



NDA 21-148/S-013

Novo Nordisk, Inc.
Attention: Mary Ann McElligott, Ph.D.
Associate V.P., Regulatory Affairs
100 College Road West
Princeton, NJ 08540

Dear Dr. McElligott:

Please refer to your supplemental new drug application dated February 23, 2006, received February 24, 2006, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Norditropin (somatropin [rDNA origin] injection).

This "Changes Being Effected" supplemental new drug application provides for the removal of the white band present on the 5 mg/1.5 ml and 15 mg/1.5 ml cartridge labels below the expiry date/control section and revisions to the Instructions for Use for the NordiPen 5, NordiPen 15, and to the Instructions Manual for the NordiPenMate to remove text pertaining to the white band on the cartridge, addition of needle disposal information and other editorial changes.

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 enclosed final printed labeling (FPL) submitted on February 23, 2006.

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 20857

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

Enclosed:

Norditropin Cartridge 5 mg/1.5 ml Container Label
Norditropin Cartridge 15 mg/1.5 ml Container Label
Instructions for Use, NordiPen 5
Instructions for Use, NordiPen 15
Instruction Manual, NordiPenMate

**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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