

## Republic of the Philippines Department of Health FOOD AND DRUG ADMINISTRATION



FDA ADVISORY No. 2019-182

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TO:

THE GENERAL PUBLIC

UNSAFE USE OF GLUTATHIONE AS SKIN LIGHTENING AGENT SUBJECT:

The Food and Drug Administration (FDA) warns the public on the dangers associated with the use of injectable lightening agents such as glutathione.

In the Philippines, several health and beauty salons, wellness spa and beauty clinics are offering all kinds of beauty enhancements, services and skin treatments. It is alarming that they also offer services such as intravenous drip or infusion using skin lightening agents including reduced glutathione, vitamin C and other injections.

To date there are no published clinical trials that have evaluated the use of injectable glutathione for skin lightening. There are also no published guidelines for appropriate dosing regimens and duration of treatment. The FDA has not approved any injectable products for skin lightening. Injectable glutathione is approved by FDA Philippines as an adjunct treatment in cisplatin chemotherapy.

Side effects on the use of injectable glutathione for skin lightening include toxic effects on the liver, kidneys, and nervous system. Also of concern is the possibility of Stevens Johnson Syndrome. Injectable glutathione is sometimes paired with intravenous Vitamin C. Vitamin C injection may form kidney stones if the urine is acidic. Large doses of Vitamin C have resulted in hemodialysis in patients with glucose-6-phosphate dehydrogenase (G6PD) deficiency.

Given that glutathione affects the production of melanin (the pigment that gives the human skin, hair and eyes their color) – there are theoretical concerns about the long term skin cancer risk.

Other potential risks include transmission of infectious agents, such as HIV, hepatitis C and B. This is of particular concern when non-medical practitioner administers this treatment or done in a non-sterile facility.

To assure that your skin conditions are treated, consult only a board-certified dermatologist. Avoid buying injectable products online and from being lured to a promising effect of medicines as beauty products.

Seek medical attention immediately if you experience any side effects and report it to FDA at pharmacovigilance@fda.gov.ph or via online reporting through our website: www.fda.gov.ph. You may also call the Center for Drug Regulation and Research at telephone number (02) 809-5596.

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