CENTER FOR DRUG EVALUATION AND RESEARCH

Approval Package for:

APPLICATION NUMBER:

761326Orig2s000

Trade Name:	Awiqli injection.
Generic or Proper Name:	insulin icodec-abae
Sponsor:	Novo Nordisk Inc.
Approval Date:	March 26, 2026
Indication:	as an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus.

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761326Orig2s000

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APPLICATION NUMBER:

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APPROVAL LETTER

BLA 761326/Original 2

BLA APPROVAL

Novo Nordisk Inc.
Attention: Hiral Palkhiwala-Shah, M.Sc.
Associate Director, Regulatory Affairs
800 Scudders Mill Road
Plainsboro, NJ 08536

Dear Hiral Palkhiwala-Shah:

Please refer to your biologics license application (BLA) received April 10, 2023, and your amendments, submitted under section 351(a) of the Public Health Service Act for Awiqli (insulin icodec-abae) injection.

We acknowledge receipt of your resubmission dated September 26, 2025, which constituted a complete response to our July 10, 2024, action letter.

LICENSING

We have approved your BLA for Awiqli (insulin icodec-abae) effective this date. You are hereby authorized to introduce or deliver for introduction into interstate commerce, Awiqli under your existing Department of Health and Human Services U.S. License No. 1261. Awiqli is indicated as an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus.

MANUFACTURING LOCATIONS

Under this license, you are approved to manufacture insulin icodec-abae drug substance at Novo Nordisk A/S in Kalundborg, Sjælland, Denmark (FEI 3002807751). The final formulated drug product will be manufactured, filled, labeled, and packaged at Novo Nordisk A/S 25a-B, Hilleroed, Hovedstaden, Denmark (FEI 3003131673). You may label your product with the proprietary name, Awiqli, and market the 700 units/mL single-patient-use FlexTouch prefilled pen with disposable needles in 3 sizes: 3 mL of 700 units/mL for a total of 2100 units, 1.5 mL of 700 units/mL for a total of 1050 units and 1.0 mL of 700 units/mL for a total of 700 units (sample only).

DATING PERIOD

The dating period for Awiqli shall be 36 months from the date of manufacture when stored at 2 to 8°C or up to 12 weeks at room temperature below 86°F (30°C) for the not in-use (unopened) pen and up to 12 weeks at room temperature below 86°F (30°C) or at 2 to 8°C for the in-use (opened) pen. The total time at room temperature cannot

exceed more than 12 weeks including in-use time. The date of manufacture shall be defined as the date of final sterile filtration of the formulated drug product. The dating period shall be [redacted] months from the date of manufacture when stored at [redacted] °C for drug substance, [redacted] months when stored at [redacted] °C for [redacted] and [redacted] months when stored at [redacted] °C for [redacted] The expiration date for the packaged product, insulin icodec-abae plus FlexTouch pen shall be dependent on the shortest expiration date of any component. Results of ongoing stability studies should be submitted throughout the dating period, as they become available, including the results of stability studies from the first three production lots.

FDA LOT RELEASE

You are not currently required to submit samples of future lots of Awiqli 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 Awiqli, 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 & 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.[1] 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 the guidance for industry *SPL Standard for Content of Labeling Technical Qs and As (October 2009)*.[2]

The SPL will be accessible via publicly available labeling repositories.

[1] See 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 at https://www.fda.gov/RegulatoryInformation/Guidances/default.htm.

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 761326.** Approval of this submission by FDA is not required before the labeling is used.

ADVISORY COMMITTEE

Your application for Awiqli was not referred to an FDA advisory committee because there were no issues that required advisory commitee discussion.

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.

We are waiving the pediatric study requirement for ages 0 to less than 10 years because the prevalence of type 2 diabetes mellitus in this age group is low and studies in this age group would be impossible or highly impracticable.

We are deferring submission of your pediatric study for ages 10 to less than 18 years for this application because this product is ready for approval for use in adults and the pediatric study has not been completed.

Your deferred pediatric study required by section 505B(a) of the Federal Food, Drug, and Cosmetic Act is a required postmarketing study. The status of this postmarketing study must be reported annually according to 21 CFR 601.28 and section 505B(a)(4)(B) of the Federal Food, Drug, and Cosmetic Act. This required study is listed below.

4974-1 Complete the multicenter, open-label, one-period, single-dose trial to evaluate the pharmacokinetic properties of insulin icodec-abae (NNC0148-0287) in children and adolescent patients ages 10 to <18 years with type 2 diabetes mellitus.

Final Report Submission: June 2026

FDA considers the term *final* to mean that the applicant has submitted a protocol, the FDA review team has sent comments to the applicant, and the protocol has been revised as needed to meet the goal of the study or clinical trial.[3]

Submit the protocol(s) to your IND 137406 with a cross-reference letter to this BLA. Reports of this required pediatric postmarketing study must be submitted as a BLA or as a supplement to your approved BLA with the proposed labeling changes you believe are warranted based on the data derived from this study. When submitting the reports, please clearly mark your submission "**SUBMISSION OF REQUIRED PEDIATRIC ASSESSMENTS**" in large font, bolded type at the beginning of the cover letter of the submission.

PROMOTIONAL MATERIALS

You may request advisory comments on proposed introductory advertising and promotional labeling. For information about submitting promotional materials, see the final guidance for industry *Providing Regulatory Submissions in Electronic and Non-Electronic Format-Promotional Labeling and Advertising Materials for Human Prescription Drugs*.[4]

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.[5] Information and Instructions for completing the form can be found at FDA.gov.[6]

REPORTING REQUIREMENTS

You must submit adverse experience reports under the adverse experience reporting requirements at 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 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

[3] See the guidance for Industry *Postmarketing Studies and Clinical Trials—Implementation of Section 505(o)(3) of the Federal Food, Drug, and Cosmetic Act (October 2019).* https://www.fda.gov/RegulatoryInformation/Guidances/default.htm.
[4] For the most recent version of a guidance, check the FDA guidance web page at https://www.fda.gov/media/128163/download.
[5] http://www.fda.gov/downloads/AboutFDA/ReportsManualsForms/Forms/UCM083570.pdf
[6] http://www.fda.gov/downloads/AboutFDA/ReportsManualsForms/Forms/UCM375154.pdf

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

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.

POST APPROVAL FEEDBACK MEETING

New biological products qualify for a post approval feedback meeting. Such meetings are used to discuss the quality of the application and to evaluate the communication process during drug development and marketing application review. The purpose is to learn from successful aspects of the review process and to identify areas that could benefit from improvement. If you would like to have such a meeting with us, call the Regulatory Project Manager for this application.

If you have any questions, contact Ajmal Mohmand, Regulatory Project Manager, at 301-796-9541 or Ajmal.mohmand@fda.hhs.gov.

Sincerely,

{See appended electronic signature page}

Lisa Yanoff, M.D.
Deputy Director
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
  - Quick Guide
- 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/

LISA B YANOFF
03/26/2026 06:57:47 PM