



FDA ADVISORY
No. **2019-326**

07 OCT 2019

TO: THE GENERAL PUBLIC

SUBJECT: Public Health Warning Against the Purchase and Consumption of the following Unregistered Food Supplements:

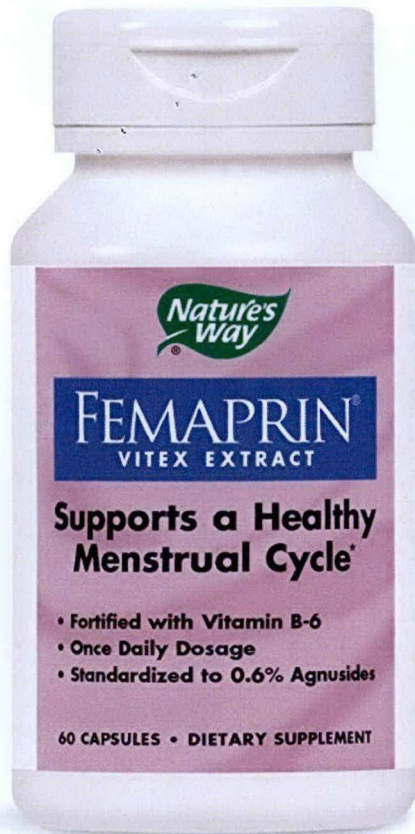
- 1. AMAZING Paragis Tea**
- 2. NATURE'S WAY FEMAPRIN Vitex Extract Supports a Healthy Menstrual Cycle Fortified with Vitamin B-6 Dietary Supplement (60 capsules x bottle)**
- 3. J.M BLESS Cinnamon Capsules 400mg Food Supplement (100 capsules x bottle)**
- 4. PARADISE ORAC-ENERGY EARTH'S BLEND One Daily Superfood Multivitamin with Iron Dietary Supplement (60 vegetarian capsules x bottle x box)**
- 5. SAMBUCOL Black Elderberry Original Formula Dietary Supplement Chewable Tablet (30 chewable tablet x bottle x box)**

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



Figure 1. Unregistered AMAZING Paragis Tea





Femaprin® is a unique formula that combines a standardized Vitex (Chaste Tree) extract with Vitamin B6 to help support a healthy menstrual cycle and reduce periodic discomfort.* Femaprin is designed to help alleviate the symptoms and discomfort of premenstrual syndrome such as bloating, breast tenderness, and mood changes.*

Double safety sealed with a printed outer shrinkwrap film and a printed inner bottle freshness seal. Do not use if either seal is broken or missing. Keep out of reach of children.

Actual Capsule Size

◆ LN14717.01 (BLK8216)



*This statement has not been evaluated by the Food & Drug Administration. This product is not intended to diagnose, treat, cure or prevent any disease.

Figure 2. Unregistered NATURE'S WAY FEMAPRIN Vitex Extract Supports a Healthy Menstrual Cycle Fortified with Vitamin B-6 Dietary Supplement (60 capsules x bottle)



Figure 3. Unregistered J.M BLESS Cinnamon Capsules 400mg Food Supplement (100 capsules x bottle)



Figure 4. Unregistered PARADISE ORAC-ENERGY EARTH'S BLEND One Daily Superfood Multivitamin with Iron Dietary Supplement (60 vegetarian capsules x bottle x box)



Figure 5. Unregistered SAMBUCOL Black Elderberry Original Formula Dietary Supplement Chewable Tablet (30 chewable tablet x bottle x box)

The FDA verified through post-marketing surveillance that the abovementioned food supplements 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 supplements have not gone through evaluation process of the FDA, the agency cannot assure their quality and safety. The use 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 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.

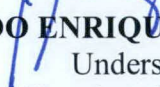
All concerned establishments are warned not to distribute violative food supplement until they have been issued the appropriate authorization, a License to Operate (LTO) for the establishment, and a CPR for the food supplement.

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.

Kindly contact the FDA Center for Food Regulation and Research through e-mail at cfrr@fda.gov.ph, or call (02) 857-1900 loc. 8112 and 8115

To report any sale or distribution of unregistered food supplement, the online reporting facility, **eReport** can be accessed at www.fda.gov.ph/ereport.

Dissemination of this advisory to all concerned is hereby requested.


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