Republic of the Philippines
Department of Health
FOOD AND DRUG ADMINISTRATION

16 AUG 2018

FDA ADVISORY
No. 2018-248

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

SUBJECT: **Public Health Warning Against the Purchase and Use of the Verified Counterfeit Drug product Jardiance 25mg Tablet**

The Food and Drug Administration (FDA) advises the public against the purchase and use of the verified counterfeit drug product Jardiance 25mg Tablet:

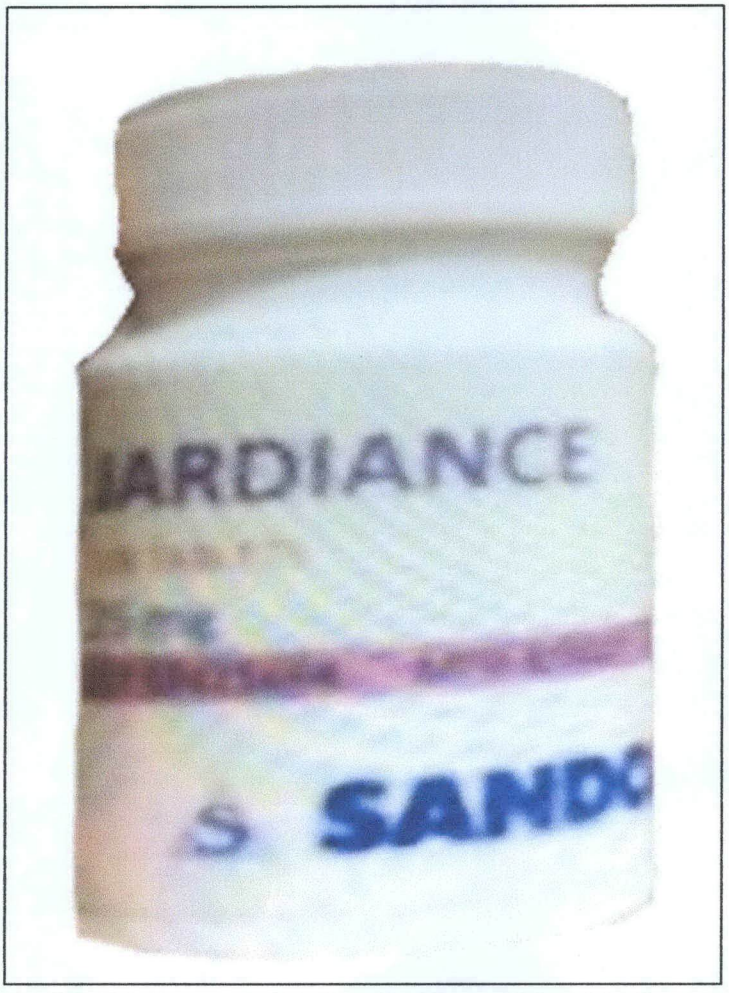
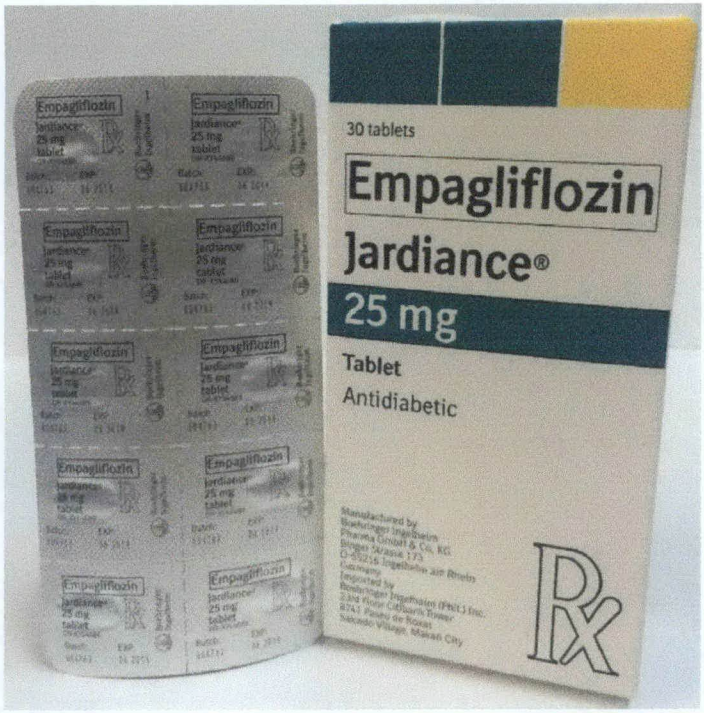
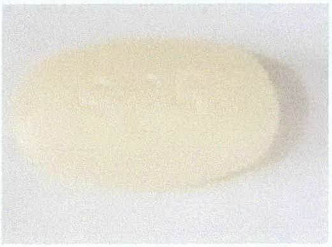


Figure 1: Verified counterfeit/fake Jardiance 25mg Tablet in a bottle

The FDA together with the Marketing Authorization Holder (MAH), Boehringer Ingelheim (Philippines), Inc. in coordination with Sandoz Philippines Corporation, have verified that the abovementioned sample drug product is counterfeit. The comparisons of the collected product and the registered and authentic one are as follows:

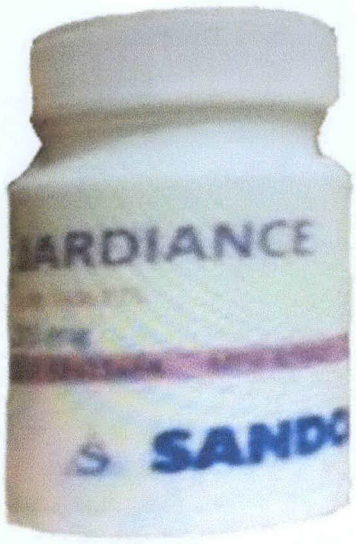
AUTHENTIC





Marketing Authorization Holder	: Boehringer Ingelheim (Philippines), Inc.
Packaging Material/Presentation	: Alu/PVC Blister Pack x 10s (Box of 30s)
Dosage Strength/Form	: 25mg Film-coated Tablet
Labeling	: With Generic Name - Empagliflozin

COUNTERFEIT



Company	: Sandoz
Packaging Material/Presentation	: Bottle
Dosage Strength/Form	: 25mg Film-coated Tablet
Labeling	: Absence of generic name and other mandatory requirements

All healthcare professionals and the general public are hereby warned as to the availability of this counterfeit drug product in the market which pose potential danger or injury to consumers. Consumers are also reminded to purchase drug products only from FDA-licensed establishments.

Likewise, all establishments and outlets are hereby warned against selling and/or dispensing this verified counterfeit drug product with the foregoing features. 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, and Republic Act No. 8203, or the Special Law on Counterfeit Drugs, therefore a penalty shall be imposed.

All Local Government Units (LGUs) and Law Enforcement Agencies (LEAs) are requested to ensure that this counterfeit 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 **report@fda.gov.ph**, or through the online reporting facility, **eReport**, at **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** and fill out all the required fields.

Dissemination of the information to all concerned is requested.

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Director General

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