DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 21-148/S-004

Novo Nordisk Inc.
Attention: Mary Ann McElligott, Ph.D.
Associate V.P., Regulatory Affairs
100 College Road West
Princeton, NJ 08540

Dear Dr. McElligott:

Please refer to your supplemental new drug application dated March 26, 2003, received March 27, 2003, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Norditropin (somatropin [rDNA origin] injection).

We acknowledge receipt of your submissions dated December 23, 2004, and March 23 and 25, 2005.

Your submission of December 23, 2004 constituted a complete response to our July 25, 2003 action letter.

This supplemental new drug application provides for revisions to the final product quality specifications and product labeling to include alternative in-use storage conditions at room temperature for the 5- and 10-mg/1.5 mL cartridges.

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.

To emphasize the different storage conditions to better inform health care professionals, patients, and caregivers, we recommend that you provide this information in a table format in the appropriate pieces of labeling.

The final printed labeling (FPL) must be identical to the following labeling submitted on the dates cited:

<u>March 23, 2005:</u>
Package Insert
Norditropin 5 mg/1.5 mL cartridge label
Norditropin 5 mg/1.5 mL cartridge carton
Norditropin 10 mg/1.5 mL cartridge label
Norditropin 10 mg/1.5 mL cartridge carton
Patient Package Insert (Norditropin NordiFlex)-Instructions for Use, and Patient Information
Norditropin NordiFlex container (pen) label 5 mg/1.5 mL

Norditropin NordiFlex container (pen) label 10 mg/1.5 mL
Norditropin NordiFlex (pen) carton, 5 mg/1.5 mL
Norditropin NordiFlex (pen) carton, 10 mg/1.5 mL

March 25, 2005:
NordiPen-5 Instructions for Use
NordiPen-10 Instructions for Use
NordiPenMate Instruction Manual

Please submit an electronic version of the FPL according to the guidance for industry titled *Providing Regulatory Submissions in Electronic Format - NDA*. Alternatively, you may submit 20 paper copies of the FPL as soon as it is available but no more than 30 days after it is printed. Individually mount 15 of the copies on heavy-weight paper or similar material. For administrative purposes, designate this submission "**FPL for approved supplement NDA 21-148/S-004**." 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, HFD-410
FDA
5600 Fishers Lane
Rockville, MD 20857

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, Chief, Project Management Staff, at (301) 827-6380.

Sincerely,

{See appended electronic signature page}

David G. Orloff, MD
Director
Division of Metabolic & Endocrine Drug Products
Office of Drug Evaluation II
Center for Drug Evaluation and Research

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

/s/

David Orloff

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