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North America Legal and Regulatory Affairs Watchdog Update

REGULATORY WATCHDOG

Health Canada

Conditional Approval Pathway

Health Canada released the newest version of the Notice of Compliance with Conditions (NOC/c) for the conditional approval pathway in Canada. This is an administrative update only.

http://www.hc-sc.gc.ca/dhp-mps/alt_formats/pdf/prodpharma/applic-demande/guide-ld/compli-conform/noccg_accd-eng.pdf

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

FDA

Recommendations for Microbial Vectors Used for Gene Therapy; Guidance for Industry

IND sponsors are being given recommendations for IND submissions for microbial vectors used for gene therapy (MVGTs) in early-phase clinical trials. This guidance focuses on the CMC information that should be submitted in an IND for MVGTs and provides an overview of preclinical and clinical considerations. This guidance also finalizes the draft guidance from October 2015 and is a supplement to the guidance entitled, “Guidance for FDA Reviewers and Sponsors: Content and Review of Chemistry, Manufacturing, and Control (CMC) Information for Human Gene Therapy Investigational New Drug Applications (INDs),” dated April 2008.

http://www.fda.gov/downloads/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation/Guidances/CellularandGeneTherapy/UCM466625.pdf

Posted: 9/15/2016

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Biological Product Deviation Reporting and HCT/P Deviation Reporting – Non-Blood Products

Changes to specific codes occurred on 10/01/2016 – refer to this new code list prior to completing a biological product deviation

http://www.fda.gov/BiologicsBloodVaccines/SafetyAvailability/ReportaProblem/BiologicalProductDeviations/ucm129739.htm?source=govdelivery&utm_medium=email&utm_source=govdelivery

New Guidance Documents

- Use of Nucleic Acid Tests to Reduce the Risk of Transmission of West Nile Virus from Living Donors of Human Cells, Tissues, and Cellular and Tissue-Based Products (HCT/Ps) **Posted 9/8/2016**

  http://www.fda.gov/ucm/groups/fdagov-public/@fdagov-bio-gen/documents/document/ucm372084.pdf

- Revised Recommendations for Reducing the Risk of Zika Virus Transmission by Blood and Blood Components. For immediate implementation. **Posted 8/26/2016**

  http://www.fda.gov/downloads/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation/Guidances/Blood/UCM518213.pdf

- Use of Nucleic Acid Tests to Reduce the Risk of Transmission of Hepatitis B Virus from Donors of Human Cells, Tissues, and Cellular and Tissue-Based Products. **Posted 8/15/2016**

  http://www.fda.gov/ucm/groups/fdagov-public/@fdagov-bio-gen/documents/document/ucm516650.pdf

- Determining Donor Eligibility for Autologous Donors of Blood and Blood Components Intended Solely for Autologous Use – Compliance Policy. **Posted 8/2/2016**

  http://www.fda.gov/ucm/groups/fdagov-public/@fdagov-bio-gen/documents/document/ucm514072.pdf