

If your email program has trouble displaying this email, [view it as a web page](#).



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

Medical Countermeasures Initiative Update

November 28, 2018



## How FDA helps make MCMs available in emergencies

### ***The first in an occasional series on the ways FDA helps prepare for and respond to public health emergencies***

During public health emergencies, medical countermeasures ([MCMs](#)) may be needed to prevent or treat diseases or conditions caused by chemical, biological, radiological, or nuclear (CBRN) agents or emerging infectious diseases, like pandemic influenza or Ebola.

Depending on the emergency and public health need, MCMs may be provided by the [Strategic National Stockpile](#) (managed by the Office of the Assistant Secretary for Preparedness and Response ([ASPR](#)), in the U.S. Department of Health and Human Services (HHS)), or through state and local stockpiles or other supplies. When needed during a public health emergency, MCMs are usually dispensed or administered to impacted individuals by healthcare workers and public health responders under official federal, state, and local emergency response plans.

In some cases, MCMs might already be approved and will be used in approved ways during a response. In other cases, the best medical products available for a response might be unapproved or need to be used in unapproved ways. Because of our role in regulating medical products, FDA may need to use special authorities to allow the use of such MCMs in impacted populations during or in anticipation of emergencies.

**Mechanisms FDA can use to allow the emergency use of MCMs include the [Emergency Use Authorization](#) (EUA) authority and several authorities related to the [emergency use of approved MCMs](#).**

## Related links:

- [MCM Emergency Use Authorities](#)
  - [MCM-Related Counterterrorism Legislation](#)
  - [Summary of process for EUA issuance](#) - graphic illustrating the process
  - [Expiration dating extension](#)
  - [Emergency dispensing orders and Emergency Use Instructions \(EUI\)](#)
- 

## Events

- **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. Advance registration is closed, including webcast registration. If space permits, onsite registration will be provided on the day of the workshop, beginning at 7:00 a.m.
  - **December 3, 2018:** [Implementation of Signal Detection Capabilities in the Sentinel System workshop](#) (Bethesda, MD and webcast) - [Registration](#) is open.
  - **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.
  - **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 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](#). Electronic or written comments can be submitted to the docket through **January 31, 2019**.
  - **New! December 13-14, 2018:** [Arizona Biosecurity Workshop](#) (Tempe, AZ) - This two-day workshop focuses on community engagement with biosecurity concerns in an applied and practical manner. The goal of this workshop is to foster awareness and to stimulate conversation about the ethical, moral and social implications of biosecurity. Register by **December 1, 2018**. Space is limited.
- 

## Information for industry

- [FDA is Advancing New Efforts to Address Drug Shortages](#) - A key component of our public health mission is to help ensure Americans have access to safe and effective medicines. That's why, as drug shortages arise, we take immediate action within our authorities, working across the FDA and with other government agencies, industry, and other stakeholders, to minimize the impact of these shortages and maintain or restore availability of critical medicines for the patients who need them. *(November 19, 2018)*
- Statement from FDA Commissioner Scott Gottlieb, M.D. and Jeff Shuren, M.D., Director of the Center for Devices and Radiological Health, on [transformative new steps to modernize FDA's 510\(k\) program to advance the review of the safety and effectiveness of medical devices](#) *(November 26, 2018)*
- 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. Comment by **January 14, 2019**. 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)

- 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 by FDA Commissioner Scott Gottlieb, M.D., on efforts to reduce animal testing through a study aimed at eliminating the use of dogs in certain trials](#) - By doing a single study to help establish a non-animal based model, we can potentially replace much of the need to use dogs in future trials with new informatics tools. (November 16, 2018)
- 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**.
  - If you missed BARDA Industry Day in October, presentations are [now available online](#).
  - [Tick-Borne Disease Working Group 2018 Report to Congress](#) (PDF, 4.6 MB) - The [Tick-Borne Disease Working Group](#), a federal advisory committee established by Congress in the 21st Century Cures Act, issued its first report, recommending a multi-pronged response to address these diseases that affect more than 300,000 Americans each year. HHS is [seeking nominations](#) of non-federal individuals who represent diverse scientific disciplines and views and are interested in being considered for appointment to this working group. Nominations must be received by **5:00 p.m. ET, December 14, 2018**.
  - The Presidential Advisory Council on Combating Antibiotic-Resistant Bacteria is [seeking information](#) from the general public and stakeholders related to efforts and strategies to combat antibiotic resistance, in an RFI that offers the opportunity for the public, including interested individuals, organizations, associations, industries, and others, to provide their input on new priority areas within each of the five goals of the [National Action Plan for Combating Antibiotic-Resistant Bacteria](#) (2015 - PDF, 519 KB) that should be considered by the United States Government. Comment using this [online form](#) by **January 7, 2019**.
- From NIH:
  - [Video: Take a Tour of the Special Clinical Studies Unit](#) - Between 2014 and 2016, during the Ebola epidemic in West Africa, several patients were transported to the United States for treatment. Some of these patients came to the National Institutes of Health, where they received care in a special isolation unit in the NIH Clinical Center. (November 16, 2018)
  - [Clinical trial of investigational Ebola treatments begins in the Democratic Republic of the Congo](#) - An international research team has begun patient enrollment in a clinical trial testing multiple investigational Ebola therapies in the Democratic Republic of the Congo (DRC). The randomized, controlled trial is enrolling patients of any age with confirmed Ebola virus disease at a treatment unit in the city of Beni. (November 27, 2018)
- You want to make a difference. FDA wants to hire you. Follow [@FDAJobs](#) on Twitter, or visit [www.fda.gov/jobs](http://www.fda.gov/jobs).

## More News & Events

from MCMi

FDA Medical Countermeasures Initiative

Did someone forward you this email? [Subscribe](#)

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



Twitter: [@FDA\\_MCMi](#)

[www.fda.gov/medicalcountermeasures](http://www.fda.gov/medicalcountermeasures)

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](http://www.fda.gov)