DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 21-148/S-016

Novo Nordisk Pharmaceuticals, 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 July 17, 2006, received July 18, 2006, 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 December 11, 2006, February 13, March 22, April 2 and 27, 2007.

This supplemental new drug application provides for the use of Norditropin Cartridges for the treatment of short stature in children with Noonan 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 attached agreed-upon labeling text.

Within 21 days of the date of this letter, submit content of labeling [21 CFR 314.50(1)] in structured product labeling (SPL) format, as described at http://www.fda.gov/oc/datacouncil/spl.html that is identical in content to the enclosed labeling text. Upon receipt and verification, we will transmit that version to the National Library of Medicine for public dissemination.

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

the Division of Metabolism and Endocrinology Products 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).

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

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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