DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

NDA 019640/S-092

SUPPLEMENT APPROVAL

Eli Lilly and Company
Attention: Patricia L. Whitaker
Consultant, Global Regulatory Affairs – U.S.
Lilly Corporate Center
Indianapolis, IN 46285

Dear Ms. Whitaker:

Please refer to your Supplemental New Drug Application (sNDA) dated and received August 23, 2013, 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 amendment dated May 5, 2014.

This Prior Approval supplemental new drug application provides for revisions to the **WARNINGS AND PRECAUTIONS** section of the package insert, regarding an increased risk of developing a second neoplasm in childhood cancer survivors treated with radiation to the brain/head for their first neoplasm and who developed subsequent growth hormone deficiency and were treated with somatropin. This supplement was submitted in response to our supplement request letter dated July 8, 2013.

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 revisions listed below and indicated in the enclosed labeling.

Revision date and Recent Major Changes date changed to "7/2014" to reflect the date of approval for this supplement.

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) along with the currently approved instructions for use (IFU), 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 that includes labeling changes 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}

Jennifer Rodriguez Pippins, MD, MPH
Deputy Director for Safety (Acting)
Division of Metabolism & Endocrinology Products
Office of Drug Evaluation II
Center for Drug Evaluation and Research

Attachments:
Content of Labeling
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/

JENNIFER R PIPPINS
07/30/2014