DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
Rockville MD 20857

NDA 19-938/S-030
NDA 19-959/S-031
NDA 19-991/S-032

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

Dear Dr. Reit:

Please refer to your supplemental new drug applications dated March 10, 2000, received March 13, 2000, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for the following drug products:

NDA 19-938/S-030	Novolin® R (human insulin [rDNA origin] injection)
NDA 19-959/S-031	Novolin® N (human insulin [rDNA origin] isophane suspension)
NDA 19-991/S-032	Novolin® 70/30 (70% human insulin [rDNA origin] isophane suspension and 30% human insulin [rDNA origin] injection)

We acknowledge receipt of your submissions dated September 21, 2000; February 28, July 2, September 5, and November 14, 2001; and January 29, 2002. Your submission of February 28, 2001, constituted a complete response to our September 12, 2000, action letter.

These supplemental new drug applications provide for the use of NovoPen® 3 PenMate®, a replacement device to be used in conjunction with NovoPen® 3 Insulin Delivery Device.

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 labeling text. Accordingly, these supplemental applications are approved effective on the date of this letter.

We remind you of your commitment dated September 5, 2001, in which you agreed to replace the text "PenFill 3 ml" with "PenMate" on the barrel of the device in comparable text size to the present text "NovoPen 3" prior to marketing the product.

The final printed labeling (FPL) must be identical to the enclosed labeling (text for the patient package insert) and must be formatted in accordance with the requirements of 21 CFR 201.66.

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-030/S-030, 19-959/S-031/S-031, 19-991/S-032/S-032." 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.

Although not an approval issue, we recommend that you consider a recommendation to replace the PenMate whenever the NovoPen® 3 is replaced.

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, (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

Enclosure: Marked-Up NovoPen 3 PenMate Instruction Manual

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

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