



NDA 21-172/S-023

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 June 15, 2005, received June 16, 2005, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for NovoLog Mix 70/30 (70% insulin aspart protamine suspension and 30% insulin aspart injection, [rDNA origin]).

This “Changes Being Effected” supplemental new drug application provides for the addition of the following statement “Shake carefully before using. See enclosed insert for proper technique” to NovoLog Mix 70/30 trade and sample carton labeling for (i) 3 mL PenFill cartridge, (ii) 3 mL FlexPen, and (iii) 10 mL vial presentations.

We completed our review of this supplemental new drug application. It is approved, effective on the date of this letter, for use as recommended in the final printed labeling (FPL) submitted on June 15, 2005.

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
Building 22, Mail Stop 4447
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

We remind you that you must comply with the requirements for an approved NDA set forth under 21 CFR 314.80 and 314.81.

If you have any questions, call Julie Rhee, Regulatory Project Manager, at (301) 796-1280.

Sincerely,

{See appended electronic signature page}

James D. Vidra, Ph.D.
Branch Chief
Branch 7, Division of Postmarketing Evaluation
Office of New Drug Quality Assessment
Center for Drug Evaluation and Research

- Enclosures:
1. NovoLog Mix 70/30 3 mL FlexPen trade carton
 2. NovoLog Mix 70/30 3 mL FlexPen sample carton
 3. NovoLog Mix 70/30 3 mL PenFill cartridge trade carton
 4. NovoLog Mix 70/30 3 mL PenFill cartridge sample carton
 5. NovoLog Mix 70/30 10 mL vial trade carton
 6. NovoLog Mix 70/30 10 mL vial sample carton

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/s/

Jim Vidra
11/14/2005 05:00:04 PM