



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration  
Rockville, MD 20857

NDA 20-280/S-061

Pfizer Inc.  
Agent for Pharmacia & Upjohn Company  
Attention: Benjamin Drosman, US Regulatory Affairs  
235 East 42<sup>nd</sup> Street  
New York, NY 10017-5755

Dear Mr. Drosman:

Please refer to your supplemental new drug application dated July 27, 2007, received July 30, 2007, 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 September 26, 2008, which constituted a complete response to our May 21, 2008 action letter.

This supplemental new drug application provides for the addition of a 31 gauge needle as an alternate needle for use with Genotropin Miniquick<sup>®</sup>.

We completed our review of this application, as amended. This application is approved, effective on the date of this letter, for use as recommended in the agreed-upon labeling text.

The final printed labeling (FPL) must be identical to the enclosed labeling (text for the Instructions for Use) submitted July 27, 2007.

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  
Suite 12B05  
5600 Fishers Lane  
Rockville, MD 20857

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

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If you have any questions, call Kati Johnson, Regulatory Project Manager, at (301) 796-1234.

Sincerely,

*{See appended electronic signature page}*

Mary H. Parks, M.D.

Director

Division of Metabolism and Endocrinology Products

Office of Drug Evaluation II

Center for Drug Evaluation and Research

Enclosure: Instructions for Use

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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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