



NDA 20-280/S-049

Pfizer Inc.
Agent for Pharmacia & Upjohn
Attention: Robert Gremban, MS
Senior Regulatory Manager
50 Pequot Avenue
New London, CT 06320

Dear Mr. Gremban:

Please refer to your supplemental new drug application dated June 27, 2005, received June 28, 2005, 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 submissions dated August 2, 2005, January 25, 26, and February 6, 21, and March 17, 2006.

This supplemental new drug application provides for the use of Genotropin® (somatropin [rDNA origin] for injection) as long-term treatment of growth failure associated with Turner Syndrome in patients who have open epiphyses.

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 package insert) submitted (e-mail) April 26, 2006.

We strongly recommend that you add a section to your annual Periodic Safety Update Report (PSUR) wherein the incidence of all adverse events (in particular, type 2 diabetes mellitus, slipped capital femoral epiphysis, scoliosis, benign intracranial hypertension, systemic hypertension and otitis media) are compared in Turner Syndrome patients and non-Turner Syndrome patients treated with Genotropin.

Please submit an electronic version of the FPL according to the guidance for industry titled *Providing Regulatory Submissions in Electronic Format - NDA*. Alternatively, you may submit 20 paper copies of the FPL as soon as it is available but no more than 30 days after it is printed. Individually mount 15 of the copies on heavy-weight paper or similar material. For administrative purposes, designate this submission "**FPL for approved supplement NDA 20-280/S-049.**" Approval of this submission by FDA is not required before the labeling is used.

All applications for new active ingredients, new dosage forms, new indications, new routes of administration, and new dosing regimens are required to contain an assessment of the safety and effectiveness of the product in pediatric patients unless this requirement is waived or deferred. We note that you have fulfilled the pediatric study requirement for this application.

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
WO 22, Room 4447
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

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, please call Ms. Jena Weber, Regulatory Project Manager, at 301-796-1306.

Sincerely,

{See appended electronic signature page}

Mary Parks, M.D.
Acting Director
Division of Metabolism and Endocrinology Products
Office of Drug Evaluation II
Center for Drug Evaluation and Research

Enclosure

**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

4/27/2006 07:04:59 AM