BLA 761313

BLA- APPROVAL
(for further manufacturing use)

Halozyme Therapeutics, Inc.
Attention: Danielle Turner
Senior Director, Regulatory Affairs
12390 El Camino Real
San Diego, CA 92130

Dear Ms. Turner:

Please refer to your biologics license application (BLA) dated and received September 20, 2022, and your amendments, submitted under section 351(a) of the Public Health Service Act for Hyaluronidase human recombinant for further manufacturing use.

LICENSING

We have approved your BLA for Hyaluronidase human recombinant for further manufacturing use effective this date. You are hereby authorized to introduce or deliver for introduction into interstate commerce Hyaluronidase human recombinant for further manufacturing use under your existing Department of Health and Human Services U.S. License No. 2187. Hyaluronidase human recombinant for further manufacturing use is to be used by argenx BV under BLA 761304 for the manufacture of the final product Vyvgart Hytrulo (efgartigimod alfa and hyaluronidase-qvfc) under a shared manufacturing arrangement.

MANUFACTURING LOCATIONS

Under this license, you are approved to manufacture the BLA, Hyaluronidase human recombinant for further manufacturing use, at Avid Bioservices Inc. 14191 Myford Rd, Tustin, California, and to ship this intermediate product to (b) (4) for further distribution and manufacturing use by argenx BV, Zwijnaarde, East Flanders, Belgium under a shared manufactured agreement.

DATING PERIOD

The dating period for Hyaluronidase human recombinant for further manufacturing use shall be (b) (4) months from the date of manufacture when stored at (b) (4) The date of manufacture shall be defined as the date of final aseptic filtration and fill of this intermediate product.

We have approved the stability protocol in your license application for the purpose of extending the expiration dating period of your intermediate product, Hyaluronidase human recombinant for further manufacturing use, under 21 CFR 601.12.

APPROVAL

We have completed our review of this application, as amended. It is approved, effective on the date of this letter, for use as described in this application.

Any changes in the manufacturing, testing, packaging, or labeling of Hyaluronidase human recombinant for further manufacturing use, 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. Furthermore, consistent with the guidance for industry *Cooperative Manufacturing Arrangements for Licensed Biologics,* you should notify licensed holder(s) of the final product application(s) of any aforementioned change(s).

CONTAINER LABEL

Submit a final container label that is identical to the enclosed container label and the submitted container label, as soon as they are available [e.g., changes consistent with annual reportable changes under 21 CFR 6101.12(d)], but no more than 30 days after they are printed. Please submit these labeling electronically according to the guidance for industry *SPL Standard for Content of Labeling Technical Qs & As.* For administrative purposes, designate this submission "**Final Carton and Container Labeling for approved BLA-FFM 761313**." Approval of this submission by FDA is not required before the labeling is used.

REPORTING REQUIREMENTS

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

If you have any questions, please contact Anh-Thy Ly, Pharm.D., Regulatory Business Process Manager, at (240) 402-1001 and anh-thy.ly@fda.hhs.gov.

Sincerely,

{See appended electronic signature page}

Emily Freilich, MD
Director (Acting)
Division of Neurology 1
Office of Neuroscience
Center for Drug Evaluation and Research

ENCLOSURE: Container Label

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/

EMILY R FREILICH
06/20/2023 03:09:51 PM