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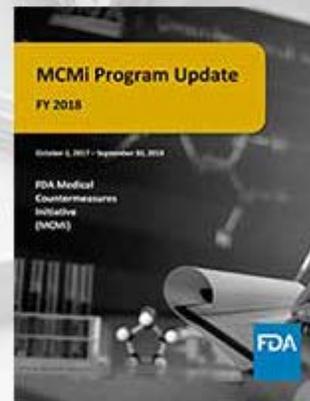
Medical Countermeasures Initiative Update

April 10, 2019

FDA: Protecting the Nation Through MCMs

In FY 2018, FDA approved **28 medical countermeasures**, including:

- ✓ The first drug with an indication for smallpox
- ✓ An auto-injector for chemical nerve agent preparedness
- ✓ The first test to screen for Zika virus in blood donations



FDA's Medical Countermeasures Initiative (MCMi) furthers the development of medical countermeasures by establishing clear regulatory pathways and effective regulatory policies and mechanisms to facilitate timely access to available medical countermeasures (MCMs).

The initiative also advances medical countermeasure regulatory science to create the tools that support timely regulatory decision-making. As our new report on the FDA's medical countermeasure-related activities and achievements in fiscal year 2018 underscores, these efforts are leading to results.

[Read the report](#)

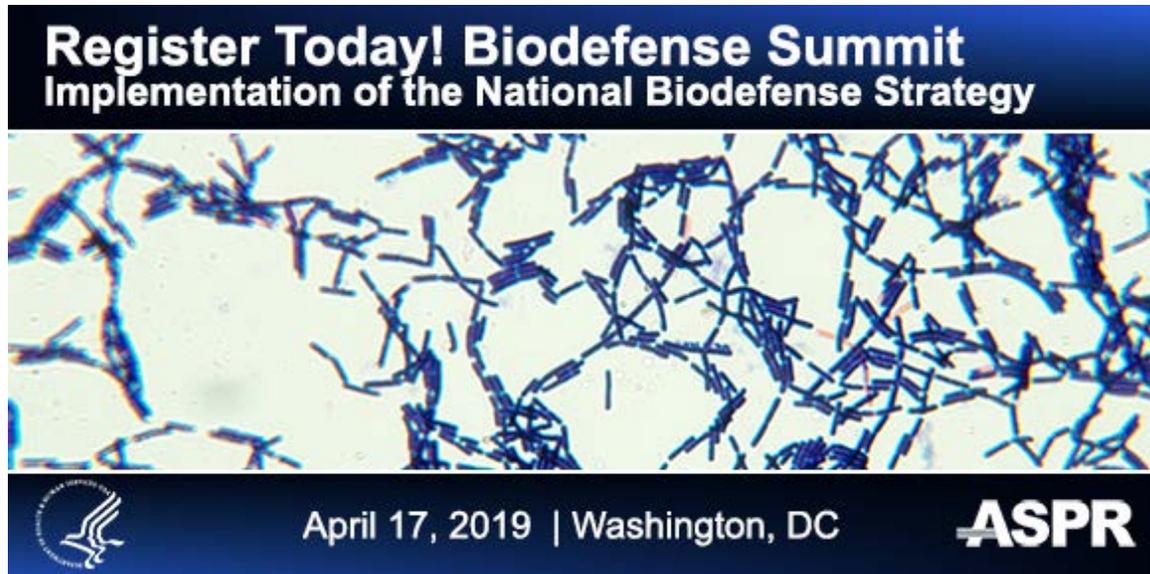
Related information

- [FDA Voices on Policy: FDA Protecting the Nation through Medical Countermeasures](#) (April 9, 2019)
- [MCMi FY 2018 Program Update - downloadable PDF](#) (4 MB)
- [MCMi News and Events](#), for the latest on MCM-related news and upcoming events

- [What are medical countermeasures?](#) (web page and infographic)
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Biodefense Summit

Implementation of the National Biodefense Strategy

A promotional banner for the Biodefense Summit. The top section is a dark blue rectangle with white text that reads "Register Today! Biodefense Summit Implementation of the National Biodefense Strategy". Below this is a microscopic image of blue-stained, branching biological structures. The bottom section is a dark blue rectangle containing the Department of Health and Human Services logo on the left, the text "April 17, 2019 | Washington, DC" in the center, and the ASPR logo on the right.

Register Today! Biodefense Summit
Implementation of the National Biodefense Strategy

April 17, 2019 | Washington, DC **ASPR**

April 17, 2019

8:00 a.m. - 5:00 p.m.

Washington, DC and webcast

Are you interested in helping set the course for the United States to combat the serious biothreats our country faces? Then join us for the [Biodefense Summit](#)! The Biodefense Summit brings together stakeholders from all levels of government and a wide range of private sector stakeholders to discuss implementation of the [National Biodefense Strategy](#) and address issues related to natural outbreaks of disease, accidents involving high consequence pathogens, or the actions of terrorists or state actors.

You can join the conversation by attending the Biodefense Summit in person, logging into the live webcast, or submitting a [public comment](#) (due by **May 1, 2019**). [Registration](#) is free and required for both in-person and online participation.

Events

- **New! April 11, 2019:** FDA Grand Rounds webcast: [Uncertainty is the only certainty there is: Potential approaches for making public health decisions](#), 12:00 - 1:00 p.m. ET, presented by Richard A. Forshee, PhD, Associate Director for Research, Office of Biostatistics and Epidemiology, FDA's Center for Biologics Evaluation and Research - Please [register](#) in advance.

- **New! April 17, 2019:** [Biodefense Summit: Implementation of the National Biodefense Strategy](#) (Washington, DC and webcast) *See details above*
- **April 17, 2019:** [Public Meeting on the Draft Guidance to Support Compliance with the Intentional Adulteration Rule](#) (College Park, MD and webcast) - To discuss the [draft guidance](#) for compliance and implementation of the “Mitigation Strategies to Protect Food Against Intentional Adulteration” rule, which was issued under the FDA Food Safety Modernization Act. [Register](#) by **April 10, 2019**.
- **April 18, 2019:** [NIIMBL Global Health Fund Workshop: Replacing Animal-based Release Testing for Vaccines](#) (Washington, DC area) - Hosted by the National Institute for Innovation in Manufacturing Biopharmaceuticals, this workshop will explore the current state of animal-based release testing and discuss alternative approaches. Organizers encourage those with in-depth knowledge of *in vitro* vaccine potency and toxicity tests to consider attending.
- **May 1, 2019:** [FY 2019 Generic Drug Regulatory Science Initiatives public workshop](#) (Silver Spring, MD and webcast) - To provide an overview of the status of regulatory science initiatives for generic drugs and an opportunity for public input on these initiatives. To attend in-person or via webcast, register by April 1, 2019 by emailing complete contact information for each attendee (including the attendee's name, title, affiliation, address, email, and telephone number) to GDUFARegulatoryScience@fda.hhs.gov. Also submit any requests to make oral presentations as part of your registration email. Submit [comments](#) by **June 1, 2019**.
- **New! May 2, 2019:** [Reagan-Udall Foundation annual public meeting](#) (Washington, DC) - The Foundation will discuss its activities and how they support FDA. Register by **5:00 p.m. ET April 30, 2019**.
- **May 14, 2019:** [Public workshop: BioCompute Objects: Tools for Communicating NGS Data and Analysis](#) (Silver Spring, MD and webcast), co-sponsored by FDA, the George Washington University and the BioCompute Partnership to engage more stakeholders in creating and using BioCompute for NGS and other bioinformatics data analysis communications with the FDA. Specifically, the workshop will have two components: use case examples, and hands on & demonstrations of new tools that leverage BioCompute. A new Precision FDA-BioCompute Challenge will also be launched at the event. Space limited; please [register](#) in advance.
- **New! May 29-30, 2019:** [Regulatory Education for Industry \(REI\) Annual Conference](#) (Boston, MA and webcast) - This course is designed to provide participants with a strong, basic foundation in understanding the FDA's drug and medical device regulatory requirements.

Information for industry

- **FDA finalizes requirements to help foster access to safe and effective tests to detect anthrax-causing bacteria** - FDA issued a [final rule](#) classifying *in vitro* diagnostic devices for the detection of *Bacillus* bacteria into class II (special controls) and continuing to require a [premarket notification \(510\(k\)\)](#) for these devices. (*March 29, 2019*)
- FDA has posted a [Compliance Program for the Inspection of Nonclinical Laboratories Conducting Animal Rule-Specific Studies \(CP 7348.007\)](#) (PDF, 173 KB) on its [Bioresearch Monitoring Program \(BIMO\) Compliance Programs web page](#). This compliance program provides instructions for the inspection of nonclinical laboratories conducting the [Animal Rule](#)-specific studies (i.e., the natural history studies that define the animal model in which the efficacy of an investigational drug or

biological product will be tested, the adequate and well-controlled animal efficacy studies intended to provide the primary evidence of effectiveness to support marketing approval of the product, and the pharmacokinetic and/or pharmacodynamic studies in animals used to select a dose and regimen in humans). Inspections of these studies are conducted to verify, to the extent practicable, the quality and integrity of the data contained in the final reports of the Animal Rule-specific studies submitted to FDA. (April 1, 2019)

- [Guidance - Pediatric Information Incorporated Into Human Prescription Drug and Biological Product Labeling](#) (PDF, 315 KB) - To assist applicants in determining the appropriate placement and content of pediatric information in human prescription drug and biological product labeling as described in the regulations for the content and format of labeling for human prescription drug and biological products. This guidance finalizes the draft guidance issued on February 28, 2013. (March 28, 2019)
 - FDA's Center for Drug Evaluation and Research (CDER) is [announcing the continuation of the Regulatory Project Management Site Tours and Regulatory Interaction Program](#) (the Site Tours Program). Interested pharmaceutical companies may send proposed agendas to CDER by **June 3, 2019**.
 - **Reminder:** [Electronic data standards for Animal Rule studies](#): The comment period for the draft CDISC Standard for Exchange Nonclinical Data (SEND) Implementation Guide for Animal Rule studies ([SENDIG-AR](#)) and the [remaining portion of the controlled terminology](#) closes on **April 29, 2019**.
 - *More: [MCM-Related Guidance by Date](#)*
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In case you missed it

- **Funding:** [FDA Announces Funding Opportunity to Help Define Durations of Use for Certain Medically Important Antimicrobial Drugs for Food Animals](#) - FDA announced a funding opportunity and Request for Applications (RFA) for studies that can help target and define durations of use for certain medically important antimicrobial drugs approved for use in the feed of food-producing animals. The agency also posted a [list of the affected products](#). FDA's Center for Veterinary Medicine (CVM) will accept research applications for the fiscal year 2019 program until **June 3, 2019**.
- FDA [announced](#) that it is exploring a framework that would allow for modifications to artificial intelligence and machine learning algorithms to be made from real-world learning and adaptation, while still ensuring that the safety and effectiveness of the software as a medical device is maintained. [Comment](#) on the [discussion paper](#) (PDF, 1.6 MB) by **June 3, 2019**. Also see: [Artificial Intelligence and Machine Learning in Software as a Medical Device](#)
- From HHS - The National Biodefense Science Board will begin [accepting applications for new members](#) on April 15, 2019. Apply by **June 15, 2019**.
- From NIH - [NIH begins first-in-human trial of a universal influenza vaccine candidate](#) (April 3, 2019)
- You want to make a difference. FDA wants to hire you. Follow [@FDAJobs](#) on Twitter, or visit www.fda.gov/jobs.

More News & Events

from MCMi

FDA Medical Countermeasures Initiative

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