



FDA ADVISORY
No. **2022-1918**

12 DEC 2022

TO : ALL HEALTHCARE PROFESSIONALS AND THE GENERAL PUBLIC

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

1. **DK Kidney Wash Capsules [Label in Foreign Language]**
2. **LS® Oldenlandia Diffusa Roxb. Capsules [Label in Foreign Language]**
3. **Huang Lian Su Tablets [Label in Foreign Language]**

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

The advertisement for DK Kidney Wash Capsules is presented in a grid format. At the top, there are three panels: a Chinese label, an English label, and a detailed English description. Below these are three images of the product packaging (two bottles and one blister pack) and a close-up of the capsules. The Chinese label on the left features the text '純正草藥製劑 副作用' and 'KIDNEY WASH capsules 洗腎丹', along with '德國新一代腎炎新藥' and '治療及預防急性慢性腎病 腎功能衰竭症'. The English label in the middle lists '(Main Treatment) Acute/Chronic glomerular nephritis, renal nephritis, uremic kidney symptoms, incomplete kidney functions, uremia, declining kidney functions and infection within the urinary track etc.' and '(Instruction for Use) Take four to five capsules orally three times a day.' The detailed English text on the right explains the product's origin from a German herbal professor's formula and lists its benefits for treating acute and chronic nephritis, including improving kidney function, reducing proteinuria, and increasing appetite. The product is manufactured by D.K. Traditional Medicines & Natural Health Products Limited in Hong Kong.

DK Kidney Wash Capsules [Label in Foreign Language]
by: D.K. Traditional Medicines & Natural Health Products Limited - Hongkong

Figure 1. Unregistered drug product





Figure 2. Unregistered drug product



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 their 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. Always check if the products are registered with the FDA by using the **FDA Verification Portal feature** accessible at <https://verification.fda.gov.ph>.

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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