DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 21-148/S-015

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

Dear Ms. Liang:

Please refer to your supplemental new drug application dated June 29, 2006, received June 30, 2006, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Norditropin Cartridges (somatropin [rDNA origin]) 5 mg/1.5 mL, 10 mg/1.5 mL, 15 mg/1.5mL.

This "Changes Being Effected" supplemental new drug application provides for the harmonization of all growth hormone package inserts primarily involving the WARNINGS and PRECAUTIONS sections.

We completed our review of this supplemental new drug application. It is approved, effective on the date of this letter, for use as recommended in the final printed labeling (FPL) submitted on June 29, 2006.

Within 21 days of the date of this letter, amend any pending application for this NDA with content of labeling in structured product labeling (SPL) format to include the changes approved in this application.

In addition, at the next printing, delete reference to "long term" with respect to treatment, since this terminology is not used with other products given for chronic use.

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 the requirements for an approved NDA set forth under 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:
Package Insert (cartridges) Identifier 8-2072-31-001-6, Date of Issue: June 2006
Package Insert (Norditropin Nordiflex) Identifier 8-2084-31-002-3, Date of Issue: June 2006

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

/s/

Mary Parks

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