



BLA 761202/S-012

## **SUPPLEMENT APPROVAL**

Samsung Bioepis Co., Ltd.  
Attention: Yelena Vaydman  
Senior Manager, Regulatory Affairs  
700 Sylvan Avenue, Bldg D  
Englewood Cliffs, NJ 07632

Dear Yelena Vaydman:

Please refer to your supplemental biologics license application (sBLA) received March 7, 2024, and your amendments, submitted under section 351(k) of the Public Health Service Act for Byooviz (ranibizumab-nuna) injection.

We acknowledge receipt of your amendment dated May 8, 2026, which constituted a complete response to our January 27, 2025, action letter.

This Prior Approval sBLA provides for Byooviz (ranibizumab-nuna), 0.5 mg (0.05 mL of 10 mg/mL) single-dose prefilled syringe (PFS) as biosimilar to and interchangeable with US-licensed Lucentis 0.5 mg (0.05 mL of 10 mg/mL) PFS.

### **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,<sup>1</sup> 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.

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<sup>1</sup> <http://www.fda.gov/ForIndustry/DataStandards/StructuredProductLabeling/default.htm>

Information on submitting SPL files using eLIST may be found in guidance for industry *SPL Standard for Content of Labeling Technical Qs and As*.<sup>2</sup>

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 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 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 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 761202/S-012.**” 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 none of these criteria apply to your supplemental application, you are exempt from this requirement.

### **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).

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<sup>2</sup> 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>.

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](http://FDA.gov).

If you have any questions, contact Lois Almoza, MS, Senior Regulatory Health Project Manager, at (240) 402-5146 or [Lois.Almoza@fda.hha.gov](mailto:Lois.Almoza@fda.hha.gov).

Sincerely,

*{See appended electronic signature page}*

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

ENCLOSURES:

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

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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.**  
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/s/  
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WILLIAM M BOYD  
09/04/2026 08:08:31 AM