

Republic of the Philippines Department of Health FOOD AND DRUG ADMINISTRATION



FDA ADVISORY No. 2018-313 2 9 OCT 2018

TO:

THE GENERAL PUBLIC

of the strengthened post-marketing surveillance of this Office:

SUBJECT:

Public Health Warning on the Presence of Nortadalafil and Tadalafil in Monitored Herbal Dietary/Food Supplements for Men

The public is hereby informed that the Food and Drug Administration (FDA) has conducted sampling of specific batches of the following herbal dietary/food supplements for men as part



Figure 1. MS FOR MALE TABLET Herbal Dietary Supplement



Figure 2. BRAVO Maca + Jatropha + Corynaea Crassa Food Supplement for Men





The analyses of FDA Laboratory showed that the aforementioned products under the following specific lot numbers / manufacturing and expiry dates have tested positive for **Nortadalafil** and **Tadalafil**:

Brand Name	Product Name	Lot no./Manufacturing/ Expiry date	Test Result(s)
1. MS FOR MALE TABLET	Herbal Dietary Supplement	Manufacturing date: 20 February 2017 Expiry date: 19 February 2021	Positive for Nortadalafil and Tadalafil
2. BRAVO	Maca + Jatropha + Corynaea Crassa (Food Supplement for Men)	Lot number: NU1Y617 Expiry date: 26 March 2019	Positive for Tadalafil

Tadalafil is a prescription drug used to treat male sexual function problems such as impotence or erectile dysfunction (ED). Nortadalafil is an analogue compound of tadalafil. The said components are prohibited in food/dietary supplements, since these pose 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 disease, bleeding problem, blood cell problems, and low or high blood pressure. Possible side effects which can occur are as follows:

- · headaches
- indigestion
- stuffy or runny nose
- flushing
- sudden loss or decrease in hearing, sometimes with ringing in the ears
- · numbness

- · back pain
- muscle aches
- · changes in vision
- dizziness
- · difficulty of breathing
- · tingling in chest, arms, neck or jaw

The presence of drug ingredients **Tadalafil** and **Nortadalafil** deems the food/dietary supplements 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:

Stop taking MS FOR MALE TABLET Herbal Dietary Supplement or BRAVO Maca
 + Jatropha + Corynaea Crassa Food Supplement for Men with the respective manufacturing date/lot number.

- 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.

Further, the public who purchased MS FOR MALE TABLET Herbal Dietary Supplement or BRAVO Maca + Jatropha + Corynaea Crassa Food Supplement for Men is advised to immediately coordinate with FDA at telephone number 857-1900 local 8105 or email us at foodsafety@fda.gov.ph. To report continuous sale or distribution of unregistered health products, kindly email us at report@fda.gov.ph.

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Director General

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