BLA 761497/Original 1

BLA APPROVAL

Emerge Bioscience Pte. Ltd.
C/O: Meitheal Pharmaceuticals, Inc.
Attention: Jinsong Liu, PhD
Executive Vice President, Regulatory & Strategic Alliances, Biopharma
8700 W. Bryn Mawr Avenue
Suite 600S
Chicago, IL 60631

Dear Dr. Liu:

Please refer to your biologics license application (BLA) received July 24, 2025, and your amendments, submitted under section 351(k) of the Public Health Service Act for Garzulys (insulin aspart-fsan) injection.

This BLA seeks licensure of Garzulys (insulin aspart-fsan) as follows:

- Garzulys (insulin aspart-fsan), 10 mL (100 units/mL) injection for subcutaneous use in a multiple-dose vial as biosimilar to (b) (4) US-Novolog (insulin aspart), 10 mL (100 units/mL) injection for subcutaneous use in a multiple-dose vial,
- Garzulys (insulin aspart-fsan), 10 mL (100 units/mL) injection for intravenous use in a multiple-dose vial as biosimilar to (b) (4) US-Novolog (insulin aspart), 10 mL (100 units/mL) injection for intravenous use in a multiple-dose vial, and
- Garzulys (insulin aspart-fsan), 3 mL (100 units/mL) injection for subcutaneous use in a single-patient-use prefilled pen as biosimilar to (b) (4) US-Novolog (insulin aspart), 3 mL (100 units/mL) injection for subcutaneous use in a single-patient-use prefilled pen.

This BLA proposes the use of Garzulys (insulin aspart-fsan) as biosimilar to (b) (4) US-Novolog (insulin aspart) to improve glycemic control in adults and pediatric patients with diabetes mellitus.

For administrative purposes, we have split BLA 761497 as follows:

- BLA 761497/Original 1 – biosimilarity (b) (4)

The subject of this correspondence is BLA 761497/Original 1. (b) (4)

All future submissions to BLA 761497/Original 1 should specify the BLA number and the Original number to which each submission pertains.

LICENSING

We have approved your BLA for Garzulys (insulin aspart-fsan) effective this date. You are hereby authorized to introduce or deliver for introduction into interstate commerce, Garzulys under your existing Department of Health and Human Services U.S. License No. 2395. Garzulys is indicated to improve glycemic control in adults and pediatric patients with diabetes mellitus.

MANUFACTURING LOCATIONS

Under this license, you are approved to manufacture insulin aspart-fsan drug substance at (b) (4) The final formulated drug product and the insulin diluting medium for Garzulys will be manufactured, filled, labeled, and packaged at (b) (4) You may label your product with the proprietary name, Garzulys, and market it in 10 mL(100 units/mL) in a multiple-dose vial, injection, for intravenous use, and 10 mL(100 units/mL) in a multiple dose vial, injection, for subcutaneous use, and 3 mL(100 units/mL) in a single-patient-use prefilled pen, injection, for subcutaneous use.

DATING PERIOD

The dating period for Garzulys single-patient-use prefilled pen shall be 24 months from the date of manufacture when stored at 2°C to 8 °C. The dating period for Garzulys multiple-dose vial shall be 18 months from the date of manufacture when stored at 2°C to 8 °C. The dating period for the insulin diluting medium for Garzulys shall be 18 months from the date of manufacture when stored at 2°C to 8°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 (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, drug product, and the insulin diluting medium for Garzulys under 21 CFR 601.12.

FDA LOT RELEASE

You are not currently required to submit samples of future lots of Garzulys 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 Garzulys, 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 AND 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 with minor editorial revisions listed below and reflected in the enclosed labeling.

- The date footer was removed from each page of the Patient Package Insert, Instructions for Use Single-Patient-Use Prefilled Pen, and Instructions for Use Multiple Dose Vial.

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. Content of labeling must be identical to the enclosed labeling (text for the Prescribing Information, Patient Package Insert, and Instructions for Use). Information on submitting SPL files using eLIST may be found in guidance for industry *SPL Standard for Content of Labeling Technical Qs and As.*[1]

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 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 761497/Original 1**." Approval of this submission by FDA is not required before the labeling is used.

[1] 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.

This product is appropriately labeled for use in all relevant pediatric populations. Therefore, no additional pediatric studies are needed at this time.

PROMOTIONAL MATERIALS

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

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.[2] Information and Instructions for completing the form can be found at FDA.gov.[3]

REPORTING REQUIREMENTS

You must submit adverse experience reports under the adverse experience reporting requirements for licensed biological products (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 for licensed biological products (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:

[2] http://www.fda.gov/downloads/AboutFDA/ReportsManualsForms/Forms/UCM083570.pdf
[3] 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

Your product is a Part 3 combination product (21 CFR 3.2(e)); therefore, you must also comply with postmarketing safety reporting requirements for an approved combination product (21 CFR 4, Subpart B). Additional information on combination product postmarketing safety reporting is available at FDA.gov.

If you have any questions, contact Michael Oyewole, Regulatory Project Manager, at Michael.Oyewole@fda.hhs.gov.

Sincerely,

{See appended electronic signature page}

Mahtab Niyyati, MD
Associate Director of Therapeutic Review (Acting)
Division of Diabetes, Lipid Disorders, and Obesity
Office of Cardiology, Hematology, Endocrinology, and Nephrology
Office of New Drugs
Center for Drug Evaluation and Research

ENCLOSURES:

- Content of Labeling
  - Prescribing Information
  - Patient Package Insert
  - Instructions for Use Single-Patient-Use Prefilled Pen
  - Instructions for Use Multiple Dose Vial
- 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/

MAHTAB NIYYATI
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