



FDA ADVISORY
No. **2020-512**

01 APR 2020

TO: THE GENERAL PUBLIC

SUBJECT: Public Health Warning on the Presence of Tadalafil in BRAVO Maca + Jatropha + Corynaea Crassa Food Supplement for Men

The public is hereby informed that the Food and Drug Administration (FDA) has conducted sampling of specific batches of **BRAVO Maca + Jatropha + Corynaea Crassa Food Supplement for Men** as part of the strengthened post-marketing surveillance of this Office.



The analyses of the FDA Laboratory showed that the abovementioned product under the specific lot number **ABV38E20T** and expiry date **20 June 2021** have tested positive for **Tadalafil**. **Tadalafil** is a prescription drug used to treat male sexual function problems such as impotence or erectile dysfunction (ED).

Tadalafil is prohibited in food/dietary supplements, since it poses potential health risks to the unwary consuming public especially those who have had a stroke, severe vision loss, persons experiencing stomach ulcers, heart problems, kidney problems, liver problems, bleeding problem, blood cell problems, and low or high blood pressure. Possible side effects which can occur are as follows:

- indigestion
- muscle aches
- flushing
- back pain
- stuffy or runny nose
- headaches



The presence of drug ingredient **Tadalafil** deems the food/dietary supplement as ADULTERATED, which is in violation of R.A. 9711 (FDA Act of 2009) and R.A. 10611, otherwise known as the Food Safety Act of 2013.

Consumers are advised to:

1. Stop taking BRAVO Maca + Jatropha + Corynaea Crassa Food Supplement for Men with lot number **ABV38E20T**.
2. Consult a healthcare professional in case you experience any of the side effects upon consumption of the product.
3. Exercise caution when purchasing food supplements for men that can be potentially adulterated with drug ingredients which can seriously harm the consumers.

The FDA shall ensure that the market authorization holder (MAH) will conduct a voluntary recall for the implicated products.

All Local Government Units (LGUs) and Law Enforcement Agencies (LEAs) are requested to ensure that the said 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 the above adulterated food supplement, utilize our online reporting facility, **eReport**, at www.fda.gov.ph/ereport, or e-mail us via foodsafety@fda.gov.ph, or call us at the Center for Food Regulation and Research (CFRR) hotline **(02) 857-1900 loc. 8115 and 8105**.

Dissemination of the information to all concerned is requested.


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