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FDA

Federal court issues US Stem Cell with a permanent injunction

This is the first of many “questionable” stem cell clinics to be cracked down on legally by
the FDA. Federal court issued a permanent injunction to ‘US Stem Cell’ clinics to stop
marketing adipose-derived stem cell treatments

Federal court issues decision holding that US Stem Cell clinics and owner adulterated
and misbranded stem cell products in violation of the law

FDA Obtains Permanent Injunction Against US Stem Cell

CBER issues FY2018 Summary Report

Director, Peter Marks issues exciting summary of a year in review.

FY 2018 Report from the Director

Commissioner of Food and Drugs - Remarks to the 2019 FDLI Annual Conference

Acting Commissioner Norman “Ned” Sharpless, MD describes his vision for FDA,
including the role CBER plays on behalf of sponsors and consumers alike

See Full Speech Here
FDA issues DRAFT Guidance - Submitting Documents Utilizing Real-World Data and Real-World Evidence to FDA for Drugs and Biologics


Workshops and Guidelines
The following workshops and guidelines have been issued since the last Watchdog:

- Recommendations for Reducing the Risk of Transfusion-Transmitted Babesiosis; Guidance for Industry
- Perspectives on In Vitro Diagnostic Devices Regulated by the Office of Blood Research and Review; Public Workshop
- Exceptions and Alternative Procedures Approved Under 21 CFR 640
- Standards Development for Regenerative Medicine Therapies
- Resources Related to Regenerative Medicine Therapies
- Framework for the Regulation of Regenerative Medicine Products

Current Summary Bases for Regulatory Action

- Summary Basis for Regulatory Action - Blood Grouping Reagent BL 1255686-88
- Summary Basis for Regulatory Action Blood Grouping Reagent BL 125684/0
- Summary Basis for Regulatory Action - Blood Grouping Reagent - BL125567/3-73/3
- May 1, 2019 Summary Basis for Regulatory Action - DENGVAXIA

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

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

- March 29, 2019 Approval Letter - Octaplas
- April 15, 2019 Approval Letter - Flublok Quadrivalent
- April 18, 2019 Approval Letter - Blood Grouping Reagents, Anti-Fya, Anti-Jka, Anti-Jkb, Anti-S, Anti-s, Anti-K, Anti-P1
- April 18, 2019 Approval Letter - Blood Grouping Reagent, Anti-k (Monoclonal) (IgG) (For Further Manufacturing Use)
- April 18, 2019 Approval Letter - Blood Grouping Reagent, Anti-k (Monoclonal)
- April 18, 2019 Approval Letter - Blood Grouping Reagent, Anti-Cw (Monoclonal)
- April 18, 2019 Approval Letter - Blood Grouping Reagent, Anti-Fyb (Monoclonal)
- April 18, 2019 Approval Letter - FLUAD
- April 24, 2019 Approval Letter - Anti-Human Globulin (Formula for Automated Testing)
- April 25, 2019 Approval Letter - Boostrix
- May 1, 2019 Approval Letter - DENGVAXIA
- May 22, 2019 Approval Letter - Intersol Solution/Platelet Additive Solution 3
- May 24, 2019 Approval Letter - ActHIB
- May 24, 2019 Approval Letter - ZOLGENSMA
Health Canada

Health Canada issues a Position Paper on Autologous Cell Therapy Products

This paper provides background on autologous cell therapy products, as well as the Canadian and International regulatory context. It addresses specific policy issues related to the regulation of autologous cell therapies, including: 1) The risks posed by autologous cell therapies; 2) The applicable federal product safety rules and how they can be complied with; and 3) The steps that are being taken by the regulator to assist in the development of these therapies.


Regulatory Decision Summaries since last Watchdog...

- Summary Basis of Decision (SBD) for Crystvita [2019-05-24]
- Summary Basis of Decision (SBD) for Unituxin [2019-05-24]

Updated Notices

Health Canada has issued the following updated notices:

- Updated Register of Certificates of Supplementary Protection and Applications [2019-05-21]