



NDA 20280/S-071

**SUPPLEMENT APPROVAL**

Pfizer, Inc.  
Agent for Pharmacia & Upjohn Co.  
Attention: Shira Rohde, PhD  
Director, Worldwide Regulatory Strategy  
235 East 42<sup>nd</sup> Street  
New York, NY 10017-5755

Dear Dr. Rohde:

Please refer to your Supplemental New Drug Application (sNDA) dated March 14, 2011, received March 14, 2011, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Genotropin (somatropin [rDNA origin] for injection.

This “Changes Being Effected” supplemental new drug application provides for a revised package insert as follows;

- Updates the HIGHLIGHTS section and Table of Contents to reflect the addition of Section 5.14
- Section 5.14 has been added to the FULL PRESCRIBING INFORMATION:  
**5.14 Pancreatitis**  
Cases of pancreatitis have been reported rarely in children and adults receiving somatropin treatment, with some evidence supporting a greater risk in children compared with adults. Published literature indicates that girls who have Turner syndrome may be at greater risk than other somatropin-treated children. Pancreatitis should be considered in any somatropin–treated patient, especially a child, who develops persistent severe abdominal pain.
- Revises the WARNINGS AND PRECAUTIONS section (5.4)
  - The title is changed to “Impaired Glucose Tolerance and Diabetes Mellitus”
  - The following sentence has been added, “New-onset Type 2 diabetes mellitus has been reported.”
- Modifies the ADVERSE REACTIONS 6.3 Post-Marketing Experience, to include: “New-onset diabetes mellitus has been reported.”

The information regarding pancreatitis was submitted in response to our supplement request letter dated October 7, 2010. The information regarding diabetes mellitus was added based on information from postmarketing observational studies.

We have completed our review of this supplemental application. 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, 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 be identical to the enclosed labeling (text for the package insert), with the addition of any labeling changes in pending “Changes Being Effectuated” (CBE) supplements, as well as annual reportable changes not included in the enclosed labeling.

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 from 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 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).

### **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 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: Content of Labeling

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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  
05/17/2011