

May 30, 2018

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Ebola virus particles (credit: NIAID)

FDA is rapidly responding to the Ebola virus outbreak in DRC

- ✓ Facilitating development & availability of medical countermeasures (MCMs) to diagnose, prevent, or treat Ebola
- ✓ Working with product sponsors to clarify regulatory & data requirements to rapidly advance MCM development
- ✓ Protecting the safety of the nation's blood supply and human cells, tissues, and cellular/tissue-based products
- ✓ Enabling access to investigational MCMs through Emergency Use Authorization (EUA) or expanded access
- ✓ Protecting consumers from fraudulent products

Learn more about our role at:
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Federal preparedness and FDA's response efforts to the Ebola virus outbreak in the Democratic Republic of Congo

Statement from FDA Commissioner Scott Gottlieb, M.D.

Time and time again we're reminded that disease knows no borders. While our globalized world and modern transportation helps promote economic prosperity, these features also provide an easier platform for the spread of emerging infectious diseases. In the past 15 years alone, we've faced nearly 10 serious outbreaks of deadly pathogens. But perhaps none of these outbreaks was as ominous and deadly as the 2014–2015 Ebola outbreak in West Africa that claimed the lives of more than 11,300 people.

The U.S. Food and Drug Administration (FDA) has long played a critical role in protecting the public from these emerging threats. In recent years, Congress has entrusted the agency with new authorities and resources to advance the development of countermeasures to address emerging threats. To pursue these mandates, the agency has built a strong team of scientists, researchers, and policy experts that are dedicated to preparing our nation to rapidly respond to emerging infectious diseases as well as chemical, biological, radiological and nuclear threats, whether these events are naturally-occurring or man-made.

During the 2014-2015 Ebola outbreak, the FDA took new steps to advance the availability of investigational medical countermeasures, including drugs, vaccines and diagnostic tests. As we closely monitor the current Ebola outbreak in the Democratic Republic of Congo (DRC), our team is employing our experiences, resources, and knowledge from the 2014-15 incidents. We're committed to helping the people of DRC effectively confront and end the current outbreak. The FDA is building on the lessons we learned from that 2014-15 Ebola epidemic to assist in the global response to this current outbreak and help mitigate the threat

by making medical products available as part of critical response efforts.

[Read the full statement](#)

Related links:

- [Ebola preparedness and response updates from FDA](#)
- [Ebola diagnostic tests currently available under Emergency Use Authorization \(EUA\)](#)
- [Ebola situation reports: Democratic Republic of the Congo](#), from the World Health Organization
- [2018 Democratic Republic of the Congo, Bikoro](#) Ebola outbreak information, from CDC

Image: Ebola virus particles (credit: NIAID) with text. FDA is rapidly responding to the Ebola virus outbreak in DRC. Learn more about our role at: www.fda.gov/medicalcountermeasures.

Final guidance for industry

Anthrax: Developing Drugs for Prophylaxis of Inhalational Anthrax

On May 24, 2018, FDA issued final guidance, [Anthrax: Developing Drugs for Prophylaxis of Inhalational Anthrax](#) (PDF, 116 KB), which is designed to assist in the development of drugs for prophylaxis (prevention) of inhalational anthrax for individuals who may be potentially exposed to or have inhaled aerosolized *Bacillus anthracis* spores, but who have not yet displayed related signs and symptoms. ([Federal Register notice](#))

Also see [FDA In Brief: As part of a longstanding program encouraging the development of medical countermeasures: new FDA policy promotes innovation to thwart inhalational anthrax](#).

EUA updates

EUA amendments

- May 18, 2018: In response to InBios International, Inc.'s request, FDA concurred with modifications to the authorized Instructions for Use labeling and fact sheets for the ZIKV Detect IgM Capture ELISA, and InBios's request to modify the name from ZIKV Detect IgM Capture ELISA to ZIKV Detect 2.0 IgM Capture ELISA. [Additional technical information, including revised fact sheets and labeling](#)
- May 15, 2018: In response to CDC's request, FDA concurred with an amendment to the Rafa Atropine Auto-Injector EUA for a change to a Rafa-planned manufacturing process. The Rafa Atropine Auto-Injector was initially authorized for emergency use for initial treatment of nerve agent or certain insecticide (organophosphorus and/or carbamate) poisoning in April 2017. [Additional information](#)



EUA revocation

- May 18, 2018: In response to a request from Zalgen Labs, LLC dated March 1, 2018, FDA revoked the EUA for emergency use of the ReEBOV Antigen Rapid Test. For additional information, see [Emergency Use Authorization--Archived Information](#)

Reminder:

Laboratory personnel using Zika diagnostic assays under EUA are encouraged to report performance concerns directly to FDA at CDRH-EUA-Reporting@fda.hhs.gov, in addition to reporting concerns to the manufacturer.

Information about Zika EUAs and amendments is available on the [FDA Zika virus response updates page](#). Also see the latest [CDC Zika Laboratory Guidance](#), last updated July 24, 2017.

Events

- **New! June 5, 2018:** [NACCHO Radiation Readiness Twitter Chat](#), 2:00 - 3:00 p.m. ET - The National Association of County & City Health Officials will host a Twitter chat to help raise awareness of radiation preparedness resources and information.
 - **June 15, 2018:** [2nd NIH-FDA Joint Agency Microbiome Meeting](#) (College Park, MD and webcast) - This meeting will present ongoing microbiome research being undertaken at the NIH and FDA. Advance [registration](#) required.
 - **New! June 22, 2018:** [Blood Products Advisory Committee public meeting](#) (Silver Spring, MD and [webcast](#)) - The Committee will hear presentations on FDA Center for Biologics Evaluation and Research (CBER) research programs including the Laboratory of Emerging Pathogens.
 - **June 25-26, 2018:** [2018 Center for Biologics Evaluation and Research \(CBER\) Science Symposium](#) (Silver Spring, MD and webcast) - participants will discuss scientific topics related to the regulation of biologics, and highlight science conducted at CBER by showcasing how scientific research informs regulatory decision-making. Topics include emerging and re-emerging diseases, and new technologies. [Register](#) to attend in-person or online by **June 18, 2018**; early registration recommended because seating and webcast connections are limited.
 - **New! 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.
 - **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**.
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Information for industry

- [FDA takes new steps to protect human research subjects in clinical trials by helping to ensure requirements on research institutions are consistently and efficiently applied](#) - FDA and the Office for Human Research Protections (OHRP) issued a joint guidance titled [Institutional Review Board \(IRB\) Written Procedures: Guidance for Institutions and IRBs](#). The guidance is intended for institutions and IRBs responsible for the review and oversight of human subject research regulated by the FDA and/or conducted or supported by the U.S. Department of Health and Human Services (HHS). The new guidance seeks to clarify requirements, reaffirm important human subject protections, and provide consistent recommendations for institutions and IRBs reviewing and overseeing research involving human subjects. This finalizes the draft guidance of the same title dated August 2016. *Also see [IRBs and Protection of Human Subjects in Clinical Trials](#) (May 17, 2018)*
- [FDA takes new steps to advance digital health, opening docket to solicit feedback on software products](#) - submit [comments](#) by **June 28, 2018**
- Slides are [available](#) from FDA's Sentinel Industry Day in April 2018 - *also see [FDA's Sentinel Initiative](#) (May 1, 2018)*
- Also see information about guidance for industry: Anthrax; Developing Drugs for Prophylaxis of

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

In case you missed it

- Interested in working at FDA? Follow the new [@FDAJobs](#) Twitter account, or visit www.fda.gov/jobs.
- [FDA video series about biosimilar and interchangeable products](#) - FDA presents a new [five-part video series](#), designed to provide an overview of biosimilar and interchangeable products and to highlight key concepts about the development and approval of these products, as well as how state-of-the-art technologies and tools are used to demonstrate biosimilarity. A biosimilar is a biological product that is highly similar to, and has no clinically meaningful differences from, an existing FDA-approved reference product. (May 22, 2018)
- From NIH - [Experimental MERS treatments enter clinical trial](#) - NIH-sponsored trial to test two human monoclonal antibodies (May 18, 2018) and [NIH begins testing Ebola treatment in early-stage trial](#) - Scientists developed monoclonal antibody from Ebola survivor (May 23, 2018)
- From CDC - CDC has a new [Emergency Partners Information Connection \(EPIC\)](#) website. The site provides visitors convenient access to emergency public health information and resources. (May 24, 2018)



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