



FDA ADVISORY
No. **2017-028**

02 MAR 2017

TO: **THE GENERAL PUBLIC**

SUBJECT: **Public Health Warning Against the Purchase and Consumption of Unregistered Phyto Science Double Stemcell**

The Food and Drug Administration (FDA) advises the public against the purchase and consumption of the following unregistered food supplement:



Figure 1. Front page of the sample brochure of unregistered Phyto Science Double Stemcell



Stem Cells Offer Hope for Aging & Damaged Skin

- Intensive researches on stem cells showed tremendous potential to repair damaged tissue and organs
- Stem cells are capable of self-renewal and can transform themselves into differentiated cells.
- Epidermal stem cells are crucial to replenish the skin cells that are lost due to continual shedding, when epidermal stem cells are depleted. The number of lost or dying skin cells outpaces the production of new cells, threatening the skin's health and appearance.
- The patented extract PhytoCellTec Malus Domestica, has been shown to stimulate human stem cell proliferation, protect stem cell against ultraviolet light-induced death, and mitigate aging-related alterations in gene expression.
- A human study showed that topical application of PhytoCellTec Malus Domestica reduce the depth of crow's feet wrinkles after only two weeks.

Double Stem Cell

Scientists from Mibelle BioChemistry have found that a novel extract derived from the stem cells of a rare apple, are cultivated for its extraordinary longevity shows tremendous ability to rejuvenate aging skin. By stimulating aging skin stem cells, this plant extract has been shown to lessen the appearance of unsightly wrinkles. Clinical trials show that this unique formulation increases the longevity of skin cells, resulting in skin that has a more youthful and radiant appearance.

PhytoScience Double Stem Cell powder, a delicious proprietary blend of the signature stem cell extracts - PhytoCellTec™ Malus Domestica (Apple Stem Cells) & PhytoCellTec™ Solar Vitis (Grape Stem Cells), enriched with phytonutrient-rich superstars - Euterpe Oleracea (Acai Berry) and Vaccinium Myrtillus (Blueberry), is exclusively formulated by Mibelle BioChemistry to effectively help you regain control and keep aging at bay.

PhytoCellTec™ Solar Vitis/Vitis Vinifera

PhytoCellTec™ Solar Vitis is based on stem cells from the Gamay Teinturier Fréaux grapes from Burgundy, which is characterized by an extremely high content of polyphenols for UV protection that has been obtained through Mibelle BioChemistry's unique PhytoCellTec™ technology.

PhytoCellTec™ Malus Domestica

PhytoCellTec™ Malus Domestica is a liposomal preparation of apple stem cells developed by a novel, patent pending plant cell culture technology - PhytoCellTec™, a novel plant cell culture technology invented by Mibelle BioChemistry to cultivate de-differentiated callus cells from a rare Swiss apple Uttwiler Spätäuber.

- Protects longevity of skin stem cells
- Delays senescence of essential cells
- Combats chronological aging
- Award winner (BSB Innovation prize for the best active ingredient 2008)

Acai Berry

Acai berry is the richest known source of potent antioxidant compounds, particularly anthocyanins & Omega 3 Fatty Acids.

- Better Heart Health
- Promotes Skin Health
- Helps with Digestive Upset
- Immune-system Boosting
- Improves Mental Function
- Aids in Weight Loss
- Anti-Aging Effects
- Energy Boost
- Improved Cellular Health
- Better blood circulation
- Neutralizes free radicals

Blueberry

Rich in a wealth of antioxidants such as anthocyanins, proanthocyanidins, resveratrol, flavonols, pterostilbene, kaempferol and tannins.

- Boost up immune system
- Neutralizes free radicals
- Aids in reducing belly fat
- Helps promote urinary tract health
- Preserves vision
- Boost brain health
- Improves heart health
- Aids in constipation & digestion

Usage Recommendation: (Sublingual)

Morning - 1 sachet under the tongue
 Evening - 1 sachet under the tongue

Best to consume on empty stomach & with water

Figure 2. Back page of the sample brochure of Phyto Science Double Stemcell

FDA post-marketing surveillance (PMS) activities have verified that the abovementioned food supplement has not gone through the registration process of the agency and has not been issued the proper authorization in the form of Certificate 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, non-consumer use, promotion, advertising or sponsorship of health products without the proper authorization from FDA is prohibited.

Accordingly, since unregistered food products and food supplements 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 health hazards to the consuming public. Food products including food supplements should not bear any misleading, deceptive, and false claims in their labels and/or any promotional materials that will provide erroneous impression on products' character or identity.

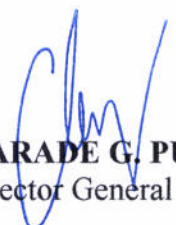
In light of the above, the public is advised not to purchase the aforementioned violative product. Moreover, the public is advised to be vigilant against food products that might not be duly registered with FDA. Always check if a food product has been registered with FDA before purchasing it by making use of the embedded *Search* feature of the FDA website accessible at www.fda.gov.ph.

All concerned establishments are warned not to distribute the above-identified violative food supplement until it has already been covered by the appropriate authorization (product registration), otherwise, regulatory actions and sanctions shall be strictly pursued.

All Local Government Units (LGUs) and Law Enforcement Agencies (LEAs) are requested to ensure that this product is 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 the above unregistered food supplement, utilize our online reporting facility, **eReport**, at www.fda.gov.ph/ereport, or e-mail us via report@fda.gov.ph, or call us at the Center for Food Regulation and Research (CFRR) hotline **(02) 857-1991 to 93**.

Dissemination of the information to all concerned is requested.


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Director General

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