



BLA 761202/S-003

SUPPLEMENT APPROVAL

Samsung Bioepis Co., Ltd.
c/o Cardinal Health 127, Inc.
Attention: Todd Phillips, PharmD, RAC
US Agent
7400 West 110th Street, Suite 300
Overland, KS 66210

Dear Dr. Phillips:

Please refer to your supplemental biologics license application (sBLA), dated and received February 8, 2022, and your amendments, submitted under section 351(k) of the Public Health Service Act for BYOOVIZ (ranibizumab-nuna) injection. This “Changes Being Effected” supplemental biologics application provides for the addition of carton and container labeling for Physician Drug Samples.

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 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 “**Final Printed Carton and Container Labeling for approved BLA 761202/S-003.**” 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).

If you have any questions about this supplement, call Derek Alberding, Clinical Analyst, at (240) 402-0963.

Sincerely,

{See appended electronic signature page}

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

ENCLOSURE:

- 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/

WILEY A CHAMBERS
08/15/2022 10:19:49 AM