

Republic of the Philippines Department of Health FOOD AND DRUG ADMINISTRATION



12 September 2013

FDA Advisory No. 2013-036

SUBJECT: PUBLIC WARNING ON UNREGISTERED BIO STEM PLUS TM OF STEM CELL NUTRITION

The FDA issued Circular No. 2013-0017 dated 8 July 2013 which required all human cells, tissues, and cellular and tissue-based products (HCT/Ps) to be registered with the FDA, otherwise, these products shall be considered illegal after 31 August 2013.

Pursuant to DOH Administrative Order No. 2013-0012, stem cells and stem cell products should be preparations of viable cells that have the capability to replicate and differentiate into different types of cells. HCT/P's are intended for implantation, transplantation, infusion or transfer into a human recipient. Products containing ingredients that are taken orally, or even applied topically, cannot pass as HCT/Ps.

The FDA has monitored the product BIO STEM PLUS TM , being advertised and sold on line thru sulit.com.ph, with deceitful health and therapeutic claims, among others:

- · Naturally increases adult stem cell circulation,
- · Aids in repair of damaged tissues,
- May assist as a helper in up to 70 known human conditions,
- · Could decrease the effects of age, and
- 70's going on 50's "kaya mag-sit up at mag ballroom dancing pa...flawless na balat, talas ng pag-iisip, at sigla ng katawan. Mga sakit na high blood, vertigo, back pain, lahat yon WALA NA!!! dahil sa BIO STEM PLUS ™ your natural Stem Cell Nutrition."

The public is hereby warned against buying and using unregistered BIO STEM PLUSTM since it is neither an FDA-approved stem cell preparation nor an approved drug product. There is no scientific and clinical studies that would support or back up its health and therapeutic claims. As advertised, stem cell is to be taken orally and will not pass as a product for registration as HCT/P.

All consumers are advised to be more vigilant and critical about on-line and digitial advertisements so as not to fall prey to the marketing schemes of internet fraudsters.

All FDA inspectors are hereby ordered to seize and confiscate all unregistered food supplements that are sold or offered for sale in outlets.









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For more information and inquiries, kindly email us at info@fda.gov.ph. To report unregistered health products or adverse reactions after using any health products, kindly email us via report@fda.gov.ph.

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