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Medical Countermeasures Initiative Update

April 24, 2019

Join the National Biodefense Science Board

Apply Today!
The National Biodefense Science Board



Applications Due June 15, 2019

ASPR

The National Biodefense Science Board (NBSB) serves as a group of thought leaders who advise the U.S. Department of Health and Human Services (HHS) Secretary and the HHS Assistant Secretary for Preparedness and Response (ASPR) on issues related to biodefense, public health emergency preparedness, response and recovery, and other issues related to national health security.

HHS ASPR is now soliciting applications for new board members. The board is looking for applicants from different professional disciplines including:

- An expert from the pharmaceutical, biotechnology, and device industries
- A state, local, tribal or territorial (SLTT) public health official
- An academic expert
- A representative of healthcare consumers

Applications will be accepted until **June 15, 2019**. If you have questions about the application process, please contact HHS at NBSB@hhs.gov.

Apply today to join the board!

Related information

- [About the National Biodefense Science Board \(from HHS\)](#)
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EUA updates



Emergency Use Authorization and related updates

Recent EUA amendments

- **April 2, 2019:** EUA amendment - DPP Ebola Antigen System (Chembio Diagnostic Systems, Inc.) - [more info](#)
- **April 18, 2019:** EUA amendment - ADVIA Centaur Zika IgM (Siemens Healthcare Diagnostic Inc.) - [more info](#)

Related EUA information for *in vitro* diagnostic devices (IVDs)

- [How to submit a Pre-EUA for IVDs to FDA](#)
 - [Information for laboratories implementing IVD tests under EUA](#)
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Events

- **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**.
- **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 20-22, 2019: Filovirus Animal Non-clinical Group (FANG) Workshop** (Rockville, MD and webcast) - To update the FANG (an interagency working group) and other members of the filovirus community on cross-cutting topics that impact vaccine and therapeutic product development and regulatory approval. Due to security requirements, if you are not a U.S. citizen, you must register at least 2 weeks before the event.
- **May 29-30, 2019: Regulatory Education for Industry (REdI) 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.
- **New! June 26-28, 2019: NIIMBL National Meeting** (Washington, DC) - The program will feature perspectives from industry and government leaders and showcase the work of the National Institute for Innovation in Manufacturing Biopharmaceuticals (NIIMBL) community as it develops the cutting-edge technologies and training programs designed to enhance patient access to life-saving medicines. FDA's Dr. Peter Marks, Director of the Center for Biologics Evaluation and Research (CBER), and Dr. Janet Woodcock, Director of the Center for Drug Evaluation and Research (CDER), are two of the featured speakers on June 27. *(fee)*

Information for industry

Reminders:

- [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**.
 - [Comments](#) on the draft guidance [Quality Considerations for Continuous Manufacturing](#) (PDF, 197 KB) are due by **May 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**.
 - **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**.
 - *More: [MCM-Related Guidance by Date](#)*
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In case you missed it



- **MCMi Fiscal Year 2018 Program Update** - FDA and our partners work every day to help facilitate development of and access to safe, effective medical countermeasures to counter emerging threats. Learn more about the steps we're taking to protect national health and security in this report. [View the PDF](#) (4 MB). Also see: [FDA Voices on Policy: FDA Protecting the Nation through Medical Countermeasures](#) (April 9, 2019)
- FDA Voices on Medical Products: [FDA's Efforts to Advance the Development of Biologics](#) - CBER is working at the forefront of 21st Century medicine. Many of the products regulated by CBER are either living cells or tissues, or are made from them, such as stem cells and genetically engineered immune cells. The Center's diverse regulatory portfolio of complex biological products includes blood components and derivatives, vaccines, allergenics, and cellular and gene therapies. It also includes certain devices, including in vitro diagnostic tests for screening the blood supply and devices for the manufacturing of blood and tissue products. Also see [CBER's FY 2018 Report from the Director](#) (April 17, 2019)
- From CDC - [10 Years Later: The Lasting Impacts of the H1N1 Flu Pandemic Response](#) - As with previous pandemics, the scientific community, including experts at CDC, took away learned lessons that influence how we prepare and monitor for future pandemics. (April 15, 2019)
- You want to make a difference. FDA wants to hire you. Follow [@FDAJobs](#) on Twitter, or visit www.fda.gov/jobs.

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