DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

NDA 19-938/S-064
NDA 19-959/S-067
NDA 19-991/S-068
NDA 20-986/S-055

**APPROVAL LETTER**

NovoNordisk 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 applications dated and received October 27, 2008, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for:

| NDA/Supplement Number | Name of Drug Product |
|---|---|
| **19-938/S-064** | **Novolin R** (human insulin [rDNA origin] injection) |
| **19-959/S-067** | **Novolin N** (human insulin [rDNA origin] isophane suspension) |
| **19-991/S-068** | **Novolin 70/30** (70% human insulin isophane suspension and 30% human insulin injection, [rDNA origin]) |
| **20-986/S-055** | **NovoLog** (insulin aspart [rDNA origin] injection) |

We acknowledge receipt of your submissions dated March 2, and May 29, 2009.

Your submission of March 2, 2009, constituted a complete response to our February 27, 2009, action letter.

These supplemental new drug applications provide for the addition of a new pen-injector (NovoPen 4) to be used with the currently approved PenFill 3 mL cartridges and NovoFine needles.

We have completed our review of these applications, as amended. These applications are approved, effective on the date of this letter, for use as recommended in the agreed-upon labeling text.

The final printed labeling (FPL) must be identical to the enclosed labeling text for the NovoPen 4 Instructions for Use Leaflet submitted May 29, 2009, and the NovoPen 4 container label submitted October 27, 2008.

Please submit an electronic version of the FPL according to the guidance for industry titled *Providing Regulatory Submissions in Electronic Format - NDA*. Alternatively, you may submit 20 paper copies of the FPL as soon as it is available but no more than 30 days after it is printed. Individually mount 15 of the copies on heavy-weight paper or similar material. For administrative purposes, designate these submissions "**FPL for approved supplement NDA 19-938/S-064, NDA 19-959/S-067, NDA 19-991/S-068, and NDA 20-986/S-055**." Approval of these submissions by FDA is not required before the labeling is used.

In addition, submit three copies of the introductory promotional materials that you propose to use for these products. Submit all proposed materials in draft or mock-up form, not final print. Send one copy to this division and two copies of both the promotional materials and the package inserts directly to:

Food and Drug Administration
Center for Drug Evaluation and Research
Division of Drug Marketing, Advertising, and Communications
5901-B Ammendale Road
Beltsville, MD 20705-1266

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

Please submit one market package of the drug product when it is available.

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 Rachel Hartford, Regulatory Project Manager, at (301) 796-0331.

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:
NovoPen 4 Instructions for Use Leaflet
NovoPen 4 Carton Label

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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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