DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

NDA 019938/S-068
NDA 019959/S-070
NDA 019991/S-071

SUPPLEMENT APPROVAL

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 Applications (sNDAs) dated June 24, 2009, received June 24, 2009, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for:

NDA 019938/S-068 Novolin R, Regular, Human Insulin Injection (rDNA origin)
NDA 019959/S-070 Novolin N NPH, Human Insulin Isophane Suspension (rDNA origin)
NDA 019991/S-071 Novolin 70/30, 70% NPH, Human Insulin Isophane Suspension and 30% Regular, Human Insulin Injection (rDNA origin)

These "Changes Being Effected" sNDAs provided for an **information sticker to alert patients of the discontinuation of Novolin device products** for the following human insulin delivery devices by December 31, 2009: Novolin InnoLet disposable pens and Novolin PenFill 3 mL cartridges for Novolin R, N and 70/30. The labeling information stickers were affixed directly on to the cartons.

We note that the Novolin R, N, and 70/30 10 mL vial human insulin products have remained and will remain on the market. 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.

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

Sincerely,

{See appended electronic signature page}

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

ENCLOSURE:
Information sticker to alert the discontinuation of Novolin device products affixed directly on to the carton

PenFill

Attention! This product is being discontinued.

Please contact your physician about alternate treatment options. For more information call Novo Nordisk at 1-800-727-6500, or visit novonordiskcare.com.

Clear Adhesive Panel

InnoLet

Attention! This product is being discontinued.

Please contact your physician about alternate treatment options. For more information call Novo Nordisk at 1-800-727-6500, or visit novonordiskcare.com.

Clear Adhesive Panel

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

/s/

AMY G EGAN
12/27/2010
Amy Egan for Mary Parks