DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 21-148/S-023

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 September 20, 2007, received September 20, 2007, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Norditropin Cartridges (somatropin [rDNA origin] injection).

We acknowledge receipt of your submissions dated October 19, 2007, July 11, 18 and 31, and October 15, 2008.

This supplemental new drug application provides for the use of Norditropin Cartridges for the treatment of growth failure in children born small for gestational age (SGA) with no catch-up by age 2-4 years.

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.

The final printed labeling (FPL) must be identical to the enclosed labeling (text for the package insert, text for the patient package insert) submitted October 15, 2008.

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
Suite 12B05
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, Regulatory Project Manager, at (301) 796-1234.

Sincerely,

{See appended electronic signature page}

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

Enclosure: Package Insert
Information for Patients/Instructions for Use
Norditropin NordiFlex 5 mg/1.5 mL
Norditropin NordiFlex 10 mg/1.5 mL
Norditropin Nordiflex 15 mg/1.5 mL

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

10/31/2008 01:41:10 PM