DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

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

Dear Dr. Reit:

Please refer to your supplemental new drug application dated December 16, 2004, received December 17, 2004, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Prandin® (repaglinide) Tablets.

This supplemental new drug application provides for changes to the Package Insert as requested by the Agency in a labeling supplement request letter issued on November 18, 2004. The supplement request asked for revisions to furnish adequate information for the safe and effective use of Prandin® (repaglinide) with insulin.

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 draft labeling submitted on December 16, 2004.

The final printed labeling (FPL) must be identical to submitted labeling (package insert submitted December 16, 2004).

Please submit the final printed labeling (FPL) electronically according to the guidance for industry titled Providing Regulatory Submissions in Electronic Format – NDA.

The electronic labeling rule published December 11, 2003, (68 FR 69009) requires submission of labeling content in electronic format effective June 8, 2004. For additional information, consult the following guidances for industry regarding electronic submissions: *Providing Regulatory Submissions in Electronic Format - NDAs* (January 1999) and *Providing Regulatory Submissions in Electronic Format – Content of Labeling* (February 2004). These guidances specify that labeling is to be submitted in *pdf* format. **To assist in our review, we request that labeling also be submitted in MS Word format.** If formatted copies of all labeling pieces (i.e., package insert, patient package insert, container labels, and carton labels) are submitted electronically, labeling does not need to be submitted in paper.

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, call Lina AlJuburi, Regulatory Project Manager, at (301) 827-6414.

Sincerely,

{See appended electronic signature page}

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

Enclosure: Draft package insert submitted December 16, 2004

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

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