Republic of the Philippines
Department of Health
FOOD AND DRUG ADMINISTRATION

08 November 2013

FDA ADVISORY
No. 2013-050

SUBJECT: RECALL OF TADALAFIL (CIALIS) 20 mg TABLET FROM THE PHILIPPINE MARKET

Based on the results of the recent investigation conducted by the Food and Drug Administration, it was found that Tadalafil (Cialis) 20 mg Tablet has been marketed by Eli Lilly Phils. Inc. without a renewed valid Certificate of Product Registration (CPR), hence unregistered. The safety, efficacy, and quality of the product need to be established again for it to be granted an authorization in the form of a CPR.

Eli Lilly Phils, Inc., the licensed importer, has committed to conduct a recall of Tadalafil (Cialis) 20 mg Tablet in compliance to Bureau Circular No. 8 s. 2001., otherwise known as "Guidelines to be Observed on the Implementation of Product Recall System."

Tadalafil (Cialis) is a drug product used for the treatment of erectile dysfunction.

The physicians are hereby warned against prescribing this product. Also, the public is advised to refrain from buying and using this product.

All FDA inspectors are hereby directed to ensure that no Tadalafil (Cialis) product can be found in Eli Lilly's distributor's warehouses and in retail drugstores.

For more information and inquiries, please email us at info@fda.gov.ph. To report unregistered health products and adverse reactions after using any health product, kindly email us via report@fda.gov.ph.

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