



NDA 020741/S-038

**SUPPLEMENT APPROVAL**

Novo Nordisk Inc.  
Attention: Mary Ann McElligott, Ph.D.  
AVP, Regulatory Strategy  
100 College Road West  
Princeton, NJ 08540

Dear Dr. McElligott:

Please refer to your Supplemental New Drug Application (sNDA) dated May 12, 2010, received May 13, 2010, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Prandin (repaglinide) tablets.

This “Changes Being Effected” supplemental new drug application proposes the deletion of the following statement under **ADVERSE REACTIONS, Infrequent Adverse Events (<1% of Patients)**: Changes in blood glucose levels may result in blurred vision and visual disturbances, especially at the initiation of treatment with hypoglycemic agents. These changes are usually transient.

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, using the FDA automated drug registration and listing system (eLIST), the content of labeling [21 CFR 314.50(l)] in structured product labeling (SPL) format, as described at <http://www.fda.gov/ForIndustry/DataStandards/StructuredProductLabeling/default.htm>, that is identical to the enclosed labeling (text for the package insert) and include the labeling changes proposed in any pending “Changes Being Effected” (CBE) supplements. 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 pending “Changes Being Effected” (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.

### **LETTERS TO HEALTH CARE PROFESSIONALS**

If you decide to issue a letter communicating important safety-related information about this drug product (i.e., a “Dear Health Care Professional” letter), we request that you submit, at least 24 hours prior to issuing the letter, an electronic copy of the letter to this NDA, to CDERMedWatchSafetyAlerts@fda.hhs.gov, and to the following address:

MedWatch Program  
Office of Special Health Issues  
Food and Drug Administration  
10903 New Hampshire Ave  
Building 32, Mail Stop 5353  
Silver Spring, MD 20993

### **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, please contact Mehreen Hai, Ph.D., Regulatory Project Manager, at (301) 796-5073.

Sincerely,

*{See appended electronic signature page}*

Mary Parks, M.D.  
Director  
Division of Metabolism & Endocrinology Products  
Center for Drug Evaluation and Research  
Food and Drug Administration

ENCLOSURE: Package Insert

Application Type/Number	Submission Type/Number	Submitter Name	Product Name
NDA-20741	SUPPL-38	NOVO NORDISK INC	PRANDIN (REPAGLINIDE) TABS 0.5/1.0/2.0MG

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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 H PARKS  
07/29/2010