NDA 20-918 June 22, 1998

Novo Nordisk Pharmaceuticals, Inc.
Attention: Barry Reit, Ph.D.
Vice President, Regulatory Affairs
100 Overlook Center
Suite 200
Princeton, New Jersey 08540-7810

Dear Dr. Reit:

Please refer to your new drug application (NDA) dated September 18, 1997, received September 23, 1997, submitted pursuant to section 505(b)(2) of the Federal Food, Drug, and Cosmetic Act for GlucaGen [glucagon (rDNA origin) for injection].

We acknowledge receipt of your submissions dated October 1 and 29, November 6, December 16 and 19, 1997, January 15, 20, and 29, February 4, 11,13, 17, and 25, March 11, 12, 16, 17, 19, and 20, April 20, May 1, 5, 6, 22 (2), and 26, and June 2, 5, 10, 16, 17, 19, and 22 (4), 1998. Your submission of March 12, 1998, extended the user fee goal date for this application to June 23, 1998.

This new drug application provides for the use of GlucaGen [glucagon (rDNA origin) for injection] for (1) for the treatment of hypoglycemia, and (2) for use as a diagnostic aid.

We have completed the review of this application, as amended, and have concluded that adequate information has been presented to demonstrate that the drug product is safe and effective for use as recommended in the submitted labeling text. Accordingly, the application is approved effective on the date of this letter.

The final printed labeling (FPL) must be identical to the draft (1) June 19, 1998, labeling text for the patient package insert, (2) the June 22, 1998, labeling text for the physician package insert, (3) the June 22, 1998, text for the immediate container, and (4) the June 22, 1998 text for cartons (Emergency Kit and Diagnostic Kit). Marketing the product with FPL that is not identical to the approved labeling text may render the product misbranded and an unapproved new drug.

Please submit 20 copies of the FPL as soon as it is available, in no case 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, this submission should be designated "FPL for approved NDA 20-918." Approval of this submission by FDA is not required before the labeling is used.

(b)(4)----------

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Protocols, data, and final reports should be submitted to your IND for this product and a copy of the cover letter sent to this NDA. If an IND is not required to meet your Phase 4 commitments, please submit protocols, data and final reports to this NDA as correspondence. In addition, under 21 CFR 314.82(b)(2)(vii), we request that you include a status summary of each commitment in your annual report to this NDA. The status summary should include the number of patients entered in each study, expected completion and submission dates, and any changes in plans since the last annual report. For administrative purposes, all submissions, including labeling supplements, relating to these Phase 4 commitments must be clearly designated "Phase 4 Commitments."

Validation of the regulatory methods has not been completed. At the present time, it is the policy of the Center not to withhold approval because the methods are being validated. Nevertheless, we expect your continued cooperation to resolve any problems that may be identified.

In addition, please submit three copies of the introductory promotional materials that you propose to use for this product. 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-40
Food and Drug Administration
5600 Fishers Lane
Rockville, Maryland 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, contact Julie Rhee, Regulatory Health Project Manager, at (301) 827-6424.

Sincerely,

Solomon Sobel, M.D.
Director
Division of Metabolic and Endocrine Drug Products
Office of Drug Evaluation II
Center for Drug Evaluation and Research