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Health Canada

Health Canada cracks down on unproven “Stem Cell Therapies”

Following last month’s Position Paper and recent FDA action on unproven therapies, Health Canada sent letters to 36 clinics across the country requesting them to stop doing unlicensed stem cell procedures until they have received regulatory approval.


They also clarified that Platelet-Rich-Plasma injections are classified as drugs


Regulatory Decision Summaries since last Watchdog...


Updated Notices

Health Canada has issued the following updated notices:

- [Updated Register of Certificates of Supplementary Protection and Applications](https://www.canada.ca/en/health-canada/services/health-canada-watchdog/2019-07-12.html) [2019-07-12]
• Release of the revised Post-Notice of Compliance (NOC) Changes - Quality Guidance [2019-07-31]

FDA

CBER issues Biological Product and HCT/P Deviation Reports

Annual Summary for Fiscal Year 2018

New Technique - functionally-relevant morphological profiling (FRMP) - allows scientists to stratify immunosuppressive MSC populations

The new technique, called functionally-relevant morphological profiling (FRMP), enabled the FDA scientists to predict how much a population of stimulated MSCs would be able to suppress key types of immune cells. This prediction is based on the appearance of distinct changes in cell morphology that happen after MSCs are exposed to interferon-gamma (IFN-gamma).

Cell analysis technique identifies subpopulations of stimulated mesenchymal stromal cells with in vitro immunosuppressive activity

Current Summary Bases for Regulatory Action

• July 3, 2019 Summary Basis for Regulatory Action - XEMBIFY
• July 8, 2019 Summary Basis for Regulatory Action - Alinity s Anti-HCV
• July 18, 2019 Summary Basis for Regulatory Action - Alinity s Anti-HBc

Current Submissions and Applications

The following are the current up-to-date lists of:

• 2019 Biological Device Application Approvals
• Clinical Investigator Status (Biologics)
• Complete List of Currently Approved NDA and ANDA Application Submissions
• Complete List of Licensed Products and Establishments
• Complete List of Currently Approved Premarket Applications (PMAs)
• Complete List of Substantially Equivalent 510(k) Device Applications
• Complete List of Licensed Products and Establishments
• 2019 Biological Device Application Approvals
• Regenerative Medicine Advanced Therapy Designation
Cumulative CBER Regenerative Medicine Advanced Therapy (RMAT) Designation Requests Received by Fiscal Year

User Fee Billable Biologic Products and Potencies Approved Under Section 351 of PHS Act

Regulatory Harmonization and Convergence

Clinical Investigator Inspection List

Updated Approvals
The following Summary Approvals & Recalls have been processed by the FDA since the last Watchdog:

- July 2, 2019 Approval Letter - FluLaval
- July 2, 2019 Approval Letter - Flucelvax
- July 2, 2019 Approval Letter - Fluad
- July 2, 2019 Approval Letter - Fluzone Quadrivalent and Fluzone High-Dose
- July 2, 2019 Approval Letter - Afluria
- July 2, 2019 Approval Letter - Flublok
- July 3, 2019 Approval Letter - XEMBIFY
- July 8, 2019 Approval Letter - ORTHO Sera
- July 8, 2019 Approval Letter - MTS Anti-IgG Card
- July 9, 2019 Approval Letter - Alinity s Anti-HCV
- July 12, 2019 Approval Letter - ALPROLIX
- July 15, 2019 Approval Letter - Flumist