



NDA 20-280/S-060

Pfizer, Inc.
Agent for Pharmacia & Upjohn Company
Attention: Benjamin Drosman
US Regulatory Affairs
235 East 42nd Street, Mail Code: 605/5/18
New York, NY 10017-5755

SUPPLEMENT APPROVAL

Dear Mr. Drosman:

Please refer to your supplemental new drug application dated June 29, 2007, received July 2, 2007, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Genotropin (somatropin [rDNA origin] for injection).

We acknowledge receipt of your submissions dated June 29, October 2, December 10, 2007, February 19, March 5 and 18, and April 4 and 15, 2008.

This supplemental new drug application provides for the use of Genotropin (somatropin [rDNA origin] for injection) for the treatment of idiopathic short stature, also called non-growth hormone-deficient short stature, defined by height SDS < -2.25, and associated with growth rates unlikely to permit attainment of adult height in the normal range, in pediatric patients whose epiphyses are not closed and for whom diagnostic evaluation excludes other causes associated with short stature that should be observed or treated by other means.

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

We are waiving the requirements of 21 CFR 201.57(d)(8) regarding the length of Highlights of prescribing information. This waiver applies to all future supplements containing revised labeling unless we notify you otherwise.

CONTENT OF LABELING

As soon as possible, but no later than 14 days from the date of this letter, please submit the content of labeling [21 CFR 314.50(l)] in structured product labeling (SPL) format as described at <http://www.fda.gov/oc/datacouncil/spl.html> that is identical to the enclosed labeling (text for the package insert). Upon receipt, we will transmit that version to the National Library of Medicine for public dissemination. For administrative purposes, please designate this submission, "**SPL for approved NDA 20-280/S-060.**"

You may request advisory comments on proposed introductory advertising and promotional labeling. To do so, submit, in triplicate, a cover letter requesting advisory comments, the proposed materials in draft or mock-up form with annotated references, and the package insert to:

Food and Drug Administration
Center for Drug Evaluation and Research
Division of Drug Marketing, Advertising, and Communications
5901-B Ammendale Road
Beltsville, MD 20705-1266

As required under 21 CFR 314.81(b)(3)(i), you must submit final promotional materials, and the package insert(s), at the time of initial dissemination or publication, accompanied by a Form FDA 2253. For instruction on completing the Form FDA 2253, see page 2 of the Form. For more information about submission of promotional materials to the Division of Drug Marketing, Advertising, and Communications (DDMAC), see www.fda.gov/cder/ddmac.

LETTERS TO HEALTH CARE PROFESSIONALS

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

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

REPORTING REQUIREMENTS

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

OTHER POSTMARKETING ACTIVITIES

We encourage the continuation of your ongoing postmarketing surveillance study entitled, KIGS Pfizer Growth International Database, which assesses the long-term efficacy and safety of GH treatment in children prescribed Genotropin and determines the relationship between the patients' clinical status, dose schedule, history of pretreatment, and response to Genotropin treatment. We also acknowledge your plan related to the marketing of Genotropin for idiopathic short stature to ensure appropriate use of Genotropin for this indication.

While this plan is not required under the FDCA or FDA regulations, we request that you provide FDA with information about any changes to this plan at the time the changes are made and periodically report to FDA data on the success of your plan to ensure appropriate use of Genotropin for idiopathic short stature.

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

Enclosure: Package Insert

**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
6/12/2008 10:32:30 AM