



NDA 19640/S-078

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 dated August 17, 2009, received August 17, 2009, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Humatrope (somatropin [rDNA origin]) for injection.

This "Changes Being Effected" supplemental new drug application provides for a revised package insert (HIGHLIGHTS and FULL PRESCRIBING INFORMATION) as follows:

- adds "Pancreatitis" to (6.1) Most Serious and/or Most Frequently Observed Adverse Reactions.
- modifies the WARNINGS AND PRECAUTIONS section (5.12) and the ADVERSE REACTIONS section, Post-Marketing Experience subsection (6.3) to add information on pancreatitis in any somatropin-treated patient, especially a child, who develops abdominal pain.
- includes in the ADVERSE REACTIONS section, Post-Marketing Experience subsection (6.3) information that hypertension, dyspnea, and sleep apnea were reported by 1% to less than 10% of adults enrolled in an ongoing post-marketing observational study.

Pursuant to the December 9, 2009 conversation between you and Robert Perlstein, MD of this division, we have waived the requirement, under 21 CFR 314.70(c)(6)(iii), that revisions to the HIGHLIGHTS section of the package insert be submitted as a prior approval supplemental application.

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, using the FDA automated drug registration and listing system (eLIST), the content of labeling [21 CFR 314.50(l)] in structured product labeling (SPL) format, as described at <http://www.fda.gov/ForIndustry/DataStandards/StructuredProductLabeling/default.htm>, that is identical to, except with the revisions indicated, the enclosed labeling and include the labeling changes proposed in any pending “Changes Being Effected” (CBE) supplements. 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 from the date of this letter, amend all pending supplemental applications for this NDA, including pending CBE supplements, with the content of labeling [21 CFR 314.50(l)(1)(i)] in MS Word format that includes the changes with the revisions indicated above approved in this supplemental application.

LETTERS TO HEALTH CARE PROFESSIONALS

If you decide to 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, at least 24 hours prior to issuing the letter, an electronic copy of the letter to this NDA, to CDERMedWatchSafetyAlerts@fda.hhs.gov, and to the following address:

MedWatch Program
Office of Special Health Issues
Food and Drug Administration
10903 New Hampshire Ave
Building 32, Mail Stop 5353
Silver Spring, MD 20993

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

Application Type/Number	Submission Type/Number	Submitter Name	Product Name
----- NDA-19640	----- SUPPL-78	----- ELI LILLY AND CO	----- HUMATROPE

This is a representation of an electronic record that was signed electronically and this page is the manifestation of the electronic signature.

/s/

MARY H PARKS
07/28/2010