DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 20-918/S-012

Novo Nordisk 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 application dated June 30, 2004, received July 1, 2004, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for GlucaGen (glucagon [rDNA origin] injection).

We acknowledge receipt of your submission dated September 27, and December 17 and 23, 2004.

This supplemental new drug application provides for the following changes:

1. Addition of GlucaGen® HypoKit under HOW SUPPLIED section in the package insert. GlucaGen® HypoKit includes a vial containing 1 mg of glucagon powder and a dispo(b)(4)----------erile Water for Reconstitution (SWFR).
2. New ---------- of SWFR. The new (b)(4)---------- (b)(4)----------

We completed our review of this application, as amended. This application is 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 (text for the package insert, text for the patient package insert, immediate container for GlucaGen vial, immediate container for Sterile Water for Reconstitution syringe, and GlucaGen 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, this submission should be designated "FPL for approved supplement NDA 21-918/S-012." Approval of this submission by FDA is not required before the labeling is used.

Submit the content of labeling in electronic format as described in 21 CFR 314.50(l)(5) and in the format described at the following website: http://www.fda.gov/oc/datacouncil/spl.html.

In addition, submit three copies of the introductory promotional materials that you propose to use for this product. Submit all proposed materials in draft or mock-up form, not final print. Send one copy to this division and two copies of both the promotional materials and the package insert directly to:

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

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

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

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. Physician insert (circular 8-9402-31-001-1)
2. INFORMATION FOR PATIENTS (GlucaGen HypoKit) (8-9402-31-001-1)
3. Carton label
4. Container label for GlucaGen vial (8-9400-31-203-1)
5. Container label for Sterile Water for Reconstitution syringe

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

/s/

Eric Colman

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Eric Colman for David Orloff