DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 19-385/S-030/ S-031/S-035

Eli Lilly and Company
Attention: Elizabeth C. Sloan, Pharm.D.
Regulatory Affairs
Lilly Corporate Center
Indianapolis, IN 46185

Dear Dr. Sloan:

Please refer to your supplemental new drug applications dated November 30, 2002 (S-030), December 5, 2000 (S-031), and February 10, 2003 (S-035), submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Permax (pergolide mesylate) tablets, and to your amendments dated February 10, 2003 (S-031 and S-035), and February 13, 2003 (S-030).

We also refer to (a) an Agency letter dated November 9, 2002, which requests revision of labeling and issuance of a "Dear Healthcare Practitioner" letter (S-035), and (b) an Agency letter dated December 19, 2002, which states that supplemental applications S-030 and S-031 are approvable.

Additional reference is made to a September 3, 2003 email from Ms. Bryn Bright to Dr. John Feeney of this Division. In that email Ms. Bright states that Lilly will agree to the wording for the Warning regarding falling asleep during activities of daily living, as discussed during several recent telephone conversations, beginning August 11.

Supplemental Application S-030

Originally this "Changes Being Effected" supplemental new drug application provided for the inclusion of two new sentences in the **PRECAUTIONS - Information for Patients** subsection of labeling. The February 13, 2003 amendment provided alternative proposed language to the **WARNINGS – Falling Asleep During Activities of Daily Living** subsection, and to the **PRECAUTIONS – Information for Patients** subsection in response to an Agency December 19, 2002 letter. The September 3, 2003 email communication agrees to accept the Agency's originally proposed language for **WARNINGS -Falling Asleep During Activities of Daily Living** subsection.

Supplemental Application S-031

This "Prior Approval" supplemental new drug application proposes the addition of a new subsection, **PRECAUTIONS – Geriatric Use**.

Supplemental Application S-035

This "Changes Being Effected" supplemental new drug application proposes changes to the **WARNINGS –Serous Inflammation and Fibrosis** subsection of labeling.

Your submissions of February 10, 2003 (S-031 & S-035) and February 13, 2003 (S-030), constitute a complete response to our approvable letter dated December 19, 2002 (S-030 and S-031), and our labeling change request letter dated November 9, 2002 (S-035). The September 3, 2003 email communication provides agreed upon labeling (Code 5.02 PV 2271-A UCP).

We have completed our review of supplemental new drug applications S-030, S-031, and S-035, as amended, and they are approved effective on the date of this letter, for use as recommended in the agreed upon labeling text provided.

The final printed labeling (FPL) must be identical to the enclosed labeling (text for the package insert)

We remind you that the **WARNINGS – Falling Asleep During Activities of Daily Living** subsection should be a Bold warning and should be the first warning in labeling. Also, we remind you that a Dear Health Care Professional letter should issue, advising practitioners about this new warning.

If additional information relating to the safety or effectiveness of these drugs becomes available, revision of the labeling may be required.

If you have any questions, call CDR Teresa Wheelous, Sr. Regulatory Management Officer, at (301) 594-2850.

Sincerely Yours

Russell Katz, M.D.
Division Director
Division of Neuropharmacology Drug Products
Office of Drug Evaluation I
Center for Drug Evaluation and Research

Enclosure:

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

/s/

Russell Katz
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