



BLA 761156/S-005

SUPPLEMENT APPROVAL

Novo Nordisk Inc.
Attention: Pratik Dherange, MS
Associate Director, Regulatory Affairs
P.O. Box 846
Plainsboro, NJ 08536

Dear Mr. Dherange:

Please refer to your supplemental biologics license application (sBLA), dated and received June 28, 2022, and your amendments, submitted under section 351(a) of the Public Health Service Act for Sogroya (somapacitan-beco) for injection.

This Prior Approval supplemental biologics license application provides for the following:

- The addition of an indication for the treatment of pediatric patients who have growth failure due to inadequate secretion of endogenous growth hormone (GH)
- A ready-to-use liquid formulation of 15 mg in a 1.5 mL cartridge (somapacitan 15 mg/1.5 mL [10 mg/mL] strength) in a single-patient-use (b) (4)-prefilled pen

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.

WAIVER OF HIGHLIGHTS ½ PAGE LENGTH REQUIREMENT FOR HIGHLIGHTS

Please note that we have previously granted a waiver of the requirements of 21 CFR 201.57(d)(8) regarding the length of Highlights of Prescribing Information.

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 Effected” (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 Effected” (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 761156/S-005.**” 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(s) 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 deferring submission of your pediatric studies because this product is ready for approval for use in pediatric patients aged 2.5 years and older and the pediatric studies have not been completed in pediatric patients aged less than 2.5 years.

Your deferred pediatric studies required under section 505B(a) of the Federal Food, Drug, and Cosmetic Act are required postmarketing studies. The status of these postmarketing studies must be reported annually according to 21 CFR 601.28 and section 505B(a)(4)(C) of the Federal Food, Drug, and Cosmetic Act.

These required studies are listed below and were previously outlined in the approval letter for BLA 761156 issued on August 28, 2020.

3890-1 Complete ongoing study NN8640-4172, a 1-year phase 2, randomized, open-label, active-control, dose-finding trial, to investigate efficacy and safety of once-weekly somapacitan versus daily Norditropin (somatropin) in pre-pubertal children with Growth Hormone Deficiency (GHD) (boys ≥ 2.5 and ≤ 10 years of age, and girls ≥ 2.5 and ≤ 9 years of age) followed by a 2-year single-arm period to evaluate safety in this cohort, and a 4-year single-arm period that also enrolls cohorts of younger children with GHD (boys and girls < 2.5 years of age) and older children with GHD (boys > 10 and ≤ 17 years of age, and girls > 9 and ≤ 17 years of age) to evaluate safety in all three cohorts.

Study Completion: October 2024
Final Report Submission: March 2025

3890-2 Complete ongoing study NN8640-4263, a 1-year phase 3 randomized, parallel group, open-label trial, to evaluate the efficacy and safety of once weekly somapacitan versus daily Norditropin (somatropin) in pre-pubertal pediatric patients (boys ≥ 2.5 and ≤ 10 years of age, and girls ≥ 2.5 and ≤ 9 years of age) with GHD, followed by a 3-year single-arm extension period to evaluate long-term safety.

Study Completion: December 2024
Final Report Submission: May 2025

Reports of these required pediatric postmarketing studies must be submitted as a biologics license application (BLA) or as a supplement to your approved BLA 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.

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*.³

As required under 21 CFR 601.12(f)(4), you must submit final promotional materials, and the Prescribing Information, at the time of initial dissemination or publication, accompanied by a Form FDA 2253. Form FDA 2253 is available at FDA.gov.⁴ Information and Instructions for completing the form can be found at FDA.gov.⁵

All promotional materials for your drug product that include representations about your drug product must be promptly revised to make it consistent with the labeling changes approved in this supplement, including any new safety-related information [21 CFR 601.12(a)(4)]. The revisions to your promotional materials should include prominent disclosure of the important new safety-related information that appears in the revised labeling. Within 7 days of receipt of this letter, submit your statement of intent to comply with 21 CFR 601.12(a)(4).

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.

³ For the most recent version of a guidance, check the FDA guidance web page at <https://www.fda.gov/media/128163/download>.

⁴ <http://www.fda.gov/downloads/AboutFDA/ReportsManualsForms/Forms/UCM083570.pdf>

⁵ <http://www.fda.gov/downloads/AboutFDA/ReportsManualsForms/Forms/UCM375154.pdf>

If you have any questions, call Linda Galgay, Regulatory Project Manager, at (301) 796-5383.

Sincerely,

{See appended electronic signature page}

Naomi Lowy, M.D.
Deputy Director
Division of General Endocrinology
Office of Cardiology, Hematology,
Endocrinology, and Nephrology
Center for Drug Evaluation and Research

ENCLOSURES:

- Content of Labeling
 - Prescribing Information
 - Patient Package Insert
 - Instructions for Use
- Carton and Container Labeling
 - Trade and Sample

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
04/28/2023 07:19:00 AM