



NDA 19-640/S-032

Eli Lilly and Company
Attention: Jeffrey T. Fayerman, PhD
Sr. Regulatory Research Scientist, US Regulatory Affairs
Lilly Corporate Center
Indianapolis, IN 46285

Dear Dr. Fayerman:

Please refer to your supplemental new drug application dated September 23, 2002, received September 24, 2002, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Humatrope [somatotropin (rDNA origin) for injection].

This "Changes Being Effected" supplemental new drug application provides for the deletion of the criteria for biochemical diagnosis of adult growth hormone deficiency from the INDICATIONS AND USAGE section of the package insert.

We completed our review of this supplemental new drug application. It is approved, effective on the date of this letter, for use as recommended in the final printed labeling (FPL) submitted on September 23, 2002.

We remind you that you must comply with the requirements for an approved NDA set forth under 21 CFR 314.80 and 314.81.

If you have any questions, call Monika Johnson, Regulatory Project Manager, at (301) 827-9087

Sincerely,

{See appended electronic signature page}

David G. Orloff, MD
Director
Division of Metabolic & Endocrine Drug Products
Office of Drug Evaluation II
Center for Drug Evaluation and Research

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/s/

David Orloff

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