



NDA 19-640/S-031

Lilly Research Laboratories
Attention: Jeffery T. Fayerman, PhD
Senior Regulatory Research Scientist
Lilly Corporate Center
Indianapolis, IN 46285

Dear Dr. Fayerman:

Please refer to your supplemental new drug application dated December 19, 2001, received December 20, 2001, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Humatrope (somatropin [rDNA origin] for injection).

Your submission of June 21, 2002, constituted a complete response to our June 13, 2002 action letter.

This supplemental new drug application provides for changes to the patient portion of the package insert to be more consistent with revisions made to the user manual.

We completed our review of this supplemental new drug application, as amended and it is approved, effective on the date of this letter for use as recommended in the final printed labeling (FPL) submitted on December 19, 2001. Please note that in future submissions, each time you propose a change to any information in the package insert, both the vial and the cartridge package inserts need to accompany the submission to assure consistency.

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, PharmD, Regulatory Project Manager, at (301) 827-6370.

Sincerely,

{See appended electronic signature page}

David G. Orloff, MD
Director
Division of Metabolic and 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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