



Republic of the Philippines  
Department of Health  
**FOOD AND DRUG ADMINISTRATION**



**FDA ADVISORY**  
No. **2016-092**

22 AUG 2016

**TO: THE GENERAL PUBLIC**

**SUBJECT: Public Health Warning on the Presence of Analogues of Tadalafil in Robust and Robust Extreme Dietary Supplements for Men**

The public is hereby informed that the Food and Drug Administration (FDA) has conducted sampling of specific batches of the food products **Robust** and **Robust Extreme Dietary Supplements for Men** upon receipt of information from the Therapeutic Goods Administration (TGA), Department of Health of the Australian Government regarding the presence of analogues of the aforementioned with *Tadalafil*, a prescription drug product used to treat male sexual function problems such as impotence or erectile dysfunction (ED).

The collected samples, after analyses of the FDA Laboratory, tested positive for the analogues of *tadalafil*, **Nortadalafil** and **2-hydroxyethyl nortadalafil**. Results are summarized as follows:

Brand Name	Product Name	Batch Nos.	Conclusion
ROBUST	Dietary Supplement for Men	RB-TTCG	Positive for the presence of <b>2-hydroxyethyl nortadalafil</b>
		RB-TTCN	Positive for the presence of <b>Nortadalafil</b>
		RB-TTCY RB-TTCG RB-TTCT	Positive for the presence of <b>Nortadalafil</b> and <b>2-hydroxyethyl nortadalafil</b>
ROBUST EXTREME	Dietary Supplement for Men	RE-TTO RE30-TTC RE30-TTA	Positive for the presence of <b>Nortadalafil</b>

The verified presence of **Nortadalafil** and **2-hydroxyethyl nortadalafil** on the respective batches deems the food/dietary supplements 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:

- difficulty of breathing
- swelling of face, lips, tongue, or throat,
- dizziness
- nausea
- pain



- numbness
- tingling in your chest, arms, neck, or jaw
- changes in vision or sudden vision loss, or
- ringing in the ears

Consumers who purchased Robust and Robust Extreme Dietary Supplements for Men with the respective batch numbers are advised to immediately coordinate with FDA at telephone number 857-1991 to 93 or email us at [foodsafety@fda.gov.ph](mailto:foodsafety@fda.gov.ph). To report continuous sale or distribution of unregistered health products, kindly email us at [report@fda.gov.ph](mailto:report@fda.gov.ph).

  
**MARIA LOURDES C. SANTIAGO, MSc, MM**  
Officer-in-Charge, Director General