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

Medical Countermeasures Initiative Update

February 12, 2018

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FDA and NRC pave way for first domestic supply of the most commonly used medical isotope in diagnostic imaging

System will help save and improve lives of patients, reduce risk of drug shortages, and strengthen national security

FDA and the Nuclear Regulatory Commission (NRC) took steps to ensure a stable and secure supply of a critical radioactive imaging product used to detect potentially life-threatening diseases. On February 8, 2018, [FDA approved the RadioGenix System](#), a unique system for producing Technetium-99m (Tc-99m), the most widely used radioisotope in medical imaging.

From FDA Commissioner Scott Gottlieb, M.D:

"This new technology was the result of a broad collaboration across the federal government and industry, and has the potential to benefit many patients as well as restore the U.S. ability to domestically supply a critical medical diagnostic tool for the first time in 30 years.

The system we've approved today will not only help save and improve the lives of patients, but will reduce the risk of drug shortages and strengthen our national security by creating a U.S.-based manufacturing capacity that is less vulnerable to supply disruptions." [Read the full statement](#)

Related links:

- [DOE/NNSA partnership with U.S. healthcare industry results in FDA approval of domestically-produced, non-uranium based Molybdenum-99](#) (February 8, 2018 press release from the National Nuclear Security Administration)
- [The American Medical Isotopes Production Act of 2012](#)

Image: Reactor pool at the High Flux Isotope Reactor (HFIR) at Oak Ridge National Laboratory. Primarily a research reactor, the HFIR is also used for production of medical isotopes. Credit: U.S. Department of Energy [Flickr](#)

FDA reports on progress advancing policies for developing next-generation antibiotics

HHS [released a report](#) to Congress on progress made in facilitating the development and approval of new antibacterial and antifungal drugs, implementing stewardship programs to ensure their judicious use and assessing the impact of the Generating Antibiotic Incentives Now (GAIN) provisions on promoting the pipeline of antibacterial and antifungal drugs.

Related links:

- [Report to Congress: Generating Antibiotic Incentives Now](#) (PDF, 545 KB) (February 2, 2018)
- [QIDP Designation Questions and Answers](#) (PDF, 390 KB) draft guidance - [comment](#) by **April 2, 2018**
- [FDA Office of Antimicrobial Products Research Activities](#)

EUA updates

EUA amendment

- February 6, 2018: DPP Zika IgM Assay System (Chembio Diagnostic Systems, Inc.) - [more info](#)

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

- **February 12, 2018:** [HHS Tick-Borne Disease Working Group meeting](#) (webcast), 12:00 - 4:00 p.m. ET
- **February 12-14, 2018:** [American Society for Microbiology \(ASM\) Biothreats](#) meeting (Baltimore, MD) - FDA experts will present during sessions including Animal Models as Drug Development Tools (*fee*)
- **New! February 13, 2018:** ASPR TRACIE webinar - [Pediatric Issues in Disasters](#) (PDF, 155 KB), 1:00 - 2:30 p.m. ET
- **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! March 5-6, 2018:** [Joint Civil & DoD CBRN Symposium](#) (Alexandria, VA), hosted by the Defense Strategies Institute (*fee*)
- **New! March 8, 2018:** [FDA Grand Rounds webcast](#) - Are Stem Cells Ready for Prime Time? A Look at FDA Research Advances in Regenerative Medicine, 12:00 - 1:00 p.m. ET, presented by Steven Bauer, PhD, Chief, Cellular and Tissue Therapy, Division of Cellular and Gene Therapies, CBER
- **New! March 19, 2018:** Public workshop - [Patient-Focused Drug Development: Developing and Submitting Proposed Draft Guidance Relating to Patient Experience Data](#) (Silver Spring, MD and webcast) - [register](#) by **March 12, 2018** - Also see [Plan for Issuance of Patient-Focused Drug Development Guidance](#) (PDF, 146 KB)
- **New! April 16, 2018:** [Evaluating Inclusion and Exclusion Criteria in Clinical Trials](#) (Washington, DC and webcast) - register by **April 12, 2018**
- **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) - **Last chance to attend: register by February 16, 2018.**

Information for industry

- Reminder for all ANDA and NDA holders: [One-time report on market status](#) for all approved drug products due **February 14, 2018.**
- FDA launched a [new set of web pages](#) that aims to provide a one-stop source for general information about Risk Evaluation and Mitigation Strategy (REMS) programs (*January 29, 2018*)
- FDA published updates to the [Payment for Research Subjects: Information Sheet](#) to clarify that reimbursement for travel expenses to and from the clinical trial site and associated costs such as airfare, parking, and lodging are acceptable under current practices. (*January 29, 2018*)
- Reminder: [Comment](#) by **March 20, 2018** on draft guidance [Material Threat Medical Countermeasure Priority Review Vouchers](#) (PDF, 174 KB) Also see: [FDA takes steps to spur development of medical countermeasures needed to protect, prepare for emerging threats to public health and national security](#) and [21st Century Cures Act: MCM-Related Cures Provisions](#)

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

In case you missed it

- [FDA-CDC Antimicrobial Resistance Isolate Bank: a Publicly Available Resource To Support Research, Development, and Regulatory Requirements](#), in the Journal of Clinical Microbiology - The FDA-CDC Antimicrobial Resistance Isolate Bank was created in July 2015 as a publicly available resource to combat antimicrobial resistance. It is a curated repository of bacterial isolates with an assortment of clinically important resistance mechanisms that have been phenotypically and genotypically characterized. Also see: [FDA-CDC Antimicrobial Resistance Isolate Bank](#)
- From FEMA - The FEMA Youth Preparedness Council is [accepting applications](#) for young leaders in grades 8-11 who are interested and engaged in advocating youth preparedness and making a difference in their communities. Applications are due **March 18, 2018.**
- From DARPA - [Reading the Body's History of Threat Exposure](#) - DARPA's new Epigenetic CHaracterization and Observation (ECHO) program aims to build a field-deployable platform technology that quickly reads someone's epigenome and identifies signatures that indicate whether that person has ever—in his or her lifetime—been exposed to materials that could be associated with weapons of mass destruction (WMD). DARPA will host a [Proposer's Day](#) on **February 23, 2018** in Arlington, VA.



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