**DEPARTMENT OF HEALTH & HUMAN SERVICES**

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 21-148/S-017

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 October 20, 2006, received October 23, 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 November 22 and December 11, 2006, June 5, August 1, 15 and 31, September 11, 2007.

This supplemental new drug application provides for the following indication: Treatment of short stature in children with Turner's syndrome.

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.

As soon as possible, but no later than 14 days from the date of this letter, please submit the content of labeling [21 CFR 314.50(l)] in structured product labeling (SPL) format as described at http://www.fda.gov/oc/datacouncil/spl.html that is identical to the enclosed labeling (text for the package insert) Upon receipt, we will transmit that version to the National Library of Medicine for public dissemination. For administrative purposes, please designate this submission, "SPL for approved NDA 21-148/S-017."

We are waiving the requirements of 21 CFR 201.57(d)(8) regarding the length of Highlights of prescribing information. This waiver applies to all future supplements containing revised labeling unless we notify you otherwise.

All applications for new active ingredients, new dosage forms, new indications, new routes of administration, and new dosing regimens are required to contain an assessment of the safety and effectiveness of the product in pediatric patients unless this requirement is waived or deferred. We note that you have fulfilled the pediatric study requirement for this application.

In addition, submit three copies of the introductory promotional materials that you propose to use for this product. Submit all proposed materials in draft or mock-up form, not final print. Send one copy to this division and two copies of both the promotional materials and the package insert directly to:

Food and Drug Administration
Center for Drug Evaluation and Research
Division of Drug Marketing, Advertising, and Communications
5901-B Ammendale Road
Beltsville, MD 20705-1266

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).

The Division strongly recommends that you add a distinct "Turner syndrome section" to your annual Periodic Safety Update Report (PSUR) wherein: 1) the incidence of all adverse events (in particular, glucose intolerance including type 2 diabetes mellitus, scoliosis, hypertension, otitis media, edema, slipped capital femoral epiphysis and benign intracranial hypertension) are compared in Turner syndrome patients and non-Turner syndrome patients treated with Norditropin; and 2) the incidence of all adverse events (in particular, glucose intolerance including type 2 diabetes mellitus and otitis media) are compared by dose (0.067 mg/kg/day vs. previously approved/recommended lower doses) in Turner syndrome children treated with Norditropin.

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
Instructions for Use/Information for Patients, 5 mg/1.5mL Norditropin NordiFlex (8-2084-31-001-x)
Instructions for Use/Information for Patients, 10 mg/1.5mL Norditropin NordiFlex (8-2085-31-001-x)
Instructions for Use/Information for Patients, 15 mg/1.5mL Norditropin NordiFlex (8-2086-31-001-x)

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

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/s/

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Mary Parks

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