BLA 761497/Original 2

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, under section 351(k) of the Public Health Service Act for Garzulys (insulin aspart-fsan) injection.

We acknowledge receipt of your amendment dated August 6 , 2026, which constituted a request for approval following our July 24, 2026, provisional determination letter.

BLA 761497 initially provided for:

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

For administrative purposes, BLA 761497 was split as follows:

- BLA 761497/Original 1 – biosimilarity
- BLA 761497/Original 2 – interchangeability

The subject of this action letter is BLA 761497/Original 2. A separate action letter was issued for BLA 761497/Original 1 on July 24, 2026.

LICENSING

We have approved your BLA 761497/Original 2 for Garzulys (insulin aspart-fsan) as an interchangeable biosimilar product 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

For information regarding approved manufacturing locations, see the Manufacturing Locations section of the approval letter for BLA 761497/Original 1 dated July 24, 2026.

FDA LOT RELEASE

For information regarding FDA lot release, see the FDA Lot Release section of the correspondence for BLA 761497/Original 1 dated July 24, 2026.

APPROVAL AND LABELING

We have completed our review of this 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, 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.

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

[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.

the claimed indication(s) in pediatric patients unless this requirement is waived, deferred, or inapplicable.

Because none of these criteria apply to your application, 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 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:

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:

[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
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 questions, call Tiffany Pfundt, Regulatory Project Manager, at (301) 796-1790, or email at tiffany.pfundt@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

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
09/15/2026 01:31:35 PM