NDA 21-028

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

Dear Dr. Reit:

Please refer to your new drug application (NDA) dated July 22, 1998, received July 23, 1998, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Velosulin BR (human buffered regular insulin [rDNA origin] injection).

We acknowledge receipt of your submissions dated September 28, November 10, December 1 and 23, 1998, and February 24, April 12, and 26, June 15, and July 1, 1999.

This new drug application provides for the use of Velosulin BR (human buffered regular insulin [rDNA origin] injection) with external insulin infusion pumps.

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 agreed upon labeling text. Accordingly, the application is approved effective on the date of this letter.

The final printed labeling (FPL) must be identical to the submitted draft labeling (package insert submitted July 6, 1999, immediate container and carton labels submitted July 22, 1998). 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 21-028." Approval of this submission by FDA is not required before the labeling is used.

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.

As of April 1, 1999, all applications for new active ingredients, new dosage forms, new indications, new routes of administration, and new dosing regimens are required to contain an assessment of the safety and effectiveness of the product in pediatric patients unless this requirement is waived or deferred (63 *FR* 66632). Because this application is only for approval of an alternative method of manufacture of Velosulin BR, it does not meet any of the above criteria, and, therefore, it is not subject to requirements for pediatric studies at this time.

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 Project Manager, at (301) 827-6424.

Sincerely,

Solomon Sobel, M.D.
Director
Division of Metabolic
and Endocrine Drug Products, HFD-510
Office of Drug Evaluation II
Center for Drug Evaluation and Research