



26 NOV 2021

FDA ADVISORY
No. **2021-3206**

TO : ALL HEALTHCARE PROFESSIONALS AND THE GENERAL PUBLIC

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

1. Collabeau Korean Collagen Better Skin from Water Dietary Supplement Capsules 60's
2. Glutax® Shiny-Glow EGF Cytokines Complexion Cell Rejuvenation Process 10,000 D Softgels 60's

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



Collabeau Korean Collagen Better Skin from Water Dietary Supplement Capsules 60's

Figure 1. Unregistered drug product



GLUTAX[®] SHINY-GLOW

EGF Cytokines Complexion
Cell Rejuvenation Process 10,000

10,000 D

DERMEDICAL SKIN SCIENCES

60 Softgels

DERMEDICAL SKIN SCIENCES
Via K. Marx, 18, Noverasco di Opera, MI, 20090, Italy
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Supplement Facts

Serving Size: 2 Softgels
Servings per Bottle: 60

Amount per Serving	Daily Value
L-Glutathione	1000mg
Hydrolyzed Egg Protein (EGF)	200mg
Minerals: Zn, Cu, Ni, H, K	200mg
Chondroitin, CoQ10, Ubiquinol, EG-10	200mg
Vitamin A	10000 IU
Vitamin B	10000 IU
Vitamin C	10000 IU
Vitamin E	10000 IU
Vitamin K-1, K2	10000 IU
Algae	10000 IU
Arginine	10000 IU
Aspartic Acid	10000 IU
Cysteine	10000 IU
Glutamine	10000 IU
Glutathione	10000 IU
Glycine	10000 IU
Hydroxyproline	10000 IU
Hydroxylysine	10000 IU
Proline	10000 IU
Serine	10000 IU
Threonine	10000 IU
Valine	10000 IU

DIRECTIONS: Take 1-2 Softgels daily, or as directed.
For best results, use with a good diet.

As with all dietary supplements, seek the advice of your medical health-care provider prior to use of this product. Pregnant or lactating women should consult their medical health-care provider prior to use.

DERMEDICAL SKIN SCIENCES **cGMP CERTIFIED**

Glutax[®] Shiny-Glow EGF Cytokines Complexion Cell Rejuvenation Process 10,000 D Softgels 60's
by: Dermedical Skin Sciences-Via K. Marx, 18, Noverasco di Opera, MI, 20090, Italy

Figure 2. 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 Certificate of Product Registration. Thus, the Agency cannot guarantee their quality, safety and efficacy. Therefore, consumption of such violative products may pose potential danger or injury to health.

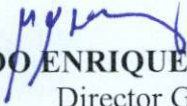
Pursuant to Republic Act No. 9711, otherwise known as the "Food and Drug Administration Act of 2009", the manufacture, importation, exportation, sale, offering for sale, distribution, transfer, promotion, advertising or sponsorship of health products without proper authorization from FDA is prohibited.

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. Always check if the products are registered with the FDA by using the **FDA Verification Portal feature** accessible at <http://verification.fda.gov.ph>.

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 ereport@fda.gov.ph. You may also call the Center for Drug Regulation and Research at telephone number (02) 8809-5596. For any suspected adverse drug reaction (ADR), report immediately to FDA through this link: <https://primaryreporting.who-umc.org/Reporting/Reporter?OrganizationID=PH> and fill out all the required fields.

Dissemination of the information to all concerned is requested.


ROLANDO ENRIQUE D. DOMINGO, MD
Director General

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