Republic of the Philippines
Department of Health
FOOD AND DRUG ADMINISTRATION

28 March 2014

FDA Advisory No. 2014-022

SUBJECT: Consumer Information - Findings on Health Products Used by Spas and Beauty, Skin, or Wellness Clinics

Spa and skin, beauty, or wellness clinics offering different types of therapies and regimens using FDA-regulated health products have flourished in cities and nearby provinces. All consumers are informed that all health products used by the said establishments require FDA market authorization.

On 2-5 December 2013, the FDA monitored the health products being offered by 15 establishments to their clients. Six (6) of the establishments were located in San Juan City, 5 in Muntinlupa City and 3 in Taguig City. Most of the establishments were inside the malls.

The results of the FDA inspection revealed the following:

1. Some establishments were using cosmetic products that were not notified with, or had no market authorization from the FDA.

2. Some unlicensed establishments were repacking the products manufactured by legitimate cosmetic manufacturers in Makati City, Davao City, Quezon City, Pasig City, Manila City, San Juan City and Cavite. After repacking the content of the products, some re-labeled them with the name of their own spa or clinic.

   Repacking of finished product is considered a manufacturing activity. Republic Act 9711 or the FDA Act of 2009 prohibits, among others, the manufacture of any health product without the proper authorization from the FDA.

3. Three clinics were offering glutathione injections to their clients.

   The FDA-approved indication for glutathione injection is to ameliorate some adverse reactions of patients to Cisplatin chemotherapy. The use of glutathione as systemic skin whitening agent has no approval from the FDA.

4. There were owners/dermatologists in possession of injectable botulinum toxin medicines.

   Owners and dermatologists are considered non-consumer users. As defined by the Implementing Rules and Regulation of the FDA Act of 2009, non-consumer users mean doctors, health workers, and other such person(s) who may be directly or indirectly in contact with or using such health products in the conduct of their profession or in the course of their work. Section 10 of Republic Act No. 9711 or the FDA Act of 2009 prohibits the non-consumer use of any health product without the proper authorization from the FDA.

However, there were no establishments directly offering "stem cell" treatment to their clients. DOH Administrative 2013-0012 defines stem cell as undifferentiated cells from multicellular organisms that have the capacity to divide and differentiate into different types of cells found in the body. With the DOH issuance, the use of "stem cell" as product name in cosmetic products is no longer allowed or tolerated.

All spas and beauty, skin or wellness clinics are advised to use only health products that have market authorization from the FDA. All medicines shall be used according to FDA-approved indication.

All unlicensed establishments are warned against repacking and/or re-labeling of FDA-notified cosmetic products.

All FDA-licensed manufacturers and distributors are likewise compelled to report spas or clinics that are repacking or re-labeling notified cosmetic products.

As non-consumer users of health products, the FDA is still studying if it will cover all spas and beauty, skin or wellness clinics in its licensing or permitting system to protect the health and welfare of the consumers.

To check if any health product is registered with the FDA, please visit the FDA website (www.fda.gov.ph) and type the name of the product in the SEARCH bar found in the upper right hand corner. To report unregistered, banned or illegal health products, please email us via report@fda.gov.ph.

For more information or clarification, kindly email us at info@fda.gov.ph.

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