DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

NDA 21148/S-035

SUPPLEMENT APPROVAL

Novo Nordisk Inc.
Attention: Mary Ann McElligott, PhD
Associate VP, Regulatory Affairs
100 College Road West
Princeton, NJ 08540

Dear Dr. McElligott:

Please refer to your Supplemental New Drug Application (sNDA) dated December 7, 2010, received December 7, 2010, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Norditropin Cartridges (somatropin [rDNA origin] injection).

This "Changes Being Effected" supplemental new drug application provides for, among other things, the following revisions to the package insert:

- Update the HIGHLIGHTS section and Table of Contents to reflect the addition of "Diabetes Mellitus" to the "Impaired Glucose Tolerance" header of Section 5.4 and to the creation of Section 5.14 (Pancreatitis).
- Creation of section 5.14 to the FULL PRESCRIBING INFORMATION:

  5.14 Pancreatitis

  Cases of pancreatitis have been reported rarely in children and adults receiving somatropin treatment, with some evidence supporting a greater risk in children compared with adults. Published literature indicates that girls who have Turner syndrome may be at greater risk than other somatropin-treated children. Pancreatitis should be considered in any somatropin-treated patient, especially a child, who develops severe persistent abdominal pain.
- Section 5.4 (Impaired Glucose Tolerance and Diabetes Mellitus) has been revised to include the sentence, "New onset type 2 diabetes mellitus has been reported in patients."
- Section 6.3 (Adverse Reactions-Post-Marketing Experience) had been revised to state that "New-onset type 2 diabetes mellitus has been reported."

The information regarding pancreatitis was submitted in response to our supplement request letter dated October 7, 2010. The information regarding diabetes mellitus was added based on information from postmarketing observational studies.

We have completed our review of this supplemental application. It is approved, effective on the date of this letter, for use as recommended in the enclosed, agreed-upon labeling text.

CONTENT OF LABELING

As soon as possible, but no later than 14 days from the date of this letter, submit the content of labeling [21 CFR 314.50(l)] in structured product labeling (SPL) format using the FDA automated drug registration and listing system (eLIST), as described at http://www.fda.gov/ForIndustry/DataStandards/StructuredProductLabeling/default.htm. Content of labeling must be identical to the enclosed labeling (text for the package insert), with the addition of any labeling changes in pending "Changes Being Effected" (CBE) supplements, as well as annual reportable changes not included in the enclosed labeling.

Information on submitting SPL files using eLIST may be found in the guidance for industry titled "SPL Standard for Content of Labeling Technical Qs and As" at http://www.fda.gov/downloads/DrugsGuidanceComplianceRegulatoryInformation/Guidances/UCM072392.pdf.

The SPL will be accessible from publicly available labeling repositories.

Also within 14 days, amend all pending supplemental applications for this NDA, including CBE supplements for which FDA has not yet issued an action letter, with the content of labeling [21 CFR 314.50(l)(1)(i)] in MS Word format, that includes the changes approved in this supplemental application, as well as annual reportable changes and annotate each change. To facilitate review of your submission, provide a highlighted or marked-up copy that shows all changes, as well as a clean Microsoft Word version. The marked-up copy should provide appropriate annotations, including supplement number(s) and annual report date(s).

REPORTING REQUIREMENTS

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 and Endocrinology Products
Office of Drug Evaluation II
Center for Drug Evaluation and Research

ENCLOSURE:
Content of Labeling (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 H PARKS
05/25/2011