



NDA 19-640/S-025

Eli Lilly & Co.
Attention: Gregory G. Enas
Director, Regulatory Affairs
Lilly Corporate Center
Indianapolis, IN 46285

Dear Mr. Enas:

Please refer to your supplemental new drug application dated June 30, 1999, received July 2, 1999, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Humatrope [Somatotropin, (rDNA origin) for injection].

This "Changes Being Effected" supplemental new drug application provides for the final printed labeling (FPL) for supplemental application -022, revised to include the labeling revisions that were included with supplemental application -023 and other minor editorial revisions. The Acknowledge and Retain letter for supplement -022 and a letter informing you that the labeling contained in supplement -023 has been superseded by a subsequently approved labeling will be issued under separate cover.

We have completed the review of this supplemental application, as amended, and have concluded that adequate information has been presented to demonstrate that the drug product is safe and effective for use as recommended in the submitted final printed labeling (patient package insert and immediate container and carton labels submitted June 30, 1999). Accordingly, the supplemental application is approved effective on the date of this letter. The package insert contained in this supplement has been superseded by that approved with supplement -026.

If a letter communicating important information about this drug product (i.e., a "Dear Health Care Professional" letter) is issued to physicians and others responsible for patient care, we request that you submit a copy of the letter to this NDA and a copy to the following address:

MEDWATCH, HF-2
FDA
5600 Fishers Lane
Rockville, MD 20857

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 Monika Johnson, Regulatory Project Manager, at 301-827-6370.

Sincerely,

{See appended electronic signature page}

David G. Orloff, M.D.

Director

Division of Metabolic and Endocrine Drug Products

Office of Drug Evaluation II

Center for Drug Evaluation and Research

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

/s/

David Orloff

6/10/02 01:31:00 PM