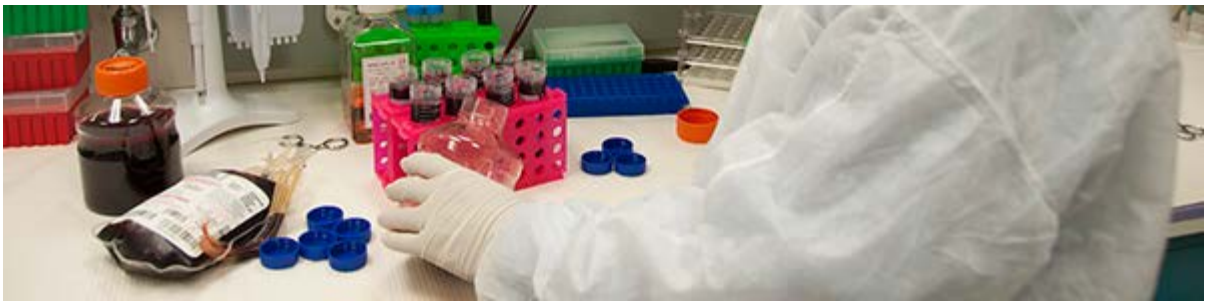
U.S. FOOD & DRUG ADMINISTRATION

Medical Countermeasures Initiative Update

December 12, 2018

Note: Due to technical issues, some subscribers may not have received our November 28, 2018 MCMi email update. A copy is available online if you'd like to catch up: FDA's role: How FDA helps make medical countermeasures available during public health emergencies (PDF, 106 KB).



Innovating to protect the U.S. blood supply from pathogens

Draft guidance recommends additional measures to help control the risk of bacterial contamination of room temperature stored platelets intended for transfusion

FDA promotes the development and adoption of innovations that can ensure the continued safety of the U.S. blood supply

"Blood and blood components are some of the most critical medical products American patients depend upon. The U.S. has one of the world's safest blood supplies. But there remains risk, albeit uncommon, of contamination with infectious diseases, particularly with blood products that are stored at room temperature," said FDA Commissioner Scott Gottlieb, M.D.

"While we've made great strides in reducing the risk of blood contamination through donor screening and laboratory testing, we continue to support innovations and blood product alternatives that can better keep pace with emerging pathogens and reduce some of the logistical challenges and costs associated with ensuring the safety of blood products. In addition to microbial testing of blood, the application of safe and effective pathogen reduction technologies is an important part of the agency's blood safety efforts. Today's updated guidance further advances the potential for technology to be used to reduce the risk of contamination of the blood supply from known and emerging pathogens, and to measurably increase the availability of safe blood products while ultimately reducing cost overall."

Read more, in the December 4, 2018 FDA in Brief

Related links:

- Draft guidance - Bacterial Risk Control Strategies for Blood Collection Establishments and Transfusion Services to Enhance the Safety and Availability of Platelets for Transfusion (PDF, 343

KB) - Comment by **February 4, 2019**.

- Blood & Blood Products

FDA research update

Universal influenza vaccine candidate reduces transmission of virus best when given nasally in mice

FDA scientists have demonstrated the ability of a universal influenza vaccine candidate to reduce the transmission of influenza virus in mice, even though this vaccine does not completely block infection by the virus. These findings are important because they suggest the vaccine could both protect recipients and reduce transmission -- even when virus strains emerge with differing envelope proteins, a type of change, that when it occurs, can make existing influenza vaccines less effective.

Also see, in *Vaccine*: Reduction of influenza virus transmission from mice immunized against conserved viral antigens is influenced by route of immunization and choice of vaccine antigen

---

Events

- **New! January 5, 2019:** Innovations in Regulatory Science Summit (San Francisco, CA), hosted by the UCSF-Stanford Center of Excellence in Regulatory Science and Innovation (CERSI) - A gathering of leaders in the academia, industry, and regulatory sectors to discuss the role of regulatory science in medical product development. Keynotes will be given by Dr. Janet Woodcock and Dr. Peter Marks, from FDA. Advance registration required. *(fee)*
- **New! January 9, 2019:** Webinar for industry - CLIA Waiver Applications Draft Guidances, 1:00 - 2:30 p.m. ET - To discuss and answer questions about two draft guidance documents intended to help manufacturers of *in vitro* diagnostic (IVD) devices apply for and receive Clinical Laboratory Improvement Amendments (CLIA) waivers.
- **New! January 24, 2019:** NICBR Winter Symposium: Novel Therapeutics (Frederick, MD), hosted by the National Interagency Confederation for Biological Research - This symposium will feature talks from the Frederick research community on novel therapeutics for infectious diseases, cancer and autoimmunity. Please register in advance.
- **New! January 30-31, 2019:** Presidential Advisory Council on Combating Antibiotic-Resistant Bacteria public meeting (Washington, DC and webcast) - Register by **January 23, 2019**. This meeting will be dedicated to hosting stakeholders to explore priority areas that have emerged since the original National Action Plan for Combatting Antibiotic-Resistant Bacteria (PDF, 519 KB) was launched in 2015. *Note: The Advisory Council is also seeking information from the general public and stakeholders related to efforts and strategies to combat antibiotic resistance. Comment on the RFI using this online form by **January 7, 2019**.*

Information for industry

Devices

FDA published two draft guidance documents that aim to help manufacturers of IVD devices apply for and receive CLIA waivers: Select Updates for Recommendations for CLIA Waiver Applications for Manufacturers of IVD Devices (PDF, 458 KB , Federal Register notice) and Recommendations for Dual 510(k) and CLIA Waiver by Application Studies (PDF, 206 KB, Federal Register notice). Both draft guidances were originally published on November 29, 2017 and have been updated based on feedback received during the open comment period. Both guidances are being re-issued as draft guidances to allow additional comments. Comment by **February 27, 2019** (see Federal Register notice links for instructions). CDRH will host a webinar for industry on these draft guidances on **January 9, 2019** . *(November 28, 2018)*

- FDA published the De Novo Classification Proposed Rule, which if finalized, would establish procedures and criteria for the De Novo classification process and become part of the Medical Device Classification Procedures (21 CFR Part 860). The De Novo pathway is used for the review of novel, low to moderate risk devices for which general controls, or general and special controls, provide a reasonable assurance of safety and effectiveness, but for which there is no existing predicate to use in determination of substantial equivalence. The proposed rule would, if finalized, facilitate appropriate classification of new types of medical devices. Comment by **March 7, 2019**. *(December 4, 2018) Also see: FDA In Brief: FDA proposes improvements to the De Novo pathway for novel medical devices to advance safe, effective, and innovative treatments for patients*

Drugs and biologics

- FDA posted a Framework for FDA's Real-World Evidence Program (PDF, 2.5 MB). FDA created this framework for evaluating the potential use of real-world evidence to help support the approval of a new indication for an already approved drug, or to help support or satisfy drug post-approval study requirements. Comment by **February 5, 2019**. *(December 6, 2018) Also see: Statement from FDA Commissioner Scott Gottlieb, M.D., on FDA's new strategic framework to advance use of real-world evidence to support development of drugs and biologics*
- *Also see the above feature for information on the draft guidance Bacterial Risk Control Strategies for Blood Collection Establishments and Transfusion Services to Enhance the Safety and Availability of Platelets for Transfusion*

Research

- RFI from NIH - The National Institutes of Health (NIH) is seeking input on a draft report: Reducing Administrative Burden for Researchers: Animal Care and Use in Research (PDF, 692 KB) - The draft report is a coordinated effort of the Director of NIH, in collaboration with the Secretary of Agriculture and the Commissioner of Food and Drugs. It describes the proposed actions that the working group has identified to reduce administrative burden on investigators while maintaining the integrity and credibility of research findings and protection of research animals. Comment by **February 5, 2019**. *(December 7, 2018)*

More: MCM-Related Guidance by Date

In case you missed it

- The ORISE Research Participation Programs at FDA accept applications from students, recent graduates, and faculty researchers year-round. Check out open research opportunities!
- FDA clears mobile medical app to help those with opioid use disorder stay in recovery programs *(December 10, 2018) Note: The HHS Secretary declared a public health emergency as a result of the opioid crisis in January 2018.*
- Reminders, from HHS:
    - Reimagining Respiratory Protection Quickfire Challenge - The HHS Biomedical Advanced Research and Development Authority (BARDA), and Johnson & Johnson Innovation, JLABS,

working with Janssen Research & Development, LLC, are calling on innovators to revolutionize respiratory protection, to submit novel ideas to better protect against the inhalation of harmful infectious agents. Apply by **February 15, 2019**.
    - HHS is seeking nominations of non-federal individuals who represent diverse scientific disciplines and views and are interested in being considered for appointment to the Tick-Borne Disease working group. Nominations must be received by **5:00 p.m. ET, December 14, 2018**.
- From NIH - Antimicrobial Resistance Diagnostic Challenge names five finalists - Selected entrants will receive $100,000 to further develop and test prototypes to improve detection of drug-resistant bacteria or differentiate between a bacterial and viral infection. *(December 3, 2018) Also see: Antimicrobial Resistance Information from FDA*
- From DoD - Reinventing Drug Discovery and Development for Military Needs - Panacea aims to generate multi-target pharmacological interventions that provide superior physiological effectiveness to help military service members complete their toughest missions. DARPA will hold a Proposers Day on **December 14, 2018**, in Arlington, Virginia, to provide more information about Panacea and answer questions from potential proposers. A forthcoming Broad Agency Announcement will fully describe the program structure and objectives.
- You want to make a difference. FDA wants to hire you. Follow @FDAJobs on Twitter, or visit www.fda.gov/jobs.

Thanks for reading. This is our last scheduled MCMi update in 2018. We'll be back with updates in January. We wish you a happy, healthy holiday season and new year!

Did someone forward you this email? ***Subscribe***

(select Emergency Preparedness and Response - FDA Medical Countermeasures Initiative (MCMi) News)

U.S. Food and Drug Administration
10903 New Hampshire Avenue, Silver Spring, MD 20993
1-888-INFO-FDA (1-888-463-6332)
Privacy Policy | www.fda.gov