Republic of the Philippines
Department of Health
FOOD AND DRUG ADMINISTRATION

FDA ADVISORY
No. 2020-765

30 APR 2020

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

SUBJECT: **Product Recall of All Batches of Ulipristal (as acetate) 5 mg Tablet (Esmya)**

All healthcare professionals and the general public are hereby advised by the Food and Drug Administration (FDA) regarding the voluntary recall by the marketing authorization holder on the affected batches of the subject product from the market. The details of the product are as follows:

DRUG PRODUCT	**ULIPRISTAL (AS ACETATE) 5 mg TABLET (ESMYA)**	
REGISTRATION NO.	**DR-XY44905**	
BATCH NO./EXP. DATE	**ES145A**	**SEPTEMBER 2021**
	ES146D	**APRIL 2022**
	ES147A	**AUGUST 2022**
MANUFACTURER	**Cenexi – 17 Rue De Pontoise, 95520 Osny, France**	
UNDER LICENSE FROM	**Laboratoire HRA Pharma – 15 Rue Beranger, 75003 Paris, France**	
IMPORTER/ DISTRIBUTOR [Marketing Authorization Holder (MAH)]	**Zuellig Pharma Corporation – Km. 14 West Service Road, South Super Hi-Way corner Edison Ave., Brgy. Sun Valley, Parañaque City**	

The MAH pursued the voluntary recall of the drug product as a precautionary measure while its safety review by the European Medicines Agency (EMA) is still ongoing due to the potential risk of liver injury with symptoms such as tiredness, loss of appetite, abdominal pain, yellowing of the skin, darkening of the urine, nausea, and vomiting.

Ulipristal is a progesterone receptor modulator which is used for the pre-operative treatment or intermittent treatment of moderate to severe symptoms of uterine fibroids in adult women of reproductive age. Ulipristal (as acetate) 5 mg Tablet (Esmya) is packed in an Alu-PVC/PVDC grey opaque duplex blister pack of 14 tablets (box of 28's and 84's).

Therefore, distributors, hospitals, retailers, pharmacies, or clinics that have the affected batches of the drug product are instructed to discontinue further distribution, sale, and use. All patients currently taking the drug product are instructed to consult with their physician or healthcare provider about treatment options. Likewise, all consumers are advised not to purchase the affected product batches and may contact

consumers are advised not to purchase the affected product batches and may contact Zuellig Pharma Corporation at telephone number (632) 8405-5121 for any question or additional information regarding the recall.

All Local Government Units (LGU) and Law Enforcement Agencies (LEAs) are requested to ensure that the affected product batches are not sold or made available in their localities or areas of jurisdiction.

For more information and inquiries, please e-mail us at **cdrr_postmarketsurveillance@fda.gov.ph**. To report continuous sale or distribution of the abovementioned, 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**. Any suspected adverse reaction experienced from the use of the products should be reported immediately to the FDA through this link: **https://primaryreporting.who-umc.org/Reporting/Reporter?OrganizationID=PH** and fill-out all of the required fields.

Dissemination of the information to all concerned is requested.

ROLANDO ENRIQUE D. DOMINGO, MD
Director General

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