



NDA 19-640/S-047, S-052

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

Dear Dr. Current:

Please refer to your following supplemental new drug applications:
S-047, dated March 7, 2005, received March 8, 2005, and
S-052, dated June 30, 2005, received July 1, 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 April 7 and August 4, 2005 to **S-047**. Your submission dated August 4, 2005 constituted a complete response to our July 26, 2005 action letter. We also acknowledge receipt of your submission dated August 9, 2005 and February 20, 2006, to **S-052**.

Supplement -047, a Changes Being Effected supplement, provides for revisions to the package insert **(PI)(cartridges)**, the patient package insert **(PPI) (cartridges)**, and **HumatroPen User Manual** to remove device specific information from the PI and PPI in preparation for the launch of a new pen injection device (HumatroPen 3).

Supplement -052, a Changes Being Effected supplement, provides for revisions to the following pieces of labeling to provide for a new reconstitution system:

- PI (cartridges and vials)**
- PPI (cartridges)**
- 6, 12, and 24 mg cartridge labels**
- 6, 12, and 24 mg kit cartons**
- Foil covering tray contained in kit**
- Diluent syringe label**
- User Manual (HumatroPen)**

This supplement was amended February 20, 2006 to include the labeling revisions contained in S-047.

We completed our review of these supplemental new drug applications, as amended. They are approved, effective on the date of this letter, for use as recommended in the final printed labeling (FPL) submitted to S-052 on June 30, 2005 (cartridge labels, foil covering, kit cartons, diluent syringe labels, User Manual [HumatroPen] and on February 20, 2006 (PI [cartridge], PPI [cartridge], and PI [vial])).

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, Regulatory Project Manager, at (301) 796-1234.

Sincerely,

{See appended electronic signature page}

Mary Parks, MD
Director
Division of Metabolism & Endocrinology Products
Office of Drug Evaluation II
Center for Drug Evaluation and Research

Enclosure:

Package Insert (cartridges)-PA9323 FSAMP

Patient Package Insert (Information for Patients)(cartridges)-PA 9330 FSAMP

Package Insert (vials)-PA1646 FSAMP

6 mg cartridge label-YL0530 FSAMX

12 mg cartridge label-YL0540 FSAMX

24 mg cartridge label-YL0550 FSAMX

6 mg diluent syringe-VL7618

12 mg and 24 mg diluent syringe-VL7619

Kit Cartons (cartridge/diluent/cartridge-syringe connector):

6 mg-SH9000FSAMS

12 mg-SH9010FSAMS

24 mg0-SH9020FSAMS

Foil covering tray (containing reconstitution steps)-FL0023FSFIL

User Manual (HumatroPen)-PA 9184 FSAMP

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/s/

Mary Parks
10/26/2006 07:09:07 PM