



NDA 20280/S-072

**SUPPLEMENT APPROVAL**

Pfizer Inc.  
Agent for Pharmacia Upjohn  
Attention: David W. Husman, PhD, RAC  
PAREXEL Consulting  
235 East 42nd Street  
New York, NY 10017-5755

Dear Dr. Husman:

Please refer to your Supplemental New Drug Application (sNDA) dated March 17, 2011, received March 17, 2011, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Genotropin (somatotropin [rDNA origin] for injection).

We acknowledge receipt of your amendment dated October 5, 2011.

This "Prior Approval" supplemental new drug application provides for the following changes to the GENOTROPIN MINIQUICK Instructions for Use (IFU):

1. Adds a new "Questions and Answers" section
2. Includes standardized language for sharps disposal in response to California regulations
3. Enhances instructions to patients to emphasize the correct placement of the needle before screwing it onto the GENOTROPIN MINIQUICK
4. Includes minor editorial changes

There are no changes to the most recently approved Prescribing Information (Package Insert) (S-071, approved May 17 2011).

We have completed our review of this supplemental application, as amended. It is approved, effective on the date of this letter, for use as recommended in the enclosed, agreed-upon labeling text and with the minor editorial revision listed below.

Change the "revised date" from September 2011 to February 2012.

## **CONTENT OF LABELING**

As soon as possible, but no later than 14 days from the date of this letter, submit the content of labeling [21 CFR 314.50(l)] in structured product labeling (SPL) format using the FDA automated drug registration and listing system (eLIST), as described at <http://www.fda.gov/ForIndustry/DataStandards/StructuredProductLabeling/default.htm>.

Content of labeling must include your currently approved Prescribing Information and all currently-approved FDA-approved patient labeling including the MiniQuick IFU, which must be identical to, except with the revision indicated, the enclosed labeling text.

Information on submitting SPL files using eLIST may be found in the guidance for industry titled "SPL Standard for Content of Labeling Technical Qs and As" at <http://www.fda.gov/downloads/DrugsGuidanceComplianceRegulatoryInformation/Guidances/UCM072392.pdf>.

The SPL will be accessible via publicly available labeling repositories.

Also within 14 days, amend all pending supplemental applications for this NDA, including CBE supplements for which FDA has not yet issued an action letter, with the content of labeling [21 CFR 314.50(l)(1)(i)] in MS Word format, that includes the changes with the revision listed above approved in this supplemental application, as well as annual reportable changes, and annotate each change. To facilitate review of your submission, provide a highlighted or marked-up copy that shows all changes, as well as a clean Microsoft Word version. The marked-up copy should provide appropriate annotations, including supplement number(s) and annual report date(s).

If you have any questions, call Linda Galgay, Regulatory Project Manager, at (301) 796-5383.

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

ENCLOSURE:

GENOTROPIN MINIQUICK Instructions for Use (IFU)

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**This is a representation of an electronic record that was signed electronically and this page is the manifestation of the electronic signature.**  
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/s/  
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MARY H PARKS  
02/06/2012