



12 August 2013

FDA ADVISORY
2013-023


**SUBJECT: ONLINE CONSUMER REPORTING ON POSSIBLE ADVERSE
EVENTS FROM HUMAN CELLS, TISSUES, AND CELLULAR
AND TISSUE-BASED PRODUCTS (STEM CELLS)**

In the interest of protecting public health and safety, the Food and Drug Administration (FDA) encourages all consumers to report suspected adverse events linked to human cells, tissues, and cellular and tissue-based products such as stem cell therapies acquired in any facility.

Those who have availed such products or therapies and have experienced any untoward event or side effect or treatment failure as well as those currently availing such are highly encouraged to submit reports through the FDA website at www.fda.gov.ph under eReport and ADR (Adverse Drug Reaction) Report section. E-mails may also be sent to report@fda.gov.ph.

All consumers are assured that all information given will be treated with utmost confidentiality. Contact details are needed in case of a need for follow-up and validation. However, anonymous reports will still be accepted.

This advisory is being issued as part of FDA's initiative to empower consumers in the surveillance and monitoring of drug safety.


KENNETH Y. HARTIGAN-GO, MD
Acting Director General

