**DEPARTMENT OF HEALTH & HUMAN SERVICES**

Public Health Service

Food and Drug Administration
Silver Spring, MD 20993

NDA 20-741/S-035

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

Dear Dr. McElligott:

Please refer to your supplemental new drug application dated November 26, 2008, received November 26, 2008, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Prandin (repaglinide) Tablets.

We acknowledge receipt of your submission dated June 4, 2009.

This supplemental new drug application provides for the following changes to the package insert:
(1) addition of language regarding drug-drug interactions with fenofibrate and with cyclosporine,
(2) addition of co-administration of gemfibrozil as a contraindication, and
(3) addition of a statement that changes in blood glucose levels may result in blurred vision and visual disturbances.

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.

As soon as possible, but no later than 14 days from the date of this letter, please submit the content of labeling [21 CFR 314.50(l)] in structured product labeling (SPL) format as described at http://www.fda.gov/oc/datacouncil/spl.html that is identical to the enclosed labeling (text for the package insert, submitted June 4, 2009**)**. Upon receipt, we will transmit that version to the National Library of Medicine for public dissemination. For administrative purposes, please designate this submission, "SPL for approved NDA 20-741/S-035."

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
Suite 12B05
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, call Julie Marchick, Regulatory Project Manager, at (301) 796-1280.

Sincerely,

*{See appended electronic signature page}*

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

Enclosure: Package Insert

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**This is a representation of an electronic record that was signed electronically and this page is the manifestation of the electronic signature.**

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/s/

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Mary Parks

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