



NDA 21-148/S-001

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 application dated August 15, 2000, received August 24, 2000, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Norditropin (somatropin [rDNA origin] injection) Cartridges, 5mg/1.5mL, 10mg/1.5mL, and 15 mg/1.5mL.

We acknowledge receipt of your submissions dated February 12 and 26, 2001. Your submission of February 26, 2001, constituted a complete response to our February 2, 2001, action letter.

This supplemental new drug application provides for the NordiPenMate auto-insertion accessory to the NordiPen (5, 10, and 15) dial-a-dose somatropin delivery system.

We have completed the review of this supplemental 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 supplemental application is approved effective on the date of this letter.

The final printed labeling (FPL) must be identical to the submitted draft labeling (carton label and patient instruction manual submitted February 26, 2001).

Please submit the copies of final printed labeling (FPL) electronically 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, this submission should be designated "FPL for approved supplement NDA 21-148/S-001." Approval of this submission 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 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 insert 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.

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 Crystal King, P.D., M.G.A., Regulatory Project Manager, at (301) 827-6423.

Sincerely,

*{See appended electronic signature page}*

David G. Orloff, M.D.  
Director  
Division of Metabolic and Endocrine Drug Products  
Office of Drug Evaluation II  
Center for Drug Evaluation and Research