

BLA 021859/S-031

SUPPLEMENT APPROVAL

Halozyme Therapeutics, Inc.
Attention: Elisa Alonso
Director, Regulatory Affairs
12390 El Camino Real
San Diego, CA 92130

Dear Elisa Alonso:

Please refer to your supplemental biologics license application (sBLA) dated and received June 29, 2018, submitted as a supplemental new drug application (sNDA) under section 505(b) of the Federal Food, Drug, and Cosmetic Act, and administratively converted on March 23, 2020, to an sBLA under section 351(a) of the Public Health Service Act (PHS Act) for HYLENEX recombinant (hyaluronidase) injection, 150 USP units/mL, and your amendments. Please also refer to our Notification of “Deemed” BLA letter dated March 23, 2020. We acknowledge receipt of your amendment dated December 18, 2023, which constituted a complete response to our August 18, 2023, action letter.

This Prior Approval supplemental biologics application provides for revisions to the Prescribing Information (PI) to comply with the content and format requirements of the Pregnancy and Lactation Labeling Rule (PLLR), as well as BLA-specific labeling revisions due to the March 23, 2020, transition.

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

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>.

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 021859/S-031.**” Approval of this submission by FDA is not required before the labeling is used.

For information on FDA’s compliance policy for requirements related to BLA-specific labeling revisions, see Guidance for Industry, *The “Deemed to be a License” Provision of the BPCI Act: Questions and Answers*.³

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).

If you have any questions, call Lois Almoza, MS, Senior Regulatory Health Project Manager at (240) 402-5146.

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

³ Available at: <https://www.fda.gov/media/119274/download>. For the most recent version of a guidance, check the FDA Guidance Documents Database at <https://www.fda.gov/RegulatoryInformation/Guidances/default.htm>.

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
01/12/2024 02:55:45 PM