



Republic of the Philippines
Department of Health
FOOD AND DRUG ADMINISTRATION



06 APR 2021

FDA ADVISORY
No. **2021-0714**

TO : ALL HEALTHCARE PROFESSIONALS AND THE GENERAL PUBLIC

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

1. OTC Taiji® Huoxiang Zheng Qi Kou Fu Ye
2. TAIJI® Fufang Huangliansu Pian
3. OTC XINXIU® Compound Paracetamol and Amantadine Hydrochloride Tablets – Fufang Anfenwan'an Pian

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



OTC Taiji® Huoxiang Zheng Qi Kou Fu Ye

Figure 1. Unregistered drug product



太极®
复方黄连素片

批准文号：国药准字Z50020118

清热燥湿，行气止痛，止痢止泻。
用于大肠湿热，赤白下痢，里急后重或暴注下泻，肛门灼热；肠炎、痢疾见上述证候者。

太极集团重庆桐君阁药厂有限公司

TAIJI® Fufang Huangliansu Pian

Figure 2. Unregistered drug product

请仔细阅读说明书并按说明使用或在药师指导下购买和使用

新秀 XINXIU

复方氨酚烷胺片 **OTC**

适用于缓解普通感冒及流行性感冒引起的发热、头痛、四肢酸痛、打喷嚏、流鼻涕、鼻塞、咽痛等症状。

修正药业集团股份有限公司

OTC XINXIU® Compound Paracetamol and Amantadine Hydrochloride Tablets
Fufang Anfenwan'an Pian

Figure 3. Unregistered drug product

FDA Post-Marketing Surveillance (PMS) activities have verified that the abovementioned drug products have not gone through the registration process of the Agency and have not been issued with proper authorization in the form of Certificate of Product Registration. Thus, the Agency cannot guarantee its quality, safety and efficacy. Therefore, consumption of such violative products 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 products until they have already been covered by the appropriate authorization, otherwise, regulatory actions and sanctions shall be strictly pursued.

All Local Government Units (LGUs) and Law Enforcement Agencies (LEAs) are requested to ensure that these products are 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.


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