DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 20-986/S-019
NDA 21-172/S-013

Novo Nordisk Pharmaceuticals, Inc.
Attention: Barry Reit, Ph.D.
Vice President, Regulatory Affairs and Quality Assurance
100 College Road West
Princeton, NJ 08540

Dear Dr. Reit:

Please refer to your supplemental new drug applications dated June 23, 2003, received June 24, 2003, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for the following products:

NDA 20-986/S-019	NovoLog (insulin aspart [rDNA origin] injection)
NDA 21-172/S-013	NovoLog Mix 70/30 (70% insulin aspart protamine suspension and 30% insulin aspart injection, [rDNA origin])

We acknowledge receipt of your submissions dated July 14, 2003, and January 5, February 12, April 7, June 30, July 29, September 17, and October 6, 2004.

Your submission of April 7, 2004, constituted a complete response to our December 19, 2003, action letter.

These supplemental new drug applications provide for the addition of color branding on the carton and immediate container labeling for NovoLog and NovoLog Mix 70/30 products. The presentations included in these supplements are (i) 10 mL vial, (ii) 3 mL PenFill cartridge, and (iii) 3 mL FlexPen Prefilled syringe.

We 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.

The final printed labeling (FPL) must be identical to the enclosed labeling (immediate container and carton labels).

Please submit the FPL electronically according to the guidance for industry titled *Providing Regulatory Submissions in Electronic Format – NDAs*. Alternatively, you may submit 20 paper copies of the FPL as soon as it is available, in no case more than 30 days after it is printed. Please individually mount 15 of the copies on heavy-weight paper or similar material. For administrative

purposes, these submissions should be designated "FPL for approved supplement NDA 20-986/S-019" and "FPL for approved supplement NDA 21-172/S-013." Approval of these submissions by FDA is not required before the labeling is used.

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, HFD-410
FDA
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 Julie Rhee, Regulatory Project Manager, at (301) 827-6424.

Sincerely,

{See appended electronic signature page}

David G. Orloff, M.D.
Director
Division of Metabolic
and Endocrine Drug Products, HFD-510
Office of Drug Evaluation II
Center for Drug Evaluation and Research

Enclosures:
1. NovoLog FlexPen carton
2. NovoLog FlexPen catron for sample
3. NovoLog FlexPen immediate container
4. NovoLog PenFill carton
5. NovoLog PenFill carton for sample
6. NovoLog PenFill immediate container
7. NovoLog vial carton
8. NovoLog vial carton for sample
9. NovoLog vial immediate container
10. NovoLog Mix 70/30 carton
11. NovoLog Mix 70/30 carton for sample
12. NovoLog Mix 70/30 immediate container
13. NovoLog Mix 70/30 PenFill carton
14. NovoLog Mix 70/30 PenFill carton for sample
15. NovoLog Mix 70/30 PenFill immediate container
16. NovoLog Mix 70/30 vial carton
17. NovoLog Mix 70/30 vial carton for sample
18. NovoLog Mix 70/30 vial immediate container

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
10/8/04 04:47:43 PM
for Dr. Orloff