BLA 761125/S-020

SUPPLEMENT APPROVAL

Novartis Pharmaceuticals Corporation
Attention: Percy Shao
Global Program Regulatory Manager
One Health Plaza
East Hanover, NJ 07936-1080

Dear Percy Shao:

Please refer to your supplemental biologics license application (sBLA), dated and received March 30, 2023, and your amendments, submitted under section 351(a) of the Public Health Service Act for Beovu® (brolucizumab-dbll) injection. This Prior Approval supplemental biologics application provides for revisions to the USE IN SPECIFIC POPULATIONS, *Pregnancy* subsection of the Prescribing Information.

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,[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 *SPL Standard for Content of Labeling Technical Qs and As*.[2] The SPL will be accessible via publicly available labeling repositories.

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).

---

[1] http://www.fda.gov/ForIndustry/DataStandards/StructuredProductLabeling/default.htm
[2] 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.

If you have any questions about this supplement, call Derek Alberding, Clinical Analyst, at (240) 402-0963. For all other inquiries regarding this BLA, please call Dheera Semidey, Senior Regulatory Project Manager, at (301) 796-3009.

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:

- Content of Labeling
    - Prescribing Information

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
09/28/2023 02:50:42 PM