DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

NDA 021368/S-017 **SUPPLEMENT APPROVAL**

Eli Lilly and Company
Attention: Nina Barchha, Pharm.D.
Associate Manager, US Regulatory Affairs
Lilly Corporate Center
Indianapolis, IN 46285

Dear Dr. Barchha:

Please refer to your supplemental New Drug Application (NDA) dated and received August 4, 2009, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for CIALIS® (tadalafil) Tablets.

We also refer to your submission dated January 27, 2010, containing a revised version of the Physician Insert incorporating the changes requested via email on January 13, 2010.

This "Changes Being Effected" supplemental new drug application provides for updates under **Recent Major Changes** in the **HIGHLIGHTS OF PRESCRIBING INFORMATION** and revisions to **CONTRAINDICATIONS** (4.2) and **WARNINGS AND PRECAUTIONS** (5.11) sections of the Physician Insert, and to the Patient Package Insert, to achieve consistency with the ADCIRCA labeling and to replace a previous contraindication. The updated labeling provides for a revised warning against use of CIALIS with other phosphodiesterase (PDE5) inhibitors including ADCIRCA. ADCIRCA also contains tadalafil and is indicated for the treatment of pulmonary arterial hypertension. In addition, the updated labeling replaces a previous contraindication in patients with known serious hypersensitivity to tadalafil. Hypersensitivity reactions, including Stevens-Johnson syndrome and exfoliative dermatitis, have been reported.

CONTENT OF LABELING

We have completed our review of this application, as amended. It is approved, effective on the date of this letter, for use as recommended in the enclosed, agreed-upon 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)(1)(i)] 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). For administrative purposes, please designate this submission "SPL for approved NDA 021368/S-017."

PROMOTIONAL MATERIALS

You may request advisory comments on proposed introductory advertising and promotional labeling. To do so, submit, in triplicate, a cover letter requesting advisory comments, the proposed materials in draft or mock-up form with annotated references, and the package insert 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

As required under 21 CFR 314.81(b)(3)(i), you must submit final promotional materials, and the package insert(s), at the time of initial dissemination or publication, accompanied by a Form FDA 2253. For instruction on completing the Form FDA 2253, see page 2 of the Form. For more information about submission of promotional materials to the Division of Drug Marketing, Advertising, and Communications (DDMAC), see http://www.fda.gov/AboutFDA/CentersOffices/CDER/ucm090142.htm.

LETTERS TO HEALTH CARE PROFESSIONALS

If you issue a letter communicating important safety related information about this drug product (i.e., a "Dear Health Care Professional" letter), we request that you submit an electronic copy of the letter to both this NDA and to the following address:

MedWatch
Food and Drug Administration
5600 Fishers Lane, Room 12B05
Rockville, MD 20857

REPORTING REQUIREMENTS

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) 796-0081.

Sincerely,

{See appended electronic signature page}

George Benson, M.D.
Deputy Director
Division of Reproductive and Urologic Products
Office of Drug Evaluation III
Center for Drug Evaluation and Research

Enclosure:
Content of Labeling

Application Type/Number	Submission Type/Number	Submitter Name	Product Name
NDA-21368	SUPPL-17	ELI LILLY AND CO	CIALIS (TADALAFIL) 20MG TABLETS

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

/s/

GEORGE S BENSON
02/01/2010