



NDA 217388/S-004

## SUPPLEMENT APPROVAL

Astrazeneca AB  
c/o Astrazeneca Pharmaceuticals LP  
Attention: Nicole Shepard  
Director, Regulatory Affairs  
1800 Concord Pike  
Wilmington, DE 19803

Dear Nicole Shepard:

Please refer to your Supplemental New Drug Application (sNDA) dated and received October 22, 2024, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Wainua (eplontersen) injection.

This “Changes Being Effectuated” supplemental new drug application provides for the following:

- 1) Update of the functions of “dibasic sodium phosphate, anhydrous” and “monobasic sodium phosphate, dihydrate” as buffering agents and disclosure of the quantity of each inactive ingredient in the USPI (United States Prescribing Information) for Section, 11 Description.
- 2) Update of the sentence which includes quantities of sodium and phosphorus to read as follows: “Each dose of WAINUA injection contains less than 5 mg of sodium and less than 5 mg of phosphorus.”

### **APPROVAL & LABELING**

We have completed our review of this supplemental application. 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 the content of labeling [21 CFR 314.50(l)] in structured product labeling (SPL) format using the FDA automated drug registration and listing system (eLIST), as described at <http://www.fda.gov/ForIndustry/DataStandards/StructuredProductLabeling/default.htm>. Content of labeling must be identical to the enclosed labeling (text for the Prescribing Information, Patient Package Insert, and Instructions for Use) with the addition of any labeling changes in pending “Changes Being Effectuated” (CBE) supplements, as well as annual reportable changes not included in the enclosed labeling.

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/DrugsGuidanceComplianceRegulatoryInformation/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 NDA, including CBE supplements for which FDA has not yet issued an action letter, with the content of labeling [21 CFR 314.50(l)(1)(i)] in MS Word format, that includes the changes approved in this supplemental application, as well as annual reportable changes, and annotate each change. To facilitate review of your submission, provide a highlighted or marked-up copy that shows all changes, as well as a clean Microsoft Word version. The marked-up copy should provide appropriate annotations, including supplement number(s) and annual report date(s).

### **CARTON AND CONTAINER LABELS**

Submit final printed carton label that is identical to enclosed carton label submitted on October 22, 2024, as soon as they are available, but no more than 30 days after they are printed. Please submit these labels 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 “**Product Correspondence – Final Printed Carton and Container Labels for approved NDA 217388/S-004.**” Approval of this submission by FDA is not required before the labeling is used.

## **REPORTING REQUIREMENTS**

We remind you that you must comply with reporting requirements for an approved NDA (21 CFR 314.80 and 314.81).

If you have any questions, contact Erica Keafer, Regulatory Business Process Manager, at (301) 796 – 1435 or [erica.keafer@fda.hhs.gov](mailto:erica.keafer@fda.hhs.gov).

Sincerely,

*{See appended electronic signature page}*

Vilayat Sayeed, Ph.D.  
Director  
Division of Product Quality Assessment II  
Office of Product Quality Assessment I  
Office of Pharmaceutical Quality  
Center for Drug Evaluation and Research

Enclosures:

- Content of Labeling
  - Prescribing Information
  - Patient Package Insert
  - Instructions for Use
- Carton Labeling



Vilayat  
Sayeed

Digitally signed by Vilayat Sayeed

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