

Republic of the Philippines Department of Health FOOD AND DRUG ADMINISTRATION



FDA ADVISORY No. **20201**033

0 4 JUN 2020

TO:

THE GENERAL PUBLIC

SUBJECT:

<u>Public Health Warning Against the Purchase and Consumption of</u> the following Unregistered Food Products and Food Supplement:

- 1. <u>21ST CENTURY Herbal Extract St. John's Wort Extract Dietary Supplement 60 Vegetarian Capsule</u>
- 2. NOW MOOD SUPPORT with St. John's Wort Dietary
 Supplement 90 Veg Capsules
- 3. NUSAPURE St. John's Wort 1100 MG Dietary Supplement 180 Veg Caps
- 4. HA SLEEP AURA Bedtime Stress Relief Blend with St.

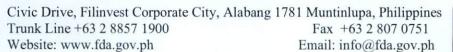
 John's, Valerian Root, GABA, Chamomile, Magnolia,

 Ashwagandha, Melatonin 60 Capsules Dietary Supplement
- 5. SOLARAY St. John's Wort Dietary Supplement 60 Tablets

The Food and Drug Administration (FDA) advises the public from purchasing and consuming the following unregistered food products and food supplements:



Figure 1. 21ST CENTURY Herbal Extract St. John's Wort Extract Dietary Supplement - 60 Vegetarian Capsule





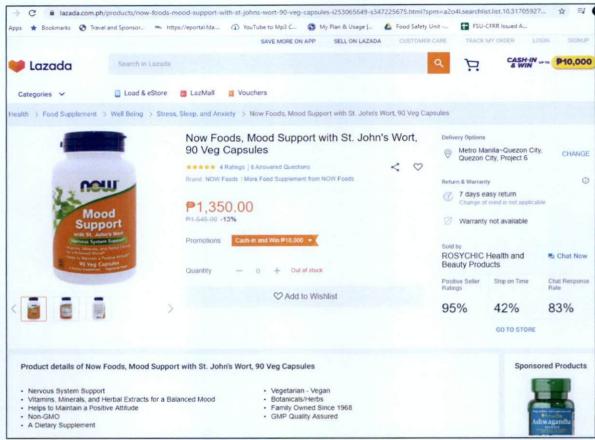


Figure 2. NOW MOOD SUPPORT with St. John's Wort Dietary Supplement 90 Veg Capsules

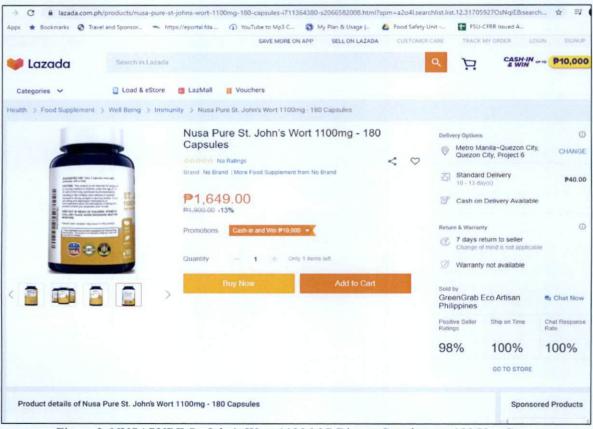


Figure 3. NUSAPURE St. John's Wort 1100 MG Dietary Supplement 180 Veg Caps

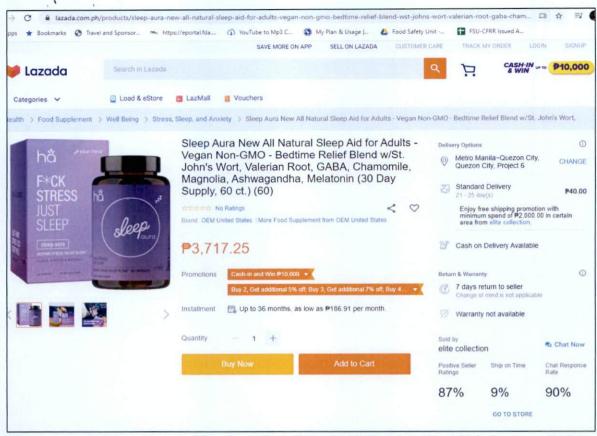


Figure 4. HA SLEEP AURA Bedtime Stress Relief Blend with St. John's Wort, Valerian Root, GABA, Chamomile, Magnolia, Ashwagandha, Melatonin 60 Capsules Dietary Supplement

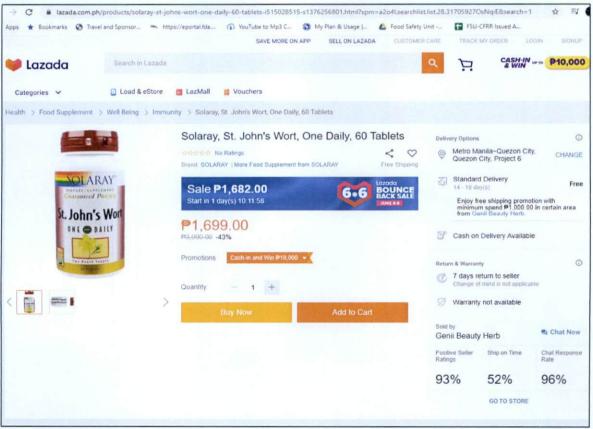


Figure 5. SOLARAY St. John's Wort Dietary Supplement 60 Tablets

The FDA verified through post-marketing surveillance that the abovementioned food products and food supplement are not authorized and the Certificates of Product Registration (CPR) have not been issued. Pursuant to the Republic Act No. 9711, otherwise known as the "Food and Drug Administration Act of 2009", the manufacture, importation, exportation, sale, offering for sale, distribution, transfer, non-consumer use, promotion, advertising or sponsorship of health products without the proper authorization is prohibited.

Since these unregistered food products and food supplement have not gone through evaluation process of the FDA, the agency cannot assure their quality and safety. The consumption of such violative products may pose health risks to consumers.

In light of the foregoing, the public is advised not to purchase the aforementioned violative products. Moreover, the public is advised to always check if a food product or food supplement is registered with the FDA. The FDA website (www.fda.gov.ph) has a Search feature which may be used by typing in the name of the product before purchasing.

All concerned establishments are warned not to distribute violative food products and food supplements until they have been issued the appropriate authorization, a License to Operate for the establishment, and a CPR for the food product or food supplement.

All FDA Regional Field Offices and Regulatory Enforcement Units, in coordination with law enforcement agencies and Local Government Units, are requested to ensure that violative products are not sold or made available in the market or areas of jurisdiction.

To report any sale or distribution of unregistered food products and food supplements, kindly contact us through email at ereport@fda.gov.ph.

Dissemination of this advisory to all concerned is hereby requested.

ROLANDO ENRIQUE D. DOMINGO, MD

Director General

DTN 20200522100221