



NDA 21-368/S-007

Lilly ICOS LLC
Attention: David Riggs, Pharm.D.
U.S. Regulatory Affairs
Lilly Research Laboratories
Lilly Corporate Center
Indianapolis, IN 46285

Dear Dr. Riggs:

Please refer to your supplemental new drug application dated July 7, 2005 received July 8, 2005, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Cialis® (tadalafil), 5mg, 10mg and 20mg.

We also acknowledge receipt of your May 10, 2006, submission, which constitutes a Complete Response to our March 15, 2006, Approvable Letter.

We also refer to your email communication dated November 17, 2006, wherein you provided a modified language and scientific rationale in response to the Division's changes to the PDE11 language under **CLINICAL PHARMACOLOGY, Mechanism of Action** provided to you via email on September 20, 2006.

We further refer to your email communication on January 8, 2007, conveying your agreement to the labeling changes made regarding PDE11 under **CLINICAL PHARMACOLOGY, Mechanism of Action** provided to you via email on September 20, 2006.

This "Prior Approval" supplement provides a revised Physician Insert (PI) which includes revisions to the label to address the following issues:

- New findings concerning PDE11
- New information from a recently completed tadalafil and alfuzosin study
- New information from a recently completed tadalafil and ritonavir study

We have completed the review of this supplemental application and have concluded that adequate information has been presented to demonstrate that the drug is safe and effective for use as recommended in the agreed upon labeling text. Accordingly, it is approved effective on the date of this letter.

Within 21 days of the date of this letter, submit content of labeling [21 CFR 314.50(1)] in structured product labeling (SPL) format, as described at <http://www.fda.gov/oc/datacouncil/spl.html>, that is identical to the enclosed labeling text. Upon receipt and verification, we will transmit that version to the National Library of Medicine for public dissemination.

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 Division of Reproductive and Urologic Products and two copies of both the promotional materials and the package insert 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

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, please call Eufrecina DeGuia, Regulatory Health Project Manager, at (301) 796-2130.

Sincerely,

{See appended electronic signature page}

Mark Hirsch, M.D.
Acting Deputy Director
Division of Reproductive and Urologic Products
Office of Drug Evaluation III
Center for Drug Evaluation and Research

Enclosure

**This is a representation of an electronic record that was signed electronically and
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/s/

Mark S. Hirsch
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