

BLA 021148/S-056, S-058

SUPPLEMENT APPROVAL

Novo Nordisk Inc.
Attention: Matthew Cavalier
Manager, Regulatory Affairs
800 Scudders Mill Road
Plainsboro, NJ 08536

Dear Matthew Cavalier:

Please refer to your supplemental biologics license application (sBLA) No. 56, received June 2, 2020, and your amendments, submitted under section 351(a) of the Public Health Service Act for Norditropin (somatropin) injection. Please also refer to our Notification of “Deemed” BLA letter dated March 23, 2020.

This Prior Approval sBLA (S-056) provides for revised product labeling for Norditropin in response to the Notification of “Deemed” BLA letter issued on March 23, 2020, so that the product labeling conforms to labeling requirements for biological products regulated under section 351 of the PHS Act. In addition, this supplement provides for the addition of statements regarding storage conditions (do not store pens directly next to the cooling element of the refrigerator).

Please also refer to your sBLA No. 58, received April 27, 2023, and your amendments, submitted under section 351(a) of the Public Health Service Act for Norditropin (somatropin) injection.

This Prior Approval sBLA (S-058) provides for revisions to the Instructions for Use (IFU) documents and carton/container labeling to state compatibility with the FlexPro PenMate device.

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 with the minor editorial revisions listed below and reflected in the enclosed labeling.

- Revision dates were updated to reflect the date of approval of this supplement.

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, as described at FDA.gov,¹ that is identical to the enclosed labeling (text for the Prescribing Information, Patient Package Insert, and Instructions for Use) and include the labeling changes proposed in any pending “Changes Being Effectuated” (CBE) supplements.

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 via publicly available labeling repositories.

Also within 14 days, amend all pending supplemental applications that include labeling changes for this BLA, including pending “Changes Being Effectuated” (CBE) supplements, for which FDA has not yet issued an action letter, with the content of labeling [21 CFR 601.12(f)] 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 BLA 021148/S-056, S-058.**” Approval of this submission by FDA is not required before the labeling is used.

For information on FDA’s compliance policy for requirements related to BLA-specific labeling revisions, see guidance for industry, *The “Deemed to be a License” Provision of the BPCI Act: Questions and Answers*.³

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

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>.

³ Available at: <https://www.fda.gov/media/119274/download>. For the most recent version of a guidance, check the FDA Guidance Documents Database at <https://www.fda.gov/RegulatoryInformation/Guidances/default.htm>.

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.

Because none of these criteria apply to your supplement applications, you are exempt from this requirement.

REPORTING REQUIREMENTS

We remind you that you must comply with reporting requirements for an approved BLA (in 21 CFR 600.80 and in 21 CFR 600.81).

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, call Elisabeth Hanan, Chief, Project Management Staff, at 240-402-0350.

Sincerely,

{See appended electronic signature page}

Naomi Lowy, MD
Deputy Director
Division of General Endocrinology
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 (5 mg, 10 mg, 15 mg, 30 mg, FlexPro PenMate)
- 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/

NAOMI N LOWY
01/31/2025 03:31:34 PM