



NDA 215256/S-029
NDA 218316/S-005

SUPPLEMENT APPROVAL

Novo Nordisk Inc.
Attention: Devraj Chakravarty
Director, Regulatory Affairs
800 Scudders Mill Road
P.O. Box 846
Plainsboro, NJ 08536

Dear Devraj Chakravarty:

Please refer to your supplemental new drug applications (sNDAs) and amendments, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Wegovy (semaglutide) injection and Wegovy (semaglutide) tablets.

NDA 215256/S-029

This Prior Approval sNDA, dated and received November 25, 2025, provides for the addition of a new Wegovy injection 7.2 mg subcutaneous weekly dose for weight reduction and maintenance long term. Corresponding revisions were made in the Prescribing Information, Medication Guide, Instructions for Use, and Carton and Container labeling.

NDA 218316/S-005

This Prior Approval sNDA, dated and received February 12, 2026, provides for alignment of the combined Wegovy injection and Wegovy tablets Prescribing Information and Medication Guide based on the addition of the 7.2 mg subcutaneous dose for Wegovy injection.

APPROVAL & LABELING

We have completed our review of these applications, as amended. They are 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 the content of labeling [21 CFR 314.50(l)] in structured product labeling (SPL) format using the FDA automated drug registration and listing system (eLIST), as described at

FDA.gov.¹ Content of labeling must be identical to the enclosed labeling (text for the Prescribing Information, Instructions for Use, and Medication Guide), with the addition of any labeling changes in pending “Changes Being Effected” (CBE) supplements, as well as annual reportable changes not included in the enclosed labeling.

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

The SPL will be accessible from publicly available labeling repositories.

Also within 14 days, amend all pending supplemental applications that include labeling changes for this NDA, including CBE supplements for which FDA has not yet issued an action letter, with the content of labeling [21 CFR 314.50(I)(1)(i)] in Microsoft Word format, that includes the changes approved in this supplemental application, as well as annual reportable changes. To facilitate review of your submission(s), provide a highlighted or marked-up copy that shows all changes, as well as a clean Microsoft Word version. The marked-up copy should provide appropriate annotations, including supplement number(s) and annual report date(s).

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 NDA 215256/S-029.**” Approval of this submission by FDA is not required before the labeling is used.

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 in pediatric patients unless this requirement is waived, deferred, or inapplicable.

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>.

We are waiving the pediatric study requirement for ages birth to less than 6 years for the Wegovy injection 7.2 mg subcutaneous weekly dose because the product does not represent a meaningful therapeutic benefit over existing therapies for pediatric patients in this age group **and** is not likely to be used in a substantial number of pediatric patients in this group.

Because of growth and development requirements in children under the age of 2, weight loss is not recommended in the 0- to 2-year-old age group. In children 2 to 6 years of age, pharmacological treatment of obesity does not represent a meaningful therapeutic benefit over existing non-pharmacological therapies (such as diet and lifestyle) and is therefore not likely to be used in a substantial number of patients. This is in line with FDA's draft guidance for industry, entitled Obesity and Overweight: Developing Drugs and Biological Products for Weight Reduction, which recommends that pediatric trials should include subjects aged 6 years and older.

We are deferring submission of your pediatric studies for ages 6 to less than 18 years for the Wegovy injection 7.2 mg subcutaneous weekly dose because this product is ready for approval for use in adults and the pediatric studies have not been completed.

Your deferred pediatric studies required by section 505B(a) of the FDCA are required postmarketing studies. The status of these postmarketing studies must be reported annually according to 21 CFR 314.81 and section 505B(a)(4)(C) of the FDCA. These required studies are listed below.

- 4975-1 Conduct a randomized, double-blind, placebo-controlled study to evaluate the safety and efficacy after 52 weeks of semaglutide 7.2 mg for the treatment of obesity in pediatric patients ages 12 to less than 18 who still require weight loss after treatment with semaglutide 2.4 mg. Collect information on dysesthesia (altered skin sensation) as an adverse event of special interest, using dedicated case report forms. Provide narrative summaries of dysesthesia adverse events in the clinical study report for this trial.

Draft Protocol Submission: June 2026

Final Protocol Submission: December 2026

Study Completion: April 2030

Final Report Submission: January 2031

- 4975-2 Conduct a randomized, double-blind, placebo-controlled study to evaluate the safety and efficacy after 52 weeks of semaglutide 7.2 mg for the treatment of obesity in pediatric patients ages 6 to less than 12 who still require weight loss after treatment with semaglutide 2.4 mg. Compare the long-term (at least 2 years) safety and tolerability of semaglutide versus placebo for the treatment of obesity in both children and adolescents

(ages 6 to less than 18 years). The trial may not be initiated until results from the semaglutide 7.2 mg adolescent trial, and the STEP YOUNG (NN9536-4512) trial in pediatric patients with obesity ages 6 to <12 years treated with semaglutide 2.4 mg, have been submitted to and reviewed by the Agency.

Draft Protocol Submission: January 2031

Final Protocol Submission: August 2031

Study Completion: October 2035

Final Report Submission: July 2036

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 protocols to your IND 126360, with a cross-reference letter to this NDA. Reports of these required pediatric postmarketing studies must be submitted as an NDA or as a supplement to your approved NDA with the proposed labeling changes you believe are warranted based on the data derived from these studies. 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.

POSTMARKETING REQUIREMENTS UNDER 505(o)

Section 505(o)(3) of the FDCA authorizes FDA to require holders of approved drug and biological product applications to conduct postmarketing studies and clinical trials for certain purposes, if FDA makes certain findings required by the statute.

We have determined that an analysis of spontaneous postmarketing adverse events reported under subsection 505(k)(1) of the FDCA will not be sufficient to assess a known serious risk of dysesthesia.

Furthermore, the active postmarket risk identification and analysis system as available under section 505(k)(3) of the FDCA will not be sufficient to assess this serious risk.

Finally, we have determined that only a clinical trial (rather than a nonclinical or observational study) will be sufficient to assess a known serious risk of dysesthesia.

Therefore, based on appropriate scientific data, FDA has determined that you are required to conduct the following trial:

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>.

U.S. Food and Drug Administration

Silver Spring, MD 20993

www.fda.gov

- 4975-3 Conduct the randomized, double-blind, active-controlled trial NN9838-7910 (comparing subcutaneous semaglutide 7.2 mg to 2.4 mg, both in combination with cagrilintide) with dysesthesia (altered skin sensation) as an adverse event of special interest. Use dedicated case report forms for data collection and provide narrative summaries of dysesthesia adverse events in the clinical study report for this trial.

The timetable you submitted on March 17, 2026, states that you will conduct this trial according to the following schedule:

Draft Protocol Submission: March 2026
Final Protocol Submission: September 2026
Trial Completion: July 2028
Final Report Submission: July 2029

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.⁴

We acknowledge that you have submitted this protocol to IND (b) (4). You may continue to submit protocols to IND (b) (4) and a letter of cross-reference to IND 126360 and NDA 215256. Submit nonclinical and chemistry, manufacturing, and controls protocols and all final report(s) to your NDA. Prominently identify the submission with the following wording in bold capital letters at the top of the first page of the submission, as appropriate: **REQUIRED POSTMARKETING PROTOCOL UNDER 505(o) , REQUIRED POSTMARKETING FINAL REPORT UNDER 505(o), REQUIRED POSTMARKETING CORRESPONDENCE UNDER 505(o).**

Section 505(o)(3)(E)(ii) of the FDCA requires you to report periodically on the status of any study or clinical trial required under this section. This section also requires you to periodically report to FDA on the status of any study or clinical trial otherwise undertaken to investigate a safety issue. Section 506B(a)(1) of the FDCA, as well as 21 CFR 314.81(b)(2)(vii) requires you to report annually on the status of any postmarketing commitments or required studies or clinical trials.

FDA will consider the submission of your annual report under section 506B(a)(1) and 21 CFR 314.81(b)(2)(vii) to satisfy the periodic reporting requirement under section 505(o)(3)(E)(ii) provided that you include the elements listed in 505(o) and 21 CFR 314.81(b)(2)(vii). We remind you that to comply with 505(o), your annual report must also include a report on the status of any study or clinical trial otherwise

⁴ 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>.

undertaken to investigate a safety issue. Failure to submit an annual report for studies or clinical trials required under 505(o) on the date required will be considered a violation of FDCA section 505(o)(3)(E)(ii) and could result in enforcement action.

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*.⁵

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 314.81(b)(3)(i)]. Form FDA 2253 is available at FDA.gov.⁶ Information and Instructions for completing the form can be found at FDA.gov.⁷

PATENT LISTING REQUIREMENTS

Pursuant to 21 CFR 314.53(d)(2) and 314.70(f), certain changes to an approved NDA submitted in a supplement require you to submit patent information for listing in the Orange Book upon approval of the supplement. You must submit the patent information required by 21 CFR 314.53(d)(2)(i)(A) through (C) and 314.53(d)(2)(ii)(A) and (C), as applicable, to FDA on Form FDA 3542 within 30 days after the date of approval of the supplement for the patent information to be timely filed (see 21 CFR 314.53(c)(2)(ii)). You also must ensure that any changes to your approved NDA that require the submission of a request to remove patent information from the Orange Book are submitted to FDA at the time of approval of the supplement pursuant to 21 CFR 314.53(d)(2)(ii)(B) and 314.53(f)(2)(iv).

REPORTING REQUIREMENTS

We remind you that you must comply with reporting requirements for an approved NDA (21 CFR 314.80 and 314.81).

Your product, Wegovy injection, is a Part 3 combination product (21 CFR 3.2(e)); therefore, you must also comply with postmarketing safety reporting requirements for an

⁵ For the most recent version of a guidance, check the FDA guidance web page at <https://www.fda.gov/media/128163/download>.

⁶ <http://www.fda.gov/downloads/AboutFDA/ReportsManualsForms/Forms/UCM083570.pdf>

⁷ <http://www.fda.gov/downloads/AboutFDA/ReportsManualsForms/Forms/UCM375154.pdf>

approved combination product (21 CFR 4, Subpart B). Additional information on combination product postmarketing safety reporting is available at FDA.gov.⁸

If you have any questions, contact Martin White, Regulatory Project Manager, at 240-402-6018.

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
 - Medication Guide
 - Instructions for Use for Wegovy injection (version previously approved August 24, 2022)
 - Instructions for Use for Wegovy HD injection
- Carton and Container Labeling for Wegovy HD

⁸ <https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products>

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
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