DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 21-172/S-034 **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 application dated November 17, 2006, received November 17, 2006, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for NovoLog Mix 70/30 (70% insulin aspart protamine suspension/30% insulin aspart injection [rDNA origin]).

We acknowledge receipt of your submissions dated December 13, 2006, and March 13, April 4, and July 13, 2007.

Your April 4, 2007, submission constituted a complete response to our March 16, 2007, action letter.

This supplemental new drug application provides for the following changes in the drug product used to fill the NovoLog Mix 70/30 FlexPen prefilled syringes: replacement of mannitol with glycerol, an increased amount of sodium chloride, batch size increase from ----------, a change in the ---------- - Specification, and a tightening of the ---------- Specification.

We have completed our review of this application, as amended. It is approved, effective on the date of this letter, for use as recommended in the agreed-upon labeling text and with the minor editorial revisions listed below.

1. In the list of inactive ingredients on the NovoLog Mix 70/30 FlexPen prefilled syringe carton labels, replace the phrase "-------- ---------- --- " with "protamine sulfate 0.32 mg/mL."

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 package insert). 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 21-172/S-034**."

CARTON LABELS

Submit final printed carton labels that are identical to the submitted NovoLog Mix 70/30 FlexPen prefilled syringe carton (trade and sample) labels, except with the revision listed above, 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 in Electronic Format – Human Pharmaceutical Product Applications and Related 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 Carton Labels for approved NDA 21-172/S-034**." Approval of this submission by FDA is not required before the labeling is used.

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

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 (DMEP)
Office of Drug Evaluation II
Center for Drug Evaluation and Research

Enclosure:
Package Insert

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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