Republic of the Philippines
Department of Health
FOOD AND DRUG ADMINISTRATION
Filinvest Corporate City
Alabang, City of Muntinlupa

02 May 2014

FDA Advisory
No. 2014 033

SUBJECT: Updates on FDA Registration of Stem Cells or Human Cells, Tissues, and Cellular and Tissue-based Products

On 13 August 2013, the undersigned issued FDA Circular No. 2013-020 to reiterate the need for hospitals and other health facilities that are offering stem cell therapies to register all human cells, tissues, and cellular and tissue-based products (HCT/Ps), pursuant to FDA Circular 2013-017, dated 08 July 2013. Accredited and licensed facilities dealing with HCT/P's must file their applications for registration at the FDA on or before 31 August 2013, otherwise the products shall be considered unapproved and unauthorized for use. (www.fda.gov.ph/attachments/article/96932/FDA%20Circular%202013-020%20-Reiteration%20of%20Registration%20of%20Human%20Cells,%20Tissues,%20and%20Cellular%20and%20Tissue-Based%20Products..pdf)

Despite the pronouncement of the FDA that it recognizes the use of stem cells in hematopoietic transplantation; corneal resurfacing with limbal stem cells; and skin regeneration with epidermal stem cells as acceptable or standard healthcare procedures, the public is hereby informed that as of today, 02 May 2014, not one stem cell or HCT Product that applied for registration has been registered by the FDA for compassionate or clinical trial use, or for general use.

All hospitals and health facilities are likewise warned that Republic Act No. 9711, otherwise known as the FDA Act of 2009, prohibits the manufacture, importation, exportation, sale, offering for sale, distribution, transfer, non-consumer use, promotion, advertising, or sponsorship of any health product that is unregistered. The use of HCT/P without the authorization or permission by the FDA is considered illegal in the country. This warning extends to all unlicensed practitioners from other countries and to tourists who visit the Philippines for leisure and medical needs.

All practitioners that offer stem cell therapy to their patients as clinical trial or for compassionate use are required to seek FDA approval or permission to ensure compliance to Good Clinical Practice, for the protection of the health and welfare of the patients. To report the use of unregistered health products or any adverse events following the use of HCT/Ps, kindly email us via report@fda.gov.ph The FDA welcomes all inquiries and comments, and may email via info@fda.gov.ph.

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