Republic of the Philippines
Department of Health
FOOD AND DRUG ADMINISTRATION

PRESS RELEASE

06 May 2014

FDA Advisory
No. 2014-034

SUBJECT: Recall of Unregistered and/or Falsified Product Registration of Pharmaceutical Products Imported and Distributed by ELI LILLY PHILIPPINES

The Food and Drug Administration has recently imposed a total of Sixteen Million Pesos (Php16,000,000.00) administrative fine against the pharmaceutical company Eli Lilly Philippines for importing and distributing unregistered products.

In the investigation conducted by the FDA which led to the filing of the case against Eli Lilly, it was found that at least 15 products distributed by Eli Lilly were unregistered and/or have falsified product registrations, specifically:

1. Cialis 20 mg Tablet
2. Cymbalta 30mg Capsule
3. Humalog 100 units per mL Solution for Injection
4. Humalog Kwikpen 100u/mL Solution for Injection
5. Humalog Mix 25 Kwikpen 100iu per mL Solution for Injection
6. Humalog Mix 25
7. Humalog Mix 50 Kwikpen
8. Stratterra 10mg Capsule
9. Stratterra 18mg Capsule
10. Stratterra 25mg Capsule
11. Straterra 40 mg Capsule
12. Strattera 60mg Capsule
13. Prozac 20mg Capsule
14. Zyprexa Zydis 10mg Orodispersible tablet
15. Zyprexa Intramascular 20mg Powder for Injection

These unregistered products are ordered recalled from the commerce and shall not be distributed. The safety, efficacy and quality of the mentioned products need to be established anew before they are authorized to be marketed. The continuous activities of importation, distribution and selling of the enumerated unregistered products and/or with falsified product registration are prohibited and punishable under the Food and Drug Administration Act of 2009.

Eli Lilly has been directed to initiate steps in informing the patients and prescribers to look for alternative products. Physicians are hereby warned against prescribing these products while the public is advised to be vigilant and refrain from buying and using them.

As part of its recall strategy, all the above listed products still in the market should be returned to Zuellig Pharma Corporation at Km. 14 West Service Road South Superhighway cor. Edison Ave., Sun Valley, Paranaque City.

Meanwhile, only the following Eli Lilly products available in the market have certificate of product registration:

Product Name	FDA Registration No.
1. Alimta 100mg Lyophilized Powder for Intravenous Infusion	DR-XY35204
2. Alimta 500mg Lyophilized Powder for I.V. Infusion	DR-XY31536
3. Gemzar 1g Powder for Injection	DR-XY42100
4. Cymbalta 60mg Capsule	DR-XY41867
5. Zyprexa Zydis 5mg Tablet	DR-XY37273
6. Forteo 250mcg/mL Solution for Injection	DR-XY29234
7. Byetta 250mcg/mL Solution for Injection (1.2mL) SC	DR-XY33256
8. Byetta 250mcg/mL Solution for Injection (2.4mL) SC	DR-XY33264
9. Effient 5mg Film-Coated Tablet	DR-XY37670
10. Effient 10mg Film-Coated Tablet	DR-XY37671

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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