DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug
Administration
Rockville MD 20857

NDA 19-938/S-033
NDA 19-959/S-035
NDA 19-991/S-036

Novo Nordisk Pharmaceuticals, Inc.
Attention: Barry Reit, Ph.D.
Vice President, Regulatory Affairs
100 Overlook Center
Princeton, NJ 08540

Dear Dr. Reit:

Please refer to your supplemental new drug applications dated October 27, 2000, received October 30, 2000 (NDA 19-938), dated October 30, 2000, received October 31, 2000 (NDAs 19-959 and 19-991), submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for the following products:

NDA 19-938/S-033	Novolin R (human insulin [rDNA origin] injection)
NDA 19-959/S-035	Novolin® N (human insulin [rDNA origin] isophane suspension)
NDA 19-991/S-036	Novolin® 70/30 (70% human insulin [rDNA origin] isophane suspension and 30% human insulin [rDNA origin] injection)

We acknowledge receipt of your submissions dated February 14 and 16, and April 19, 2001; February 8, and March 8, 15, and 20, 2002. Your submission of February 8, 2002, constituted a complete response to our February 2, 2001, action letter.

These supplemental new drug applications provide for the use of NovoPen 3 Demi insulin delivery device with Novolin R PenFill 3 mL, Novolin N PenFill 3 mL, or Novolin 70/30 PenFill 3 mL cartridges and NovoFine needles. These supplemental new drug applications also provide for a revised patient package insert for Novolin R PenFill 3 mL, Novolin N PenFill 3 mL, and Novolin 70/30 PenFill 3 mL cartridges to include the use of NovoPen 3 Demi insulin delivery device with the cartridges.

We have completed the review of these supplemental applications, as amended, and have concluded that adequate information has been presented to demonstrate that the drug products are safe and effective for use as recommended in the agreed upon enclosed labeling text. Accordingly, these supplemental applications are approved effective on the date of this letter.

The final printed labeling (FPL) must be identical to the enclosed labeling (text for the NovoPen 3 Demi Instruction Manual and for the patient package insert). Please include a circular number on the final printed patient package insert.

Please submit the copies of final printed labeling (FPL) electronically to each application according to the guidance for industry titled *Providing Regulatory Submissions in Electronic Format - NDA* (January 1999). Alternatively, you may submit 20 paper copies of the FPL as soon as it is available but no more than 30 days after it is printed. Please individually mount ten of the copies on heavy-weight paper or similar material. For administrative purposes, these submissions should be designated "FPL for approved supplement NDA 19-938/S-033, 19-959/S-035, 19-991/S-036." Approval of these submissions by FDA is not required before the labeling is used.

In addition, please submit three copies of the introductory promotional materials that you propose to use for these products. All proposed materials should be submitted in draft or mock-up form, not final print. Please submit one copy to this Division and two copies of both the promotional materials and the package inserts directly to:

Division of Drug Marketing, Advertising, and Communications, HFD-42
Food and Drug Administration
5600 Fishers Lane
Rockville, Maryland 20857

If a letter communicating important information about this drug product (i.e., a "Dear Health Care Professional" letter) is issued to physicians and others responsible for patient care, we request that you submit a copy of the letter to this NDA and a copy to the following address:

MEDWATCH, HF-2
FDA
5600 Fishers Lane
Rockville, MD 20857

Please submit one market package of the drug product when it is available.

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) 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. NovoPen 3 Demi Instruction Manual
2. PenFill patient package insert for Novolin R, Novolin N, and Novolin 70/30

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

/s/

David Orloff

4/15/02 10:14:06 AM