DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 19-640/S-070

Eli Lilly and Company
Attention: Beth C. Weinberg, RPh
Manager, US Regulatory Affairs
Lilly Corporate Center
Indianapolis, IN 46285

Dear Ms. Weinberg:

Please refer to your supplemental new drug application dated March 31, 2008, received March 31, 2008, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Humatrope (somatropin [rDNA origin]) Injection.

We acknowledge receipt of your submissions dated April 18, May 12, September 12, 2008, and January 7, 2009.

Your submission of September 12, 2008 constituted a complete response to our August 25, 2008 action letter.

This supplemental new drug application provide for three reusable, mechanical pen-injectors (HumatroPen 6, HumatroPen 12 and HumatroPen 24) designed for self-administration of human growth hormone, using the currently approved Humatrope 3 mL cartridges (6 mg, 12 mg, and 24 mg). The supplement also provides for a hidden needle cover to provide the option to inject with the needle hidden from view.

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 (HumatroPen 6 carton and user manual submitted September 12, 2008. HumatroPen 12 and 24 cartons and user manuals submitted January 7, 2009, and the Hidden Needle Cover User Manual submitted September 12, 2008).

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
Suite 12B05
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 Kati Johnson, Regulatory Project Manager, at (301) 796-1234.

Sincerely,

{See appended electronic signature page}

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

Enclosure: HumatroPen 6 Carton
HumatroPen 6 User Manual
HumatroPen 12 Carton
HumatroPen 12 User Manual
HumatroPen 24 Carton
HumatroPen 24 User Manual
Hidden Needle Cover-Instructions for Use

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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