

Republic of the Philippines Department of Health FOOD AND DRUG ADMINISTRATION



20 November 2013

FDA Advisory No. 2013 - 055

SUBJECT: RECALL OF UNREGISTERED PRODUCTS MARKETED BY ELI LILLY (PHILIPPINES) INC.

Based on the results of the recent investigations conducted by the Food and Drug Administration, it was found that there are products marketed by Eli Lilly (Philippines) Inc. without valid Certificates of Product Registration (CPR), hence unregistered.

In compliance to Bureau Circular No. 8 s. 2001, otherwise known as "Guidelines to be Observed on the Implementation of Product Recall System," Eli Lilly (Philippines) Inc., the licensed importer, has been mandated by the Food and Drug Administration (FDA) to conduct recall of the following products:

Brand Name	Generic Name	Dosage Strength and Dosage Form
Prozac	Fluoxetine	20 mg Capsule
Strattera	Atomoxetine	10 mg Capsule
Strattera	Atomoxetine	18 mg Capsule
Strattera	Atomoxetine	25 mg Capsule
Strattera	Atomoxetine	40 mg Capsule
Strattera	Atomoxetine	60 mg Capsule
Zyprexa Zydis	Olanzapine	10 mg Orodispersible Tablet
Zyprexa IM	Olanzapine	10 mg Powder for Injection (IM)

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

All FDA inspectors are hereby directed to ensure that the abovementioned products will not be found in Eli Lilly's distributor's warehouses and in retail drugstores after Eli Lilly has concluded the recall process.

For more information and inquiries, please email us at <u>info@fda.gov.ph</u>. To report any concern regarding health products, including adverse reactions, kindly email us at report@fda.gov.ph.

KENNETH Y. HARTIGAN-GO, MD Acting Director General

