

BLA 761428

**BLA APPROVAL**

Novo Nordisk Inc.  
Attention: Ge (Larry) Bai, PhD  
Director, Regulatory Affairs  
P.O. Box 846  
800 Scudders Mill Road  
Plainsboro, NJ 08536

Dear Dr. Bai:

Please refer to your biologics license application (BLA) received July 31, 2024, and your amendments, submitted under section 351(a) of the Public Health Service Act for Alhemo (concizumab-mtci) injection.

### **LICENSING**

We have approved your BLA for Alhemo (concizumab-mtci) effective this date. You are hereby authorized to introduce or deliver for introduction into interstate commerce, Alhemo, under your existing Department of Health and Human Services U.S. License No. 1261. Alhemo is indicated for routine prophylaxis to prevent or reduce the frequency of bleeding episodes in adult and pediatric patients 12 years of age and older with hemophilia A (congenital factor VIII deficiency) without FVIII inhibitors and hemophilia B (congenital factor IX deficiency) without FIX inhibitors.

### **MANUFACTURING LOCATIONS**

Under this license, you are approved to manufacture concizumab-mtci drug substance at (b) (4) The final formulated drug product will be manufactured and filled at Novo Nordisk A/S, Kalundborg Sjælland 4400 Denmark (FEI: 3002807751). The device assembly, labeling, and secondary packaging will occur at Novo Nordisk A/S, Vaerlose, Hovenstaden 3500 Denmark (FEI: 3015545250). You may label your product with the proprietary name, Alhemo, and market it in the following:

- 60 mg/1.5 mL (40 mg/mL) in a single-patient-use prefilled pen
- 150 mg/1.5 mL (100 mg/mL) in a single-patient-use prefilled pen
- 300 mg/3 mL (100 mg/mL) in a single-patient use-prefilled pen

**DATING PERIOD**

The dating period for Alhemo shall be 24 months from the date of manufacture when stored at 2°C to 8 °C, including an in-use period of 4 weeks below 30°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 (b) (4)°C.

**FDA LOT RELEASE**

You are not currently required to submit samples of future lots of Alhemo 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 Alhemo, 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.<sup>1</sup> Content of labeling must be identical to the enclosed labeling (text for the Prescribing Information, Instructions for Use, and Medication Guide). 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)*.<sup>2</sup>

The SPL will be accessible via publicly available labeling repositories.

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<sup>1</sup> See <http://www.fda.gov/ForIndustry/DataStandards/StructuredProductLabeling/default.htm>

<sup>2</sup> 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 this drug product for this indication has an orphan drug designation, you are exempt from this requirement.

## **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*.<sup>3</sup>

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 601.12(f)(4)]. Form FDA 2253 is available at [FDA.gov](http://FDA.gov).<sup>4</sup> Information and Instructions for completing the form can be found at [FDA.gov](http://FDA.gov).<sup>5</sup>

## **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:

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

<sup>4</sup> <http://www.fda.gov/downloads/AboutFDA/ReportsManualsForms/Forms/UCM083570.pdf>

<sup>5</sup> <http://www.fda.gov/downloads/AboutFDA/ReportsManualsForms/Forms/UCM375154.pdf>

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

We have now administratively closed this BLA. Therefore, carton and container final printed labeling (if requested above), all 15-day alert reports, periodic (including quarterly) adverse drug experience reports, field alerts, annual reports, supplements, promotional materials and other submissions should be addressed to the parent **BLA 761315** for this product, not to this BLA. **In the future, do not make submissions to this BLA.**

#### **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, call the Regulatory Project Manager for this application.

If you have any questions, please contact Rolanda Bailey, Regulatory Project Manager, at (240) 402-5631 or email at [Rolanda.Bailey@fda.hhs.gov](mailto:Rolanda.Bailey@fda.hhs.gov).

Sincerely,

*{See appended electronic signature page}*

Tanya Wroblewski, MD  
Deputy Director  
Division of Nonmalignant Hematology  
Office of Cardiology, Hematology,  
Endocrinology, and Nephrology  
Center for Drug Evaluation and Research

ENCLOSURES:

- Content of Labeling
  - Prescribing Information
  - Medication Guide
  - Instructions for Use

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**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.**  
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