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North America Legal and Regulatory Affairs Watchdog Update

REGULATORY WATCHDOG

Health Canada

"Certificate of Supplementary Protection Regulations" Guidance Document Publication

As of September 21, 2017, the Office of Patented Medicines and Liaison, within the Office of Submissions and Intellectual Property, Therapeutic Products Directorate, will administer sections 104 to 134 of the Patent Act and the Certificate of Supplementary Protection Regulations. The purpose of this Guidance Document is to outline the roles and responsibilities of applicants and the Therapeutic Products Directorate with respect to certificates of supplementary protection and applications.
Link Here

eCTD Pilot for Clinical Trial Regulatory Activities – Extension

Health Canada is announcing an extension to the eCTD pilot for clinical trial regulatory activities in electronic common technical document (eCTD) format. The objective of this extension is to provide further opportunity for sponsors to participate in the pilot project, thus enabling more comprehensive experience using eCTD format for clinical trial regulatory activities, for both Health Canada as well as external stakeholders.
Link Here

FDA

FDA approves CAR-T cell therapy to treat adults with certain types of large B-cell lymphoma

The FDA has approved the second gene therapy product, Yescarta manufactured by Kite Pharma, Inc. Yescarta is intended to treat adult patients with certain types of large B-cell lymphoma who have not responded to or who have relapsed after at least two other kinds of treatment. Yescarta carries a boxed warning for Cytokine Release Syndrome. The FDA is requiring long-term follow-up of patients treated with Yescarta.
Link here.

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FDA simplifies Institutional Review Board review requirements for physicians seeking individual patient expanded access

The Food and Drug Administration has updated Form FDA 3926 and its instructions, as well as other related guidance documents regarding the institutional review board (IRB) review requirements for individual patient expanded access treatment use of investigational drugs. These changes will allow for a waiver of the requirement for review and approval at a convened IRB meeting if the physician obtains concurrence by the IRB chairperson (or designated IRB member) before the treatment use begins.

Form FDA 3926 and instructions
Please Note: you may need to open the page in Internet Explorer. If you see a "please wait" message, right click (or control-click on Mac) and select the "save as" option to download the document as a PDF to your computer before opening it

Additionally, the Expanded Access to Investigational Drugs for Treatment Use – Questions and Answers Guidance has been updated to address how the Agency reviews adverse event data in the expanded access context and to reference the 21st Century Cures Act requirement that expanded access policies be publicly posted.

Guidance Documents:

Individual Patient Expanded Access Applications: Form FDA 3926 Guidance

Expanded Access to Investigational Drugs for Treatment Use – Questions and Answers Guidance

Waiver of IRB Requirements for Drug and Biological Product Studies Information Sheet

Complete List of Currently Approved NDA and ANDA Application Submissions (PDF - 21KB)

Currently Approved CBER NDAs/ANDAs – 43 as of Oct 12, 2017.
Link to PDF (21 KB)

Complete List of Licensed Products and Establishments

For Vaccines, Blood and Biologics. Includes product approval dates – current as of September 30, 2017.
Link Here

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Complete List of Substantially Equivalent 510(k) Device Applications (PDF - 319KB)

Updated list of Currently Cleared CBER 510(k) Clearances - as of Oct 04, 2017.
Link to PDF (319KB)

Complete List of Currently Approved Premarket Approvals (PMAs) (PDF - 29KB)

Updated list of Currently Approved CBER Device Premarket Applications (PMAs) - as of Oct 04, 2017.
Link to PDF (29KB)

New FDA Guidance on Using Animal Studies to Evaluate Organ Preservation Devices

The shortage of organs available for transplants has propelled a new wave of innovation in organ preservation technologies. These technologies are evaluated in animal models to demonstrate that they are suitable for clinical experience. The intent of this draft guidance is to provide recommendations regarding best practices for utilizing animal studies for the evaluation of organ preservation devices.

Link to PDF