



NDA 20-280/S-064

Pfizer, Inc.
Agent for Pharmacia & Upjohn
Attention: Ben Drosman
US Regulatory Affairs
235 East 42nd Street
New York, NY 10017-5755

SUPPLEMENT APPROVAL

Dear Mr. Drosman:

Please refer to your supplemental new drug application dated November 29, 2007, received November 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 submissions dated January 30, April 1 and 29, 2009.

This supplemental new drug application provides for a new manufacturer (Vetter Pharma-Fertigung, Ravensburg, Germany) for the Genotropin MiniQuick single dose, disposable injection devices available as 0.2 mg, 0.4 mg, 0.6 mg, 0.8 mg, 1.0 mg, 1.2 mg, 1.4 mg, 1.6 mg, 1.8 mg, and 2.0 mg.

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.

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-064.**"

CARTON, IMMEDIATE CONTAINER LABELS, USER MANUAL

Submit final printed carton, container labels and the User Manual (Instructions for Use) that are identical to the enclosed labeling as soon as they are available, but no more than 30 days after they are printed. Please submit these labels electronically according to the guidance for industry titled *Providing Regulatory Submissions in Electronic Format – Human Pharmaceutical Product Applications and Related Submissions Using the eCTD Specifications (October 2005)*. Alternatively, you may submit 12 paper copies, with 6 of the copies individually mounted on heavy-weight paper or similar material. For administrative purposes, designate this submission "**Final Printed Carton and Container Labels for approved NDA 20-280/S-064**" Approval of this submission by FDA is not required before the labeling is used.

Marketing the product with FPL that is not identical to the approved labeling text may render the product misbranded and an unapproved new drug.

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
5600 Fishers Lane; Room 12B05
Rockville, MD 20857

REPORTING REQUIREMENTS

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 MiniQuick Instructions for Use
 Genotropin .2 mg container and carton label
 Genotropin .4 mg container and carton label
 Genotropin .6 mg container and carton label
 Genotropin .8 mg container and carton label
 Genotropin 1.0 mg container and carton label
 Genotropin 1.2 mg container and carton label
 Genotropin 1.4 mg container and carton label
 Genotropin 1.6 mg container and carton label
 Genotropin 1.8 mg container and carton label
 Genotropin 2.0 mg container and carton label

**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
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