DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 21-148/S-018

Novo Nordisk, Inc.
Attention: Nina Liang, PhD
Manager, Regulatory Affairs
100 College Road West
Princeton, NJ 08540

Dear Dr. Liang:

Please refer to your supplemental new drug application dated December 19, 2006, received December 19, 2006, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Norditropin (somatropin [rDNA origin]) Cartridges.

We acknowledge receipt of your submissions dated May 22, and July 13, 2007.

Your submission of May 22, 2007 constituted a complete response to our April 26, 2007 action letter.

This supplemental new drug application provides for NordiFlex PenMate™, a new auto-insertion accessory for use with Norditropin® NordiFlex prefilled, multi-dose pen devices. It also provides for a revised airshot procedure, which is done to prepare the pen device prior to initial use.

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

Submit final printed carton labels and pen device Instructions for Use that are identical to the enclosed labeling 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 titled *Providing Regulatory Submissions in Electronic Format – Human Pharmaceutical Product Applications and Related Submissions Using the eCTD Specifications (October 2005)*. Alternatively, you may submit 12 paper copies, with 6 of the copies individually mounted on heavy-weight paper or similar material. For administrative purposes, designate this submission "**Final Printed Carton and Pen Device Instructions for approved NDA 21-148/S-018**." Approval of this submission by FDA is not required before the labeling is used.

If you issue a letter communicating important information about this drug product (i.e., a "Dear Health Care Professional" letter), we request that you submit a copy of the letter to this NDA and a copy to the following address:

MEDWATCH
Food and Drug Administration
5515 Security Lane
HFD-001, Suite 5100
Rockville, MD 20852

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 Kati Johnson, Regulatory Project Manager, at (301) 796-1234.

Sincerely,

{See appended electronic signature page}

Mary H. Parks, MD
Director
Division of Metabolism & Endocrinology Products
Office of Drug Evaluation II
Center for Drug Evaluation and Research

Enclosure: NordiFlex PenMate Carton (8-4240-31-301-1)
NordiFlex PenMate User Manual (8-4240-31-001-1)
Norditropin NordiFlex 5 mg/1.5 mL Instructions for Use/Patient Information
Norditropin NordiFlex 10 mg/1.5 mL Instructions for Use/Patient Information
Norditropin NordiFlex 15 mg/1.5 mL Instructions for Use/Patient Information

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/s/

Mary Parks

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