



NDA 19640/S-086

**SUPPLEMENT APPROVAL**

Eli Lilly and Company  
Attention: Beth Weinberg  
Manager, US Regulatory Affairs  
Lilly Corporate Center  
Indianapolis, IN 46285

Dear Ms. Weinberg:

Please refer to your Supplemental New Drug Application (sNDA) dated and received April 19, 2011, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Humatrope (somatropin [rDNA origin]) for injection.

We acknowledge receipt of your amendments dated June 17 and August 1, 2011.

This “Changes Being Effected” supplemental new drug application revises the text in the Humatrope Pen User Manuals “IMPORTANT INFORMATION...” section as follows:

- DO NOT share your HumatroPen [xx] mg or needles with anyone else. You may give an infection to them, or get an infection from them.

In addition, the supplement provides for minor changes including the addition of a literature revised date.

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.

**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(1)] 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 instructions for use (Pen User Manuals) for the HumatroPens, with the addition of any labeling changes in pending “Changes Being Effected” (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).

### **ADDITIONAL COMMENTS**

In a May 31, 2011, email to the project manager, you agreed to add the newly approved text to the Package Insert (PI), Full Prescribing Information, Patient Counseling Information section, with the next labeling (PI) supplement.

- **DO NOT share your HumatroPen [xx] mg or needles with anyone else. You may give an infection to them, or get an infection from them.**

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

ENCLOSURES:

Pen User Manuals 6 mg, 12 mg, and 24 mg.

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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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AMY G EGAN  
08/22/2011  
Amy Egan for Mary Parks