DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

NDA 21148/S-044

SUPPLEMENT APPROVAL

Novo Nordisk, Inc.
Attention: Robert B. Clark
Vice President, Regulatory Affairs
P.O. Box 846
Plainsboro, NJ 08536

Dear Mr. Clark:

Please refer to your Supplemental New Drug Application (sNDA) dated June 16, 2015, received June 16, 2015, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Norditropin Cartridges (somatropin [rDNA origin] injection).

We acknowledge receipt of your amendment dated June 29, 2015.

This supplemental new drug application provides for carton (b) (4) labeling for the Norditropin PenMate auto-insertion accessory for use with the Norditropin FlexPro 5, 10, and 15 mg/mL prefilled pens.

We have completed our review of this supplemental application. It is approved, effective on the date of this letter, for use as recommended in the enclosed, agreed-upon labeling text.

CARTON AND IMMEDIATE CONTAINER LABELS

Submit final printed carton and thermal transfer labels that are identical to the enclosed labels as soon as they are available, but no more than 30 days after they are printed. Please submit these labels electronically according to the guidance for industry *Providing Regulatory Submissions in Electronic Format – Human Pharmaceutical Product Applications and Related Submissions Using the eCTD Specifications (June 2008)*. For administrative purposes, designate this submission "Final Printed Carton and Container Labels for approved NDA 21148/S-044." Approval of this submission by FDA is not required before the labeling is used.

Marketing the product with FPL that is not identical to the approved labeling text may render the product misbranded and an unapproved new drug.

REPORTING REQUIREMENTS

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

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

Sincerely,

{See appended electronic signature page}

Jean-Marc Guettier, M.D.
Director
Division of Metabolism and Endocrinology Products
Office of Drug Evaluation II
Center for Drug Evaluation and Research

ENCLOSURE:
Carton (b) (4) labeling

This is a representation of an electronic record that was signed electronically and this page is the manifestation of the electronic signature.

/s/

JENNIFER R PIPPINS
07/07/2015
For Dr. Guettier