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North America Legal and Regulatory Affairs Watchdog Update

REGULATORY WATCHDOG

FDA

FDA announces a comprehensive policy framework for the development and oversight of regenerative medicine products

***** Closes loophole on often-misused "same-day" procedures*****

The framework – outlined in a suite of four guidance documents – builds upon the FDA's existing risk-based regulatory approach to more clearly describe what products are regulated as drugs, devices, and/or biological products. This includes clarification on "Same Surgical Procedure Exception under 21 CFR 1271.15(b): Questions and Answers Regarding the Scope of the Exception") – stating that *fat stem cells are not going to be exempt from oversight as a drug even in the context of a same surgical procedure.*

https://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/UCM585345.htm

Final Guidance Document 1

Final Guidance Document 2

Draft Guidance Document 1

Draft Guidance Document 2

FDA Issues Warning against Self Administration of Gene Therapies

Because the world is upside down… The FDA has actually had to issue an official warning against Do-It-Yourself Gene Therapies…

https://www.fda.gov/BiologicsBloodVaccines/CellularGeneTherapyProducts/ucm586343.htm

You can find some background reading here, here and here.

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FDA approves first biosimilar for the treatment of certain breast and stomach cancers

The U.S. Food and Drug Administration today approved Ogivri (trastuzumab-dkst) as a biosimilar to Herceptin (trastuzumab) for the treatment of patients with breast or metastatic stomach cancer (gastric or gastroesophageal junction adenocarcinoma) whose tumors overexpress the HER2 gene (HER2+). Ogivri is the first biosimilar approved in the U.S. for the treatment of breast cancer or stomach cancer and the second biosimilar approved in the U.S. for the treatment of cancer.

https://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm587378.htm

FDA releases draft document entitled "Expedited Programs for Regenerative Medicine Therapies for Serious Conditions; Draft Guidance for Industry."

The draft guidance, when finalized, will provide stakeholders engaged in the development of regenerative medicine therapies with FDA's current thinking on the expedited development and review of these products.

https://www.fda.gov/downloads/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation/Guidances/CellularandGeneTherapy/UCM585414.pdf

Updated Instructions for using Electronic Human Cell and Tissue Establishment Registration System (eHCTERS)

Can be found here.

Health Canada

Health Canada Releases Guidance Document: Quality (Chemistry and Manufacturing) Guidance: New Drug Submissions (NDSs) and Abbreviated New Drug Submissions (ANDSs)

Comments and suggestions received from the consultation between August 31, 2016 and October 7, 2016 on the draft version of the guidance were reviewed and considered in the finalization of this document. The results of this consultation are available by email on request to: bps_enquiries_enquetes_bsp@hc-sc.gc.ca

https://www.canada.ca/en/health-canada/services/drugs-health-products/drug-products/announcements/notice-quality-chemistry-manufacturing-guidance-new-drug-submissions-ndss-abbreviated-new-drug-submissions.html

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Quality (Chemistry and Manufacturing) Guidance: New Drug Submissions (NDSs) and Abbreviated New Drug Submissions (ANDSs)

ADDENDUM - Quality (Chemistry and Manufacturing) Guidance: Questions and Answers

Glossary of Quality Terms

Certified Product Information Document Guidance Document

CPID-CE Template

Health Canada Announces Updated Register of Certificates of Supplementary Protection and Applications

Human and Veterinary use – for more information see here.

Revised Validation rules for regulatory transactions submitted to Health Canada in the electronic Common Technical Document (eCTD) format

Health Canada is pleased to announce the revised validation rules for regulatory transactions in the electronic Common Technical Document (eCTD) format.

https://www.canada.ca/en/health-canada/services/drugs-health-products/drug-products/applications-submissions/guidance-documents/ectd/notice-validation-rules-regulatory-transactions-submitted-health-canada-electronic-common-technical-document-format-2016-12-1.html