U.S. FOOD & DRUG ADMINISTRATION

Medical Countermeasures Initiative Update

April 25, 2018

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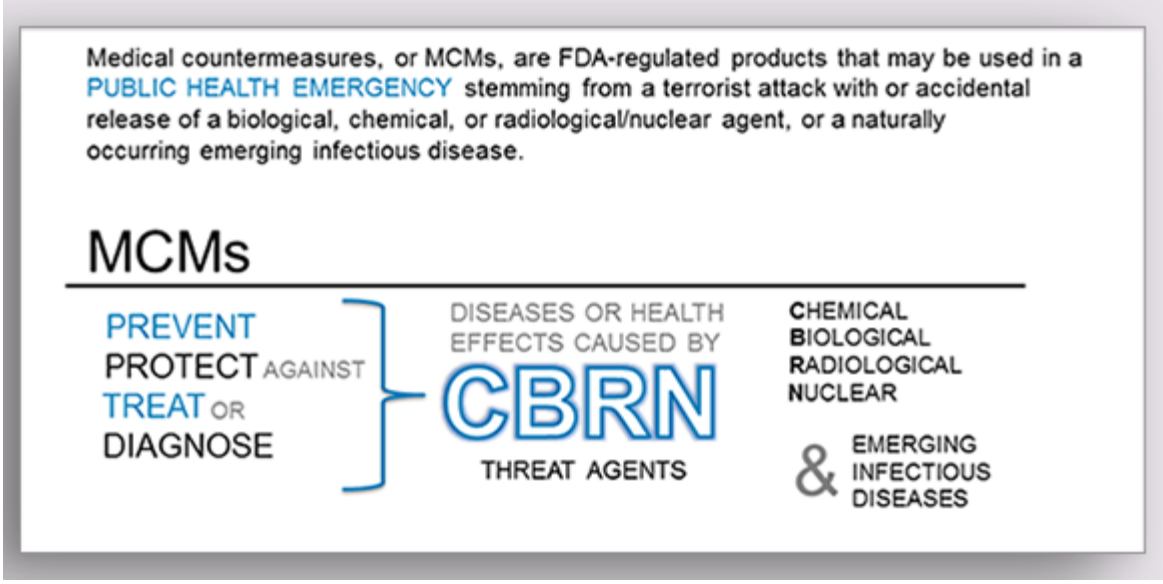
What are MCMs?



Learn more about medical countermeasures (MCMs)—or help others learn—with our new **infographic** (PDF, 251 KB).

Image: (part of infographic) Medical countermeasures, or MCMs, are FDA-regulated products that may be used in a public health emergency stemming from a terrorist attack with or accidental release of a biological, chemical, or radiological/nuclear agent, or a naturally occurring emerging infectious disease. Full text description of entire infographic.

FDA authorizes new use of test

First to identify the emerging pathogen *Candida auris*

On April 20, 2018, FDA authorized the first test to identify the emerging pathogen *Candida auris* (*C. auris*), which can cause serious infections in hospitalized patients. *C. auris* is a yeast that can cause serious infections in hospitalized patients (e.g., bloodstream infections) and is frequently resistant to multiple antifungal drugs used to treat Candida infections.

“Although mass spectrometry technology has been a powerful scientific tool since the 1980s, it is only within that the last five years that it has been effectively used for the identification of microbiological organisms and is now a widely recognized

standard of practice for clinical laboratories," said Donald St. Pierre, acting director of the Office of In Vitro Diagnostics and Radiological Health in the FDA's Center for Devices and Radiological Health (CDRH).

"The FDA has confidence in this technology and recognizes the need to rapidly address outbreaks both for *C. auris* and for other pathogenic microorganisms to help protect Americans through the recognition and identification of emerging infectious pathogens."

Related links:

- General information about *C. auris* from CDC
- *C. auris* fact sheet (CDC)
- Tracking *C. auris* - maps showing U.S. and worldwide cases (CDC)
- Recommendations for Infection Prevention and Control for *C. auris* (CDC)

Image: A strain of C. auris cultured in a petri dish at CDC. (Credit: Shawn Lockhart/CDC)

EUA updates

EUA amendment

- April 16, 2018: CDC Zika MAC-ELISA - In response to CDC's request, FDA concurred with modifications to the authorized Instructions for Use labeling - *Additional technical information, including updated labeling*

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! May 1, 2018:** Antimicrobial Drugs Advisory Committee public meeting (Bethesda, MD) - The committee will discuss new drug application (NDA) 208627 for tecovirimat, sponsored by SIGA Technologies Inc., for the proposed indication of the treatment of smallpox disease caused by variola virus in adults and pediatric patients. This product was developed under the Animal Rule.
- **May 7, 2018:** 1918 Pandemic Flu Symposium - 100 years of Influenza Pandemics and Practice: 1918-2018 (Atlanta, GA), hosted by the Rollins School of Public Health at Emory University, in partnership with CDC - registration required
- **May 10, 2018:** Tick-Borne Disease Working Group public meeting (webcast) - For its fourth meeting, the Working Group will focus on the findings and basis for the draft reports from the work of the six Subcommittee Working Groups that were established on December 12, 2017.
- **New! May 10, 2018:** FDA Grand Rounds webcast - FDA's Predictive Toxicology Roadmap: Implications and Opportunities for Stakeholders, 12:00 - 1:00 p.m. ET, presented by Suzanne Fitzpatrick, PhD, DABT, ERT, Senior Advisor for Toxicology, FDA Center for Food Safety and Applied Nutrition (CFSAN) - please register in advance - *also see FDA's Predictive Toxicology Roadmap*
- **New! May 15-16, 2018:** FDA Regulatory Education for Industry (REdI) Spring 2018 (San Francisco, CA and webcast) - advance registration required
- **New! May 22, 2018:** Public Workshop of the Committee on the Use of Elastomeric Respirators in Health Care (Washington, DC), hosted by NASEM - topics include decision-making and implementation in emergencies
- **May 24, 2018:** FY 2018 Generic Drug Regulatory Science Initiatives Public Workshop (Silver Spring, MD and webcast) - FDA will take information obtained from the public workshop into account in developing fiscal year 2019 regulatory science plans.
- **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.
- **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.
- **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 **3:00 p.m. ET August 6, 2018.**

Information for industry

- Guidance for industry - Special Protocol Assessment (PDF, 182 KB) - This guidance provides information about the procedures and general policies adopted by the Center for Drug Evaluation and Research and the Center for Biologics Evaluation and Research for special protocol assessment (SPA). Several protocols are eligible for SPA, including animal efficacy protocols for studies intended to provide primary evidence of effectiveness required for approval or for licensure for products developed under the Animal Rule. This guidance finalizes the draft guidance of the same name issued May 4, 2016, and replaces the guidance of the same name issued May 17, 2002. (Federal Register notice) *Also see: FDA In Brief: FDA advances policies to bring greater predictability and certainty to the drug development process (April 16, 2018)*
- FDA is conducting a Model-Informed Drug Development (MIDD) Pilot Program to facilitate the development and application of exposure-based, biological, and statistical models derived from preclinical and clinical data sources. MIDD approaches use a variety of quantitative methods to help balance the risks and benefits of drug products in development. When successfully applied, MIDD approaches can improve clinical trial efficiency, increase the probability of regulatory success, and optimize drug dosing/therapeutic individualization in the absence of dedicated trials. FDA will accept

requests to participate in the program on a continuous basis beginning on **April 13, 2018 through June 15, 2022**. See the Federal Register notice for additional information. *(April 17, 2018)*

- **Funding opportunity:** Enhancing Innovations in Emerging Technologies for Advanced Manufacturing of Complex Biologic Products (R01) - FDA's Center for Biologics Evaluation and Research (CBER) seeks to support the application of novel technologies for advanced manufacturing of complex biologic products, and innovative analytical approaches to improve product manufacturing and quality through active research. One such technology is continuous manufacturing, defined as manufacturing using a continuous process, rather than a batch-process approach. This emerging technology has the potential to improve agility, flexibility, cost, and robustness in the development of manufacturing processes. In addition, CBER seeks other innovative technologies for advancing manufacturing of complex biologics such as regenerative medicine products and vaccines. Submit letters of intent by **May 7, 2018**.

More: MCM-Related Guidance by Date

In case you missed it

- Did you know? Generics work the same as brand-name medicines. Find out why.
- Statement from FDA Commissioner Scott Gottlieb, MD, on new efforts to enhance and modernize the FDA's approach to medical device safety and innovation - *also see Medical Device Safety Action Plan: Protecting Patients, Promoting Public Health (PDF, 10 MB) (April 17, 2018)*
- Learn why diversity in clinical research is important by listening to FDA Office of Minority Health's new podcast (video, 17 minutes) featuring U.S. Army veterans discussing clinical trials. *(April 2018)*
- From HHS - HHS purchases anthrax antitoxin for Strategic National Stockpile - Acquisition augments anthrax treatments currently stockpiled *(April 23, 2018)*
- From CDC - CDC released its 10th annual preparedness report, the Public Health Preparedness and Response 2018 National Snapshot. The Snapshot highlights preparedness activities and investments at the federal, state, and local levels, and features stories that demonstrate the impact of these activities. *(April 16, 2018)*
- From CDC/NIOSH - Filtering out Confusion: Frequently Asked Questions about Respiratory Protection - The National Personal Protective Technology Laboratory (NPPTL), part of the National Institute for Occupational Safety and Health (NIOSH) has released new fact sheets on respirator fit testing, user seal check, and respirator reuse and extended use. *(April 9, 2018)*
- From HHS ASPR - Decontamination Decoded: Disrobing, Dry Wiping Removes 99% of Chemical Contaminants - ASPR's Biomedical Advanced Research and Development Authority (BARDA) sponsored a set of scientific studies on chemical decontamination. The results of these studies, codified as the Primary Response Incident Scene Management (PRISM) Guidance for Chemical Incidents, will help local emergency management planners and first responders prepare for and respond to disasters involving chemical agents. *(April 11, 2018)*

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"What are MCMs?" infographic | FDA authorizes first test to identify emerging pathogen Candida auris

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