

NDA 20-280/S-023

Pharmacia & Upjohn  
Attention: Cynthia J. Blanchard  
Regulatory Manager  
7000 Portage Road  
Unit 0633-298-113  
Kalamazoo, MI 49001-0199

Dear Ms. Blanchard:

Please refer to your supplemental new drug application dated December 22, 1999, received December 23, 1999, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Genotropin (somatropin [rDNA origin] for injection).

We acknowledge receipt of your submissions dated February 11, March 6 and 7, April 17 and 28, and May 3, 12, 17, 18, and 26, 2000.

This supplemental new drug application provides for the use of Genotropin (somatropin [rDNA origin] for injection) for the treatment of pediatric patients with Prader-Willi syndrome.

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.

You are not required to complete a pediatric assessment for this application because it is not covered by the Pediatric Rule (21 CFR 314.55(a)).

The final printed labeling (FPL) must be identical to the submitted draft labeling (package insert submitted May 26, 2000).

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 supplement NDA 20-280/S-023." 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-40  
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 Practitioner" 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

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,

John K. Jenkins, M.D.  
Acting Director  
Division of Metabolic and Endocrine Drug Products  
Office of Drug Evaluation II  
Center for Drug Evaluation and Research