

Republic of the Philippines Department of Health FOOD AND DRUG ADMINISTRATION

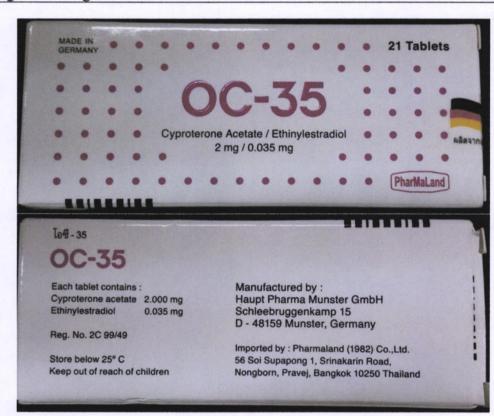


FDA ADVISORY No. 2015 -042

SUBJECT: Public Health Warning Against the Use of the Unregistered

Drug Product "Cyproterone Acetate + Ethinylestradiol
(OC-35) 2 mg/ 0.035 mg Tablet" Sold Online

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



CYPROTERONE ACETATE + ETHINYLESTRADIOL (OC-35) 2 MG/ 0.035 MG TABLET

Manufactured by: Haupt Pharma Munster GmbH – Schleebruggenkamp 15 D-48159 Munster, Germany

Figure 1.Unregistered Drug Product

The abovementioned drug product poses potential danger or injury to the consuming public and the importation, selling or offering for sale of such is in direct violation of Republic Act No. 9711 or the Food and Drug Administration Act of 2009.



In the interest of protecting public health and safety, and pursuant to Section 12 of R.A. No. 9711, the Field Regulatory Operations Office (FROO) Officers are hereby ordered to seize the aforementioned unregistered drug product found in the market.

All establishments and outlets are hereby warned against selling and/or dispensing the above identified product. Anyone found selling the said product will be penalized.

Likewise, all local government units and law enforcement agencies are requested to ensure that this product is not sold or offered for sale in their localities or area of jurisdiction.

All consumers are advised to purchase their medications only from FDA-licensed establishments. Please note that in addition to inspection of establishments, product evaluation, registration and testing are measures that the government undertakes to ensure the quality, safety and efficacy of health products. Please look for the FDA Registration number on the product label. Moreover, please be reminded that drug products registered with FDA Philippines bear in their labels information in English and/or in Filipino for all consumers to understand. Lastly, it is hereby reiterated that at present, there is no FDA-licensed pharmacy that is selling medicines online.

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), report immediately to FDA through this link: www.fda.gov.ph/adr-report-new and fill out all the required fields.

JANETTE P. LORETO-GARIN, MD, MBA-H
Secretary of Health
Acting Director General

Acting Director General

Made

Pursuant to DPO 2015-1845

DTN: 20150617094225