



FDA ADVISORY
No. **2021-2210**

26 AUG 2021

TO: ALL HEALTHCARE PROFESSIONALS AND THE GENERAL PUBLIC

SUBJECT: Public Health Warning Against the Purchase and Use of the Verified Counterfeit Sildenafil Citrate (Viagra®) 100 mg Film-Coated Tablet

The Food and Drug Administration (FDA) advises the public against the purchase and use of the verified counterfeit Sildenafil Citrate (Viagra®) 100 mg Film-Coated Tablet:

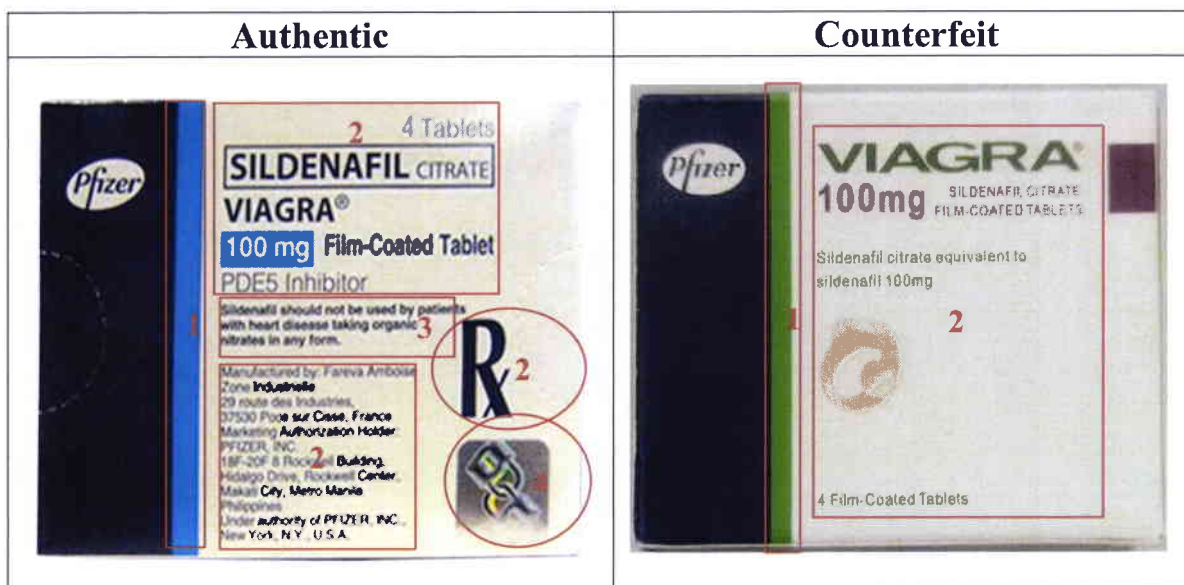


Figure 1. Comparison between the Authentic and Verified Counterfeit Sildenafil Citrate (Viagra®) 100 mg Film-Coated Tablet (Lot # R102338413; Expiry date: 01 2025)

The FDA together with the Marketing Authorization Holder (MAH), PF OFG Philippines, Inc. (A Viartis Company), have verified that the above-mentioned sample drug product is counterfeit. The comparison of the collected counterfeit drug product and the distinguishing feature of the authentic are as follows:

PARAMETER	AUTHENTIC	COUNTERFEIT
Carton	<p>Front Panel:</p> <ol style="list-style-type: none"> Carton with Pfizer logo and blue bands on the left portion. Printed with SILDENAFIL CITRATE inside a generic box, 4 tablets on top, VIAGRA brand name, 100 mg Film-Coated Tablet, PDE5 Inhibitor, manufacturer, MA 	<p>Front Panel:</p> <ol style="list-style-type: none"> Carton with Pfizer logo, blue and green bands on the left portion. Printed with VIAGRA 100mg Sildenafil Citrate Film-Coated Tablets, Sildenafil citrate equivalent to sildenafil



	holder, and Rx symbol. 3. With text: Sildenafil should not be used by patients with heart disease taking organic nitrates in any form. 4. A hologram sticker at the bottom right depicting two interlocks.	100mg, orange circular logo, and 4-Film Coated Tablets text at the bottom left.
Manufacturer	Fareva Amboise, Zone Industrielle, 29 route des Industries, 37530 Poce sur Cisse, France	None observed

All healthcare professionals and the general public are hereby warned as to the availability of this counterfeit drug product in the market which poses potential danger or injury to consumers. Consumers are also reminded to purchase drug product only from FDA-licensed establishments. Always check if a product is registered with the FDA by using the FDA Verification Portal feature accessible at <http://verification.fda.gov.ph>.

Likewise, all establishments and outlets are hereby warned against selling and/or dispensing of this drug product with the abovementioned features of a counterfeit drug product. 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. Anyone found selling the said counterfeit drug product will be penalized.

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 counterfeit 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) 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.


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