DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 19-938/S-037

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 July 10, 2002, received July 11, 2002, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Novolin R (human insulin [rDNA origin] injection).

We acknowledge receipt of your submission dated May 18 and November 17, 2005.

Your submission of May 18, 2005, constituted a complete response to our April 15, 2005, action letter.

This supplemental new drug application provides for the use of NovoPen® 3 PenMate® with NovoPen insulin delivery devices.

We 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.

The final printed labeling (FPL) must be identical to the enclosed labeling (text for the NovoPen 3 PenMate Instruction Manual, text for the Information for the patient for Novolin R 3 mL PenFill cartridge, immediate container and carton label for 3 mL PenFill cartridge, and NovoPen 3 PenMate carton labels).

Please submit an electronic version of the FPL according to the guidance for industry titled *Providing Regulatory Submissions in Electronic Format - NDAs*. 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 this submission "**FPL for approved supplement NDA 19-938/S-037**." Approval of this submission 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 this product. 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
Division of Drug Marketing, Advertising, and Communications
Central Document Room
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
Building 22, Mail Stop 4447
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

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 Julie Rhee, Regulatory Project Manager, at (301) 827-6424.

Sincerely,

{See appended electronic signature page}

David G. Orloff, M.D.
Director
Division of Metabolism
and Endocrinology Products
Office of Drug Evaluation II
Center for Drug Evaluation and Research

Enclosures:
1. NovoPen 3 PenMate Instruction Manual
2. Information for the patient for Novolin R PenFill
3. NovoPen 3 PenMate carton label
4. Container label for Novolin R 3 mL PenFill cartridge
5. Carton label for Novolin R 3 mL PenFill cartridge

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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