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Medical Countermeasures Initiative Update

September 11, 2019



FDA Action Makes Blood Product More Accessible to Warfighters in Combat

A recent action by FDA will help the military treat severely injured warfighters suffering from traumatic bleeding on the battlefield

In August 2019, FDA granted a variance request submitted by the Army Blood Program for the use of cold stored platelets in theater for the Department of Defense (DoD).

The issuance of this variance clears the way for platelets, a key blood component, to be refrigerated and stored for up to 14 days prior to treating bleeding patients when conventional platelet products are not available or their use is not practical.

The approval of the variance request is another important action under the collaboration between FDA and DoD to expedite the development and availability of safe and effective medical products that are essential to the health of U.S. military service members.

[Read the DoD release](#)

Related links:

Delivering Promising New Medicines Without Sacrificing Safety and Efficacy



All drugs approved under FDA's expedited programs are held to the same approval standards as other FDA drug approvals. Learn more about Fast Track, Breakthrough Therapy, Regenerative Medicine Advanced Therapy, and Priority Review designations, and Accelerated Approval in this [FDA Voices post](#) by Janet Woodcock, M.D., Director, Center for Drug Evaluation and Research and Peter Marks, M.D., Ph.D., Director, Center for Biologics Evaluation and Research.

Events

- **Today, with live webcast! September 11-12, 2019: 2019 FDA Science Forum** (Silver Spring, MD) - [Agenda](#) available. Don't miss the Oubreak! track.
- **September 18, 2019: Implementing FDA's Predictive Toxicology Roadmap: An Update of FDA Activities** public workshop (Silver Spring, MD and webcast) Register by **September 16, 2019**.
- **New! September 18-19, 2019: Workshop on Standards for NGS Detection of Viral Adventitious Agents in Biologics and Biomanufacturing** (Gaithersburg, MD) - This National Institute of Standards and Technology (NIST) workshop, co-organized with FDA, will focus on the development of different types of standards for supporting standardization of Next Generation Sequencing (NGS) for detection of adventitious viruses in biologics (including viral vaccines, gene therapies, and biotherapeutics). Register by **today September 11, 2019**.
- **September 25-26, 2019: 2019 Complex Generic Drug Product Development Workshop** (College Park, MD and webcast) - FDA will link GDUFA science and research on complex products to product-specific guidance development, discuss pre-ANDA meetings and review, and examine various areas of complex product science, hosted by [CDER Small Business & Industry Assistance](#).

- **October 3, 2019:** [Developing Real-World Data and Evidence to Support Regulatory Decision-Making](#) (Washington, DC) - Through extensive engagement with the stakeholder community, FDA published a [framework](#) (PDF) for the Agency's RWE Program in December 2018. This conference will bring together leading experts to discuss questions about and topics addressed in the framework, as well as emerging topics in the development of real-world data and evidence.
 - **October 9, 2019:** [Vaccines and Related Biological Products Advisory Committee](#) (Silver Spring, MD and [webcast](#)) - The committee will meet in open session to discuss and make recommendations on the selection of strains to be included in an influenza virus vaccine for the 2020 southern hemisphere influenza season.
 - **October 16-17, 2019:** [Regulatory Education for Industry \(REdI\): Pharmaceutical Quality Symposium](#) (College Park, MD and [webcast](#)) - FDA will discuss the latest developments in pharmaceutical quality and provide case studies that illustrate the most effective ways to address quality issues and interact with the agency.
 - **November 8, 2019:** [Vaccines and Related Biological Products Advisory Committee public meeting](#) (Silver Spring, MD and [webcast](#)) - The committee will discuss and make recommendations on the development of chikungunya vaccines.
 - **New! November 12-14, 2019:** [Regulatory Education for Industry \(REdI\): Clinical Investigator Training Course](#) (College Park, MD) This course provides an intermediate-level study of clinical trial principles with in-depth coverage of clinical trial design, issues in safety and efficacy, investigator responsibilities, understanding the investigator brochure, and FDA requirements across Centers. Upon completion, attendees should understand pre-clinical research, clinical trials, and FDA submissions for licensure of medical products. Registration is now open.
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Information for industry

- De Novo guidance updates:
 - Final guidance - [Consideration of Uncertainty in Making Benefit-Risk Determinations in Medical Device Premarket Approvals, De Novo Classifications, and Humanitarian Device Exemptions](#) - Describes the FDA's consideration of uncertainty when determining benefit-risk for certain premarket decisions on medical devices based on the totality of the valid scientific evidence, and outlines a rigorous, methodical approach for the consideration of uncertainty when assessing the benefits and risks of a medical device and for determining when it may be appropriate to shift some data collection from the premarket to the postmarket phase. On **October 16, 2019**, FDA will host a [webinar for stakeholders](#) interested in learning more about this final guidance. *(August 29, 2019)*
 - FDA also updated the guidance, [Factors to Consider When Making Benefit-Risk Determinations in Medical Device Premarket Approval and De Novo Classifications](#), which describes the principal factors, including uncertainty of benefits and risks, the FDA considers when making benefit-risk determinations for certain premarket decisions. Appendices B and C of this guidance are updated with a revised Benefit-Risk Determination Worksheet that incorporates the same factors for benefit-risk determinations described in the guidance. The revised worksheet provides structure to guide and organize the benefit-risk factors and to support consistent decision-making. *(August 29, 2019)*
 - Final guidance - [Acceptance Review for De Novo Classification Requests](#) - To explain the

procedures and criteria FDA intends to use in assessing whether a request for an evaluation of automatic class III designation (De Novo classification request or De Novo request) meets a minimum threshold of acceptability and should be accepted for substantive review. This guidance also includes a De Novo Acceptance Checklist and a Recommended Content Checklist. *(September 6, 2019)*

- FDA is [requesting nominations](#) for voting members to serve on the Device Good Manufacturing Practice Advisory Committee (DGMPAC) and the Medical Devices Advisory Committee (MDAC) device panels in the Center for Devices and Radiological Health. Nominations received on or before **October 29, 2019** will be given first consideration.
 - **Reminder:** FDA is [requesting nominations](#) for voting members to serve on the Blood Products Advisory Committee. Nominations received on or before **October 21, 2019** will be given first consideration.
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In case you missed it

- The National Institutes of Health (NIH) announced the publication of [Reducing Administrative Burden for Researchers: Animal Care and Use in Research](#) (PDF, 824 KB), a report by the NIH, the United States Department of Agriculture (USDA), and FDA. The report describes the recommendations of the 21st Century Cures Act, Section 2034(d), Working Group and decisions of the agencies. *(August 28, 2019)*
- From TRISH - Join the Translational Research Institute for Space Health (TRISH) for a **September 19, 2019** [webinar](#) in preparation for a 2019 solicitation, Human-Based Models to Study Space Radiation and Countermeasures.
- From the National Association of County & City Health Officials (NACCHO) - Disasters and emergencies expose the fault lines in our nation's health security. Submit an abstract for the [2020 Preparedness Summit](#), Fixing Our Fault Lines: Addressing Systemic Vulnerabilities, and contribute strategies, best practices, and tools for addressing systemic vulnerabilities to create more prepared and resilient communities. [Abstracts](#) are due **September 17, 2019**.
- From HHS/ASPR - [BARDA Industry Day](#) will be **October 15-16, 2019**. [Registration](#) is open. BARDA is [accepting applications](#) for Lightning Talks from industry through **September 13, 2019** (deadline extended).
- You want to make a difference. FDA wants to hire you. Follow [@FDAJobs](#) on Twitter, or visit www.fda.gov/jobs.



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