DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 20-986/S-037

Novo Nordisk, Inc.
Attn: 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 March 24, 2006, received March 27, 2006, submitted under section 505(b)(1) of the Federal Food, Drug, and Cosmetic Act for NovoLog® (insulin aspart [rDNA origin]) Injection.

We acknowledge receipt of your submissions dated December 5 and 21, 2006, and January 9 and 12, 2007.

This supplemental new drug application provides for a change in the Pregnancy Category from "Pregnancy Category C" to "Pregnancy Category B" in the "Pregnancy - Teratogenic Effects - Pregnancy Category" heading of that subsection in the PRECAUTIONS section of the physician insert. Additional related changes were made to other subsections of the PRECAUTIONS section. Conforming changes to the patient package inserts (FlexPen and Vial/Cartridge) were also made.

We have 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.

CONTENT OF LABELING

Within 21 days of the date of this letter, submit revised content of labeling [21 CFR 314.50(l)] in structured product labeling (SPL) format, as described at http://www.fda.gov/oc/datacouncil/spl.html, that is identical in content to the enclosed labeling (package insert submitted January 12, 2007, patient package inserts (FlexPen and PenFill/Vial) submitted January 12, 2007). Upon receipt and verification, we will transmit that version to the National Library of Medicine for public dissemination.

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
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
5515 Security Lane
HFD-001, Suite 5100
Rockville, MD 20852

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 Enid Galliers, Chief, Project Management Staff, at 301-796-1211.

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

Enclosures:
Package Insert
Patient Package Insert – FlexPen
Patient Package Insert – PenFill/Vial

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

/s/

Mary Parks

1/26/2007 04:00:17 PM