



21 May 2014

**FDA CIRCULAR**  
No. 2014-013

**SUBJECT: Re-assessment of the Application of Stem Cell Therapy for Corneal Resurfacing with Limbal Stem Cells**

The Department of Health (DOH) issued Administrative Order No. 2013-0012 with the objectives of protecting the public and assuring the safety of patients by setting standards for health facilities that offer stem cell therapy. Likewise, the Food and Drug Administration (FDA), issued FDA Circular No. 2013-017 for the purpose of regulating stem cells, cellular or tissue products and ensure that these health products meet the standards of safety, efficacy, and quality.

The FDA recognizes the following applications of stem cell therapy as part of the standard health care treatment: (1) hematopoietic stem cell transplantation; (2) corneal resurfacing with limbal stem cells; and (3) skin regeneration with epidermal stem cells, as cited in FDA Circular No. 2013-020.

In the light of the commitment of FDA to fulfill its mandate, the Center for Drug Regulation and Research is in the process of re-assessing the application of stem cell therapy for corneal resurfacing with limbal stem cells. All stem cell practitioners, clinicians or researchers are hereby requested to report or share their experience, both successful and failure, on the use of corneal resurfacing with limbal stem cells.

All reports or information may be submitted to the FDA Public Assistance, Information, and Receiving (PAIR) Unit, Alabang, Muntinlupa City from Monday to Friday at 8:00 am to 5:00 pm or via e-mail: [rsobligacion@fda.gov.ph](mailto:rsobligacion@fda.gov.ph).

  
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