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North America Legal and Regulatory Affairs

Watchdog Update

REGULATORY WATCHDOG

Health Canada

New Website

Health Canada has redesigned their website. Note that the website includes many other institutions within the Federal government of Canada. Health-specific information can be found here

https://www.canada.ca/en/health-canada.html

GMP can be found here

https://www.canada.ca/en/health-canada/services/drugs-health-products/compliance-enforcement/good-manufacturing-practices.html

What's new for Compliance and Enforcement can be found here

https://www.canada.ca/en/health-canada/services/drugs-health-products/compliance-enforcement/what-new.html

Guidance Documents related to Enforcement Activities can be found here

https://www.canada.ca/en/health-canada/services/drugs-health-products/compliance-enforcement/activities.html

Guidance for Master Files

"The Therapeutic Products Directorate and the Biologics and Genetic Therapies Directorate jointly developed the guidance document to provide direction on the procedures that allow MF Holders to file quality information that is considered Confidential Business Information directly with Health Canada."

http://www.hc-sc.gc.ca/dhp-mps/prodpharma/activit/announce-annonce/mf-notice-avis-fm-eng.php

FDA

ODAC Recommendation of Approval for BLA 125646 Tisagenlecleucel from Novartis Pharmaceuticals Corporation

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The Oncologic Drugs Advisory Committee has unanimously voted to recommend approval of Tisagenlecleucel, Novartis' CAR-T product. See article by Bruce Levine in the Telegraft, Vol 24, Issue 3 for more information.

FDA Public Information is available here:

Draft Agenda

https://www.fda.gov/downloads/AdvisoryCommittees/CommitteesMeetingMaterials/Drugs/OncologicDrugsAdvisoryCommittee/UCM566160.pdf

Draft Questions

https://www.fda.gov/downloads/AdvisoryCommittees/CommitteesMeetingMaterials/Drugs/OncologicDrugsAdvisoryCommittee/UCM566161.pdf

ODAC Roster

https://www.fda.gov/downloads/AdvisoryCommittees/CommitteesMeetingMaterials/Drugs/OncologicDrugsAdvisoryCommittee/UCM566163.pdf

Briefing Information on the Product

https://www.fda.gov/AdvisoryCommittees/CommitteesMeetingMaterials/Drugs/OncologicDrugsAdvisoryCommittee/ucm566165.htm

What's New for Biologics

FDA Listing of all biologics-related additions to the website

https://www.fda.gov/BiologicsBloodVaccines/NewsEvents/WhatsNewforBiologics/default.htm

DRAFT Guidance: Use of Electronic Records and Electronic Signatures in Clinical Investigations Under 21 CFR Part 11 – Questions and Answers

Detailed document provided guidance about electronic systems in a Q&A style. Provides information about validation, use of electronic records as source documents and many other useful topics.

https://www.fda.gov/ucm/groups/fdagov-public/@fdagov-drugs-gen/documents/document/ucm563785.pdf?source=govdelivery&utm_medium=email&utm_source=govdelivery

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Guidance: Form FDA 3674 - Certifications To Accompany Drug, Biological Product, and Device Applications/Submissions

Guidance on how to comply with Title VIII – the form is used to link the information that the NIH has on Clinical Trials with the information that the FDA has on that product.

https://www.fda.gov/RegulatoryInformation/Guidances/ucm125335.htm?source=govdelivery&utm_medium=email&utm_source=govdeliveryd

Updated Process for Qualification of Drug Development Tools Under New FD&C Act Section 507

Due to the 21st Century Cures Act, there is a section that formally establishes an updated, multi-stage process for Drug Development Tool qualification.

https://www.fda.gov/Drugs/DevelopmentApprovalProcess/DrugDevelopmentToolsQualificationProgram/ucm561587.htm?source=govdelivery&utm_medium=email&utm_source=govdelivery

Guidance Documents CBER is Planning to Publish During Calendar Year 2017

CATEGORY – Tissues and Advanced Therapies:

• Deviation Reporting for Human Cells, Tissues, and Cellular and Tissue-Based Products Regulated Solely Under Section 361 of the Public Health Service Act and 21 CFR Part 1271; Final Guidance for Industry

• Devices Used In The Recovery, Isolation, or Delivery of Regenerative Medicine Advanced Therapies; Draft Guidance for Industry

https://www.fda.gov/downloads/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation/Guidances/UCM431409.pdf