



May 8, 2019

## Extending Expiration Dates of Doxycycline Tablets and Capsules in Strategic Stockpiles

**Final guidance for government public health and emergency response stakeholders to support anthrax emergency preparedness**

This document provides guidance to government stakeholders, under the FD&C Act, on testing to extend the shelf life (i.e., expiration date) of stockpiled doxycycline tablets and capsules for public health emergency preparedness and response purposes for an anthrax emergency.

[View the guidance](#)

### Related information

- [Federal Register notice](#) (April 25, 2019)
- [Expiration Dating Extension](#), including doxycycline-specific information

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## Collaborating to support public health emergency preparedness



### FDA and HHS/ASPR renew agreement

FDA and the HHS Office of the Assistant Secretary for Preparedness and Response (ASPR) renewed an interagency Memorandum of Understanding ([MOU 225-19-013](#)) to provide a framework for coordination and collaborative efforts related to the development and availability of MCMs in public health medical emergencies. The original MOU was signed in 2012.

## Related information

- [MCM-Related Cooperative Arrangements](#)
- [MCMi Collaborations](#)



## Check out the newly redesigned FDA.gov website

FDA is pleased to announce the launch of our newly redesigned [public website](#). We've made [improvements](#) to provide a more modern and customer-centric web experience. [Let us know what you think!](#)

For feedback specific to medical countermeasure-related content, or if you need help finding something, contact [AskMCMi@fda.hhs.gov](mailto:AskMCMi@fda.hhs.gov).

## Update your bookmarks to FDA web pages, including:

- [Medical Countermeasures Initiative](#)
- [Emergency Use Authorization](#)
- [MCMi News and Events](#)
- [MCM Issues, including Ebola preparedness and response](#)

## Events

- **New! May 9, 2019:** [FDA Grand Rounds webinar](#) - Gaining Insight into the Patient's Experience by Harnessing the Power of Social Listening and FDA Archival Data, 12:00 - 1:00 p.m. ET, presented by Christine Lee, PharmD, PhD, FDA Center for Drug Evaluation and Research
- **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 16, 2019:** [Characterizing the Food and Drug Administration's Approach to Benefit-Risk Assessment Throughout the Medical Product Life Cycle](#) public meeting (Silver Spring, MD and webcast) - To gather industry, patient, researcher, and other stakeholder input on applying FDA's Benefit-Risk Framework throughout the human drug lifecycle and best approaches to communicating FDA's benefit-risk assessment. Input from this meeting will support development of a draft guidance on benefit-risk assessment for new drugs and biologics and result in a publicly available summary report. [Register](#) by **May 10, 2019**.
- **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 an American citizen, you must register no later than 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, hosted by [CDER Small Business & Industry Assistance](#).

- **New! June 6, 2019: Antimicrobial Drugs Advisory Committee public meeting** (Silver Spring, MD and webcast) - The committee will discuss new drug application (NDA) 212862, pretomanid tablets for oral administration, submitted by The Global Alliance for TB Drug Development, Inc., proposed as part of a combination regimen with bedaquiline and linezolid in adults for the treatment of pulmonary extensively drug resistant and treatment-intolerant or non-responsive multidrug-resistant tuberculosis (TB).
- **June 26-28, 2019: NIIMBL 2019 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)*

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## Information for industry

### Reminders:

- [Comments](#) on the draft guidance [Quality Considerations for Continuous Manufacturing](#) 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**.

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## In case you missed it

- [First FDA-approved vaccine for the prevention of dengue disease in endemic regions](#) - FDA announced approval of Dengvaxia, the first vaccine approved for the prevention of dengue disease caused by all dengue virus serotypes (1, 2, 3 and 4) in people ages 9 through 16 who have laboratory-confirmed previous dengue infection and who live in endemic areas. Dengue is endemic in the U.S. territories of American Samoa, Guam, Puerto Rico and the U.S. Virgin Islands. *(May 1, 2019)*
- [FDA Voices on Food: Rapid Response Teams Mark 10 Years of Collaboration on Public Health Emergencies](#) - Responding to health emergencies, such as the current multi-state outbreak of *Salmonella Carrau* linked to pre-cut melons, has long been a top priority at the FDA. The agency is working with the Centers for Disease Control and Prevention and our state partners to trace the specific source of these melons and collect samples for laboratory analysis. The outbreak required multiple agencies to work together to inspect and investigate. Such an effort was also required to trace the 2018 *E. coli* outbreak linked to romaine lettuce from California. *(April 25, 2019)*
- From HHS - The National Biodefense Science Board is [accepting applications](#) for new members. Apply by **June 15, 2019**.
- You want to make a difference. FDA wants to hire you. Follow [@FDAJobs](#) on Twitter, or visit [www.fda.gov/jobs](http://www.fda.gov/jobs).



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