



BLA 761202/S-007

SUPPLEMENT APPROVAL

Samsung Bioepis Co., Ltd.
c/o Cardinal Health Regulatory Sciences
Attention: Brian Cudney
Director, Chemistry, Manufacturing, and Controls
7400 West 110th Street
Suite 300
Overland Park, KS 66210

Dear Mr. Cudney:

Please refer to your supplemental biologics license application (sBLA) dated and received December 20, 2022, and your amendment, submitted under section 351(k) of the Public Health Service Act for Byooviz (ranibizumab-nuna) injection.

This Prior Approval sBLA provides for an update to Section 16 (How Supplied/Storage and Handling) of the Byooviz United States Prescribing Information (USPI) to include the storage of unopened drug product vials up to 86°F (30°C) for up to 72 hours prior to use.

APPROVAL & LABELING

We have completed our review of this sBLA, 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](http://www.fda.gov)¹, 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.

Information on submitting SPL files using eLIST may be found in the guidance for industry titled *SPL Standard for Content of Labeling Technical Qs and As* at <http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM072392.pdf>.

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 Effected” (CBE) supplements,

for which FDA has not yet issued an action letter, with the content of labeling [21 CFR 601.12(f)] in MS Word format that includes the changes approved in this supplemental application.

REQUIRED PEDIATRIC ASSESSMENTS

Under the Pediatric Research Equity Act (PREA) (21 U.S.C. 355c), all applications for new active ingredients, 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 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).

If you have any questions, call Anh-Thy Ly, Regulatory Business Process Manager, at (240) 402 - 1001.

Sincerely,

{See appended electronic signature page}

Patrick Lynch, Ph.D.
Director
Division of Biotechnology Review and Research I
Office of Biotechnology Products
Office of Pharmaceutical Quality
Center for Drug Evaluation and Research

Enclosure:
Content of Labeling



Patrick
Lynch

Digitally signed by Patrick Lynch

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