

Republic of the Philippines Department of Health FOOD AND DRUG ADMINISTRATION



FDA ADVISORY No. 2020 - | 922-A

0 9 NOV 2021,

TO:

THE GENERAL PUBLIC

SUBJECT:

<u>Lifting the Advisory on the Voluntary Recall of HARDMAN</u> Dietary Supplement for Men w/ Tongkat Ali, Ginkgo Biloba +

Herbal Extracts with Batch No. H2

The Food and Drug Administration (FDA) informs the public that FDA Advisory No. 2020-1922 or "Public Health Warning on the Presence of Sildenafil in HARDMANTM Dietary Supplement for Men w/ Tongkat Ali, Ginkgo Biloba + Herbal Extracts" dated 22 October 2020 is hereby lifted.

After due evaluation of the submitted documents of the Market Authorization Holder (MAH), the requirements for the termination of the voluntary recall has been satisfactorily met in accordance with FDA Circular No. 2016-012, known as the "Guidelines on Product Recall".

The issuance of this advisory shall not in any manner preclude this Office from issuing subsequent orders it may deem necessary and appropriate, should there be findings of any violation of the company to the existing laws, rules, and regulations.

Dissemination of this advisory to all concerned is hereby requested.

ROLANDO ENRIQUE D. DOMINGO, MD
Director General

DTN 20201016093724



