



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 20-280/S-055

Pfizer, Inc.
Agent for Pharmacia & Upjohn
Attention: Ben Drosman
US Regulatory Affairs
235 East 42nd Street
New York, NY 10017-7807

Dear Mr. Drosman:

Please refer to your supplemental new drug application dated December 19, 2006, received December 21, 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 March 19, 2007, containing revised labeling .

This "Changes Being Effected" supplemental new drug application provides for the addition of a 31 gauge needle as an alternate needle for use with the Genotropin Pen 5 and Genotropin Pen 12 injection devices and corresponding labeling revisions to the "Instructions for Use" (IFU) for the respective devices .

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 March 17, 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
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 and Endocrinology Products
Office of Drug Evaluation II
Center for Drug Evaluation and Research

Attachment:

Genotropin Pen 5 Instructions for Use (LAB-0225-4.0, Revised March 2007)

Genotropin Pen 12 Instructions for Use (LAB-0224-5.0, Revised March 2007)

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

/s/

Mary Parks

7/22/2007 06:02:14 PM