



## North America Legal and Regulatory Affairs

### Watchdog Update



#### Health Canada

Nothing to report

#### FDA

[A new report](#) by the Bipartisan Policy Center offers recommendations to accelerate the availability of safe and effective cellular therapies to Americans and improve U.S. competitiveness in the global marketplace.

<http://bipartisanpolicy.org/press-release/bipartisan-regrow-act-would-advance-regenerative-cell-therapy/>

#### **Public Hearing; Request for Comments – Draft Guidance’s Relating to the Regulation of Human Cells, Tissues or Cellular or Tissue-Based Products – Rescheduled**

There has been considerable interest in the Public Hearing, “Request for Comments – Draft Guidances Relating to the Regulation of Human Cells, Tissues or Cellular or Tissue-Based Products,” scheduled to take place on April 13, 2016. Due to this interest, and to give stakeholders additional time to provide comments to the agency, FDA intends to extend the comment period for the draft guidance documents, and has rescheduled the hearing for September 12 and 13, 2016, at Masur Auditorium on the campus of the National Institutes of Health.

<http://www.fda.gov/BiologicsBloodVaccines/NewsEvents/WorkshopsMeetingsConferences/ucm462125.htm>

There will also be a Public Workshop on September 8, 2016 on a similar topic “Scientific Evidence in the Development of Human Cells, Tissues, and Cellular and Tissue-Based Products Subject to Premarket Approval.”

<http://www.fda.gov/BiologicsBloodVaccines/NewsEvents/WorkshopsMeetingsConferences/ucm492499.htm>

#### **ORISE Fellowships: Cell and Gene Therapy**

Two contract fellowship positions are available in the Division of Cellular and Gene Therapies to perform laboratory research. Candidates with relevant experience at the BS, MS, MD or PhD level will be considered for this position.

<http://www.fda.gov/AboutFDA/CentersOffices/OfficeofMedicalProductsandTobacco/CBER/ucm492480.htm>

**The Safety Graphics Working Group produces guidelines for creating graphs that clearly communicate data without extensive captions or cluttering annotations**

Refer to link below for the examples.

<http://www.fda.gov/downloads/BiologicsBloodVaccines/ScienceResearch/UCM490777.pdf>