



11 OCT 2022

FDA ADVISORY
No. **2022-1755**

TO : ALL HEALTHCARE PROFESSIONALS AND THE GENERAL PUBLIC

SUBJECT : Public Health Warning Against the Purchase and Use of the Unregistered Drug Product “Exceed Vigra and Cialis Maximum Powerful 2800 mg X 6 Pills”

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

The advertisement for 'Maximum Powerful' pills includes the following elements:

- Top Left:** A box with Chinese text: '最新壮阳极品' (Newest premium product for strengthening yang), '批准文号: 藏卫药准字(2008)第1018号' (Approval No. 藏卫药准字(2008)第1018号), '执行标准: Q/RTD05-2008', and '15分钟起效 功效持续168小时 2800mg X 6粒' (15 minutes effect, efficacy lasts 168 hours, 2800mg X 6 pills). It also mentions '对前列腺炎有良好的疗效 高血压、心脏病、酒后可以放心使用' (Good efficacy for prostatitis, safe for use with high blood pressure, heart disease, and after drinking).
- Top Right:** A box with English text: 'Novel highest grade yang invigorating product', 'exceed vigra and cialis', 'MAXIMUM POWERFUL', 'Take effect in 15 minutes and last for 168 hours', 'Be of good therapeutic effects on prostatitis', 'Safe use of the product for patients of high blood pressure or cardiac disease or after drinking', and '2800mg X 6Pills'.
- Bottom Left:** A blister pack of six pills, each in a white and blue wrapper with 'BAIWEI百威' and 'USA' printed on it.
- Bottom Center:** A blister pack of six dark, round pills.
- Bottom Right:** A product box with Chinese text: '说明书' (Instructions), 'MAXIMUM POWERFUL', and detailed information about the product's ingredients, efficacy, and usage.

Exceed Vigra and Cialis Maximum Powerful 2800 mg X 6 Pills
 Manufacturer: Tibetan Health-Care Association “Sheng Yang” – Tibetan Autonomous Region, Lassa City, Ming Zu Str. 118

Figure 1: Unregistered drug product



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

DR. SAMUEL A. ZACATE
Director General

DTN:



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