DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

NDA 21148/S-043

SUPPLEMENT APPROVAL

Novo Nordisk, Inc.
Attention: Robert B. Clark
Vice President, Regulatory Affairs
100 College Road West
Princeton, NJ 08540

Dear Mr. Clark:

Please refer to your Supplemental New Drug Application (sNDA) dated March 30, 2015, received March 30, 2015, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Norditropin Cartridges (somatropin [rDNA origin] injection).

This supplemental new drug application provides for an Information Sticker to be placed on the side panel of the carton label to alert the discontinuation of the Norditropin Nordiflex 30 mg/3 mL pen.

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.

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:
Information Sticker

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

/s/

JEAN-MARC P GUETTIER
06/12/2015