BLA 761202/S-020

SUPPLEMENT APPROVAL

Samsung Bioepis Co., Ltd.
c/o Samsung Bioepis United States Inc
Attention: Yelena Vaydman
Senior Manager, Regulatory Affairs
700 Sylvan Ave, Bldg D
Englewood Cliffs, NJ 07632

Dear Yelena Vaydman:

Please refer to your supplemental biologics license application (sBLA) received March 31, 2026, and your amendments, submitted under section 351(k) of the Public Health Service Act for Byooviz (ranibizumab-nuna) injection.

This "Changes Being Effected" sBLA provides for the addition of a physician sample presentation of the BYOOVIZ 0.5 mg (0.05 mL of 10 mg/mL) single-dose vial.

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.

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-020**." Approval of this submission by FDA is not required before the labeling is used.

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, MS, Senior Regulatory Health Project Manager, at (240) 402-5146.

Sincerely,

{See appended electronic signature page}

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

ENCLOSURES:

- 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
09/01/2026 08:48:50 AM