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North America Legal and Regulatory Affairs Watchdog Update

REGULATORY WATCHDOG

Health Canada

Nothing to Report

FDA

510(k) approvals

- **Origen Transfer Bag approved by FDA:**
  http://www.fda.gov/BiologicsBloodVaccines/BloodBloodProducts/ApprovedProducts/SubstantiallyEquivalent510kDeviceInformation/ucm526215.htm **Posted 10/21/2016**

- **Thermo Fisher CW3 Cell Washer:**
  Centrifuge, cell-washing, automated for immuno- hematology
  http://www.fda.gov/BiologicsBloodVaccines/BloodBloodProducts/ApprovedProducts/SubstantiallyEquivalent510kDeviceInformation/ucm525387.htm **Posted 10/07/2016**

New Guidance Documents

- Revised Recommendations for Determining Eligibility of Donors of Human Cells, Tissues, and Cellular and Tissue-Based Products Who Have Received Human-Derived Clotting Factor Concentrates; Guidance for Industry (PDF - 55KB) **Posted: 11/17/2016**

- Amendment to Guidance for Industry: Use of Serological Tests to Reduce the Risk of Transmission of Trypanosoma cruzi Infection in Whole Blood and Blood Components Intended for Transfusion; Draft Guidance for Industry (PDF - 117KB)
  Posted: 11/9/2016

- Collection of Race and Ethnicity Data in Clinical Trials.
  http://www.fda.gov/downloads/RegulatoryInformation/Guidances/UCM126396.pdf?source=govdelivery&utm_medium=email&utm_source=govdelivery **Posted 10/26/2016**

- Software a Medical Device (SaMD): Clinical Evaluation.
  http://www.fda.gov/ucm/groups/fdagov-public/@fdagov-meddev-gen/documents/document/ucm524904.pdf **Posted 10/14/2016**

- ANDA Submissions-Prior approval supplements under GDUFA.
  http://www.fda.gov/downloads/drugs/guidancecomplianceregulatoryinformation/guidances/ucm400630.pdf **Posted 10/14/2016**

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- 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) http://www.fda.gov/ucm/groups/fdagov-public/@fdagov-bio-gen/documents/document/ucm372084.pdf **Posted 9/8/2016**

- Revised Recommendations for Reducing the Risk of Zika Virus Transmission by Blood and Blood Components. For immediate implementation. http://www.fda.gov/downloads/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation/Guidances/Blood/UCM518213.pdf **Posted 8/26/2016**

- 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. http://www.fda.gov/ucm/groups/fdagov-public/@fdagov-bio-gen/documents/document/ucm516650.pdf **Posted 8/15/2016**

- Determining Donor Eligibility for Autologous Donors of Blood and Blood Components Intended Solely for Autologous Use – Compliance Policy. http://www.fda.gov/ucm/groups/fdagov-public/@fdagov-bio-gen/documents/document/ucm514072.pdf **Posted 8/2/2016**

- Transcript for the Public Workshop held on Sept 8th is now publicly available.

    - http://www.fda.gov/downloads/BiologicsBloodVaccines/NewsEvents/WorkshopsMeetingsConferences/UCM530238.pdf?source=govdelivery&utm_medium=email&utm_source=govdelivery

- Transcripts for the Public Hearing held Sept 12-13th are now publicly available.

    - The 12th: http://www.fda.gov/downloads/BiologicsBloodVaccines/NewsEvents/WorkshopsMeetingsConferences/UCM532350.pdf?source=govdelivery&utm_medium=email&utm_source=govdelivery

    - The 13th: http://www.fda.gov/downloads/BiologicsBloodVaccines/NewsEvents/WorkshopsMeetingsConferences/UCM532633.pdf?source=govdelivery&utm_medium=email&utm_source=govdelivery