



NDA 19-640/S-058

Eli Lilly and Company
Attention: William Current, PhD
Associate Director, Regulatory Affairs
Lilly Corporate Center
Indianapolis, IN 46285

Dear Dr. Current:

Please refer to your supplemental new drug application dated December 22, 2005, received December 23, 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 May 3, June 8, and October 27, 2006.

This supplemental new drug application provides for the use of Humatrope for the following indication: treatment of short stature or growth failure in children with SHOX (short stature homeobox-containing gene) deficiency whose epiphyses are not closed.

We completed our review of this supplemental new drug application, as amended. It is approved, effective on the date of this letter, for use as recommended in the attached final printed labeling (FPL) submitted on October 27, 2006.

All applications for new active ingredients, new dosage forms, new indications, new routes of administration, and new dosing regimens are required to contain an assessment of the safety and effectiveness of the product in pediatric patients unless this requirement is waived or deferred. We note that you have fulfilled the pediatric study requirement for this application.

In addition, submit three copies of the introductory promotional materials that you propose to use for this product. Submit all proposed materials in draft or mock-up form, not final print. Send one copy to this division and two copies of both the promotional materials and the package insert(s) directly to:

Food and Drug Administration
Center for Drug Evaluation and Research
Division of Drug Marketing, Advertising, and Communications
5901-B Ammendale Road
Beltsville, MD 20705-1266

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
5515 Security Lane
HFD-001, Suite 5100
Rockville, MD 20852

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

Sincerely,

{See appended electronic signature page}

Mary H. Parks, MD

Director

Division of Metabolism & Endocrinology Products

Office of Drug Evaluation II

Center for Drug Evaluation and Research

Enclosed: Package Insert (cartridges): PA 9324 FSAMP
 Package Insert (vials): PA 1647 AMP

**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
11/1/2006 11:09:26 AM