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**U.S. FOOD & DRUG
ADMINISTRATION**

Medical Countermeasures Initiative Update

November 14, 2018

Emergency Use Authorization (EUA)

FDA authorizes emergency use of first Ebola fingerstick test with portable reader

November 9, 2018: FDA issued an [EUA](#) for a rapid, single-use test for the detection of Ebola virus (*Zaire ebolavirus*). This is the second Ebola rapid antigen fingerstick test available under EUA, but the first that uses a portable battery-operated reader, which can help provide clear diagnostic results outside of laboratories and in areas where patients are likely to be treated.

With the issuance of the EUA for the DPP Ebola Antigen System to Chembio Diagnostic Systems Inc., the FDA has now issued EUAs for nine nucleic acid tests and two rapid diagnostic tests for Ebola virus detection in human specimens.

[Read more](#)

Related links:

- [DPP Ebola Antigen System technical information](#), including fact sheets (also includes information about other Ebola diagnostics authorized under EUA)
- [Ebola Preparedness and Response Updates from FDA](#)



FDA and DoD formalize collaboration

To advance medical products in support of American military personnel

Under the MOU, FDA will work closely to expedite review of priority DoD products.



On November 2, 2018, FDA and the Department of Defense (DoD) Office of Health Affairs [signed a Memorandum of Understanding](#) (MOU) regarding medical product development and assessment. This builds upon the work of both agencies to foster and prioritize the efficient development of safe and effective medical products intended to save the lives of American service members.

Image: FDA Commissioner Scott Gottlieb, MD, (left), and Tom McCaffery, acting Assistant Secretary of Defense for Health Affairs sign the MOU. Under the MOU, FDA will work closely with DoD to expedite review of priority DoD products.

Related links:

- [FDA/DoD Collaborations](#)
- [MOU 225-19-001](#)
- [Statement from FDA Commissioner Scott Gottlieb, M.D., on agency's approval of Dsuvia and the FDA's future consideration of new opioids](#) (November 2, 2018)

Events

- **November 19, 2018:** [Leveraging Real-World Treatment Experience from Expanded Access Protocols](#) (Silver Spring, MD), hosted by the Reagan-Udall Foundation for the FDA - Building on the Reagan-Udall Foundation for the FDA's work with FDA and other stakeholders to develop the [Expanded Access Navigator](#), this meeting will convene stakeholders from government, industry, academia, and patient groups to discuss Expanded Access process issues. Register to attend.
- **November 27, 2018:** [Identifying the Root Causes of Drug Shortages and Finding Enduring Solutions public meeting](#) (Washington, DC and webcast) - This meeting will give stakeholders the opportunity to provide input on the underlying systemic causes of drug shortages, and make recommendations for actions to prevent or mitigate drug shortages. To attend in-person, [register](#) by **November 21, 2018**.
- **November 27-28, 2018:** [Readiness for Microbial Threats 2030: Exploring Lessons Learned Since the 1918 Influenza Pandemic - A Workshop](#) (Washington, DC), hosted by the National Academies of Sciences, Engineering, and Medicine - The workshop will focus on overcoming the structural and behavioral obstacles to achieving greater preparedness, in order to identify immediate and short-term actions that will have the greatest impact on global health security by 2030.
- **November 29-30, 2018:** [Pathogen Reduction Technologies for Blood Safety public workshop](#) (Silver

Spring, MD and webcast) - to foster the development and implementation of pathogen reduction technologies for blood components intended for transfusion. [Register](#) by **November 8, 2018**.

- **New! December 3, 2018:** [Implementation of Signal Detection Capabilities in the Sentinel System workshop](#) (Bethesda, MD and webcast) - [Registration](#) is open.
- **New! December 3, 2018:** [HHS Tick-Borne Disease Working Group meeting](#) (webcast) - The Working Group will [review](#) the work of the public comments subcommittee, discuss the release of the 2018 Report to Congress, recognize the subcommittee members for their contributions to the 2018 Report, and address the next steps and transition to a new Working Group for the 2020 Report to Congress.
- **New! December 11, 2018:** [Drug Development Tool Process Under the 21st Century Cures Act and Prescription Drug User Fee Act VI public meeting](#) (Silver Spring, MD and webcast) - To attend in-person, [register](#) by **November 30, 2018**. Also see *Information for industry below*

Information for industry

- Draft guidance - [Meta-Analyses of Randomized Controlled Clinical Trials to Evaluate the Safety of Human Drugs or Biologic Products](#) (PDF, 227 KB). To provide guidance to sponsors submitting investigational new drug applications (INDs), new drug applications (NDAs), biologics license applications (BLAs), or supplemental application on the appropriate use of prospective meta-analyses to assess a product risk. This draft guidance specifically focuses on meta-analyses for evaluating safety data from randomized, controlled trials. [Comment](#) by **January 7, 2019**. Also see: [FDA in Brief: FDA advances new guidelines for analysis of clinical trials evaluating safety of drug and biologic products](#), and [Enhancing Regulatory Science - Methodologies for Meta-Analysis](#) (November 6, 2018)
- On **December 11, 2018**, FDA will hold a [public meeting](#) to discuss taxonomy for biomarkers and related concepts used in drug development, and planning activities to define a framework with appropriate standards and scientific approaches to support qualification for a specified context of use. To attend in-person, [register](#) by **November 30, 2018**. In addition to providing input at the public meeting, stakeholders are invited to submit comments through the [public docket](#) through **January 31, 2019**.
- FDA is [proposing to amend](#) its regulations to implement a provision of the 21st Century Cures Act and add an exception to informed consent requirements for certain FDA-regulated clinical investigations that present no more than minimal risk to human research participants. The proposed rule, if finalized, would allow the Institutional Review Board (IRB) responsible for the review and approval of the research to waive or alter certain elements of informed consent, or to waive the requirement to obtain informed consent entirely, under limited conditions. Also see: [FDA In Brief: FDA takes steps to allow greater flexibility for clinical investigators about informed consent in minimal risk situations](#) (November 13, 2018)
- FDA is [posting links to computer code and a roadmap](#) that will allow researchers and developers to customize and use the newly created MyStudies app. Patients can securely enroll and participate in large scale pragmatic clinical trials or registries involving multiple health care systems or data sources. The agency expects that the MyStudies app will aid researchers and industry in collecting real world patient level data and that these data, when linked to existing electronic health data, will promote efficiencies in drug development and drug safety monitoring processes. The MyStudies app is also capable of supporting clinical trials that comply with FDA guidance and regulations regarding data authenticity, integrity, and confidentiality. Also see: [FDA In Brief: FDA launches new digital tool to help capture real world data from patients to help inform regulatory decision-making](#) (November 6, 2018)
- Reminder for pharmaceutical industry: the annual [drug listing certification requirement deadline](#) is **December 31, 2018**.

More: [MCM-Related Guidance by Date](#)

In case you missed it

- [Statement from FDA Commissioner Scott Gottlieb, M.D., on new efforts to strengthen FDA's expanded access program - Expanded Access](#) "provides a pathway for patients to gain access to investigational drugs, biologics and medical devices for serious diseases and immediately life-threatening conditions outside of clinical trials when no comparable or satisfactory approved alternative therapy options are available. We're taking new steps to improve this framework." (November 8, 2018)
- [The Medical Device Ecosystem and Cybersecurity — Building Capabilities and Advancing Contributions](#) - Cybersecurity is among FDA's top priorities for protecting and promoting public health. Read the latest FDA Voices highlighting recent steps we've taken to solidify our role in medical device cybersecurity. (November 1, 2018)
- From HHS - [HHS Officials Deliver Remarks at the Fifth Annual Global Health Security Agenda Ministerial Meeting](#) (3-minute video, November 7, 2018) Also see: [U.S. Government Participates in Fifth Annual Global Health Security Agenda Ministerial Meeting](#)
- From HHS/ASPR - [FDA approval of anti-seizure drug provides a new tool for protecting Americans during a chemical attack](#) (October 31, 2018)
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