



NDA 21-368/S-012

Lilly ICOS, Inc.
Attention: David Riggs, Pharm.D.
Associate Manager
U.S. Regulatory Affairs
Lilly Research Laboratories
c/o Lilly Corporate Center
Indianapolis, IN 46285

Dear Dr. Riggs:

Please refer to your supplemental New Drug Application (NDA) dated September 27, 2007, received September 28, 2007, under section 505(b) of the Federal Food, Drug, and Cosmetic Act for CIALIS® (tadalafil) tablets.

We also acknowledge receipt of your email correspondence dated October 3 and 8, 2007, conveying your agreement to the Division's recommended changes to the CIALIS Package Insert (PI) and Patient Package Insert (PPI).

This Prior Approval supplement provides for revisions to CIALIS labeling in response to the Division's request that the potential risk of sudden hearing loss be addressed in the product labeling for PDE5 inhibitors. Specifically, this supplement provides for labeling changes under the following sections of the CIALIS labeling:

- **PRECAUTIONS, Information for Patients**
- **ADVERSE REACTIONS, *Otologic***
- **Postmarketing surveillance, *Otologic***
- **Possible Side Effects** section of the PPI

Additionally, as requested, you also included in this submission, a proposal for a risk communication plan regarding these changes. We find the proposal reasonable and appropriate.

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-012."

In addition, submit three copies of the introductory promotional materials that you propose to use for this/these product(s). 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 Health 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
10/18/2007 11:50:48 AM