DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 19-640/S-046

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

Dear Dr. Fayerman:

Please refer to your supplemental new drug application dated March 3, 2005, received March 4, 2005, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Humatrope (somatropin [rDNA origin] for injection).

We acknowledge receipt of your submissions dated August 18, 2005, and March 13, 2006.

Your submission of August 18, 2005 constituted a complete response to our July 26, 2005 action letter.

This supplemental new drug application provides for a new pen-injector (HumatroPen 3) intended for use exclusively with the approved Humatrope cartridges. The corresponding device labeling included in the application is a User Manual, QuickGuide, and Carton.

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.

The final printed labeling (FPL) must be identical to the enclosed labeling (text for the User Manual submitted March 13, 2006, text for the QuickGuide and Carton submitted August 18, 2005).

Please submit an electronic version of the FPL according to the guidance for industry titled *Providing Regulatory Submissions in Electronic Format - NDA*. For administrative purposes, designate this submission "**FPL for approved supplement NDA 19-640/S-046**." Approval of this submission by FDA is not required before the labeling is used.

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
Food and Drug Administration
White Oak Building 22, Room 4447
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

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 Kati Johnson, Chief, Project Management Staff, at (301) 796-1234.

Sincerely,

{See appended electronic signature page}

Mary Parks, M.D.
Acting Director
Division of Metabolism & Endocrinology Products
Office of Drug Evaluation II
Center for Drug Evaluation and Research

Enclosure: User Manual (submitted March 13, 2006)
QuickGuide (submitted August 18, 2005)
Carton (submitted August 18, 2005)

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

/s/

Mary Parks

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