



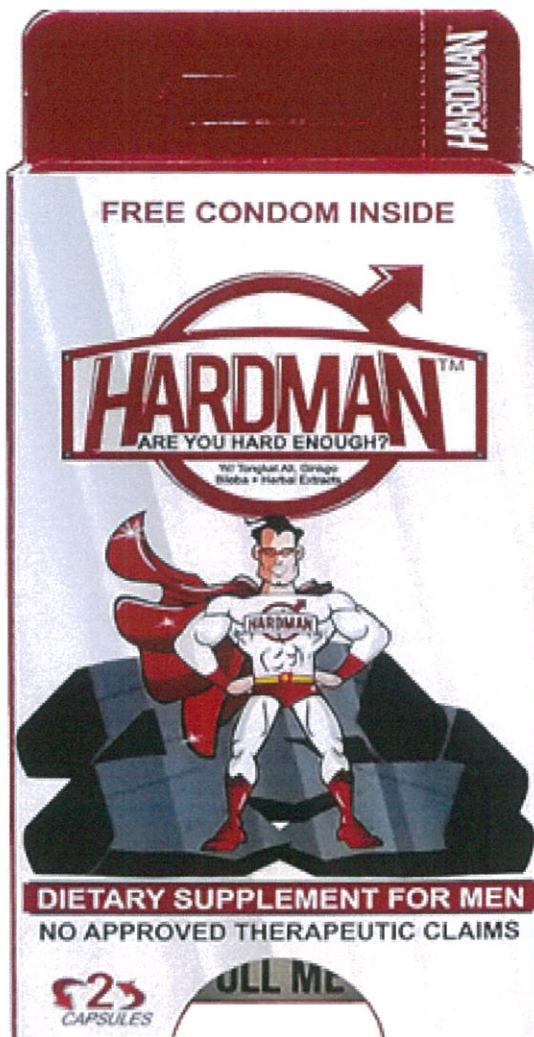
FDA ADVISORY
No. 2020-1922

22 OCT 2020

TO: THE GENERAL PUBLIC

SUBJECT: Public Health Warning on the Presence of Sildenafil in
HARDMAN™ Dietary Supplement for Men w/ Tongkat Ali,
Ginkgo Biloba + Herbal Extracts

The public is hereby informed that the Food and Drug Administration (FDA) has conducted sampling of specific batches of **HARDMAN™ Dietary Supplement for Men w/ Tongkat Ali, Ginkgo Biloba + Herbal Extracts** 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 batch number **H2**, with manufacturing date **15 January 2020**, and expiry date **14 January 2022** has tested positive for **Sildenafil**. **Sildenafil** is a drug used to treat male sexual function problems such as impotence or erectile dysfunction (ED).

Sildenafil is prohibited in food/dietary supplements, since it poses potential health risks to the unwary consuming public especially those who have had a stroke, vision loss, persons experiencing problems with food passing through the esophagus, heart problems, peyronie's disease, liver problems, and low blood pressure. Possible side effects which can occur are as follows:

- headaches
- facial flushing
- dyspepsia
- dizziness
- palpitation
- nasal congestion
- abnormal vision



The presence of drug ingredient *Sildenafil* 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 **HARDMAN™ Dietary Supplement for Men w/ Tongkat Ali, Ginkgo Biloba + Herbal Extracts** with batch number **H2**.
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/dietary supplements for men that can be potentially adulterated with drug ingredients which can seriously harm the consumers.

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.


ROLANDO ENRIQUE D. DOMINGO, MD
Director General



DTN 20201016093724