DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 21-368/S-013

Lilly ICOS, Inc.
Attention: Lori de los Reyes, RN, MSN
Associate Regulatory Consultant
U.S. Regulatory Affairs
Lilly Corporate Center
Indianapolis, IN 46285

Dear Ms. de los Reyes:

Please refer to your supplemental new drug application (NDA) dated May 5, 2008, received May 6, 2008, submitted under section 505(b) of the Federal Food, Drug and Cosmetic Act for CIALIS® (tadalafil).

We also acknowledge receipt of your amendment sent via email on August 6, 2008.

This Prior Approval supplement provides for the addition of the term "transient global amnesia" to the **ADVERSE REACTIONS** section, **Postmarketing Experience** subsection, ***Nervous*** subsection of the CIALIS labeling. This is in response to the Supplement Request letter from the Division dated March 26, 2008.

We have completed our review of this application and it is approved, effective on the date of this letter, for use as recommended in the enclosed labeling text.

As soon as possible, but no later than 14 days from the date of this letter, please submit the content of labeling [21 CFR 314.50(l)] 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 for the package insert, text for the patient package insert). Upon receipt, we will transmit that version to the National Library of Medicine for public dissemination. For administrative purposes, please designate this submission, "SPL for approved NDA 21-368/S-013."

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 the Division of Reproductive and Urologic Products and two copies of both the promotional materials and the package insert(s) directly to:

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

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 Eufrecina DeGuia, Regulatory Project Manager, at (301) 796-0881.

Sincerely,

{See appended electronic signature page}

Scott Monroe, M.D.
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 this page is the manifestation of the electronic signature.

/s/

Scott Monroe

8/7/2008 10:10:32 PM