



**FDA ADVISORY**  
No. **2019-149**

13 0 MAY 2019

**TO : ALL HEALTHCARE PROFESSIONALS AND THE GENERAL PUBLIC**

**SUBJECT : Public Health Warning Against the Purchase and Use of the Following Unregistered Drug Products:**

1. Pirenoxine sodium Eye Drops Paineizhang (Baineitine) 15mL
2. Silver Water Eye Drops 10mL
3. Tropicamide with Phenylephrine Hydrochloride Ophthalmic Solution (TM PLUS EYE DROPS)
4. NATAMYCIN OPHTHALMIC SUSPENSION IP (NATAK) EYE DROPS 5ml
5. Natural Healing Eye Drops

The Food and Drug Administration (FDA) advises the public against the purchase and use of the following unregistered drug products:



**Figure 1.** Unregistered drug product





**Figure 2.** Unregistered drug product



**Figure 3.** Unregistered drug product



**NATAMYCIN OPHTHALMIC SUSPENSION IP (NATAK) EYE DROPS 5ml**  
Marketed by: PHARMTAK Ophthalmics I) Pvt. Ltd. 50-52, The Discovery, Borivali  
(E) Mumbai - 400 066

**Figure 4.** Unregistered drug product



**Natural Healing Eye Drops**  
Manufactured by: Heal the World Foundation

**Figure 5.** Unregistered drug product

FDA Post-Marketing Surveillance (PMS) activities have verified that the abovementioned drug products have not gone through the registration process of the agency and have not been issued with proper authorization in the form of Certificate of Product Registration.

Pursuant to Republic Act No. 9711, otherwise known as the "Food and Drug Administration Act of 2009", the manufacture, importation, exportation, sale, offering for sale, distribution, transfer, promotion, advertising or sponsorship of health products without proper authorization from FDA is prohibited.

Accordingly, since these unregistered drug products have not gone through evaluation and testing process of the FDA, the agency cannot guarantee their efficacy, quality and safety. These violative products may pose potential danger or injury if administered.

In light of the above, the public is advised not to purchase the aforementioned violative products and to be vigilant against drug products that might not be duly registered with the FDA. To check if a drug product has been registered with the FDA, use the embedded *Search* feature of the FDA website accessible at [www.fda.gov.ph](http://www.fda.gov.ph). You may also look for the FDA Registration number on the product label.

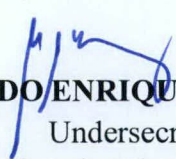
All concerned establishments and/or entities are warned not to distribute the above-identified violative drug products until these have already been covered by the appropriate authorization, otherwise regulatory actions and sanctions shall be strictly pursued.

The Bureau of Customs is urged to restrain the importation or entry of these unregistered products.

All Local Government Units (LGUs) and Law Enforcement Agencies (LEAs) are requested to ensure that these products are not sold or made available in their localities or areas of jurisdiction.

For more information and inquiries, please e-mail us at [info@fda.gov.ph](mailto:info@fda.gov.ph). To report continuous sale or distribution of unregistered health products, kindly e-mail us via [report@fda.gov.ph](mailto:report@fda.gov.ph), or through the online reporting facility, **eReport**, at [www.fda.gov.ph/ereport](http://www.fda.gov.ph/ereport). You may also call the Center for Drug Regulation and Research at telephone number (02)809-5596. For any suspected adverse drug reaction (ADR), report immediately to FDA through this link: [www.fda.gov.ph/adr-report-new](http://www.fda.gov.ph/adr-report-new) and fill out all the required fields.

Dissemination of the information to all concerned is requested.

  
**ROLANDO ENRIQUE D. DOMINGO, MD, DPBO**  
Undersecretary of Health  
Officer-in-Charge, Director General



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