Volume 25, No. 1 February, 2018

ISCT International Society for Cellular Therapy

TELEGRAFT MEMBER NEWSLETTER

# North America Legal and Regulatory Affairs Watchdog Update

REGULATORY WATCHDOG

## Health Canada

### Health Canada Adopts International Conference on Harmonisation of Technical Requirements for the Registration of Pharmaceuticals for Human Use (ICH) Guidelines

More Information Here

### Notice: Consultation on the Use of a Foreign-sourced Reference Product as a Canadian Reference Product

More Information Here

## FDA

### FY2017 Report from the Director

Summary document of last year's major challenges and accomplishments at CBER.
More Information Here

Also available are summaries of 2017 Biological Device Application Approvals and 2017 Biological License Application Approvals.

### FDA Outlines Planned Guidance Documents for 2018

The FDA has issued the 2018 Guidance Agenda of planned guidance documents it will publish in 2018.
PDF Document Here

### Last chance to register to attend the Biologics Effectiveness and Safety (BEST)

ISCT International Society for Cellular Therapy
TELEGRAFT
MEMBER NEWSLETTER

## Sentinel Initiative Industry Day

To continue the work of the BEST Program after the initial one-year contracts expire, CBER seeks to identify vendors that have the capability and capacity to provide large sources of patient data, enhanced tools, and infrastructure to expand and enhance the current post-market surveillance system. The purpose of the Industry Day is for CBER to publicly communicate its requirements and provide an opportunity for the vendors to ask questions. Specifically, CBER will discuss an overview of its requirements and needs to build additional capacity for: 1) biologics post-market near real-time safety and effectiveness surveillance, 2) access to large sources of clinical patient-centered data particularly EHR, and 3) innovative approaches to conduct surveillance utilizing sophisticated query tools, machine learning, artificial intelligence, and natural language processing.

The Industry Day will start with presentations by CBER representatives. CBER representatives will then present and answer questions that have been submitted by participants in advance. Next, vendors will have the opportunity to ask any additional questions during the Question and Answer session.

Advanced registration is required to attend the meeting, and on-site registration will not be available.

**Date and Time of event:** Feburary 12, 2018, 1-5 PM

**Attendance registration period:** January 16, 2018 to February 9, 2018

**Registration period to submit questions:** January 16, 2018 to February 2, 2018

**Location:**
U.S. Food and Drug Administration
10903 New Hampshire Ave.
White Oak, Building 31 (Great Room)
Silver Spring, MD 20993

**Webcast Address**: https://collaboration.fda.gov/industryday2018/

**Backup Date:** February 16, 2018 in case of inclement weather

ISCT International Society for Cellular Therapy
TELEGRAFT
MEMBER NEWSLETTER

**Registration:**
To register for the Industry Day, please visit the following Website: https://www.eventbrite.com/e/industry-day-2018-tickets-41093453626.

More Information Here

### FDA Updates Formal Resolution Process

FDA releases version 2 of their SOP 8005: Formal Dispute Resolution Process.

PDF Document Here

### Updates to FDA eSubmitter Software

The FDA's eSubmitter software is part of an electronic submissions process that is available for voluntary use by sponsors, manufacturers, and importers to create a variety of submission types within the drug, blood, device, radiological health, tobacco, animal drug and animal food regulated industries.
More Information Here

### SOPP 8795: Posting and Announcement of Premarket Approval Application and Humanitarian Device Exemption Approvals and Denials

PDF Document Here

ISCT
International Society for Cellular Therapy
TELEGRAFT
MEMBER NEWSLETTER