



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration  
Rockville, MD 20857

NDA 19-640/S-040

Eli Lilly & Company  
Attention: Jeffrey T. Fayerman, Ph.D.  
Director, US Regulatory Affairs  
Lilly Corporate Center  
Indianapolis, IN 46285

Dear Dr. Fayerman:

Please refer to your supplemental new drug application dated April 29, 2004, received April 30, 2004, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Humatrope® (somatropin [rDNA origin] for Injection).

This "Changes Being Effected" supplemental new drug application provides for revisions to the CONTRAINDICATIONS and WARNINGS sections of the package insert regarding use in patients with Prader-Willi syndrome. This supplement was submitted in response to our letter dated March 17, 2004.

We completed our review of this application, as amended. This application is approved, effective on the date of this letter, for use as recommended in the attached agreed-upon labeling text (Identifier-PA 1643 AMP).

If you issue a letter communicating important information about this drug product (i.e., a "Dear Health Care Professional" letter), we request that you submit a copy of the letter to this NDA and a copy to the following address:

MEDWATCH, HFD-410  
FDA  
5600 Fishers Lane  
Rockville, MD 20857

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 Monika Johnson, Regulatory Project Manager, at (301) 827-9087.

Sincerely,

*{See appended electronic signature page}*

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

Enclosure (package insert)

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**This is a representation of an electronic record that was signed electronically and  
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/s/

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David Orloff

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