DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 20-986/S-053
NDA 21-172/S-043
NDA 21-536/S-023

NovoNordisk Inc.
Attention: Mary Ann McElligott, Ph.D.
Associate Vice President, Regulatory Affairs
100 College Road West
Princeton, NJ 08540

SUPPLEMENT APPROVAL

Dear Dr. McElligott:

Please refer to your supplemental new drug applications dated May 28, 2008, received May 28, 2008, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for:

NDA/Supplement Number	Name of Drug Product
20-986/S-053	**NovoLog** (insulin aspart [rDNA origin] injection)
21-172/S-043	**NovoLog Mix 70/30** (70% insulin aspart protamine suspension and 30% insulin aspart, [rDNA origin] injection)
21-536/S-023	**Levemir** (insulin detemir [rDNA origin] injection)

We acknowledge receipt of your submissions dated November 14, 2008.

These supplemental new drug applications provide for the following changes: new layout and figures for the FlexPen Instructions for Use and reduced reading grade level for Flex Pen Instructions for Use and Patient Package Inserts. In addition, the NovoLog Mix 70/30 and Levemir FlexPen Instructions for Use Leaflets were standardized with the currently approved NovoLog FlexPen Instructions for Use Leaflet.

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.

CONTENT OF LABELING

As soon as possible, but no later than 14 days from the date of this letter, please submit the 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 to the enclosed labeling (text for the patient package inserts and text for the Instruction for Use Leaflets). Upon receipt, we will transmit that version to the National Library of Medicine for public dissemination. For administrative purposes, please designate this submission "SPL for approved NDA NDA 20-986/S-053, NDA 21-172/S-043, and NDA 21-536/S-023."

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

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

Enclosures:
NovoLog Patient Package Insert
NovoLog FlexPen Instruction for Use Leaflet
NovoLog Mix 70/30 Patient Package Insert
NovoLog Mix 70/30 FlexPen Instruction for Use Leaflet
Levemir Patient Package Insert
Levemir FlexPen Instruction for Use Leaflet

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

/s/

Eric Colman

11/28/2008 12:32:48 PM

Eric Colman for Mary Parks