



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 20-280/S-066

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

Dear Mr. Drosman:

Please refer to your supplemental new drug application dated October 14, 2008, received October 14, 2008, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Genotropin (somatropin [rDNA origin] for injection).

This supplemental new drug application provides for a change in the multi-dose product names Genotropin 5.8 mg (to 5 mg) and 13.8 mg (to 12 mg), and associated labeling revisions. Revised labeling includes the package insert, and the following for both the 5 mg and 12 mg products: two-chamber cartridge label, cartridge carton, Pen Device carton and Instructions for Use.

We completed our review of this application. 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 package insert, two-chamber cartridge label, cartridge carton, Pen Device carton and Instructions for Use submitted October 14, 2008).

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).

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: Package Insert
 Genotropin 5 mg Two-Chamber Cartridge Label
 Genotropin 5 mg Cartridge Container
 Genotropin Pen 5 Carton
 Genotropin Pen 5 Instructions for Use

 Genotropin 12 mg Two-Chamber Cartridge Label
 Genotropin 12 mg Cartridge Container
 Genotropin Pen 12 Carton
 Genotropin Pen 12 Instructions for Use

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/s/

Mary Parks
12/15/2008 11:37:40 AM