Volume 28, No. 3 May, 2021

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MEMBER NEWSLETTER

North America Legal and Regulatory Affairs Watchdog Update

REGULATORY WATCHDOG

Bambi Grilley, RPh, CCRC, CCRP, CIP, RAC
Director, Early Product Development and Clinical Research
Center for Cell and Gene Therapy, Baylor College of Medicine
Houston, TX, USA

This newsletter includes links to issues and activities that might be of interest both on the Health Canada as well as the FDA websites. Please note that you can follow HC and FDA on Facebook and Twitter. You can also subscribe to receive emails from the FDA at https://www.fda.gov/about-fda/contact-fda/get-email-updates

The Watchdog Focus: Update on Regenerative Medicines

In November 2017, the FDA released a regenerative medicine policy framework intended to facilitate development of regenerative medicine therapies. At that time the FDA also indicated that they intended to exercise enforcement discretion for certain regenerative medicines in order to give manufacturers and the agency time to determine what requirements would apply. The original enforcement discretion period (EDP) was to expire in November 2020 but was later extended through May 2021. That EDP has now expired.

In anticipation of the expiration of the EDP, the FDA released a guidance document entitled Regulatory Considerations for Human Cells, Tissues, and Cellular and Tissue-Based Products: Minimal Manipulation and Homologous Use**.** Additionally, in early June 2021, Peter Marks, MD, authored an FDA Voices column entitled Innovative Regenerative Medicine Therapies – Patient Safety Comes First reiterating not only the end of the EDP but also the current status of enforcement actions as well as future plans. And finally, the FDA released a document entitled Important Patient and Consumer Information About Regenerative Medicine Therapies intended to provide information directly to consumers.

Regenerative medicines and their regulation are of direct interest to the ISCT Membership. Therefore, under the guidance of the ISCT Presidential Task Force (PTF) on the Use of Unproven and/or Unethical Cell and Gene Therapy, ISCT organized and hosted a public facing 90-minute webinar on June 17th. Laertis Ikonomou chaired and moderated the session. Other participants included Leigh Turner as a subject-matter expert, Wilson Bryan from the FDA, Michael Lehmicke from ARM, and Virginia Lyons who is a

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Vermont State Senator who presented a case study based on Vermont legislative actions in this field. The webinar recording will be available on the ISCT website and will be accessible for both members and non-members.

Health Canada

As part of the Health and Biosciences Sector Regulatory Review Roadmap, Health Canada is proposing to modernize the regulatory framework for clinical trials related to human drugs, medical devices, non-prescription drugs, and natural health products. In late May, Health Canada launched a consultation paper (Clinical Trials Modernization: Consultation Paper) inclusive of a questionnaire intended to obtain feedback from interested stakeholders to validate and inform further policy development. Please note that it will be closed to new input on July 4, 2021.

What's new in biologics, radiopharmaceuticals and genetic therapies can be found at:
https://www.canada.ca/en/health-canada/services/drugs-health-products/biologics-radio-pharmaceuticals-genetic-therapies/what-new-biologics-radiopharmaceuticals-genetic-therapies-health-canada.html

Information for health product manufacturers and distributors in relation to COVID-19:
https://www.canada.ca/en/health-canada/services/drugs-health-products/covid19-industry.html

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FDA

What's new for Biologics including Approval and Determination Letters:
https://www.fda.gov/vaccines-blood-biologics/news-events-biologics/whats-new-biologics

COVID-19 Information and Resources:
https://www.fda.gov/emergency-preparedness-and-response/counterterrorism-and-emerging-threats/coronavirus-disease-2019-covid-19

Guidance Documents:
https://www.fda.gov/regulatory-information/search-fda-guidance-documents

Upcoming Conferences:
https://www.fda.gov/vaccines-blood-biologics/news-events-biologics

Updated Approvals and Listings:

Complete List of Licensed Products and Establishments

Complete List of Substantially Equivalent 510(k) Device Applications

Complete List of Currently Approved Premarket Approvals (PMAs)

Complete List of Currently Approved NDA and ANDA Application Submissions

2021 Biological Approvals

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Keywords:

- ISCT Regulatory Affairs
- *Health Canada*
- *Food and Drug Administration*
- ISCT North American Regional LRA Committee
- COVID-19
- Regenerative Medicine
- Enforcement Discretion Period
- Clinical Trials Modernization: Consultation Paper

Brief Summary:

Approvals and consultation updates from Heath Canada and the Food and Drug Administration for the period April 2021 to May 2021.