NDA 022332/S-011

GENERAL ADVICE

Eli Lilly and Company
Attention: Sarnali Mitra Malwade
Manager – Global Regulatory Affairs
Lilly Corporate Center
Indianapolis, IN 46285

Dear Ms. Malwade:

Please refer to your supplemental new drug application (sNDA) submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Adcirca (tadalafil) tablets.

We also refer to our approval letter dated September 15, 2020, which contained an error.

That approval letter inadvertently omitted the approved Patient Package Insert; it is enclosed now with this letter, along with the Prescribing Information enclosed in our September 15, 2020 action letter.

This General Advice letter acknowledges the error described above and incorporates the correction of the error. The effective approval date will remain September 15, 2020, the date of the original approval letter.

If you have any questions, please call Michael Monteleone, Associate Director for Labeling, at (301) 796-1952.

Sincerely,

{See appended electronic signature page}

Mary Ross Southworth, PharmD
Deputy Director for Safety
Division of Cardiology and Nephrology
Office of Cardiology, Hematology, Endocrinology, and Nephrology
Center for Drug Evaluation and Research

ENCLOSURE(S):

- Content of Labeling
  - Prescribing Information
  - Patient Package Insert

This is a representation of an electronic record that was signed electronically. Following this are manifestations of any and all electronic signatures for this electronic record.

/s/

MARY R SOUTHWORTH
09/18/2020 01:46:57 PM

NDA 022332/S-011

SUPPLEMENT APPROVAL

Eli Lilly and Company
Attention: Sarnali Mitra Malwade
Manager – Global Regulatory Affairs
Lilly Corporate Center
Indianapolis, IN 46285

Dear Ms. Malwade:

Please refer to your supplemental new drug application (sNDA) dated December 18, 2018, received December 18, 2018, and your amendments, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Adcirca (tadalafil) 20 mg tablets.

This Prior Approval supplemental new drug application provides for revisions to labeling pursuant to the Pregnancy Lactation and Labeling Rule, (PLLR). In addition, organizational and editorial revisions have been made throughout labeling.

APPROVAL & 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.

CONTENT OF LABELING

As soon as possible, but no later than 14 days from the date of this letter, submit the content of labeling [21 CFR 314.50(l)] in structured product labeling (SPL) format using the FDA automated drug registration and listing system (eLIST), as described at FDA.gov.[1] Content of labeling must be identical to the enclosed labeling (text for the Prescribing Information), with the addition of any labeling changes in pending "Changes Being Effected" (CBE) supplements, as well as annual reportable changes not included in the enclosed labeling.

Information on submitting SPL files using eList may be found in the guidance for industry *SPL Standard for Content of Labeling Technical Qs and As*.[2]

[1] http://www.fda.gov/ForIndustry/DataStandards/StructuredProductLabeling/default.htm
[2] We update guidances periodically. For the most recent version of a guidance, check the FDA Guidance Documents Database https://www.fda.gov/RegulatoryInformation/Guidances/default.htm.

The SPL will be accessible from publicly available labeling repositories.

Also within 14 days, amend all pending supplemental applications that include labeling changes for this NDA, including CBE supplements for which FDA has not yet issued an action letter, with the content of labeling [21 CFR 314.50(l)(1)(i)] in Microsoft Word format, that includes the changes approved in this supplemental application, as well as annual reportable changes. To facilitate review of your submission(s), provide a highlighted or marked-up copy that shows all changes, as well as a clean Microsoft Word version. The marked-up copy should provide appropriate annotations, including supplement number(s) and annual report date(s).

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, please call Michael Monteleone, Associate Director for Labeling, at (301) 796-1952.

Sincerely,

{See appended electronic signature page}

Mary Ross Southworth, PharmD
Deputy Director for Safety
Division of Cardiology and Nephrology
Office of Cardiology, Hematology, Endocrinology, and Nephrology
Center for Drug Evaluation and Research

ENCLOSURE(S):
- Content of Labeling
  - Prescribing Information

This is a representation of an electronic record that was signed electronically. Following this are manifestations of any and all electronic signatures for this electronic record.

/s/

MARY R SOUTHWORTH
09/15/2020 03:48:24 PM