DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 20-986/S-049 & S-050
NDA 21-172/S-038 & S-039
NDA 21-536/S-020 & S-021

Novo Nordisk 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 submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for:

NDA/ Supplement #	Drug Name	Submission Date	Received Date
20-986/S-049	NovoLog (insulin aspart [rDNA origin] injection)	March 3, 2008	March 3, 2008
20-986/S-050	NovoLog (insulin aspart [rDNA origin] injection)	March 7, 2008 August 26, 2008	March 7, 2008 (Amendment)
21-172/S-038	NovoLog Mix 70/30 (70% insulin aspart protamine suspension and 30% insulin aspart, [rDNA origin] injection)	March 3, 2008	March 3, 2008
21-172/S-039	NovoLog Mix 70/30 (70% insulin aspart protamine suspension and 30% insulin aspart, [rDNA origin] injection)	March 7, 2008 August 26, 2008	March 7, 2008 (Amendment)
21-536/S-020	Levemir (insulin detemir [rDNA origin] injection)	March 3, 2008	March 3, 2008
21-536/S-021	Levemir (insulin detemir [rDNA origin] injection)	March 7, 2008 August 26, 2008	March 7, 2008 (Amendment)

The March 3, 2008, supplemental new drug applications provide for global harmonization of the trade carton layout by increased use of the approved colors in areas without text and the addition of text and pen images. The March 7, 2008, supplemental new drug applications provide for a new sample kit packaging configuration that also incorporates the global harmonization use of color.

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

CARTON LABELS

Submit final printed trade carton labels that are identical to the enclosed labels submitted March 3, 2008, and final printed sample kit carton labels that are identical to the enclosed labels submitted August 26, 2008. Submit the trade and sample kit carton labels as soon as they are available, but no

more than 30 days after they are printed. Please submit these labels electronically according to the guidance for industry titled *Providing Regulatory Submissions Using the eCTD Specifications (October 2005)*. Alternatively, you may submit 12 paper copies, with 6 of the copies individually mounted on heavy-weight paper or similar material. For administrative purposes, designate this submission **"Final Printed Trade and Sample Kit Carton Labels for approved supplements NDA 20-986/S-049 & S-050, NDA 21-172/S-038 & S-039, and NDA 21-536/S-020 & S-021."**

Marketing the product with FPL that is not identical to the approved labeling text may render the product misbranded and an unapproved new drug.

LETTERS TO HEALTH CARE PROFESSIONALS

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

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

Enclosures:
NovoLog FlexPen trade carton
NovoLog FlexPen sample kit carton
NovoLog Mix 70/30 trade carton
NovoLog Mix 70/30 sample kit carton
Levemir FlexPen trade carton
Levemir FlexPen sample kit carton

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

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