DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 20-563/S-041

Eli Lilly and Company
Attention: Jeffrey L. Winn, D.D.S.
Senior Regulatory Research Scientist
U.S. Regulatory Affairs
Lilly Corporate Center
Indianapolis, IN 46285

Dear Dr. Winn:

Please refer to your supplemental new drug application dated May 28, 2003, received May 29, 2003, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Humalog® (insulin lispro [rDNA origin] injection).

We acknowledge receipt of your submissions dated June 10, July 23, and September 29, 2003.

This supplemental new drug application provides for (1) Abbott Laboratories, McPherson, Kansas, as an additional Humalog vial manufacturing site, and (2)(b)(4)---------- ---------- (b)(4)---------- --- ----- ---------- - -

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 agreed-upon labeling text.

The final printed labeling (FPL) must be identical to the enclosed labeling (text for the package insert, text for the patient package insert, immediate container and carton labels).

We remind you that you must submit patient information on form FDA 3542, *Patent Information Submitted Upon and After Approval of an NDA or Supplement*, within 30 days of the date of this letter as required by 21 CFR 314.53(c)(2)(ii) and 314.53(d)(2) at the address provided by 21 CFR 314.53(d)(4). The form may be obtained at http://www.fda.gov/opacom/morechoices/fdaforms/cder.html. To expedite review of this patent declaration form, we request you submit an additional copy of the form to this application and to the Center for Drug Evaluation and Research "Orange Book" staff at

Food and Drug Administration
Office of Generic Drugs, HFD-610
Orange Book Staff
7500 Standish Place
Metro Park North II
Rockville, MD 20855-2773

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, HFD-410
FDA
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 Julie Rhee, Regulatory Project Manager, at (301) 827-6424.

Sincerely,

{See appended electronic signature page}

David G. Orloff, M.D.
Director
Division of Metabolic
and Endocrine Drug Products, HFD-510
Office of Drug Evaluation II
Center for Drug Evaluation and Research

Enclosures:
1. Physician insert (A2.0 NL 4520 AMP)
2. INFORMATION FOR THE PATIENT VIAL (A2.0 NL 4530 AMP)
3. Carton label (NL 3800 AMS)
4. Immediate container label (NL 4030 AMX)

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
9/29/03 03:06:06 PM
for Dr. Orloff