

## Republic of the Philippines Department of Health FOOD AND DRUG ADMINISTRATION



FDA ADVISORY No. 2020-1270

JUN 2 5 2020

TO : ALL HEALTHCARE PROFESSIONALS AND THE GENERAL

**PUBLIC** 

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

- 1. OTC Miconazole Nitrate Cream [as reflected in the package insert]
- 2. OTC Xiguashuang Runhou Pian [as reflected in the package insert]
- 3. OTC Yunnan Baiyao Qiwuji
- 4. Huanglian Shangqing Pian
- 5. Jin qian cao ke li 10g
- 6. OTC Fufang Anfennamin Keli
- 7. OTC Longzexiongdanjiaonang
- 8. Ganciclovir for Injection 0.25g
- 9. OTC Fuyang Keli [as reflected in the package insert]
- 10. OTC Vitamin E Soft Capsules
- 11. Potassium Chloride Injection 10ml:1g
- 12. Fu Fang Gan Cao Suan An Zhu She Ye 2ml
- 13. SPH Xinhuang Pian
- 14. Fenhuangy I'an Zhusheye 2mL: 0.5g
- 15. Chloramphenicol Eye Drops 8mL
- 16. Front OTC Sulfur Ointment
- 17. OTC Naolibao Wan
- 18. OTC 21 Super-Vita Tablet 60's
- 19. Hu Gan Pian
- 20. Osteoform Compound Bone Nutrition Formula 30g
- 21. OTC Dezhong [as reflected in the primary and secondary packaging]
  OTC Biyankang Pian [as reflected in the package insert]
- 22. Flunarizine Hydrochloride Capsules 20's [as reflected in the package insert]
- 23. Xinqin Keli yosemade
- 24. Lincomycin Hydrochloride Injection 2ml:0.6g
- 25. OTC Xuanmai Ganjie Keli [as reflected in the package insert]



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



Figure 4. Unregistered drug product



Figure 5. Unregistered drug product



Figure 6. Unregistered drug product



Figure 7. Unregistered drug product



Figure 8. Unregistered drug product



Figure 9. Unregistered drug product



Figure 10. Unregistered drug product



Figure 11. Unregistered drug product



Figure 12. Unregistered drug product



Figure 13. Unregistered drug product



Figure 14. Unregistered drug product



Figure 15. Unregistered drug product



Figure 16. Unregistered drug product



Figure 17. Unregistered drug product



Figure 18. Unregistered drug product



Figure 19. Unregistered drug product



Figure 20. Unregistered drug product



Figure 21. Unregistered drug product



Figure 22. Unregistered drug product



Figure 23. Unregistered drug product



Figure 24. Unregistered drug product



Figure 25. 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. Thus, the Agency cannot guarantee its quality, safety and efficacy. Therefore, consumption of such violative products may pose potential danger or injury to health.

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.

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

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 <a href="mailto:info@fda.gov.ph">info@fda.gov.ph</a>. To report continuous sale or distribution of unregistered health products, kindly e-mail us via <a href="mailto:ereport@fda.gov.ph">ereport@fda.gov.ph</a>. You may also call the Center for Drug Regulation and Research at telephone number (02) 8809-5596. For any suspected adverse drug reaction (ADR), report immediately to FDA through this link:

<a href="mailto:https://primaryreporting.who-unc.org/Reporting/Reporter?OrganizationID=PH">https://primaryreporting.who-unc.org/Reporting/Reporter?OrganizationID=PH</a> and fill out all the required fields.

Dissemination of the information to all concerned is requested.

ROLANDO ENRIQUE D. DOMINGO, MD
Director General

DTN: 20200528083417