BLA 021172/S-076

SUPPLEMENT APPROVAL

Novo Nordisk Inc.
Attention: Elizabeth D'Amato
Director, Regulatory Affairs
800 Scudders Mill Road
P.O. Box 846
Plainsboro, NJ 08536

Dear Ms. D'Amato:

Please refer to your supplemental biologics license application (sBLA), dated and received October 19, 2021, and your amendments, submitted under section 351(a) of the Public Health Service Act for NovoLog Mix 70/30 (insulin aspart protamine and insulin aspart) injectable suspension.

This Prior Approval sBLA provides for updates to the product labeling to align the unbranded and branded labeling, and other updates to conform with current labeling guidance.

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

- The revision date has been updated in the highlights of the prescribing information (PI), on the patient package insert (PPI), and on the instructions for use (IFUs) to accurately reflect the month of approval.

WAIVER OF 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 021172/S-076**." Approval of this submission by FDA is not required before the labeling is used.

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.

[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.

If you have any questions, call Ajmal Mohmand, Regulatory Project Manager, at 301-796-4951.

Sincerely,

{See appended electronic signature page}

Michelle Carey, M.D., M.P.H.
Associate Director for Therapeutics
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 (Branded)
  - Prescribing Information
  - Patient Package Insert
  - Vial Instructions for Use
  - FlexPen Instructions for Use
- Carton and Container Labeling (Branded)
- Content of Labeling (Unbranded)
  - Prescribing Information
  - Patient Package Insert
  - Vial Instructions for Use
  - FlexPen Instructions for Use
- Carton and Container Labeling (Unbranded)

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/

MICHELLE CAREY
02/28/2023 10:44:42 AM