Director, Division of Ophthalmology
Office of Specialty Medicine
Office of New Drugs
Center for Drug Evaluation and Research

ENCLOSURE(S):

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

31 Page(s) of Draft Labeling have been Withheld in Full as B4 (CCI/TS) immediately following this page

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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/

WILEY A CHAMBERS
11/16/2023 03:46:21 PM