



NDA 20-280/S-057

Pfizer, Inc.  
US Agent for Pharmacia & Upjohn Company  
Attention: Diane G. Rocco  
US Regulatory Affairs  
235 East 42<sup>nd</sup> Street  
New York, NY 10017

Dear Ms. Rocco:

Please refer to your supplemental new drug application dated August 31, 2006, received September 1, 2006, 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 submission dated December 15, 2006, containing modified structured product labeling (SPL).

This “Changes Being Effected” supplemental new drug application provides for harmonization of growth hormone product package inserts, particularly involving the CONTRAINDICATIONS, WARNINGS, and PRECAUTIONS sections.

We completed our review of this supplemental new drug application, as amended. It is approved, effective on the date of this letter, for use as recommended in the attached final printed labeling (FPL) submitted on August 31, 2006.

Within 21 days of the date of this letter, amend any pending application for this NDA with content of labeling in structured product labeling (SPL) format to include the changes approved in this application.

In addition, at the next printing:

1. Delete reference to “long term” with respect to treatment for any indication, since this terminology is not used with other products given for chronic use.
2. In the following sentence in the CONTRAINDICATIONS section, delete the hyphen in “preexisting”: “Any pre-existing malignancy should be inactive and its treatment complete prior to instituting therapy with somatropin.”
3. In the DOSAGE AND ADMINISTRATION section, Adult Patient subsection, delete “more” from the following sentence: “Alternatively, taking into account more recent literature, a starting dose of approximately 0.2 mg/day...”

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

MEDWATCH  
Food and Drug Administration  
5515 Security Lane  
HFD-001, Suite 5100  
Rockville, MD 20852

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 Kati Johnson, Regulatory Project Manager, at (301) 796-1234.

Sincerely,

*{See appended electronic signature page}*

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

Attachment: Package Insert (LAB-0222-9.0)

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**This is a representation of an electronic record that was signed electronically and  
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/s/

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Mary Parks  
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