**FDA ADVISORY**

No. 20240642

18 APR 2024

**TO:** **THE GENERAL PUBLIC**

**SUBJECT:** **Public Health Warning Against the Purchase and Consumption of the Unregistered Food Product MANHATTAN BIOLOGICAL MAXMAN due to the Presence of a Drug Component, Sildenafil Citrate**

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The Food and Drug Administration (FDA) warns all healthcare professional and the general public **NOT TO PURCHASE AND CONSUME** the unregistered food product:


Figure 1. Unregistered MANHATTAN BIOLOGICAL MAXMAN with presence of a Drug Component, Sildenafil Citrate

The FDA verified through post-marketing surveillance that the abovementioned food product is not registered and no corresponding Certificate of Product Registration (CPR) has been issued. Pursuant to the 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, non-consumer use, promotion, advertising or sponsorship of health products without the proper authorization is prohibited.

Furthermore, the collected samples with expiry date of **30 07 2028**, after analyses of the FDA Laboratory, **tested positive for Sildenafil Citrate**. Sildenafil Citrate is a prescription drug product used to treat male sexual function problems such as impotence or erectile dysfunction (ED).

The verified presence of ***Sildenafil Citrate*** deems the food/dietary supplements belonging to the respective batch as ADULTERATED; thus, posing potential health risks to the unwary consuming public, especially those with heart problems, kidney disease, liver disease or high or low blood pressure. Possible side effects which can occur are as follows:

- *headache*
- *diarrhea*
- *dizziness or lightheadedness*
- *priapism*
- *indigestion*
- *nasal congestion*
- *urinary tract infection*
- *changes in vision or sudden vision loss, or*
- *rashes*

All concerned establishments are warned not to distribute, advertise, or sell the said violative food supplement, 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**. You may also look for the FDA Registration number on the product label, if available or simply type the name of the product.

All Law Enforcement Agencies (LEAs) and Local Government Unit (LGUs) are requested to ensure that this product is not sold or made available in the market or areas of jurisdiction.

The Bureau of Customs is urged to restrain the entry of the unregistered imported product.

For more information and inquiries about this advisory, kindly contact the FDA Center for Food Regulation Office and Research through email **cfrr@fda.gov.ph** indicating on the subject, the concerned Advisory, or call **(02)8857-1900** local **8105** and **8112**.

To report any sale or distribution of unregistered food supplements, kindly email us at **ereport@fda.gov.ph**.

Dissemination of this advisory to all concerned is hereby requested.

**DR. SAMUEL A. ZACATE**
Director General

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