DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 21-368

Lilly ICOS LLC
Attention: Catherine Melfi, Ph.D.
U.S. Regulatory Affairs
Lilly Research Laboratories
Lilly Corporate Center
Indianapolis, IN 46285

Dear Dr. Melfi:

Please refer to your new drug application dated June 28, 2001, received June 29, 2001, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Cialis® (tadalafil), tablets 5mg, 10mg and 20mg.

We acknowledge receipt of your submissions dated June 28, July 24, August 27, September 10, 17, 18, and 25, October 1, 22, 25, and 30, November 5, and December 6, 2001; January 14 and 23, February 1, 6, 26, and 28, March 4, 6, 12, 18, 20, 22, and 25, April 1, 4, 5, and 16, May 10 (2), 14, 16, 24, and 30, June 6, 13, and 28, August 6, 8, 22, and 26, September 5, 12, 24, and 30, November 15 and 27, 2002, February 13, April 16 and 24, May 16, 27, and 30, June 5, 17, 24, and 26, July 15 and 22, August 7, 11, 19, and 29, September 11, October 9, 14, 15, 20 (2), and 24 (2), and November 5, 11, 12, 17, 19, and 20, 2003.

The May 27, 2003 submission constituted a complete response to our April 29, 2002 action letter.

This new drug application provides for the use of Cialis® (tadalafil) tablets for the treatment of erectile dysfunction.

We completed our review of this application, as amended. It 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). Marketing the product with FPL that is not identical to the approved labeling text may render the product misbranded and an unapproved new drug.

Please submit an electronic version of the FPL according to the guidance for industry titled *Providing Regulatory Submissions in Electronic Format - NDA*. Alternatively, you may submit 20 paper copies of the FPL as soon as it is available but no more than 30 days after it is printed. Individually mount 15 of the copies on heavy-weight paper or similar material. For administrative purposes, designate this submission "**FPL for approved NDA 21-368.**" Approval of this submission by FDA is not required before the labeling is used.

We remind you of the postmarketing study commitment you made in a letter dated November 19, 2003. The commitment is listed below:

1. To conduct a randomized, placebo-controlled study investigating the effects of Cialis® (tadalafil) tablets on color vision and retinal physiology (electroretinography) following multiple daily doses. The timeline is as follows:

Protocol Submission	within 3 months of the date of this letter
Study Initiation	within 10 months of the date of this letter
Final Report Submission	within 18 months of the date of this letter

In addition, submit three copies of the introductory promotional materials that you propose to use for this product. 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:

Division of Drug Marketing, Advertising,
and Communications, HFD-42
Food and Drug Administration
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).

The MedWatch-to-Manufacturer Program provides manufacturers with copies of serious adverse event reports that are received directly by the FDA. New molecular entities and important new biologics qualify for inclusion for three years after approval. Your firm is eligible to receive copies of reports for this product. To participate in the program, please see the enrollment instructions and program description details at www.fda.gov/medwatch/report/mmp.htm.

If you have any questions, please call Eufrecina DeGuia, Regulatory Health Project Manager at (301) 827-4260.

Sincerely,

{See appended electronic signature page}

Florence Houn, M.D., M.P.H.
Director
Office of Drug Evaluation III
Center for Drug Evaluation and Research

Enclosures:
Physician Insert
Patient Package Insert

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

/s/

Florence Houn
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