U.S. FOOD & DRUG ADMINISTRATION

Medical Countermeasures Initiative Update

July 11, 2018

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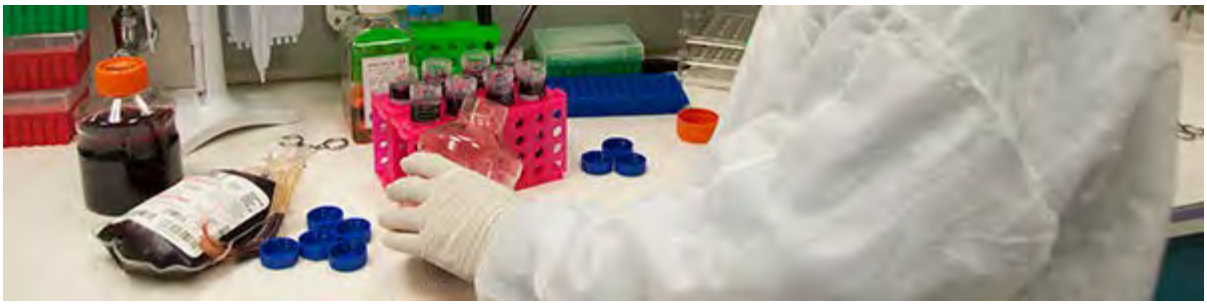

Revised Zika virus guidance for blood collection establishments

FDA announces revised guidance on the testing of donated blood and blood components

FDA has revised recommendations for testing blood donations for the Zika virus. When Zika virus first emerged, the unknown course of the epidemic and the observed severe effects from the disease indicated that individual donor testing was needed to ensure the continued safety of the blood supply. Now, given the significant decrease in cases of Zika virus infection in the U.S. and its territories, we are moving away from testing each individual donation to testing pooled donations. **Read the full statement** *(July 6, 2018)*

In related news, on July 5, 2018, FDA approved the Procleix Zika Virus Assay, manufactured by Grifols Diagnostics Solutions, Inc. The Procleix Zika Virus Assay is a qualitative nucleic acid test for the detection of Zika virus RNA in individual plasma specimens obtained from volunteer donors of whole blood and blood components for transfusion. The assay is intended for use by blood collection establishments to detect Zika virus in blood donations. It is not intended for use as an aid in the diagnosis of Zika virus infection. For more information, see the approval letter (PDF, 41.2 KB).

Related links:

- Zika virus response updates from FDA
- Revised Recommendations for Reducing the Risk of Zika Virus Transmission by Blood and Blood Components (Federal Register notice, July 9, 2018)
- FDA approves first test for screening Zika virus in blood donations (October 5, 2017)
- Blood & Tissue Safety: Geographic areas at increased risk for Zika virus transmission through blood or tissue donation (CDC)

EUA updates

FDA issues EUA for freeze-dried plasma product to support American military personnel

July 9, 2018: FDA issued (PDF, 208 KB) an Emergency Use

Authorization (EUA) to the U.S. Department of Defense (DoD) to enable the emergency use of Pathogen-Reduced Leukocyte-Depleted Freeze-Dried Plasma (referred to as French FDP) manufactured by the Centre de Transfusion Sanguine des Armées.

Under the EUA, this product is authorized for the treatment of U.S. military personnel with severe or life-threatening hemorrhage due to traumatic injuries sustained in the conduct of military operations in situations when plasma is not available for use or when its use is not practical.

Related links:

- News release: FDA takes action to support American military personnel by granting an authorization for freeze-dried plasma product to enable broader access while the agency works toward approval of the product *(July 10, 2018)*
- French FDP EUA information, including fact sheets and instructions for use

Events

- **July 18-19, 2018:** Blood Products Advisory Committee public meeting (Silver Spring, MD and webcast) - The Committee will meet in open session to discuss and provide advice regarding bacterial risk control strategies for blood collection establishments and transfusion services to enhance the safety and availability of platelets for transfusion.
- **New! July 24, 2018:** HHS Tick-Borne Disease Working Group meeting (webcast) - The Working Group will review and vote on the content of the five chapters that will be included in the Working Group's Report to Congress.
- **New! July 30-31, 2018:** Continuous Manufacturing for the Modernization of Pharmaceutical Production: A Workshop (Washington, DC), hosted by the National Academies of Sciences, Engineering, and Medicine's Board on Chemical Sciences and Technology, and sponsored by FDA and the Biomedical Advanced Research and Development Authority (BARDA). This workshop will discuss the business and regulatory concerns associated with adopting continuous manufacturing techniques to produce biologics, such as enzymes, monoclonal antibodies, and vaccines.
- **New! August 9, 2018:** FDA Grand Rounds webcast - How Simulation Can Transform Regulatory Pathways, presented by Tina Morrison, PhD, Deputy Director, Division of Applied Mechanics, Center for Devices and Radiological Health (CDRH), FDA - 12:00 - 1:00 p.m. ET. CE credit available; please register in advance.
- **August 13-14, 2018:** Pediatric Medical Device Development public meeting (Silver Spring, MD and webcast), to identify strategies to enhance the medical device ecosystem to cultivate development and innovation of devices that serve the unique needs of pediatric populations. To attend in-person, register by **4:00 p.m. ET August 6, 2018.**
- **New! August 21-22, 2018:** Public workshop - Development of Non-Traditional Therapies for Bacterial Infections (Silver Spring, MD and webcast) Discussions will focus on pre-clinical development, early stage clinical trials, and phase 3 clinical trial designs to evaluate safety and efficacy of non-traditional therapies intended to serve as primary or adjunctive therapy to existing antibacterial drugs. FDA is particularly interested in discussing pre-clinical and clinical development of several types of non-traditional therapies, including monoclonal antibodies, immunomodulators, lysins, and other non-traditional therapies. Register by **August 14, 2018.**
- **New! September 12, 2018:** Public hearing on FDA's Predictive Toxicology Roadmap - FDA is seeking

comments on how to foster the development and evaluation of emerging toxicological methods and new technologies and incorporate them into regulatory review, as applicable. To attend, register by **August 29, 2018**. *Also see: FDA's Predictive Toxicology Roadmap (PDF, 2.2 MB)*

Information for industry

- FDA issued a draft guidance for industry, Smallpox (Variola Virus) Infection: Developing Drugs for Treatment or Prevention (PDF, 120 KB), to assist sponsors in all phases of development of antiviral drugs for the treatment or prevention of smallpox (variola virus) infection. This draft guidance addresses nonclinical development, key study design considerations for animal efficacy studies to support potential new drug application (NDA)/biologics license application (BLA) submissions under the Animal Rule, and considerations for obtaining a human safety database. This draft guidance revises the draft guidance for industry entitled Smallpox (Variola) Infection: Developing Drugs for Treatment or Prevention issued on November 23, 2007. Submit comments by **September 10, 2018**. *(July 10, 2018)*
- Drugs must meet quality standards that ensure every dose is safe, effective, and capable of providing its intended benefit. Quality metrics help with monitoring quality control systems and processes to ensure these standards are met. FDA's new Quality Metrics Feedback Program, developed in response to stakeholder feedback, encourages meetings with FDA and drug manufacturers to initiate discussions on quality metrics. The agency's new Quality Metrics Site Visit Program (CDER and CBER) provides on-site, first hand learning opportunities to FDA staff and also provides our stakeholders with more opportunities for quality metrics dialogue with FDA. Submit a proposal to participate in this program by **August 28, 2018**.
- In response to public feedback, FDA updated the format of the Antibacterial Susceptibility Test Interpretive Criteria web pages for clarity. The new format includes the pathogens that FDA recognizes as part of a standard and any exceptions, additions, or additional FDA-identified susceptibility test interpretive criteria for certain drug-bacteria combinations not included in a recognized standard. *Also see: FDA-Recognized Antimicrobial Susceptibility Test Interpretive Criteria (June 27, 2018)*
- FDA announces program to enhance early communications with biological product developers - The FDA's new INTERACT (INitial Targeted Engagement for Regulatory Advice on CBER ProducTs) meeting program was created to facilitate early interactions between sponsors and CBER staff. It replaces the existing CBER pre- pre-Investigational New Drug (IND) meeting process for all products across the center. *(June 22, 2018)*
- New webinar recording available: FDA's Overview of the Regulatory Framework and FDA's Guidance for the Development and Approval of Biosimilar and Interchangeable Products in the US - *also see more webinars, presentations, and articles on biosimilars (June 20, 2018)*

More: MCM-Related Guidance by Date

In case you missed it

- FDA issues guidance to help animal drug manufacturers meet antimicrobial sales data reporting requirements - FDA is committed to limiting resistance arising from the use of antibiotics in food-producing animals, while continuing to ensure the availability of safe and effective antibiotics for use in animals and humans. Compliance with the reporting requirements for the sale and distribution of antimicrobials in food-producing animals is important to our overall efforts to understand and combat antimicrobial resistance. *(June 28, 2018)*
- Ultraviolet germicidal irradiation of influenza-contaminated N95 filtering facepiece respirators - New publication (July 2018) in the *American Journal of Infection Control*. For more information about this

MCMi regulatory science project, see Optimizing Respirator Decontamination to Ensure Supplies for Emergency Preparedness.

- From HHS - HHS enlists AktiVax to develop improved auto-injector for nerve agent antidotes *(June 25, 2018)*
- Interested in working at FDA? Follow @FDAJobs on Twitter, or visit www.fda.gov/jobs.

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