



NDA 20280/S-068

**SUPPLEMENT APPROVAL**

Pfizer, Inc.  
Agent for Pharmacia & Upjohn  
Attention: Ben Drosman RPh, MBA  
Director, Worldwide Regulatory Affairs & Quality Assurance  
235 East 42<sup>nd</sup> Street  
New York, NY 10017-5755

Dear Mr. Drosman:

Please refer to your supplemental new drug application dated August 6, 2009, received August 6, 2009, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Genotropin® (somatropin [rDNA origin] for injection).

This “Changes Being Effected” supplemental new drug application provides for the following revisions to the package insert:

1. Modification of the HIGHLIGHTS and FULL PRESCRIBING INFORMATION sections to include both non-weight based dosing and weight-based dosing of adult patients with growth hormone deficiency (GHD).
2. Revision to the HIGHLIGHTS and FULL PRESCRIBING INFORMATION sections, Warnings and Precautions subsections to include information that patients with hypopituitarism should have their other hormonal replacement treatments closely monitored during somatropin treatment.
3. Revision to the FULL PRESCRIBING INFORMATION, Indications and Usage and Adult Patients subsections to advise patients with Childhood Onset GHD whose epiphyses are closed to be reevaluated before continuation of somatropin therapy.
4. Revision to the FULL PRESCRIBING INFORMATION, Dosage and Administration, and Dosing of Pediatric Patients subsections to provide additional dosing information of pediatric patients.
5. Revision to the wording of the FULL PRESCRIBING INFORMATION, Drug Interaction subsection, 11 $\beta$ -Hydroxysteroid Dehydrogenase Type 1.
6. Revision to the wording of the FULL PRESCRIBING INFORMATION, Drug Interaction subsection, Pharmacologic Glucocorticoid Therapy and Supraphysiologic Glucocorticoid Treatment.

We have completed our review of this application, as amended. It is approved, effective on the date of this letter, for use as recommended in the enclosed, agreed upon labeling text, which is identical to the content of labeling [21 CFR 314.50(I)(1)(i)] in structured product labeling (SPL) format submitted on August 6, 2009.

**LETTERS TO HEALTH CARE PROFESSIONALS**

If you issue a letter communicating important safety related information about this drug product (i.e., a “Dear Health Care Professional” letter), we request that you submit an electronic copy of the letter to both this NDA and to the following address:

MedWatch  
Food and Drug Administration  
5600 Fishers Lane, Room 12B05  
Rockville, MD 20857

**REPORTING REQUIREMENTS**

We remind you that you must comply with reporting requirements for an approved NDA (21 CFR 314.80 and 314.81).

If you have any questions, call Linda Galgay, Regulatory Project Manager, at (301) 796-5383.

Sincerely,

*{See appended electronic signature page}*

Mary H. Parks, MD  
Director  
Division of Metabolism and Endocrinology Products  
Office of Drug Evaluation II  
Center for Drug Evaluation and Research

Enclosure: Package Insert

Application Type/Number	Submission Type/Number	Submitter Name	Product Name
NDA-20280	SUPPL-68	PHARMACIA AND UPJOHN CO	GENOTROPIN (SOMATROPIN) FOR INJECTION

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

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/s/

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MARY H PARKS  
02/02/2010