

January 17, 2018

[Take our email
survey](#)



Material Threat MCM PRV Guidance

FDA takes steps to spur development of medical products needed to protect, prepare for national security threats

The [21st Century Cures Act](#) established a new priority review voucher (PRV) program to encourage development of certain drug and biologic material threat medical countermeasures (MCMs). MCMs are FDA-regulated products that can be used to diagnose, prevent, protect from, or treat conditions associated with chemical, biological, radiological, or nuclear threats, or emerging infectious diseases.

Today FDA issued a draft guidance, [Material Threat Medical Countermeasure Priority Review Vouchers](#) (PDF, 174 KB), which explains how FDA intends to implement the material threat MCM PRV program. To ensure that your comments are considered before FDA begins work on the final version of the guidance, submit [comments](#) by **March 20, 2018**.

Related links:

- [FDA In Brief: FDA takes steps to spur development of medical countermeasures needed to protect, prepare for emerging threats to public health and national security](#)
- [More about the material threat MCM PRV program](#)
- [Federal Register notice](#)
- [What are medical countermeasures?](#)

Image: Pill bottles, representing medical countermeasures (Shutterstock)

FDA and DoD launch program to expedite availability of medical products for the emergency care of American military personnel

On January 16, 2018, FDA and the Department of Defense (DoD) [announced the launch](#) of a joint program to prioritize the efficient development of safe and effective medical products intended for deployed American military personnel.

The framework for the program was put in place through [H.R.4374](#), which authorized DoD to request, and FDA to

provide, assistance to expedite development and the FDA's review of products to diagnose, treat, or prevent serious or life-threatening diseases or conditions facing American military personnel.



[View the initial work plan for products relevant to DoD.](#)

Image: Combat medics assigned to the 29th Brigade Engineer Battalion, 3rd Brigade Combat Team, "Broncos," 25th Infantry Division, conduct an exercise at the Marine Corps Training Area Bellows, Hawaii, on Jan. 10, 2018. (U.S. Army [photo](#) by Staff Sgt. Armando R. Limon, 3rd Brigade Combat Team, 25th Infantry Division)

Events

- **New! January 17, 2018:** Senate HELP Committee hearing: [Facing 21st Century Public Health Threats: Our Nation's Preparedness and Response Capabilities, Part I](#), 10:00 a.m. (Washington, DC and webcast) - FDA Commissioner Scott Gottlieb, MD will testify
- **January 30-31, 2018:** Public workshop - [Fostering Digital Health Innovation: Developing the Software Precertification Program](#) (Bethesda, MD and webcast) - register by **4:00 p.m. ET January 18, 2018**
- **February 7-8, 2018:** [Tenth Annual Sentinel Initiative Public Workshop](#) (Bethesda and Silver Spring, MD, and webcast) - The stakeholder community will discuss a variety of topics on active medical product surveillance. To attend in-person or via webcast, register [here for Day 1](#) and/or [here for Day 2](#) by **February 6, 2018**. To attend both days, please register separately for each.
- **New! February 15-19, 2018:** [American Association for the Advancement of Science annual meeting](#) (Austin, TX) - FDA's [RADM Carmen T. Maher, MA, BSN, RN, RAC](#), will present on [FDA's role in medical countermeasure development](#) February 18, 2018 at 9:00 a.m. CT (*fee*)
- **New! February 28, 2018:** [Enhanced Drug Distribution Security Under the Drug Supply Chain Security Act \(DSCSA\) public meeting](#) (Silver Spring, MD) - register by **January 26, 2018** - *more:* [about DSCSA](#)
- **April 17-20, 2018:** [Preparedness Summit](#) (Atlanta, GA) - The theme for the conference is Strengthening National Health Security: Mastering Ordinary Responses, Building Resilience for Extraordinary Events. [Registration](#) is now open. (*fee*)
- **April 23-27, 2018:** [Achieving Data Quality and Integrity in Maximum Containment Laboratories course](#) (Bethesda, MD) - **Registration is now open!** Register by **February 16, 2018**.

Information for industry

- Guidance - [Best Practices for Communication Between Investigational New Drug Application Sponsors and the Food and Drug Administration](#) (PDF, 191 KB) - This guidance finalizes the draft guidance issued on December 9, 2015. ([Federal Register notice](#)) Also see [FDA In Brief: FDA provides guidance on improving the agency's interactions with product developers to make the drug development process more informed and efficient](#) (December 28, 2017)
- Reminder: [Comment](#) by **January 19, 2018** on draft guidance [Clarification of Orphan Designation of Drugs and Biologics for Pediatric Subpopulations of Common Diseases](#) (PDF, 117 KB) Also see: [FDA takes step to close orphan drug loophole that let drug developers sidestep pediatric studies](#)

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

In case you missed it

- Statements by FDA Commissioner Scott Gottlieb, MD: [updates on some ongoing shortages related to IV fluids](#) (January 16, 2018) and [update on recovery efforts in Puerto Rico, and continued efforts to mitigate IV saline and amino acid drug shortages](#) (January 4, 2018)
- FDA issued a [warning letter](#) to a Florida manufacturer of *in vitro* diagnostic tests for distributing Zika tests without an approved FDA application. See *information about* [diagnostics currently available under Emergency Use Authorization](#) (December 7, 2017)
- In early January 2018, FDA released the [Healthy Innovation, Safer Families: FDA's 2018 Strategic Policy Roadmap](#). In addition, the FDA Center for Drug Evaluation and Research (CDER) released a 2017 report: [Advancing Health through Innovation: New Drug Approvals and Other Drug Therapy Advances of 2017](#) (PDF, 2.8 MB), and the FDA Center for Biologics Evaluation and Research (CBER) released its [CBER FY 2017 Report from the Director](#).
- From NIH - The National Institutes of Health released a [Phase 1 trial update](#) on an experimental treatment for Middle East Respiratory Syndrome Coronavirus (MERS-CoV) (January 10, 2018), and provided an update on [NIAID's MERS-CoV work in Jordan](#) (January 3, 2018)
- From CDC - CDC released new data in its [AR Investment Map](#), which shows early progress by states to combat antibiotic resistance (January 10, 2018)
- From the State Department - NextGen and the U.S. Department of State are hosting the [2018 Infectious Disease Mapping Challenge](#) for undergraduate and graduate students. To participate, sign up by **January 19, 2018**. Also see a [webinar recording about this challenge](#)
- From DARPA - [Going to the Source to Prevent Viral Disease Outbreaks](#) - A new program from the Defense Advanced Research Projects Agency (DARPA), Preventing Emerging Pathogenic Threats (PREEMPT) aims to predict and contain viral mutations to prevent cross-species transmission of disease from animals and insects to humans. DARPA will hold a [Proposers Day](#) on **January 30, 2018**, in Arlington, Virginia, to provide more information about PREEMPT and to answer questions from potential proposers.



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

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