CENTER FOR DRUG EVALUATION AND RESEARCH

Approval Package for:

APPLICATION NUMBER:

761125Orig1s000

Trade Name:	BEOVU (brolucizumab-dbll) injection for intravitreal injection.
Generic or Proper Name:	brolucizumab-dbll
Sponsor:	Novartis Pharmaceuticals Corporation
Approval Date:	October 7, 2019
Indication:	indicated for the treatment of Neovascular (Wet) Age-Related Macular Degeneration (AMD)

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APPROVAL LETTER

U.S. FOOD & DRUG ADMINISTRATION

BLA 761125

BLA APPROVAL

Novartis Pharmaceuticals Corporation
Attention: Franklin Akomeah, PhD
Global Regulatory Director
4800 Overton Plaza
Suite 300
Fort Worth, TX 76109

Dear Dr. Akomeah:

Please refer to your biologics license application (BLA) dated and received February 7, 2019, and your amendments, submitted under section 351(a) of the Public Health Service Act for BEOVU (brolucizumab-dbll) injection for intravitreal injection.

LICENSING

We are issuing Department of Health and Human Services U.S. License No. 1244 to Novartis Pharmaceuticals Corporation, East Hanover, NJ under the provisions of section 351(a) of the Public Health Service Act controlling the manufacture and sale of biological products. The license authorizes you to introduce or deliver for introduction into interstate commerce, those products for which your company has demonstrated compliance with establishment and product standards.

Under this license, you are authorized to manufacture the product BEOVU (brolucizumab-dbll) injection. BEOVU is indicated for the treatment of neovascular age-related macular degeneration.

MANUFACTURING LOCATIONS

Under this license, you are approved to manufacture BEOVU drug substance at (b) (4) (b) (4) The final formulated drug product will be manufactured, filled, labeled, and packaged at Novartis Pharma Stein AG, Stein, Switzerland. Secondary packaging will occur at Novartis Pharma Stein AG, Stein, Switzerland, (b) (4) (b) (4) (b) (4) You may label your product with the proprietary name, BEOVU, and market it in a vial kit including one 6 mg/0.05 mL dosage in a 2 mL single-dose vial of BEOVU and a filter needle.

DATING PERIOD

The dating period for BEOVU shall be 18 months from the date of manufacture when stored at 5°C ± 3°C. The date of manufacture shall be defined as the date of final sterile filtration of the formulated drug product. The dating period for your drug substance shall be (b) (4) months from the date of manufacture when stored at less than (b) (4) °C.

FDA LOT RELEASE

You are not currently required to submit samples of future lots of BEOVU and each kit component to the Center for Drug Evaluation and Research (CDER) for release by the Director, CDER, under 21 CFR 610.2. We will continue to monitor compliance with 21 CFR 610.1, requiring completion of tests for conformity with standards applicable to each product prior to release of each lot.

Any changes in the manufacturing, testing, packaging, or labeling of BEOVU, or in the manufacturing facilities, will require the submission of information to your biologics license application for our review and written approval, consistent with 21 CFR 601.12.

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, which is identical to the package insert submitted on October 3, 2019.

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] Content of labeling must be identical to the enclosed labeling (Prescribing Information). 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.

CARTON AND CONTAINER LABELING

We acknowledge your September 18 and 27, and October 4, 2019, submissions containing printed 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 761125**." Approval of this submission by FDA is not required before the labeling is used.

[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 at https://www.fda.gov/RegulatoryInformation/Guidances/default.htm.

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