DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 21-148/S-007

Novo Nordisk Pharmaceuticals, Inc.
Attention: Barry Reit, Ph.D.
Vice President, Regulatory Affairs & Quality Assurance
100 College Road West
Princeton, NJ 08540

Dear Dr. Reit:

Please refer to your supplemental new drug application dated December 12, 2003, received December 15, 2003, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Norditropin® Cartridges (somatropin [rDNA origin] injection), 5 mg/1.5 mL, 10 mg/1.5 mL, 15 mg/1.5 mL.

We acknowledge receipt of your submissions dated October 20 and 21, 2004.

Your submission dated October 20, 2004, constituted a complete response to our October 13, 2004, action letter.

This supplemental NDA provides for the use of Norditropin® to treat adults with growth hormone deficiency.

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 final printed labeling submitted on October 20, 2004, for the package insert (PI), and October 21, 2004, for the patient information inserts (PPI) (3).

We note that the PI and PPI's incorporate the labeling approved with supplement 006, on October 1, 2004. The labeling for supplement-006 provides for the addition of the Norditropin NordiFlex® Pen. An acknowledge and retain letter for the labeling for S-006 will issue under separate cover.

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, The Division of Metabolic and Endocrine Drug Products, HFD-510, two copies of both the promotional materials and the package insert directly to:

Division of Drug Marketing, Advertising, and Communications, HFD-42
Food and Drug Administration
5600 Fishers Lane
Rockville, MD 20857

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, please call Ms. Jena Weber, Regulatory Project Manager, at 301-827-6422.

Sincerely,

{See appended electronic signature page}

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

Enclosures (Package insert +
patient package inserts (3)

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

11/1/04 04:57:00 PM