



NDA 19-377/S-046

NDA 19-571/S-037

Eli Lilly and Company  
Attention: William L. Current, Ph.D.  
Associate Director, U.S. Regulatory Affairs  
Lilly Corporate Center  
Indianapolis, IN 46285

Dear Dr. Current:

Please refer to your supplemental new drug applications dated July 25, 2005, received July 26, 2005, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for the following products:

NDA 19-377/S-046 Humulin L (human insulin [rDNA origin] zinc suspension)  
NDA 19-571/S-037 Humulin U (human insulin [rDNA origin] extended zinc suspension)

These "Changes Being Effected" supplemental new drug applications provide for a revision to the carton label for 10 mL vial to include a statement to let patients know about the upcoming discontinuation of the above products.

We completed our review of these supplemental new drug applications. They are approved, effective on the date of this letter, for use as recommended in the final printed labeling (FPL) submitted on July 25, 2005.

In addition, submit three copies of the introductory promotional materials that you propose to use for these products. 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 inserts directly to:

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

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If you issue a letter communicating important information about these drug products (i.e., a “Dear Health Care Professional” letter), we request that you submit a copy of the letter to the NDA and a copy to the following address:

MEDWATCH  
Food and Drug Administration  
WO 22, Room 4447  
10903 New Hampshire Avenue  
Silver Spring, MD 20993-0002

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 Julie Rhee, Regulatory Project Manager, at (301) 796-1280.

Sincerely,

*{See appended electronic signature page}*

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

Enclosures: 1. Humulin L carton labeling (FC 3722 AMS and SF 5353 AMS)  
2. Humulin U carton labeling (FC 3711 AMS and SF 5365 AMS)

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/s/

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Mary Parks

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