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

Medical Countermeasures Initiative Update

July 31, 2018

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Protecting and promoting public health

Advancing FDA's medical countermeasures (MCM) mission

The U.S. Food and Drug Administration's wide-ranging public health responsibilities include the vital role we play on the frontlines of national security by facilitating the development and availability of safe and effective medical countermeasures. These are the vaccines, diagnostics and therapeutics that are needed to protect our nation from chemical, biological, and radiological and nuclear threats, whether naturally occurring, accidental, or deliberate. As in so many areas of public health, our work here is critical, and we are ever-cognizant of its urgency.

One of the many areas in which the agency is continuing to take steps to facilitate the development of medical countermeasures to protect Americans is with respect to the threat of [smallpox](#).

[Read more](#) about recent developments in smallpox preparedness, and FDA's other recent work on MCMs in an FDA Voice blog by Anna Abram, FDA's Deputy Commissioner for Policy, Planning, Legislation and Analysis.

Related links:

- [21st Century Cures Act: MCM-Related Cures Provisions](#)
- [MCM-Related Counterterrorism Legislation](#)
- [Animal Rule Information](#)
- [MCM Regulatory Science](#)

Drug Trial Snapshot: TPOXX

TPOXX is a drug for the treatment of smallpox disease



Smallpox is a serious and highly contagious viral disease that causes fever, rash and deep skin scars and may progress to death. No cases of naturally occurring smallpox disease have happened since the late 1970s because worldwide vaccination led to the eradication of smallpox.

The World Health Assembly declared naturally occurring smallpox eradicated worldwide in 1980, following an unprecedented global immunization campaign. However, small amounts of the variola virus – the virus that causes smallpox – still exist for research purposes. Despite the eradication of naturally occurring smallpox disease, there are longstanding concerns that the variola virus could be used as a weapon. Since routine vaccination was discontinued in the 1970s, many people would be at high risk of getting very ill or dying if exposed to this highly contagious virus.

Drug Trials Snapshots provide consumers with information about who participated in clinical trials that supported the FDA approval of new drugs. [View the Drug Trial Snapshot for TPOXX.](#)

Related links:

- [FDA approves the first drug with an indication for treatment of smallpox](#) (July 13, 2018)
- [Smallpox Preparedness and Response Updates from FDA](#)
- [About Drug Trials Snapshots](#)

Events

- **August 9, 2018:** [FDA Grand Rounds](#) webcast - How Simulation Can Transform Regulatory Pathways, presented by Tina Morrison, PhD, Deputy Director, Division of Applied Mechanics, Center for Devices and Radiological Health (CDRH), FDA - 12:00 - 1:00 p.m. ET. CE credit available; please [register](#) in advance.
- **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 **4:00 p.m. ET August 6, 2018.**
- **August 21-22, 2018:** Public workshop - [Development of Non-Traditional Therapies for Bacterial Infections](#) (Silver Spring, MD and [webcast](#)) Discussions will focus on pre-clinical development, early stage clinical trials, and phase 3 clinical trial designs to evaluate safety and efficacy of non-traditional therapies intended to serve as primary or adjunctive therapy to existing antibacterial drugs. FDA is particularly interested in discussing pre-clinical and clinical development of several types of non-traditional therapies, including monoclonal antibodies, immunomodulators, lysins, and other non-traditional therapies. Register by **August 14, 2018.**
- **New! August 22-23, 2018:** [Workshop: Exploring Medical and Public Health Preparedness for a Nuclear Incident](#) (Washington, DC), hosted by The National Academies of Sciences, Engineering, and Medicine - Participants will explore current assumptions behind and the status of medical and public health preparedness for a nuclear incident, examine potential changes in approach, and discuss challenges and opportunities for capacity building in the current threat environment.
- **New! September 4, 2018:** [Facilitating Competition and Innovation in the Biological Products Marketplace](#) (Silver Spring, MD) - FDA is announcing a public hearing on FDA's approach to enhancing competition and innovation in the biological products marketplace, including by facilitating greater availability of biosimilar and interchangeable products. Electronic or written [comments](#) will be

accepted after the public hearing until **September 21, 2018**.

- **September 12, 2018:** [Public hearing on FDA's Predictive Toxicology Roadmap](#) - FDA is seeking comments on how to foster the development and evaluation of emerging toxicological methods and new technologies and incorporate them into regulatory review, as applicable. To attend, [register](#) by **August 29, 2018**. Also see: [FDA's Predictive Toxicology Roadmap](#) (PDF, 2.2 MB)

Information for industry

- FDA finalized the guidance for industry, [Labeling for Biosimilar Products](#) (PDF, 285 KB). This guidance provides an overview of FDA's recommendations for biosimilar product labeling and is intended to assist industry in developing labeling for submission in proposed biosimilar product applications. A biosimilar product is a biological product that is approved based on a demonstration that it is highly similar to an FDA-approved biological product, known as a reference product. The biosimilar also must be shown to have no clinically meaningful differences in terms of safety and effectiveness from the reference product. Also see: [Biosimilars Action Plan](#) (PDF, 383 KB) (July 18, 2018)
- [FDA issues policy to facilitate the use of electronic health record data in clinical investigations](#) - FDA published a guidance for industry, [Use of Electronic Health Record Data in Clinical Investigations](#) (PDF, 327 KB). The guidance provides recommendations for sponsors, clinical investigators, contract research organizations (CROs), institutional review boards (IRBs), and other interested parties on the use of electronic health record (EHR) data in FDA-regulated clinical investigations. (July 18, 2018)
- FDA's CDRH is [announcing the 2019 Experiential Learning Program \(ELP\)](#). This training is intended to provide CDRH and other FDA staff with an opportunity to understand laboratory practices, quality system management, patient perspective/input, and challenges that impact the medical device development life cycle. FDA invites medical device industry, academia, and health care facilities, and others to participate in this formal training program for CDRH and other FDA staff, or to contact CDRH for more information regarding the ELP. Submit electronic proposals for participation in the ELP within the dates provided at the [ELP website](#). (July 30, 2018)
- Reminder: [Comments](#) are due on the draft guidance for industry, [Smallpox \(Variola Virus\) Infection: Developing Drugs for Treatment or Prevention](#) (PDF, 120 KB) by **September 10, 2018**.

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

In case you missed it

- Drug shortages update: Statement by FDA Commissioner Scott Gottlieb, M.D., on the [formation of a new work group](#) to develop focused drug importation policy options to address access challenges related to certain sole-source medicines with limited patient availability, but no blocking patents or exclusivities (July 19, 2018)
- [Descriptive Analyses in the Sentinel System for the FDA Office of Counterterrorism and Emerging Threats \(OCET\)](#) - A new OCET-sponsored project to explore how the Sentinel System may inform study protocols for MCM safety and effectiveness has been added to the Sentinel website. This project will also provide a baseline for comparison during a public health emergency. Also see [Medical Countermeasure Monitoring and Assessment](#) (July 18, 2018)
- FDA is [requesting](#) that any consumer organizations interested in participating in the selection of voting and/or nonvoting consumer representatives to serve on its advisory committees or panels notify FDA in writing. FDA is also requesting nominations for voting and/or nonvoting consumer representatives to serve on advisory committees and/or panels for which vacancies currently exist or are expected to occur in the near future. Send a letter or email stating interest by **August 29, 2018**.
- From NIH - [Tickborne diseases are likely to increase, say NIH officials](#) - The incidence of tickborne

infections in the United States has risen significantly within the past decade. It is imperative, therefore, that public health officials and scientists build a robust understanding of pathogenesis, design improved diagnostics, and develop preventive vaccines, according to a new [commentary](#) in the New England Journal of Medicine from leading scientists at the National Institute of Allergy and Infectious Diseases (NIAID), part of the National Institutes of Health (NIH). (July 25, 2018)

- From NIH - [Broadly acting antibodies found in plasma of Ebola survivors](#) - Scientists supported by NIAID have discovered a set of powerful, broadly neutralizing antibodies (bNAbs) in the blood of Ebola virus disease survivors. In animal studies, two of these antibodies provided substantial protection against disease caused by *Zaire ebolavirus*, *Bundibugyo ebolavirus* and *Sudan ebolavirus*, the three species known to cause fatal human illness. (July 17, 2018)
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