DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 20-918/S-017

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 14, 2005, received June 15, 2005, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for GlucaGen (glucagon for injection [rDNA origin]) solution, 1 mg (1 IU).

This "Changes Being Effected" supplemental new drug application provides for the use of a different NDC and barcode number on the Sterilie Water for Reconstitution (1 mL) vial container label to differentiate it from the GlucaGen (1 mg) vial container label in the GlucaGen Diagnostic Kit package.

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 14, 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 Hampsire 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

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

/s/

Jim Vidra

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