[FDA CIRCULAR NO. 2013-020, August 13, 2013]

REITERATION OF REGISTRATION OF HUMAN CELLS, TISSUES, AND CELLULAR AND TISSUE-BASED PRODUCTS

Pursuant to the Food and Drug Administration (FDA) Circular 2013-0017 issued last July 8, 2013, all human cells, tissues, and cellular and tissue-based products (HCT/P's) are required to be registered under the Philippine regulatory agency.

Accredited and licensed facilities dealing with HCT/P's must file their applications for registration at the FDA before August 31, 2013. Otherwise, these products shall be considered unapproved and unauthorized for use.

Currently, FDA recognizes the following widely accepted application of stem cell therapy: (1) hematopoietic stem cell transplantation; (2) corneal resurfacing with limbal stem cells; and (3) skin regeneration with epidermal stem cells.

Researches dealing with HCT/P's and the propagation of such other than their approved use are all considered clinical investigations and will have to comply with the existing FDA process and guidelines as directed in FDA Circular 2012-007 "Recognition of Ethical Review Board/ Committee (ERB/ERC) for the Purposes of the Conduct of Clinical Trials on Investigational Medicinal Products in the Philippines and for Other Purposes" and in the International Conference on Harmonisation (ICH) Guidelines for Good Clinical Practice.

Strict compliance is mandatory. FDA will pursue perpetrators who expose the Filipino public to the dangers of unapproved human cells and cellular-based products and will ensure that they are punished to the full extent of the law.

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