



FDA ADVISORY
No.: **2021-1035**

14 MAY 2021

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 IPSEN Smecta® Montmorillonite Powder - Mengtuoshi San [as reflected in the package insert]
2. OTC Xiaoyao Wan [as reflected in the package insert]
3. Tetracycline Tablets [Label in Foreign Language]
4. Hugan Pian [as reflected in the package insert]
5. OTC Liuwei Dihuang Wan [as reflected in the package insert]

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

**OTC IPSEN Smecta® Montmorillonite Powder
Mengtuoshi San [as reflected in the package insert]
by: Ipsen**

Figure 1. Unregistered drug product





OTC Xiaoyao Wan [as reflected in the package insert]

Figure 2. Unregistered drug product



Tetracycline Tablets [Label in Foreign Language]

Figure 3. Unregistered drug product



Hugan Pian [as reflected in the package insert]
 by: Ji Lin Sheng Mi Zhi Kang Yao Ye You Xian Ze Ren Gong Si

Figure 4. Unregistered drug product



OTC Liuwei Dihuang Wan [as reflected in the package insert]

Figure 5. 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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Director General

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