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International Society ISCT Cell & Gene Therapy

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MEMBER NEWSLETTER

North America Legal and Regulatory Affairs Watchdog Update

REGULATORY WATCHDOG

Health Canada

Consultation for Mandatory Requirements of using Electronic Common Technical Document (eCTD) Format when Submitting Master Files (MFs)

Health Canada is considering January 1st, 2019 as the date for mandatory filing of all New Master Files in eCTD format. Feedback for this proposal is being solicited.

Open on May 7, 2018 and will close to new input on August 10, 2018.

Read this and add your vote here

Notice: Publication of Update to the Guidance Document: Patented Medicines (Notice of Compliance) Regulations

Health Canada is pleased to announce the publication of an update to the Guidance Document: Patented Medicines (Notice of Compliance) Regulations.

All drug submissions seeking a notice of compliance, including those submitted to the TPD, the Biologics and Genetic Therapies Directorate, the Natural and Non-prescription Health Products Directorate and the Veterinary Drugs Directorate, are assessed to determine if the Patented Medicines (Notice of Compliance) Regulations apply.

Amendments to the Patented Medicines (Notice of Compliance) Regulations came into force on September 21, 2017. The Guidance Document has been updated in accordance with the amendments.

FDA

FDA Releases Updated Approvals Lists through to 5/31/2018:

2018 Biological License Application Approvals
2018 Biological License Application Supplement Noteworthy Approvals
2018 Biological Device Application Approvals

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Complete List of Currently Approved NDA and ANDA Application Submissions (PDF - 84KB)
Complete List of Currently Approved Premarket Approvals (PMAs) (PDF - 82KB)
Complete List of Substantially Equivalent 510(k) Device Applications (PDF - 1.7MB)
Complete List of Licensed Products and Establishments
Exceptions and Alternative Procedures Approved Under 21 CFR 640.120 (PDF - 100KB)

FDA Publishes Center for Biologics Evaluation and Research 2018 Center for Biologics Evaluation and Research Science Symposium Agenda - June 25-26

For a detailed agenda, click here

As of October 1, 2018, CBER will Send Regulatory Communications EXCLUSIVELY Via Secure Email

In an effort to streamline and facilitate communication with sponsors and protect proprietary and company confidential information, CBER will increase the use of secure email for regulatory communications. Therefore, CBER's outgoing email communications that contain regulatory information will occur with recipients who only have a secure email account with FDA. Communication that is not regulatory in nature, such as logistics on how to get to the White Oak Campus, or general information that does not relate to regulatory information may be sent by unsecure email.

More details here

Summary Bases for Regulatory Action

May 25, 2018 - Procleix WNV Assay (PDF - 258KB)

May 25, 2018 - NGI Ultraqual Multiplex PCR Assay for HCV, HIV-1,HIV-2, and HBV (PDF - 278KB)