Republic of the Philippines
Department of Health
FOOD AND DRUG ADMINISTRATION

FDA ADVISORY No. 2018-112

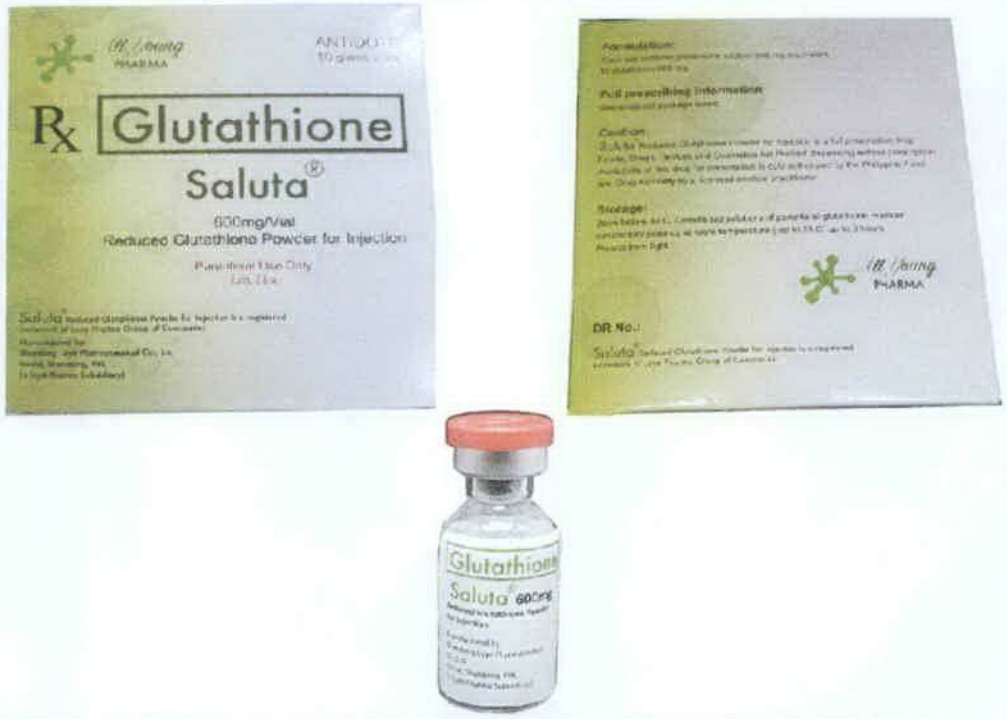
23 MAR 2018

TO : ALL HEALTHCARE PROFESSIONALS AND THE GENERAL PUBLIC

SUBJECT : Public Health Warning Against the Purchase and Use of the Following Unregistered Drug Products:

1. **Glutathione (Saluta) 600 mg/Vial Reduced Glutathione Powder for Injection**
2. **Glutathione (Saluta) 1200 mg /Vial Reduced Glutathione Powder for Injection**
3. **Glutathione (Saluta) 1800 mg/Vial Reduced Glutathione Powder for Injection**
4. **TAD 1200 mg Reduced Glutathione**
5. **Glutax 5GS Micro Advance by 6 and Twin pack**
6. **TAD 5000 mg Reduce Glutathione**

The Food and Drug Administration (FDA) advises the public against the purchase and use of the following unregistered drug products:

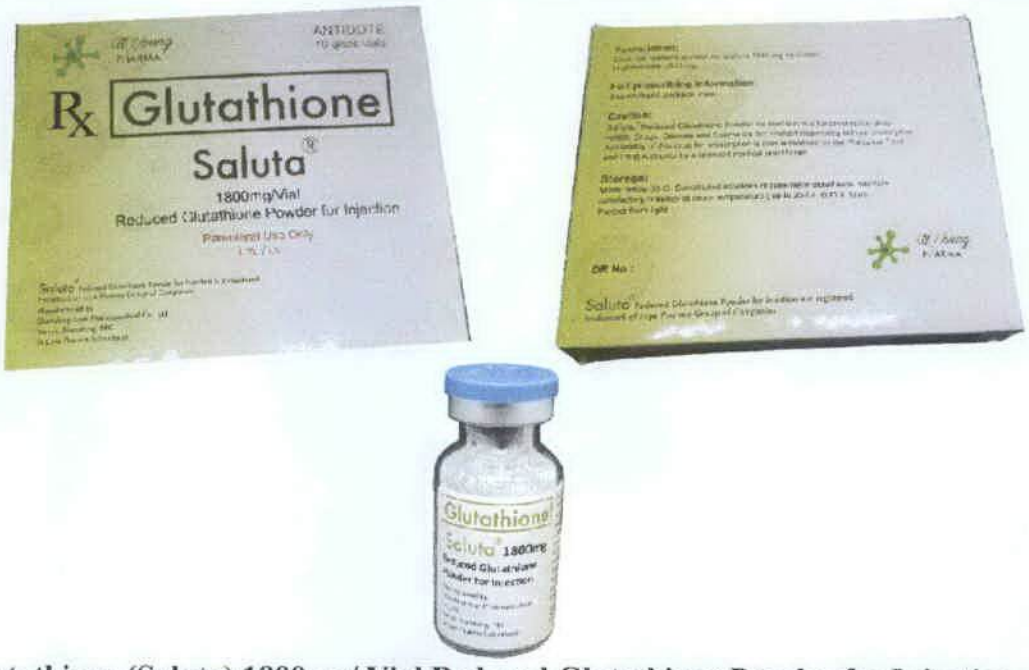


Glutathione (Saluta) 600 mg/Vial Reduced Glutathione Powder for Injection
Manufactured by: **Shandong Luye Pharmaceutical Co., Ltd – Yantai, Shandong, PRC (a Luye Pharma Subsidiary)**
Imported by: **All Young Pharma**
Distributed by : **MBE**

Figure 1. Unregistered drug product

Glutathione (Saluta) 1200 mg/Vial Reduced Glutathione Powder for Injection
Manufactured by: **Shandong Luye Pharmaceutical Co., Ltd – Yantai, Shandong, PRC (a Luye Pharma Subsidiary)**
Imported by: **All Young Pharma**
Distributed by : **MBE**

Figure 2. Unregistered drug product



Glutathione (Saluta) 1800mg/ Vial Reduced Glutathione Powder for Injection
Manufactured by: **Shandong Luye Pharmaceutical Co., Ltd – Yantai, Shandong, PRC (a Luye Pharma Subsidiary)**
Imported by: **All Young Pharma**
Distributed by : **MBE**

Figure 3. Unregistered drug product

TAD 1200 mg Reduced Glutathione
Marketing Authorization Holder: **BIOMEDICA FOSCAMA GROUP SPA – Via Degli Uffici del Vicario, 49 00186 Rome Italy**

Figure 4. Unregistered drug product

Glutax 5GS Micro Advance
Marketing Authorization Holder: **DERMEDICAL SKIN SCIENCES – Via K. Marx , 18, Noverasco di Opera, MI, 20090, Italy**

Figure 5. Unregistered drug product

TAD 5000 mg Reduced Glutathione
Marketing Authorization Holder: **DERMEDICAL SKIN SCIENCES – Via K. Marx, 18, Noverasco di Opera, MI, 20090, Italy**

Figure 6. Unregistered drug product

FDA Post-Marketing Surveillance (PMS) activities have verified that the abovementioned drug products have not gone through the registration process of the agency and have not been issued with proper authorization in the form of Certificates of Product Registration.

Pursuant to 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, promotion, advertising or sponsorship of health products without proper authorization from FDA is prohibited.

Accordingly, since these unregistered drug products have not gone through evaluation and testing process of the FDA, the agency cannot guarantee their quality and safety. The consumption of such violative products may pose potential danger or injury if administered.

In light of the above, the public is advised not to purchase the aforementioned violative products and to be vigilant against drug products that might not be duly registered with the FDA. Always check if a drug product has been registered with the FDA before purchasing it by making use of the embedded *Search* feature of the FDA website accessible at www.fda.gov.ph. You may also look for the FDA Registration number on the product label.

All concerned establishments and/or entities are warned not to distribute the above-identified violative drug products until they have already been covered by the appropriate authorization, otherwise, regulatory actions and sanctions shall be strictly pursued.

All Local Government Units (LGUs) and Law Enforcement Agencies (LEAs) are requested to ensure that these products are not sold or made available in their localities or areas of jurisdiction.

For more information and inquiries, please e-mail us at **info@fda.gov.ph**. To report continuous sale or distribution of unregistered health products, kindly e-mail us via **report@fda.gov.ph**, or through the online reporting facility, **eReport**, at **www.fda.gov.ph/ereport**. You may also call the Center for Drug Regulation and Research at telephone number **(02)809-5596**. For any suspected adverse drug reaction (ADR), report immediately to FDA through this link: **www.fda.gov.ph/adr-report-new** and fill out all the required fields.

Dissemination of the information to all concerned is requested.

NELA CHARADE G. PUNO, RPh
Director General

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