BLA 761165

BLA APPROVAL

Coherus BioSciences, Inc.
Attention: Theresa LaVallee, PhD
Chief Development Officer, Head Regulatory Affairs
333 Twin Dolphin Drive
Suite 600
Redwood City, CA 94065

Dear Dr. LaVallee:

Please refer to your biologics license application (BLA) dated and received August 2, 2021, and your amendments, submitted under section 351(k) of the Public Health Service (PHS) Act for CIMERLI (ranibizumab-eqrn) injection, 0.3 mg (6 mg/mL) and 0.5 mg (10 mg/mL).

LICENSING

We have approved your BLA for CIMERLI (ranibizumab-eqrn) effective this date. You are hereby authorized to introduce or deliver for introduction into interstate commerce, CIMERLI under your existing Department of Health and Human Services U.S. License No. 2023. CIMERLI is indicated for the treatment of Neovascular (Wet) Age-Related Macular Degeneration (AMD), Macular Edema Following Retinal Vein Occlusion (RVO), Diabetic Macular Edema (DME), Diabetic Retinopathy (DR), and Myopic Choroidal Neovascularization (mCNV).

MANUFACTURING LOCATIONS

Under this license, you are approved to manufacture ranibizumab-eqrn drug substance at (b) (4) The final formulated drug product will be manufactured and filled at (b) (4) (b) (4) The bulk vials are labeled and packaged at (b) (4) You may label your product with the proprietary name, CIMERLI, and market it in 0.3 mg (6 mg/mL) and 0.5 mg (10 mg/mL) single-dose vials.

DATING PERIOD

The dating period for CIMERLI shall be 36 months from the date of manufacture when stored at 5 ± 3°C, protected from light. 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 (b) (4) °C.

We have approved the stability protocols in your license application for the purpose of extending the expiration dating period of your drug substance under 21 CFR 601.12.

EXCLUSIVITY FOR FIRST INTERCHANGEABLE BIOLOGICAL PRODUCT

CIMERLI (ranibizumab-eqrn) 0.3 mg (6 mg/mL) single-dose vial and CIMERLI (ranibizumab-eqrn) 0.5 mg (10 mg/mL) single-dose vial are the first biological products relying on their respective reference products, to receive a determination of interchangeability for any condition of use. Therefore, with this approval, Coherus BioSciences, Inc. is eligible for a period of first interchangeable exclusivity under section 351(k)(6) of the PHS Act for the CIMERLI (ranibizumab-eqrn) 0.3 mg (6 mg/mL) single-dose vial and for the CIMERLI (ranibizumab-eqrn) 0.5 mg (10 mg/mL) single-dose vial.

As provided by section 351(k)(6), "the Secretary shall not make a determination under paragraph (4) that the second or subsequent biological product is interchangeable for any condition of use until the earlier of—

(A) 1 year after the first commercial marketing of the first interchangeable biosimilar biological product to be approved as interchangeable for that reference product;

(B) 18 months after—

(i) a final court decision on all patents in suit in an action instituted under subsection (*l*)(6) against the applicant that submitted the application for the first approved interchangeable biosimilar biological product; or

(ii) the dismissal with or without prejudice of an action instituted under subsection (*l*)(6) against the applicant that submitted the application for the first approved interchangeable biosimilar biological product; or

(C)

(i) 42 months after approval of the first interchangeable biosimilar biological product if the applicant that submitted such application has been sued under subsection (*l*)(6) and such litigation is still ongoing within such 42-month period; or

(ii) 18 months after approval of the first interchangeable biosimilar biological product if the applicant that submitted such application has not been sued under subsection (*l*)(6).

For purposes of this paragraph, the term "final court decision" means a final decision of a court from which no appeal (other than a petition to the United States Supreme Court for a writ of certiorari) has been or can be taken."

For each interchangeable biosimilar biological product approved by this letter, please submit a general correspondence to this 351(k) BLA informing the Agency of the date of the first commercial marketing within 30 days of such date. Please also submit a duplicate copy of the correspondence via email to PurpleBook@fda.hhs.gov.

Additionally, if applicable, please submit a general correspondence to this 351(k) BLA informing the Agency of the date of any final court decision (as defined in section 351(k)(6)) on all patents in suit in an action instituted under subsection (*l*)(6) or the date of dismissal with or without prejudice of any action instituted under subsection (*l*)(6)

within 30 days of such date or within 30 days of this approval if such date occurred prior to approval. Please also submit a duplicate copy of the correspondence via email to PurpleBook@fda.hhs.gov.

FDA LOT RELEASE

You are not currently required to submit samples of future lots of CIMERLI 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 CIMERLI, or in the manufacturing facilities, will require the submission of information to your BLA 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.

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.[1] Content of labeling must be identical to the enclosed labeling (text for the 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 (October 2009)*.[2] The SPL will be accessible via publicly available labeling repositories.

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 761165**." Approval of this submission by FDA is not required before the labeling is used.

[1] See 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.

REQUIRED PEDIATRIC ASSESSMENTS

Under the Pediatric Research Equity Act (PREA) (21 U.S.C. 355c), all applications for new active ingredients (which includes new salts and new fixed combinations), 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, this requirement is not applicable.

POSTMARKETING COMMITMENTS NOT SUBJECT TO THE REPORTING REQUIREMENTS UNDER SECTION 506B

We remind you of your postmarketing commitments:

4307-1 Complete drug substance transport validation study and submit the final transportation validation report.

The timetable submitted on July 22, 2022, states that this study will be conducted and the final report submitted by September 30, 2023.

4307-2 Complete bulk drug product (BDP) and drug product (DP) transport validation studies and submit the final transportation validation report.

The timetable submitted on July 22, 2022, states that these studies will be conducted and the final report submitted by September 30, 2023.

Please submit chemistry, manufacturing, and controls protocols and all postmarketing final reports to this BLA. In addition, under 21 CFR 601.70 you should include a status summary of each commitment in your annual progress report of postmarketing studies to this BLA. The status summary should include expected summary completion and final report submission dates, any changes in plans since the last annual report. All submissions, including supplements, relating to these postmarketing commitments should be prominently labeled **"Postmarketing Commitment Protocol," "Postmarketing Commitment Final Report," or "Postmarketing Commitment Correspondence."**

PROMOTIONAL MATERIALS

You may request advisory comments on proposed introductory advertising and promotional labeling. For information about submitting promotional materials, see the final guidance for industry *Providing Regulatory Submissions in Electronic and Non-Electronic Format-Promotional Labeling and Advertising Materials for Human Prescription Drugs*.[3]

[3] For the most recent version of a guidance, check the FDA guidance web page at https://www.fda.gov/media/128163/download.

You must submit final promotional materials and Prescribing Information, accompanied by a Form FDA 2253, at the time of initial dissemination or publication [21 CFR 314.81(b)(3)(i)]. Form FDA 2253 is available at FDA.gov.[4] Information and Instructions for completing the form can be found at FDA.gov.[5]

REPORTING REQUIREMENTS

You must submit adverse experience reports under the adverse experience reporting requirements at 21 CFR 600.80. Prominently identify all adverse experience reports as described in 21 CFR 600.80. You must submit distribution reports under the distribution reporting requirements at 21 CFR 600.81.

You must submit reports of biological product deviations under 21 CFR 600.14. You should promptly identify and investigate all manufacturing deviations, including those associated with processing, testing, packing, labeling, storage, holding and distribution. If the deviation involves a distributed product, may affect the safety, purity, or potency of the product, and meets the other criteria in the regulation, you must submit a report on Form FDA 3486 to:

Food and Drug Administration
Center for Drug Evaluation and Research
Division of Compliance Risk Management and Surveillance
5901-B Ammendale Road
Beltsville, MD 20705-1266

Biological product deviations, sent by courier or overnight mail, should be addressed to:

Food and Drug Administration
Center for Drug Evaluation and Research
Division of Compliance Risk Management and Surveillance
10903 New Hampshire Avenue, Bldg. 51, Room 4207
Silver Spring, MD 20903

POST APPROVAL FEEDBACK MEETING

New biological products qualify for a post approval feedback meeting. Such meetings are used to discuss the quality of the application and to evaluate the communication process during drug development and marketing application review. The purpose is to learn from successful aspects of the review process and to identify areas that could benefit from improvement. If you would like to have such a meeting with us, please contact Michael Puglisi, the Regulatory Project Manager for this application.

[4] http://www.fda.gov/downloads/AboutFDA/ReportsManualsForms/Forms/UCM083570.pdf
[5] http://www.fda.gov/downloads/AboutFDA/ReportsManualsForms/Forms/UCM375154.pdf

If you have any questions, please contact Michael Puglisi, Regulatory Project Manager, at michael.puglisi@fda.hhs.gov or at (301) 796-0791.

Sincerely,

{See appended electronic signature page}

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

ENCLOSURES:

- Content of Labeling
  - Prescribing Information
- 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
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