FDA ADVISORY
No. ~~2024-0534~~

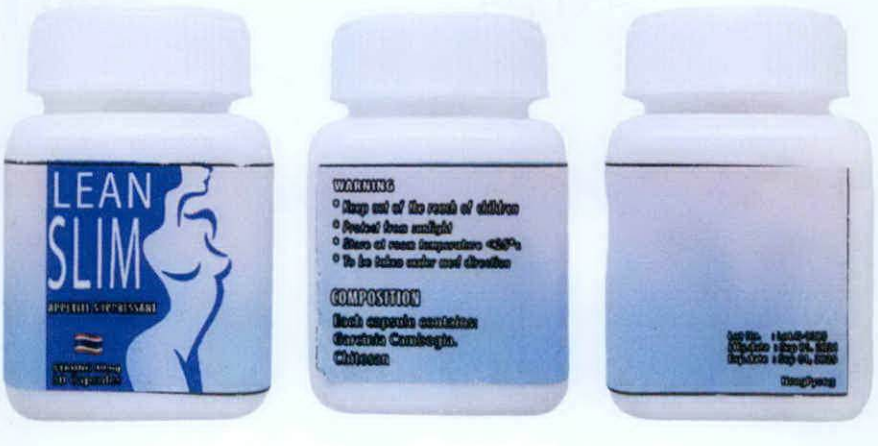
15 MAR 2024

TO : ALL HEALTHCARE PROFESSIONALS AND THE GENERAL PUBLIC

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

1. **Lean Slim Appetite Suppressant Strong Capsule 30's**
2. **Lean Slim Appetite Suppressant Mild Capsule 30's**
3. **Dianne ® - 35 Cyproterone acetate 2.00 mg/ Ethinylestradiol 0.035 mg Sugar-Coated Tablet [Label in foreign language]**
4. **Androcur® Siproteron asetat [Label in foreign language] 50 mg Tablet**
5. **Androcur ™ (Cyproterone acetate) [Label in foreign language] 50 mg Tablet**

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



Lean Slim Appetite Suppressant Strong Capsule 30's

Figure 1. Unregistered drug product

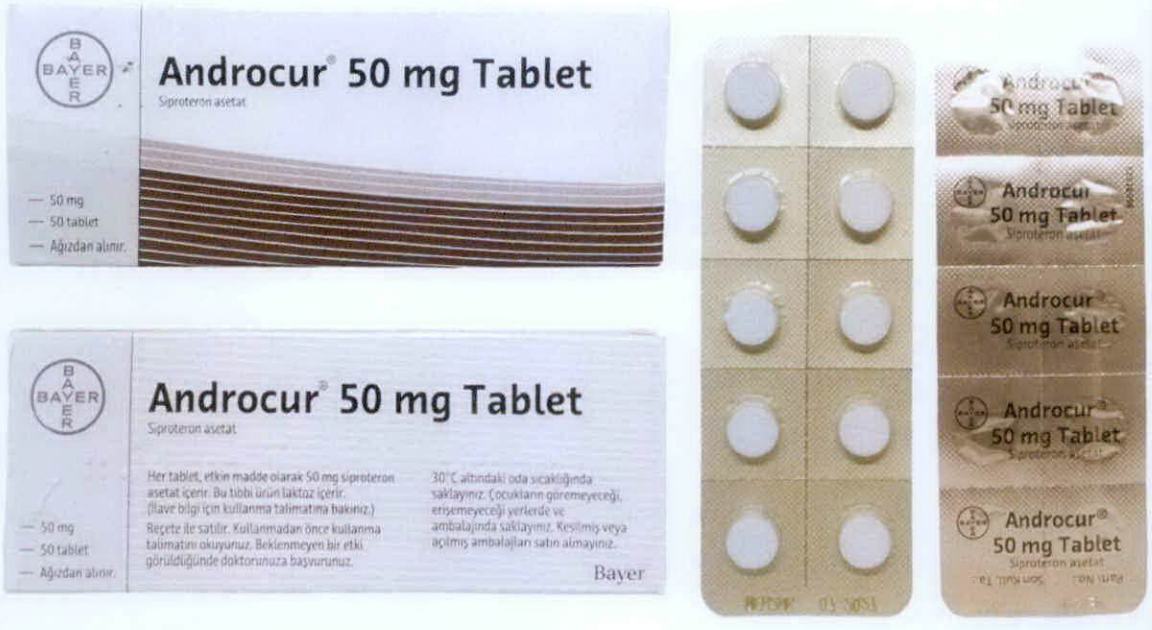
Lean Slim Appetite Suppressant Mild Capsule 30's

Figure 2. Unregistered drug product

Diane ® - 35 Cyproterone acetate 2.00 mg/ Ethinylestradiol 0.035 mg Sugar-Coated Tablet [Label in foreign language]

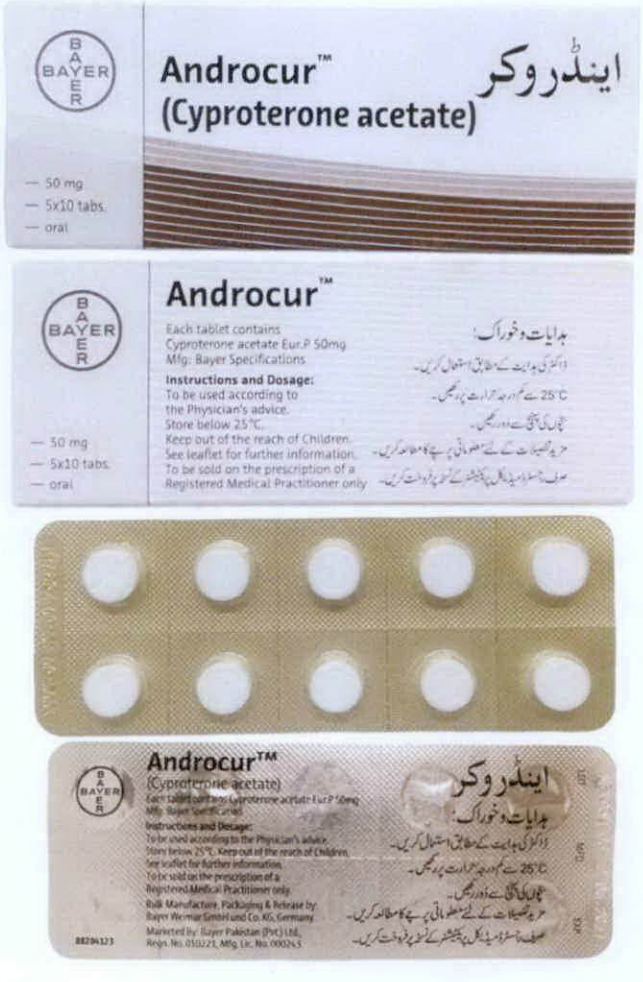
Note: The registered Cyproterone acetate + Ethinylestradiol 2.0 mg/ 35 mg Sugar-Coated Tablet (Diane-35) has Registration no. DR- XY46840.
Manufactured by Bayer Weimar GmbH und Co. KG; Imported by Bayer Philippines, Inc.

Figure 4. Unregistered drug product



Androcur® Siproteron asetat [Label in foreign language] 50 mg Tablet

Figure 3. Unregistered drug product



Androcur ™ (Cyproterone acetate) [Label in foreign language] 50 mg Tablet

Figure 4. Unregistered drug product

FDA Post-Marketing Surveillance (PMS) activities have verified that the abovementioned drug products has not gone through the registration process of the Agency and has not been issued with proper authorization in the form of Certificate of Product Registration. Thus, the Agency cannot guarantee its quality and safety. Therefore, consumption of such violative product 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 product until it has been covered by the appropriate authorization, otherwise, regulatory actions and sanctions shall be strictly pursued. Always check if a product is registered with the FDA by using the **FDA Verification Portal feature** accessible at **https://verification.fda.gov.ph**.

All Local Government Units (LGUs) and Law Enforcement Agencies (LEAs) are requested to ensure that this product is 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**. To report continuous sale or distribution of unregistered health products, kindly e-mail us via **ereport@fda.gov.ph**. 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: **https://primaryreporting.who-umc.org/Reporting/Reporter?OrganizationID=PH** and fill out all the required fields.

Dissemination of the information to all concerned is requested.

DR. SAMUEL A. ZACATE
Director General

DTN: 20240222144442