Republic of the Philippines
Department of Health
FOOD AND DRUG ADMINISTRATION

24 November 2014

FDA Advisory
No. 2014-084

SUBJECT: PUBLIC HEALTH WARNING AGAINST THE USE OF UNREGISTERED GLUTAX 5GS KIT

The Food and Drug Administration (FDA) advises the public against the use of the unregistered Glutax 5GS kit being offered for sale online or in some dermatologic clinics. Glutax 5GS kit contains the following:

1. Glutathione 5000 mg + Alpha Lipoic Acids 200 mg (Glutax 5GS) Powder for Injection (IM/IV) in glass vial
2. Vitamin E 300 mg + Pro-Vitamin B3 250 mg + Pro-Vitamin B5 100 mg (Glutax 5GS) Solution for Injection (IM/IV) in glass ampule
3. Ascorbic acid 1500 mg/ Collagen extract 350 mg (Glutax 5GS) Solution for Injection (IM/IV) in glass ampule

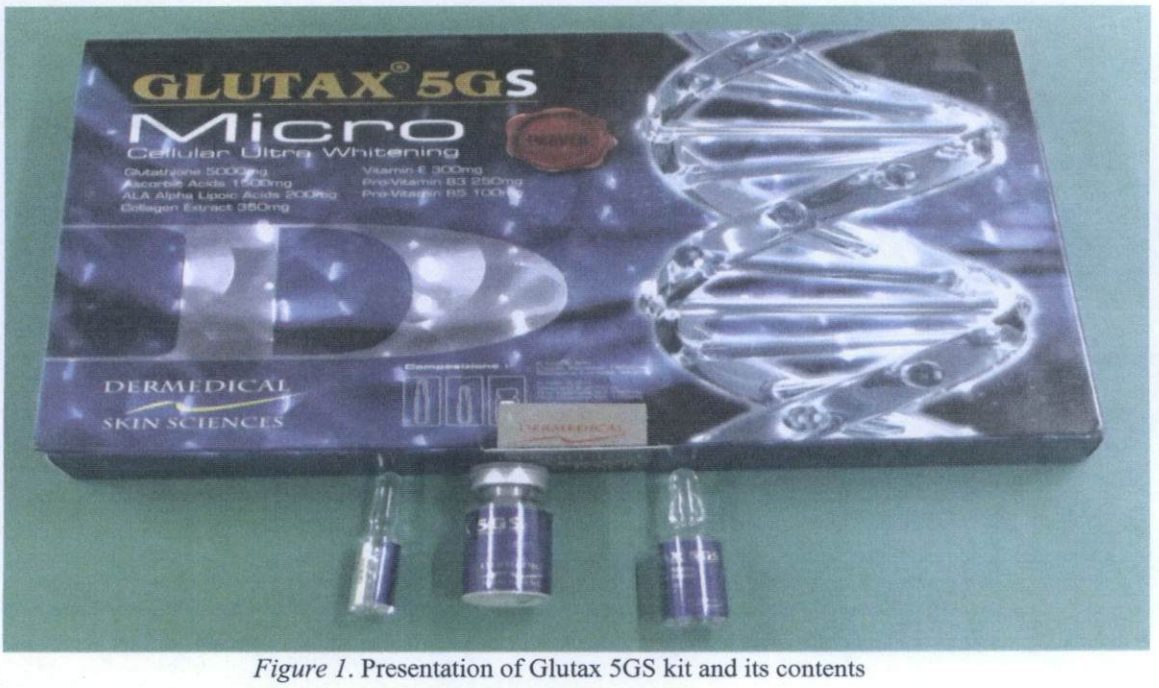

Figure 1. Presentation of Glutax 5GS kit and its contents

Upon determination by the Food and Drug Administration, the said kit and the products it contains are confirmed to be unregistered.

The public is also reminded that glutathione-containing injectables and vitamin-containing drug products to be administered through the IM/IV route require a prescription and should be administered by healthcare practitioners.

All consumers are advised to use only FDA-registered health products and to look for the FDA Registration number or DR number on the labels, when drug products are

concerned. The FDA registration and evaluation procedures ensure that all drug products comply with safety, efficacy and quality standards, and that these products are manufactured under the strict requirements of the current Good Manufacturing Practice (cGMP).

All FDA inspectors are hereby ordered to seize unregistered Glutax 5GS Kit or its contents from all outlets or establishments where they are found or offered for sale or use.

All establishments and outlets are hereby warned that importation, distribution, or sale of any unregistered drug product are subject to sanctions and penalties stipulated in Republic Act No. 3720, as amended by Republic Act No. 9711, otherwise known as the "Food and Drug Administration Act of 2009".

For more information and inquiries, please email us at info@fda.gov.ph. To report violating establishments or persons, any suspected counterfeit/ unregistered health products, and/or adverse reactions after using any health product, kindly email us via report@fda.gov.ph or call (02)807-8275.

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