



20 February 2015

FDA Advisory
No. **2015-010**

**SUBJECT: PUBLIC HEALTH WARNING AGAINST THE USE OF THE
FOLLOWING UNREGISTERED DRUG PRODUCTS**

The Food and Drug Administration advises the public against the use of the following unregistered products:



Bisacodyl (Delax) 5 mg Tablet



Conjugated Estrogens USP (Conjugase-0.625) 0.625 mg Tablet



Bicalutamide 50 mg Tablet



Isosorbide dinitrate (Hartsorb Sublingual) 5 mg Tablet

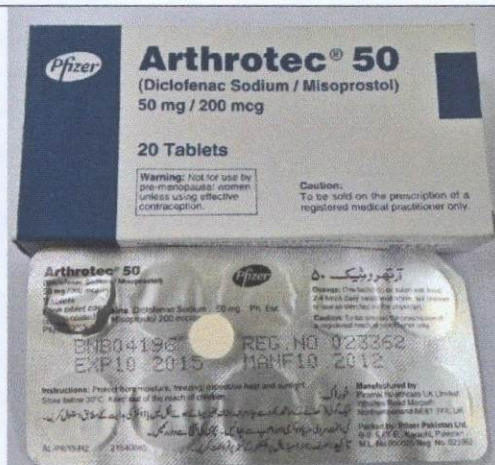




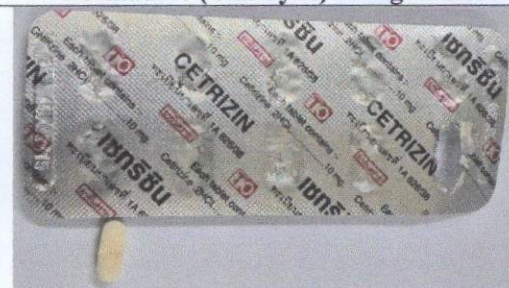
Flunarazine (Sobelin) 5 mg Capsule



Loratadine (Clatidyne) 10 mg Tablet



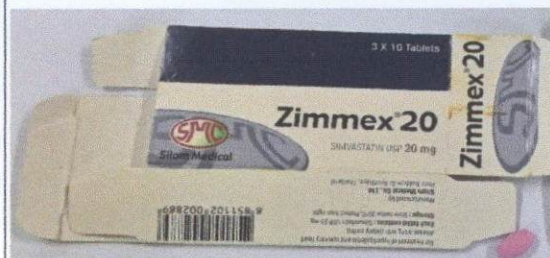
Diclofenac Sodium + Misoprostol (Arthrotec 50) 50 mg/ 200 mcg Tablet



Cetirizine, 2HCl (Cetrizin) 10 mg Tablet



Clindamycin (Clindacap-300) 300 mg Tablet



Simvastatin (Zimmex 20) 20 mg Tablet



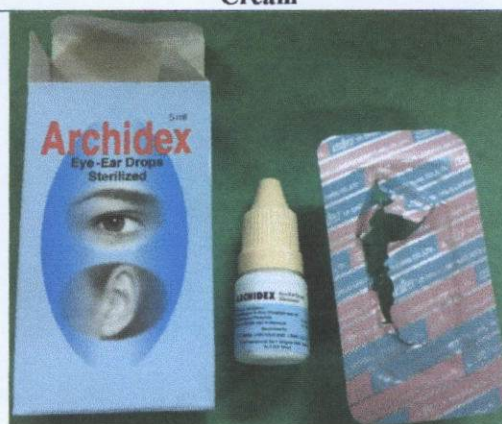
Rosiglitazone maleate (Avandia) 4 mg Tablet



Gentamicin sulfate (Gentaderm) 0.1 g/100 g Cream



Nystatin (Tystatin) Oral Suspension



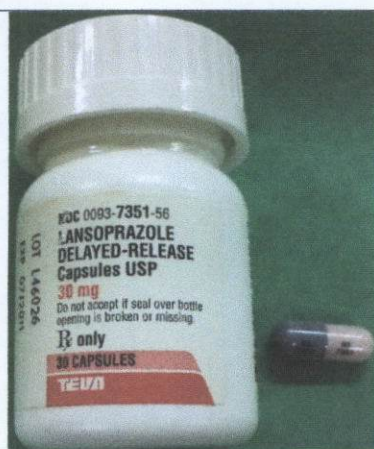
Dexamethasone Sodium Phosphate + Neomycin Sulfate (Archidex) Eye-Ear Drops



Omeprazole (Omeprazole GPO) 20 mg Capsule



Roxithromycin (Roxthrin) 150 mg Tablet



Lansoprazole 30 mg Delayed-Release Capsule



Ketoconazole (Ninazol) 200 mg Tablet


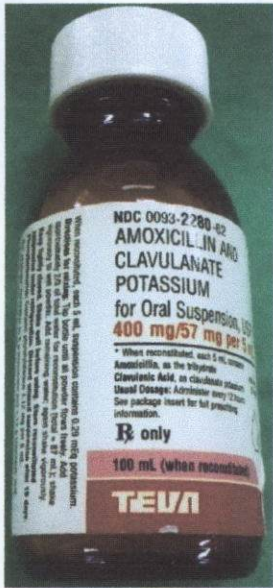


 <p>Paracetamol (SaRa) 500 mg Tablet</p>	 <p>Amoxicillin + Clavulanate Potassium 400 mg/ 57 mg per 5 mL Oral Suspension</p>
 <p>Cefuroxime Axetil (Cefuroxime) 250 mg/ 5 mL Oral Suspension</p>	 <p>Cefdinir 250 mg/ 5 mL Oral Suspension</p>

Table 1.Unregistered Drug Products

The field Food and Drug Regulation Officers are ordered to confiscate the aforementioned unregistered drug products found in the market.

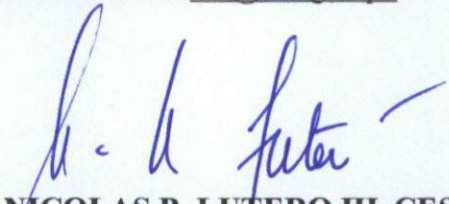
All local government units and law enforcement agencies are requested to ensure that these products are not sold or offered for sale in their localities or area of jurisdiction.

All drug establishments and outlets are hereby warned that importation, distribution, or sale of any unregistered drug product is subject to sanctions and penalties stipulated in Republic Act No. 3720, as amended by Republic Act No. 9711, otherwise known as the "Food and Drug Administration Act of 2009" and Republic Act No. 8203, otherwise known as "Special Law on Counterfeit Drugs".

All consumers are advised to purchase their medications only from FDA-licensed establishments. Please note that product evaluation and registration is a

measure that the government undertakes to ensure the safety and efficacy of health products. Please look for the FDA Registration number on the product label.

For more information and inquiries, please email us at info@fda.gov.ph. To report continuous sale or distribution of unregistered health products kindly email us via report@fda.gov.ph or you may call the telephone number (02)807-8275. For any suspected adverse drug reaction (ADR), please email us via adr@fda.gov.ph.



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