



NDA 21-536/S-015

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

Dear Dr. McElligott:

Please refer to your supplemental new drug application dated January 17, 2007, received January 17, 2007, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Levemir (insulin detemir [rDNA origin] injection).

We acknowledge receipt of your submission dated January 19, 2007.

This supplemental new drug application provides for the following change in the drug product used to fill the 3 mL PenFill Cartridges: replacement of 30 mg mannitol with 16 mg glycerol.

We have 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.

(b)(4)

Please submit the final printed carton labels electronically that are identical to the enclosed trade and sample FlexPen carton labels (submitted January 17, 2007.) For administrative purposes, designate this submission "**Final Printed Carton Labels for approved supplement NDA 21-536/S-015.**" Approval of this submission by FDA is not required before the labeling is used.

Marketing the products with FPL that is not identical to the approved labeling text may render the product misbranded and an unapproved new drug.

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 Enid Galliers, Chief, Project Management Staff, at 301.796.1211.

Sincerely,

{See appended electronic signature page}

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

Enclosures:

Package Insert
Patient Package Insert – 3 mL PenFill Cartridge & 10 mL vial
Patient Package Insert – FlexPen 3 mL Prefilled Pen
Carton Label – FlexPen – Sample
Carton Label – FlexPen – Trade

**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

5/16/2007 08:55:28 PM