



PHEPCONNECTS

W E B I N A R

U.S. Food and Drug Administration (FDA) **Emergency Response Authorities and** **Access to Medical Countermeasures**

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Purpose

- Provide an overview of FDA's tools and authorities for facilitating the availability of medical countermeasures (MCMs) for emergency preparedness and response
- Provide an overview of FDA's response to COVID-19, focusing on Emergency Use Authorizations (EUAs)
- Provide web links to MCM-related resources

Presenters



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Webinar Outline

- Emergency Use Authorization (EUA) Authority
 - Overview of FDA's COVID-19 Response
- Other Emergency Use Authorities for Approved MCMs:
 - Emergency Dispensing Orders
 - Emergency Use Instructions
 - Expiration Dating Extensions
 - Waivers of current Good Manufacturing Practice (cGMP) Requirements
- Liability Protections: PREP Act
- Resources

Subtopic 1

Emergency Use Authorization (EUA) Authority



What is a medical countermeasure (MCM)?

- During public health emergencies, MCMs may be needed to prevent or treat diseases or conditions caused by chemical, biological, radiological, or nuclear (CBRN) or emerging infectious disease threats, like pandemic influenza, Zika virus, and SARS-CoV-2
- FDA is responsible for reviewing the safety and effectiveness of MCMs—including drugs, therapeutic biologics, vaccines, and devices, such as diagnostic tests—to counter these threats
- MCMs include:
 - Qualified countermeasures as defined in section 319F–1(a)(2)(A) of the Public Health Service Act (PHS Act) (42 USC. § 247d–6a(a))(2)(A)
 - Qualified pandemic or epidemic products as defined in section 319F–3(i)(7) of the PHS Act (42 USC. § 247d–6d(i)(7))
 - Security countermeasures as defined in section 319F-2(c)(1)(B) of the PHS Act (42 USC § 247d–6b(c)(1)(B))

What if an MCM is needed for use during a response before it's been approved by FDA?

- Goal: FDA approval before stockpiling and use during a response
- But that is not always possible. For example:
 - There might not be any approved products for the threat or condition
 - An approved product might need to be used in unapproved ways (e.g., in a new age group; for a new threat or condition; without an individual prescription)
 - There might be supply shortages of an approved product
 - Clinical trial environment might not be practical
- **Expanded access mechanisms** (FD&C Act §§ 561)
 - Investigational New Drug application (IND) (21 CFR Part 312)
 - Investigational Device Exemption (IDE) (21 CFR Part 812)
- **Emergency use mechanisms**
 - Emergency Use Authorization (EUA) (FD&C Act § 564)
 - Other emergency use authorities (FD&C Act §§ 564A, 564B)

Emergency Use Authorization (EUA)

- Established by Project BioShield Act of 2004; authority delegated to the Commissioner of Food and Drugs (FDA)
- Amended by:
 - PAHPRA (2013) (to provide additional pre-event flexibilities, among other things)
 - 21st Century Cures Act (2016) (to add animal drugs)
 - P.L. 115-92 (2017) (to provide additional flexibilities for DoD)
- Part of the post-9/11 Federal Government focus on MCM stockpiling and preparedness for counterterrorism
 - Provided physicians and public health officials an “important new tool” for public health and medical care under emergency conditions
- Recognition there will always be promising new drugs, biological products, and devices in the pipeline, as well as promising investigational uses

Emergency Use Authorization (EUA)

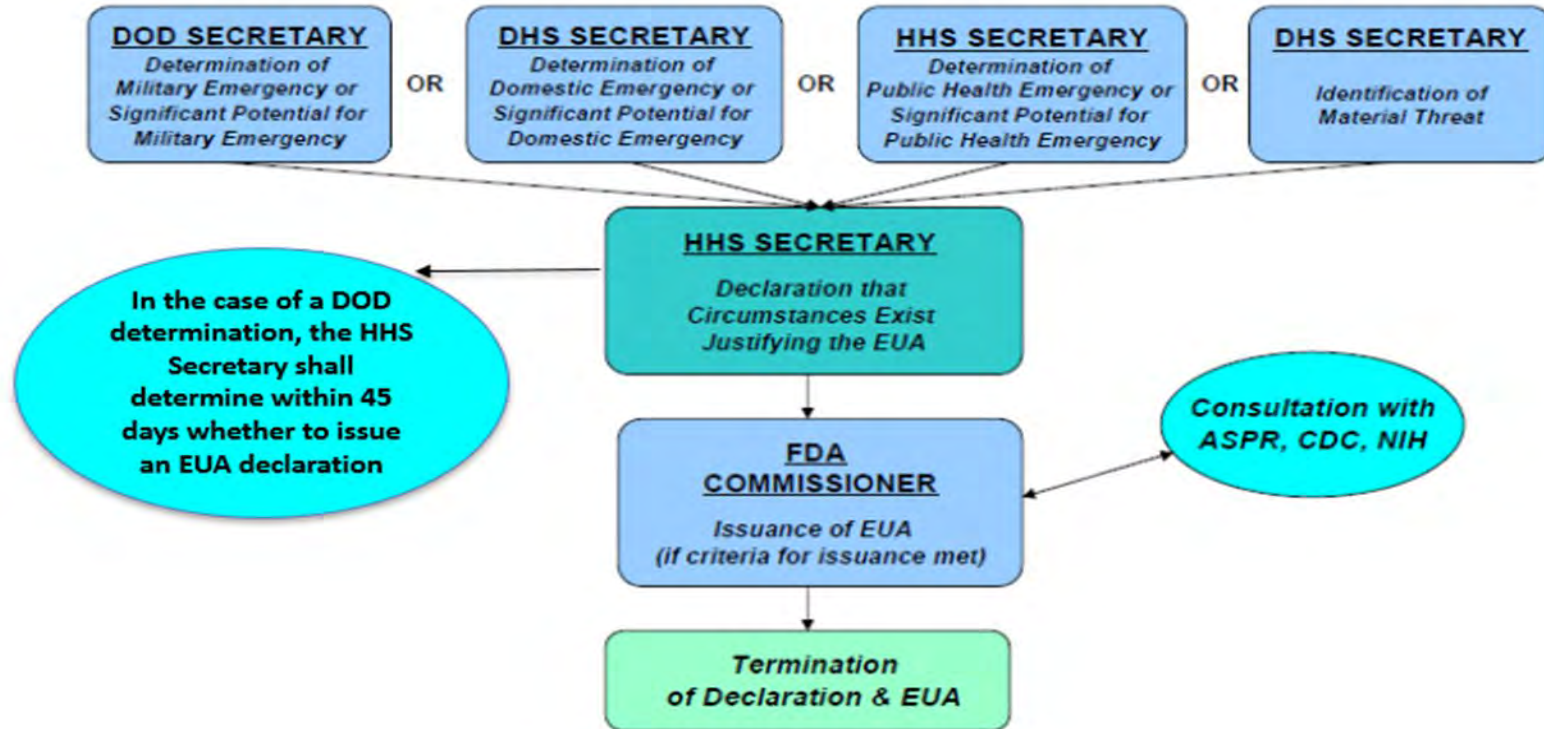


- What is an EUA?
 - A legal mechanism FDA can use to facilitate access to critical medical products during certain defined emergency events
- With an EUA, FDA can authorize for use in emergencies involving a CBRN agent(s) [and, for DoD, an agent or agents that may cause, or are otherwise associated with, an imminently life-threatening and specific risk to United States military forces] the:
 - Use of unapproved MCMs or
 - Unapproved use of approved MCMs (e.g., for a new indication, such as amoxicillin for anthrax)
- FDA EUA page: <https://www.fda.gov/emergency-preparedness-and-response/mcm-legal-regulatory-and-policy-framework/emergency-use-authorization>
- FDA EUA guidance: <https://www.fda.gov/regulatory-information/search-fda-guidance-documents/emergency-use-authorization-medical-products-and-related-authorities>

Emergency Use Authorization (EUA)

- When scientific evidence is available to support MCM use in a CBRN emergency, issuing an EUA enables response stakeholders to use, or prepare to use, an MCM without violating provisions of the FD&C Act
- Requested by government (e.g., CDC, ASPR, DoD) or industry sponsors; FDA may prioritize requests if needed
- Can help to ensure availability of applicable PREP Act liability protections
- Materials (e.g., letter of authorization, fact sheets) may be amended/reissued after initial issuance if needed
- Before FDA issuance, multiple steps with other government partners are required (as outlined on the next slide)

Summary of EUA Issuance Process



Example of EUA Issuance Process: COVID-19 Vaccine

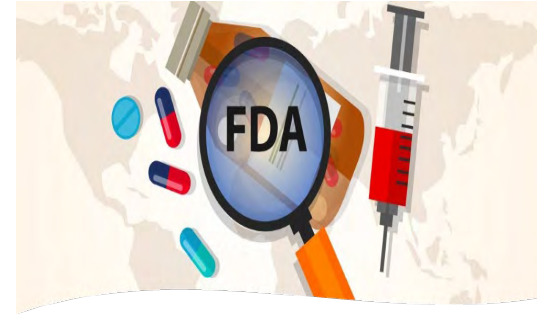
- **2/4/20: HHS issued an EUA determination**
 - Pursuant to Section 564(b)(1)(C) of the FD&C Act, the Secretary of HHS determined that there is a public health emergency that has a significant potential to affect national security or the health and security of United States citizens living abroad, and that involves the virus that causes COVID-19
- **3/27/20: HHS issued an EUA declaration for drugs and biological products**
 - On the basis of the 2/4/20 HHS EUA determination, the Secretary of HHS declared that circumstances exist justifying the authorization of emergency use of drugs and biological products during the COVID-19 pandemic, pursuant to Section 564 of the FD&C Act, subject to terms of any authorization issued under that section
- **12/18/20: FDA issued an EUA for Moderna's COVID-19 vaccine**
 - Issuance based on the above determination and declaration

EUA Criteria for Issuance and Conditions

- **Criteria for issuance:** Based on the totality of scientific evidence available to FDA –
 - Serious or life-threatening illness/condition caused by the agent(s) referred to in the HHS Secretary’s EUA declaration
 - Reasonable belief the product “may be effective” in preventing, diagnosing, or treating serious or life-threatening diseases or conditions caused by the agent(s)
 - Known/potential benefits outweigh known/potential risks
 - Provides for a lower level of evidence than the "effectiveness" standard FDA uses for product approvals
 - Case-by-case: Recommended safety and effectiveness data requirement can vary depending on the nature of the emergency and product candidate
 - No adequate, approved, and available alternative to the product
- **Conditions of authorization:** Safeguards specific to each EUA are required, some are discretionary to protect the public

FDA Review of EUA Requests

- FDA review timelines and action on an EUA request depend on:
 - The product profile – What product data are available to support a risk/benefit analysis?
 - The existence, if any, of pending applications (i.e., IND, pre-EUA) for the product – What does FDA already know about the product?
 - The nature of the emergency – How imminent is the threat?
 - Other relevant factors – Product data in related disease states, safety information?
- Although the time required for FDA action will vary, in an emergency situation that is occurring or believed imminent, a request for consideration for an EUA could be acted upon within a matter of hours or days



What's typically included in an EUA package?

- Letter of authorization
 - Addressed to the EUA requester (e.g., the ASPR; the CEO of a diagnostic company); signed by FDA's Chief Scientist
 - Includes the scope of authorization [e.g., “for the prevention of Coronavirus Disease 2019 (COVID-19) for individuals 18 years of age] and conditions (e.g., reporting of adverse events)
- Fact Sheet for Healthcare Providers
- Fact Sheet for Recipients and Caregivers
- Instructions for use (if applicable)
- Other labeling, review memo, etc. (if applicable)
- Public materials posted on FDA's EUA website: <https://www.fda.gov/emergency-preparedness-and-response/mcm-legal-regulatory-and-policy-framework/emergency-use-authorization> (including *Federal Register* notices of EUA issuances)

Subtopic 2

Overview of FDA's Response to COVID-19

Overview of FDA's COVID-19 Response Roles

- Engaging and collaborating with interagency and SLTT partners
- Monitoring for fraudulent product, halting the sale of products with fraudulent claims related to COVID-19
- Actively monitoring medical and food product supply chains
- Facilitating the development of diagnostics, vaccines, and therapeutics
- Approving medical products
- Monitoring for adverse events
- Issuing guidance documents for regulated industry
- Public communications
- Facilitating imports of medical products needed for the response (e.g., PPE)
- Facilitating access to MCMs, including through issuing EUAs
- etc...

Early COVID-19 Response – Access to Treatment

- Expanded Access (21 CFR 312):
 - Use of an investigational drug outside of a clinical trial to treat a patient with a serious or immediately life-threatening disease or condition
 - No comparable or satisfactory alternative treatment options
- In the early days of the COVID-19 response, CDER was receiving a large number of requests for use of investigational treatment products under expanded access
 - To manage the large volume of requests (particularly for remdesivir), CDER established a 24/7 call center
- Issuance of EUA streamlined the large scale patient access to investigational treatment

Overview of COVID-19 Response EUAs (January 19, 2021)

- Therapeutics: 8 EUAs for products to treat COVID-19 and serious conditions caused by COVID-19
 - One treatment (remdesivir) is currently approved by the FDA for use in COVID-19
 - Hydroxychloroquine/chloroquine, remdesivir, monoclonal antibodies, convalescent plasma, supportive care (intubation, dialysis)
- Devices:
 - *Testing*: 319 tests & sample collection devices authorized under EUAs
 - *Other*: EUAs for PPE, blood purification devices, PPE decon systems, infusion pumps, ventilators/ventilator accessories, etc.
- Vaccines: 2 EUAs issued for COVID-19 vaccines (Pfizer & Moderna)
- FDA's EUA Website: <https://www.fda.gov/emergency-preparedness-and-response/mcm-legal-regulatory-and-policy-framework/emergency-use-authorization>



Reference: <https://www.fda.gov/media/137005/download>

COVID-19 Response – Guidance Development

- The FDA has issued more than 70 guidance documents to provide updated policies, transparency, and regulatory flexibility on:
 - Diagnostics, personal protective equipment, other medical devices, investigational treatment with convalescent plasma, conduct of clinical trials of medical products, blood supply, hand sanitizers, food safety and supply, telemedicine and other topics.
- [COVID-19 Guidance Website](#)

Examples of Other FDA COVID-19 Response Activities

- Fraudulent products – 1281 fraudulent products identified, FDA issuing warning letters and alerting marketplaces
- Hand Sanitizers – issued policy for methanol testing and maintain a [website of “do not use” hand sanitizers](#)
- [COVID-19 Resources for Health Professionals](#) provides quick and easy access to FDA information for health care professionals.
- Translations of vaccine EUA Fact Sheets into multiple languages
- [COVID-19 FAQs](#) (Spanish version available)
 - Hand sanitizers, testing, PPE, food safety, animal food safety
- etc.

Subtopic 3

Other Emergency Use Authorities for Approved MCMs:

Emergency Dispensing Orders, Emergency Use Instructions, Expiry Dating Extensions

Other MCM Emergency Use Authorities

- During emergency responses, certain uses of approved medical products may be needed to achieve critical public health goals, but could violate provisions of the FD&C Act, for example:
 - Dispensing a drug product beyond its labeled expiration date
 - Giving recipients of a vaccine simplified fact sheets about the product that are not part of its FDA-approved labeling
- Section 564A of the FD&C Act (PAHPRA, 2013)
 - Emergency dispensing orders
 - Expiry dating extensions
 - Emergency use instructions
 - Waivers of certain cGMP and REMS requirements
- Section 564B of the FD&C Act (PAHPRA, 2013)
 - To allow for holding/stockpiling of **unapproved** product

Emergency Dispensing Orders

- Established by PAHPRA (2013), this authority allows FDA to facilitate the availability and use of eligible, approved MCMs needed during public health emergencies without FDA needing to issue an EUA [FD&C Act § 564A(d)]
- FDA may allow emergency dispensing [including mass dispensing at a point of dispensing (POD)] of **approved** MCMs during an actual CBRN emergency, without requiring an individual prescription for each recipient of the MCM, if
 - (1) permitted by state law or
 - (2) in accordance with an order issued by FDA

Emergency Dispensing Orders in the Field



- To date, FDA has issued two (2) emergency dispensing orders:
 - [Doxycycline for inhalational anthrax PEP](#) (2016)
 - [Ciprofloxacin for inhalational anthrax PEP](#) (2016)
- In the above orders, the term “stakeholder(s)” is defined as the public agency or its delegate that has legal responsibility and authority for responding to an incident, based on political or geographical boundary lines (e.g., city, county, tribal, State, or Federal), or functional (e.g., law enforcement or public health range) or sphere of authority to prescribe, administer, deliver, distribute, or dispense oral doxycycline products in an emergency situation
- FDA worked closely with CDC on these orders and in the development of the CDC-issued emergency use instructions (EUI) that accompany them

Emergency Use Instructions (EUI)

- Established by PAHPRA (2013), this authority allows CDC to facilitate the availability of streamlined information about the use of eligible, approved MCMs needed during public health emergencies without FDA needing to issue an EUA (FD&C Act § 564A(e))
- Authority was delegated to the CDC Director (2013); when feasible, FDA and CDC will coordinate issuance of an emergency dispensing order and EUI for an MCM
 - An FDA-CDC MOU was developed to guide interactions when CDC calls upon FDA to review EUI
- CDC may create and issue, and government stakeholders may disseminate, EUI (also referred to as fact sheets for recipients of an MCM and for health care professionals) about the FDA-approved conditions of use for such MCMs before or during a CBRN event

Excerpt of EUI for Ciprofloxacin for Post-Exposure Prophylaxis (PEP) of Anthrax

Emergency Use Instructions for Healthcare Providers

This fact sheet provides instructions for the use of ciprofloxacin for post-exposure prophylaxis (PEP) during an emergency involving anthrax (referred to as Emergency Use Instructions (EUI) fact sheet). Ciprofloxacin is FDA-approved for PEP of inhalation anthrax – to reduce the incidence or progression of disease following exposure to aerosolized *Bacillus anthracis* (*B. anthracis*).¹ The Food and Drug Administration (FDA) has also issued an order permitting the emergency dispensing of oral formulations of ciprofloxacin without a prescription during an anthrax emergency to individuals who may have been exposed to *B. anthracis*.²

What is inhalation anthrax?

Anthrax is a serious disease caused by the spore-forming bacterium *B. anthracis*. Inhalation anthrax is the most deadly form of the disease, with a historical mortality rate of approximately 90% for untreated cases. Inhalation anthrax occurs when an individual inhales aerosolized spores. It is not spread from person to person. Early symptoms include fever, chills, fatigue, cough or headache. Later symptoms include shortness of breath, chest pain, confusion or nausea. Symptoms usually occur within 7 days of inhaling anthrax spores, but can

Print Factsheet

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Why should I use ciprofloxacin?
Ciprofloxacin is effective against the spore-forming bacterium *B. anthracis*. Ciprofloxacin is FDA-approved for PEP of inhalation anthrax – to reduce the incidence or progression of disease following exposure to aerosolized *B. anthracis*.¹ The Food and Drug Administration (FDA) has also issued an order permitting the emergency dispensing of oral formulations of ciprofloxacin without a prescription during an anthrax emergency to individuals who may have been exposed to *B. anthracis*.²

What is the correct dose of ciprofloxacin for PEP of anthrax?
The full EUI regimen is 400 mg. During an anthrax emergency, ciprofloxacin tablets are available in 250 mg and 500 mg strengths. Adults should take 250 mg twice daily (BID) for 60 days. Children should take 10 mg/kg twice daily (BID) for 60 days. The maximum daily dose is 1,000 mg.

What are the common side effects of ciprofloxacin?
Common side effects of ciprofloxacin include nausea, vomiting, diarrhea, dizziness, headache, and fatigue. Serious side effects include tendonitis, tendon rupture, and peripheral neuropathy.

What are the contraindications of ciprofloxacin?
Ciprofloxacin is contraindicated in patients with a known hypersensitivity to ciprofloxacin or other quinolones. It is also contraindicated in patients with a history of tendonitis or tendon rupture.

What are the precautions of ciprofloxacin?
Ciprofloxacin should be used with caution in patients with a history of seizures, diabetes, and kidney disease. It should also be used with caution in patients taking other medications that may interact with ciprofloxacin.

Weight in pounds (kg)	Dose* (mg) (mg/kg)	Number of 250 mg and 500 mg tablets (or capsules)
100 (45.4)	250 (5.5)	1 (250 mg)
110 (50.0)	275 (6.1)	1 (250 mg) + 1 (25 mg)
120 (54.4)	300 (6.7)	1 (250 mg) + 2 (25 mg)
130 (59.0)	325 (7.3)	1 (250 mg) + 3 (25 mg)
140 (63.5)	350 (7.8)	1 (250 mg) + 4 (25 mg)
150 (68.0)	375 (8.4)	1 (250 mg) + 5 (25 mg)
160 (72.6)	400 (8.9)	1 (250 mg) + 6 (25 mg)
170 (77.1)	425 (9.5)	1 (250 mg) + 7 (25 mg)
180 (81.6)	450 (10.0)	1 (250 mg) + 8 (25 mg)
190 (86.2)	475 (10.6)	1 (250 mg) + 9 (25 mg)
200 (90.7)	500 (11.1)	1 (250 mg) + 10 (25 mg)

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What are the interactions of ciprofloxacin?
Ciprofloxacin may interact with other medications, including theophylline, warfarin, and tizanidine. It may also interact with certain supplements, including St. John's wort.

What are the pregnancy and breastfeeding considerations for ciprofloxacin?
Ciprofloxacin is not recommended for use during pregnancy or breastfeeding.

What are the storage and disposal instructions for ciprofloxacin?
Ciprofloxacin should be stored at room temperature (20°C to 25°C) and protected from light. It should be disposed of according to the instructions on the label.

What are the contact information and references for ciprofloxacin?
For more information, contact the FDA at 1-800-FDA-1088. For more information, visit the FDA website at www.fda.gov.

What are the copyright and trademark information for ciprofloxacin?
Ciprofloxacin is a registered trademark of Bayer AG. All other trademarks are the property of their respective owners.

What are the disclaimer and liability information for ciprofloxacin?
This fact sheet is for informational purposes only and does not constitute an offer of medical advice. It is not intended to be used as a substitute for professional medical advice.

What are the additional information and resources for ciprofloxacin?
For more information, visit the FDA website at www.fda.gov.

[Ciprofloxacin for Post-Exposure Prophylaxis of Anthrax Emergency Use Instructions for Healthcare Providers](#) [PDF – 2 pages]



EUI Instructions for Making Doxy Suspension from Tablets

A. Get the supplies you need



You will need these items to make doses of doxycycline for children and adults who cannot swallow pills:

- 1 doxycycline hyclate tablet (100 mg)
- 1 metal teaspoon
- 1 oral syringe or medicine spoon (if available)
- 2 small bowls
- small amount of drinking water (4 teaspoons or 20 mL)
- 1 of these foods or drinks to make the crushed doxycycline taste better*:
 - milk, including breast milk and formula for infants
 - chocolate milk
 - chocolate pudding
 - apple juice mixed with 2 to 4 teaspoons of sugar

C. Measure the right amount of Doxycycline



1. Find your child's weight on the [chart below](#). *Weight is better, but if you don't know how much your child weighs, find your child's age on the chart.*
2. Follow the row of your child's weight or age across to the column "**Amount of Doxycycline & Water Mixture to Measure.**"
3. **Measure** the amount of doxycycline and water mixture for your child's weight or age from the first bowl. *For a one-half (½) teaspoon dose, fill the teaspoon halfway or use an oral syringe (if available). It is better to give a little more of the medicine than not enough.*
4. Place this amount into the **second bowl**. This is **one dose** that should be mixed with food or drink.

B. Soak the tablet in water and crush it



1. Put 1 doxycycline hyclate tablet in a small bowl.
2. Add 4 teaspoons (20 mL) of water to the same bowl.
3. Let the tablet soak in the water for at least 10 minutes to soften it.
4. Crush the tablet with the back of the metal spoon until you can't see any pieces of the tablet in the water.
5. Stir the tablet and water to mix it well.

You have now made the doxycycline and water mixture.

D. Mix the dose with food or drink



- Mix the dose (measured amount of doxycycline and water mixture) in the second bowl with **3 teaspoons** of one of the following:
 - Milk, including breast milk and formula for infants
 - Chocolate milk
 - Chocolate pudding**OR**
 - Apple juice mixed with 2 to 4 teaspoons of sugar

You now have one dose, mixed with food or drink.

- Stir well before giving it to your child

E. Give the dose



- Give your child **all** of the doxycycline, water and food mixture from the second bowl. Make sure your child swallows all of it. This is one dose.
- Do this once **every 12 hours** (once in the morning AND once at night) **each day** for as long as directed

Expiration Dating Extensions

- To help prepare for public health emergencies, MCMs may be stockpiled by federal or SLTT governments and even by some private sector partners
- A medical product is typically labeled by the manufacturer with an expiration date. This reflects the time period during which the product is expected to remain stable, or retain its identity, strength, quality, and purity, when it is properly stored according to its labeled storage conditions
- In some cases, testing has shown that certain properly stored medical products can be used beyond their labeled expiration date if they retain their stability. Recognizing stakeholders' MCM stockpiling challenges, FDA is engaged, when appropriate, in various expiration dating extension activities:
 - Initiated by the manufacturer
 - Shelf-Life Extension Program (SLEP)
 - Emergency use authorities
 - Enforcement discretion

Shelf-Life Extension Program (SLEP)

- SLEP is a federal program for extending the useful life of certain federally-stockpiled medical products (not available for SLTT partners)
 - MCMs that are owned by components of DoD or other federal program participants such as the Strategic National Stockpile (SNS)
- SLEP is designed to defer drug replacement costs for date-sensitive stockpiles of drugs by extending their useful shelf life beyond the manufacturer's original labeled expiration date
 - FDA laboratory personnel test drugs to assure stability and quality before an expiry dating extension is granted
- In FY 2019, FDA granted shelf-life extensions for approximately 2,000 lots (batches) of MCM drugs

Expiration Dating Extension Authority Example: Doxycycline Shelf Life Extension

- In response to 2011-2013 rising doxycycline pricing as well as stakeholders' overarching concerns about being able to replace existing stockpiles, FDA developed a guidance where state and local stockpilers can test doxycycline product and submit test results to FDA to support an FDA decision about extending its useful shelf life, thereby deferring replacement costs
 - Section 564A(b) of the FD&C Act
 - [Doxycycline Shelf Life Extension Guidance](#)
 - [Current Doxycycline Expiration Extensions](#) (to July 2022)
 - Extrapolation to others properly holding the same lots
- Based on government stakeholder needs, FDA continues to review scientific data to determine whether additional extensions of other MCMs may be supported outside of SLEP
- <https://www.fda.gov/emergency-preparedness-and-response/mcm-legal-regulation-and-policy-framework/expiration-dating-extension>

Waivers of Certain cGMP and REMS Requirements

- Under Section 564A(c) of the FD&C Act, FDA may waive otherwise applicable manufacturing requirements [current Good Manufacturing Practices (cGMPs)], such as storage or handling, to accommodate emergency response needs
 - Examples:
 - Doxycycline and ciprofloxacin emergency dispensing orders (defined temporary storage temperature deviations during an anthrax response)
 - To facilitate access to certain ventilators during the COVID-19 response
- Under Section 505-1 of the FD&C Act, the waiver authority for risk evaluation and mitigation strategies ([REMS](#)) encompasses any element for MCMs to mitigate the health effects of a CBRN emergency

Subtopic 4

Liability Protections:

Public Readiness and Emergency Preparedness (PREP) Act

PREP Act (2005)

- An HHS (not FDA) authority; a PREP Act declaration is specifically for the purpose of providing immunity from liability, and is different from, and not dependent on, other emergency declarations
- Authorizes the Secretary of HHS to issue a PREP Act declaration, which provides immunity from liability (except for willful misconduct) for claims:
 - of loss caused, arising out of, relating to, or resulting from administration or use of countermeasures to diseases, threats, and conditions
 - determined by the Secretary to constitute a present, or credible risk of a future public health emergency
 - to entities and individuals involved in the development, manufacture, testing, distribution, administration, and use of such countermeasures
- Immunity is not available for:
 - Death or serious physical injury caused by willful misconduct
 - Foreign claims where the U.S. has no jurisdiction

PREP Act

- “Covered countermeasures”
 - Types are defined in law (e.g., “qualified pandemic or epidemic product”)
 - Include medical products that are approved or authorized for emergency use (under EUA, IND/IDE, other emergency use authorities; NIOSH-cleared respirators for COVID)
- Established the Countermeasures Injury Compensation Program (CICP) for product-related injuries (42 CFR part 110)
 - For “serious physical injuries”; payer of last resort
 - Funds must be appropriated by Congress
 - <https://www.hrsa.gov/cicp/>
- Additional information:
 - Questions about the PREP Act should be directed to HHS
 - <https://www.phe.gov/Preparedness/legal/prepact/Pages/default.aspx>

PREP Act Declarations Issued

- Anthrax medical countermeasures
- Acute radiation syndrome medical countermeasures
- Botulinum toxin medical countermeasures
- Medical countermeasures against COVID-19
- Ebola disease therapeutics
- Ebola disease vaccines
- Marburgvirus and/or Marburg disease countermeasures
- Nerve agents and certain insecticides countermeasures
- Pandemic influenza medical countermeasures
- Smallpox medical countermeasures
- Zika virus vaccines

Available Resources

Resources

- COVID-19 updates (FDA): <https://www.fda.gov/emergency-preparedness-and-response/counterterrorism-and-emerging-threats/coronavirus-disease-2019-covid-19>
- Sign up for Medical Countermeasures Initiative (MCMi) email updates (FDA): <https://www.fda.gov/emergency-preparedness-and-response/counterterrorism-and-emerging-threats/medical-countermeasures-initiative-mcmi>
- EUA (FDA)
 - Main EUA page (including COVID-19 EUAs): <https://www.fda.gov/emergency-preparedness-and-response/mcm-legal-regulatory-and-policy-framework/emergency-use-authorization>
 - EUA guidance: <https://www.fda.gov/regulatory-information/search-fda-guidance-documents/emergency-use-authorization-medical-products-and-related-authorities>
- MCM expiration dating extensions (FDA): <https://www.fda.gov/emergency-preparedness-and-response/mcm-legal-regulatory-and-policy-framework/expiration-dating-extension>
- Emergency dispensing orders (FDA): <https://www.fda.gov/emergency-preparedness-and-response/mcm-legal-regulatory-and-policy-framework/emergency-dispensing-orders>
- Emergency use instructions (CDC): https://www.cdc.gov/anthrax/public-health/eui-antibiotics.html?CDC_AA_refVal=https%3A%2F%2Fwww.cdc.gov%2Fanthrax%2Fmedical-c-use-doxycycline-ciprofloxacin.html
- PREP Act (HHS): <https://www.phe.gov/Preparedness/legal/prepact/Pages/default.aspx>

Questions



For more information, contact CDC
1-800-CDC-INFO (232-4636)
TTY: 1-888-232-6348 www.cdc.gov

Please send your suggestions for future webinar topics to:
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The findings and conclusions in this report are those of the authors and do not necessarily represent the official position of the Centers for Disease Control and Prevention.

