FDA LEGAL PREPAREDNESS TOOLS FOR DISTRIBUTING & DISPENSING MEDICAL COUNTERMEASURES

2012 Public Health Law Conference:
"Federal Primer: Public Health Emergency Laws & Policies"

October 12, 2012

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Office of the Commissioner

U.S. Food and Drug Administration
Medical Countermeasures Initiative

OVERVIEW

- FDA's Roles in Regulating Medical Products and Medical Countermeasures (MCMs)
- Legal and Regulatory Preparedness Tools for the Use of MCMs during Public Health Emergencies
- Recent FDA Issues and Developments in Support of Local, State, and Federal Mass Dispensing Efforts
- Additional Resources

FDA's Roles in Regulating Medical Products and Medical Countermeasures

Overview of FDA's Roles

- An agency within HHS, FDA is responsible for:
  - Protecting public health by assuring foods are safe, wholesome, sanitary, and properly labeled, and human and veterinary drugs, vaccines, other biological products, and medical devices intended for human use are safe and effective
  - Protecting public from electronic product radiation
  - Assuring cosmetics and dietary supplements are safe/properly labeled
  - Regulating tobacco products
  - Advancing public health by helping to speed product innovations
  - Helping public get accurate science-based information they need to use medicines, devices, and foods to improve their health
- Geographic scope
  - 50 United States, District of Columbia, Puerto Rico, Guam, Virgin Islands, American Samoa, and other U.S. territories and possessions

FDA Regulation of Medical Products

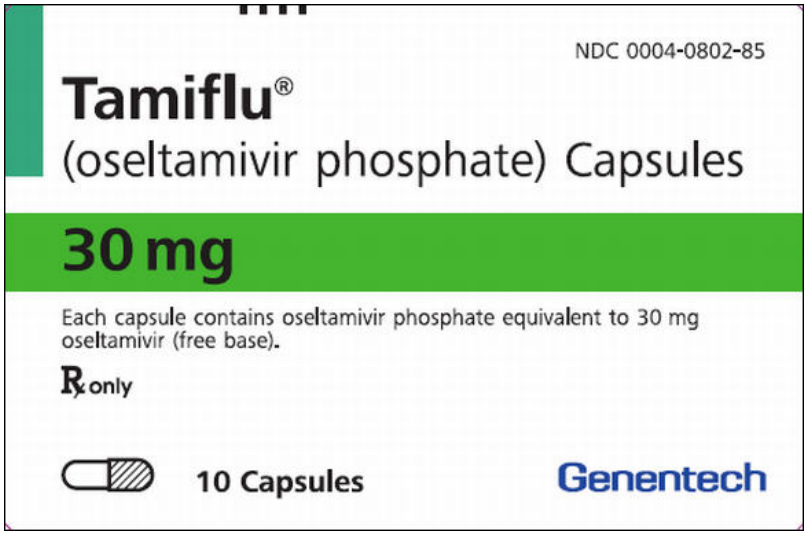
- Among the products FDA regulates are 3 categories of diagnostic, preventive, or therapeutic products:
  - Drugs (e.g., antibiotics)
  - Biologics (e.g., vaccines)
  - Medical devices (e.g., in vitro diagnostics, ventilators)
- Legal and regulatory authorities
  - Federal Food, Drug, and Cosmetic (FD&C) Act (*as amended*)
    - 21 U.S.C. 301 *et seq.;* 21 C.F.R. (Food and Drugs)
  - Public Health Service (PHS) Act (*as amended*)
    - 42 U.S.C. 262, 264, 266, 282; 21 C.F.R. 601.2(a)

FDA Review and Approval—The Basics

- Sponsor submits data to FDA to seek permission to market its product with specific labeling for a specific purpose
  - **Drugs:** New Drug Application (NDA), Abbreviated NDA (ANDA), Supplemental NDA (sNDA)
  - **Biologics:** Biologics License Application (BLA)
  - **Devices:** Premarket Approval (PMA), 510(k) Premarket Notification
- Risk-benefit analysis
- Expiry dating
- Current Good Manufacturing Practices (CGMPs)
- Labeling

Labeling

- FD&C Act prohibits "introduction…into interstate commerce of any…drug [or] device…that is…misbranded." (§ 301)
- Label
  - "A display of written, printed, or graphic material upon the immediate container" (FD&C Act § 201(k))
- Labeling
  - More expansive—includes all printed material distributed with a product (FD&C Act § 201(m))
- FDA-approved drug product labeling is the primary source of information about a drug's safety and effectiveness
  - Directed at health care professionals, but may include information directed at patients and that also must be FDA-approved
  - Requirements for Prescription Information: http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/LawsActsandRules/ucm084159.htm



HIGHLIGHTS OF PRESCRIBING INFORMATION

These highlights do not include all the information needed to use BIOTHRAX safely and effectively. See full prescribing information for BIOTHRAX.

BIOTHRAX (Anthrax Vaccine Adsorbed)
Suspension for Intramuscular Injection
Initial U.S. Approval: 1970

----------RECENT MAJOR CHANGES----------
- Indications and Usage (1) December 2008
- Dosage and Administration (2.1, 2.2) December 2008

----------INDICATIONS AND USAGE----------

BioThrax is a vaccine indicated for the active immunization for the prevention of disease caused by *Bacillus anthracis*, in persons between 18 and 65 years of age at high risk of exposure. Since the risk of anthrax infection in the general population is low, routine immunization is not recommended. The safety and efficacy of BioThrax in a post-exposure setting have not been established.

----------DOSAGE AND ADMINISTRATION----------
- Immunization consists of a series of five 0.5 mL intramuscular doses. Administer 1 dose at 0 and 4 weeks and 6, 12, and 18 months.
- Individuals are not considered protected until they have completed the full vaccination series.
- Subsequent booster injections of 0.5 mL of BioThrax at one-year intervals are recommended for those who remain at risk. (2.2)

----------DOSAGE FORMS AND STRENGTHS----------
- Suspension for injection in 5.0 mL multidose vials containing 10 doses each. (3,11)

----------CONTRAINDICATIONS----------
- Severe allergic reaction (e.g. anaphylaxis) after a previous

----------WARNINGS AND PRECAUTIONS----------
- Administer with caution to patients with a possible history of latex sensitivity because the vial stopper contains dry natural rubber and may cause allergic reactions. (5.1).
- Pregnant women should not be vaccinated against anthrax unless the potential benefits of vaccination have been determined to outweigh the potential risk to the fetus. If this drug is used during pregnancy, or if the patient becomes pregnant while taking this product, the patient should be apprised of the potential hazard to the fetus. (8.1)

----------ADVERSE REACTIONS----------

The most common (≥10%) local (injection-site) adverse reactions observed in clinical studies were tenderness, pain, erythema and arm motion limitation. The most common (≥5%) systemic adverse reactions were muscle aches, fatigue and headache. (6)

Serious allergic reactions, including anaphylactic shock, have been observed during post-marketing surveillance in individuals receiving BioThrax.

To report SUSPECTED ADVERSE REACTIONS, contact Emergent BioSolutions at 1-877-246-8472 or VAERS at 1-800-822-7967 or www.vaers.hhs.gov.

----------DRUG INTERACTIONS----------
- Immunosuppressive therapies may diminish the immune response to BioThrax. (7.2)

----------USE IN SPECIFIC POPULATIONS----------
- Safety and effectiveness of BioThrax have not been established in pregnant women or nursing mothers, or in pediatric or geriatric populations. (5, 8.1, 8.3, 8.4, 8.5)

See Section 17 For PATIENT COUNSELING INFORMATION.

Sources of images: http://dailymed.nlm.nih.gov/dailymed/drugInfo.cfm?id=75689; www.fda.gov

Practice of Medicine

- FDA generally does not regulate the practice of medicine
  - Once a product is approved or cleared, a licensed health care professional has the freedom to use that product for any purpose, even if the use is inconsistent with the product's approved labeling
  - Even in the midst of a public health emergency, FDA does not regulate the practice of medicine
- However, to protect the public's health, FDA and the courts are very strict in preventing marketers from promoting products for uses for which they are not approved or cleared by FDA

How Does This All Apply to MCMs?

- Urgency, often combined with demand beyond capabilities of traditional pharmacy or medical models, might necessitate:
  - Advance planning, sometimes with incomplete information
  - Flexible approaches for stockpiling and dispensing/administration
- Some MCMs are intended to be used during emergencies consistent with their approved labeling
  - No need for further FDA review/authorization
- Other MCMs are intended to be used during emergencies in ways beyond their approved labeling OR are not yet approved for *any* use (but might be helpful for a response due to the lack of other suitable alternative products)
  - Special legal/regulatory approaches needed

Medical Countermeasures Initiative (MCMi)

- Launched in August 2010 to build upon FDA's ongoing work to ensure the nation has the necessary MCMs for high priority CBRN and emerging infectious disease threats
- To promote the *development* of MCMs by enhancing FDA's regulatory processes and fostering establishment of clear regulatory pathways for MCMs; to facilitate *timely access* to MCMs by establishing effective regulatory policies/mechanisms
- 3-pillar approach:
  - Pillar I: Enhancing regulatory review processes for the highest priority MCMs and related technologies
  - Pillar II: Advancing regulatory science for MCM development and evaluation
  - **Pillar III: Modernizing the legal, regulatory, and policy framework for effective public health response**

Legal and Regulatory Preparedness Tools for the Use of MCMs during Public Health Emergencies

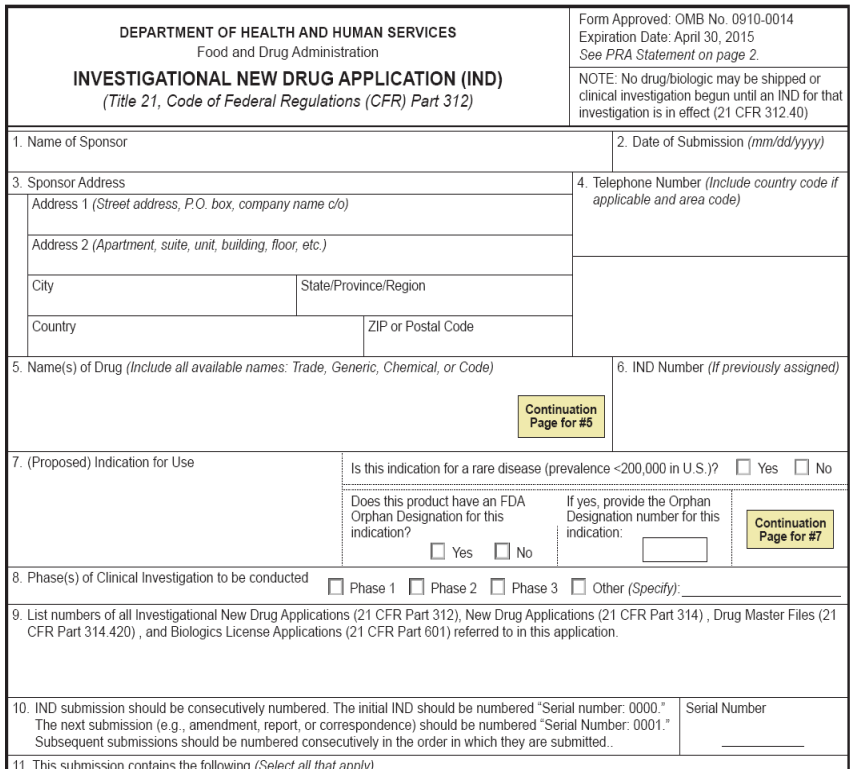
Investigational New Drug Application (IND)

- To be used in human testing in the U.S., in most cases:
  - A drug (including a biologic drug) must be covered by an IND
  - A device must be covered by an investigational device exemption (IDE)
- INDs and IDEs are reviewed by FDA, which has the authority to halt investigations proposed to be carried out under these applications
- IND and IDE regulations require patient safeguards, including in most cases:
  - Institutional Review Board (IRB) supervision
  - Informed consent by subjects
  - Reporting to FDA

Investigational New Drug Application (IND)

- In some circumstances, an IND may be the most appropriate mechanism for use of an investigational/unapproved product for a public health emergency

- Types of INDs:
  - Emergency use IND
    - Individual/single patient access for serious diseases
  - Expanded access trial under an IND
    - Intermediate-sized patient populations
  - Treatment IND
    - Widespread access



DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

INVESTIGATIONAL NEW DRUG APPLICATION (IND)
(Title 21, Code of Federal Regulations (CFR) Part 312)

Form Approved: OMB No. 0910-0014
Expiration Date: April 30, 2015
See PRA Statement on page 2.

NOTE: No drug/biologic may be shipped or clinical investigation begun until an IND for that investigation is in effect (21 CFR 312.40)

1. Name of Sponsor

2. Date of Submission *(mm/dd/yyyy)*

3. Sponsor Address

Address 1 *(Street address, P.O. box, company name c/o)*

Address 2 *(Apartment, suite, unit, building, floor, etc.)*

City | State/Province/Region

Country | ZIP or Postal Code

4. Telephone Number *(Include country code if applicable and area code)*

5. Name(s) of Drug *(Include all available names: Trade, Generic, Chemical, or Code)*

Continuation Page for #5

6. IND Number *(If previously assigned)*

7. (Proposed) Indication for Use

Is this indication for a rare disease (prevalence <200,000 in U.S.)? ☐ Yes ☐ No

Does this product have an FDA Orphan Designation for this indication? ☐ Yes ☐ No

If yes, provide the Orphan Designation number for this indication:

Continuation Page for #7

8. Phase(s) of Clinical Investigation to be conducted ☐ Phase 1 ☐ Phase 2 ☐ Phase 3 ☐ Other *(Specify)*: _____

9. List numbers of all Investigational New Drug Applications (21 CFR Part 312), New Drug Applications (21 CFR Part 314) , Drug Master Files (21 CFR Part 314.420) , and Biologics License Applications (21 CFR Part 601) referred to in this application.

10. IND submission should be consecutively numbered. The initial IND should be numbered "Serial number: 0000." The next submission (e.g., amendment, report, or correspondence) should be numbered "Serial Number: 0001." Subsequent submissions should be numbered consecutively in the order in which they are submitted..

Serial Number _____

11. This submission contains the following *(Select all that apply)*

Emergency Use Authorization (EUA)

- Section 564 of the FD&C Act
  - Established by Project BioShield Act (2004) (Public Law 108-276)
- If FDA grants an EUA request, it is finding that, in a particular type of emergency, if the EUA's conditions are observed:
  - An FDA-approved product (drug, biologic, or device) may be used during the emergency in a way that is inconsistent with the limitations of its FDA approval, or
  - A product that is not yet FDA-approved may be permitted to be used during the emergency (despite lacking the quantum of data that would be necessary for a full approval by FDA)
- EUA use is *not* investigational, so IRB approval and informed consent are not required

Why Might an EUA Be Needed?

- Novel/investigational products may be the best available products to meet the medical and public health needs of an emergency
- Changes from FDA-approved labeling, expiration dating, dosing schedules, prescribing, etc. requirements would render the product misbranded or unapproved under federal law
- Requirements for clinical investigations or expanded access would be difficult to meet in emergency scenarios (e.g., mass casualty, mass dispensing, mass vaccination)
- Potential gaps exist for Public Readiness and Emergency Preparedness (PREP) Act liability coverage
  - e.g.) PREP Act declarations can cover MCMs that are authorized for emergency use under EUAs

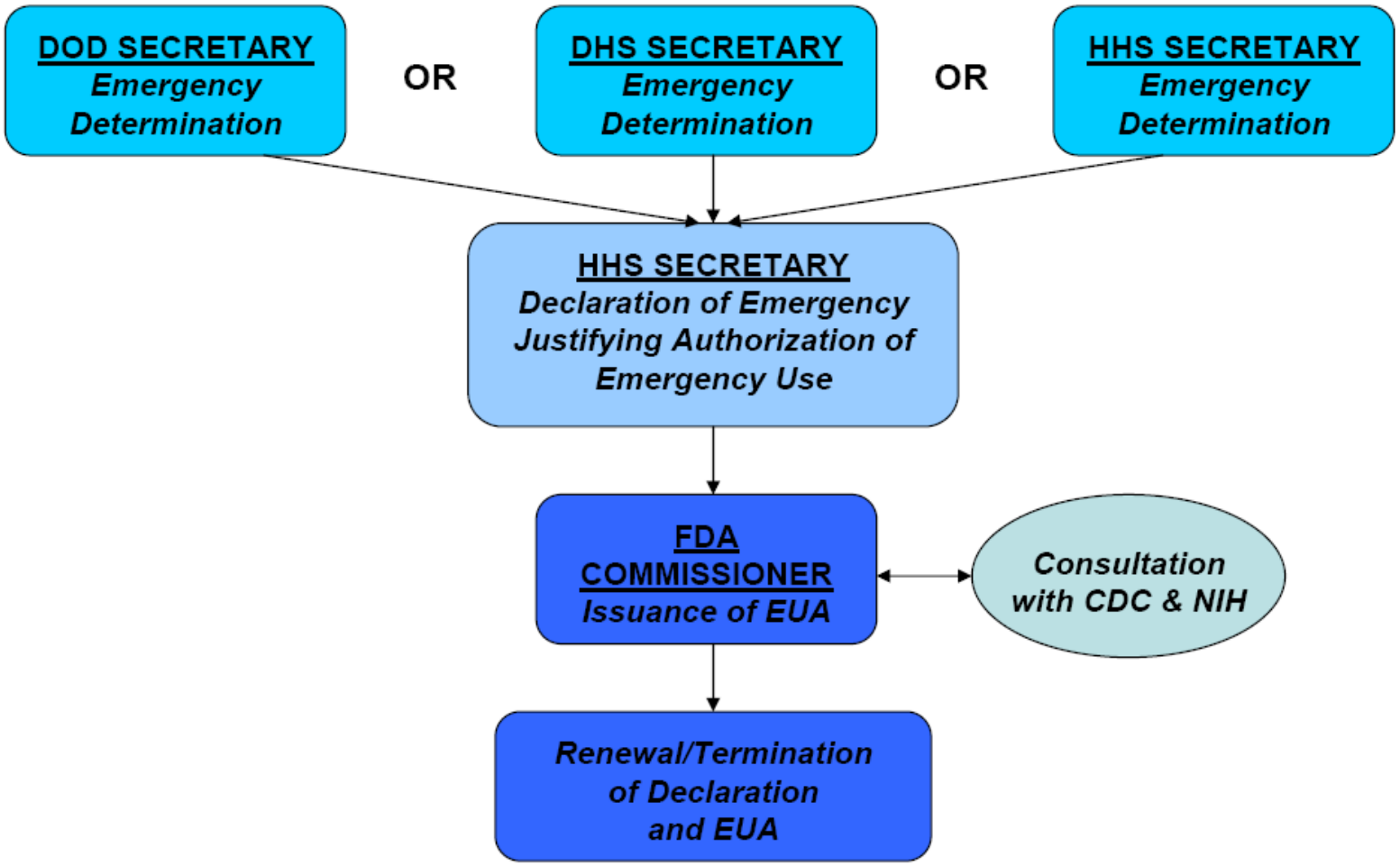
EUA Conditions of Authorization

- EUAs include *conditions of authorization*, which address elements of the authorization, such as:
  - Information on the emergency use of the MCM
    - e.g.) fact sheets for recipients and for health care professionals; home preparation instructions
  - Dispensing and screening procedures
  - Record keeping and monitoring of adverse events
  - Waiver of CGMP requirements
- An EUA's conditions also clarify roles of various entities
  - e.g.) for CDC, state and local public health authorities, sponsors

EUA Issuance

- EUA efforts are led by FDA's Office of Counterterrorism and Emerging Threats (OCET)
- Typically, FDA receives EUA requests from U.S. Government partners (e.g., ASPR, CDC) and product sponsors
- Criteria for issuance:
  - Serious/life-threatening illness/condition caused by CBRN agent
  - Reasonable belief that the product may be effective
  - Product's known/potential benefits outweigh its known/potential risks
  - No adequate, approved, available alternative to the product
- After an EUA is issued, it is published in the *Federal Register* and posted on the FDA website for public access

Steps for Issuing an EUA



Summary of EUA Activity

Year	Threat	MCM	Requester	Status
2005	Anthrax	AVA	DoD	Terminated
2008	Anthrax	Doxycycline hyclate tablets (USPS/CRI home & workplace kits)	ASPR/BARDA	Amended (2009, 2010, 2011-see below)
2009	H1N1 Influenza Pandemic	Antivirals	Various	Terminated
		IVDs	Various	Terminated
		PPE	CDC	Terminated
2011	Anthrax	All oral formulations of doxycycline (mass dispensing)	CDC	Current
2011	Anthrax	All oral formulations of doxycycline (National Postal Model home & workplace kits)	ASPR/BARDA	Current
Ongoing	Various—Pre-EUA activity	Various	Various	Pre-EUA

Recent FDA Issues and Developments in Support of Local, State, and Federal Mass Dispensing Efforts

Doxycycline Mass Dispensing EUA

- CDC requested that FDA issue an EUA for oral formulations of doxycycline products for inhalational anthrax to facilitate stakeholders' anthrax preparedness and response activities

- This EUA was possible because of the following:

  – DHS Secretary's determination of significant potential for a domestic emergency involving *B. anthracis* (2008)

  – HHS Secretary's declaration of emergency justifying the authorization of emergency use of doxycycline hyclate tablets for post-exposure prophylaxis (PEP) (2008, 2009, 2010)

    - HHS Secretary's renewal and amendment of the above HHS declaration to apply to <u>all</u> oral formulations of doxycycline (July 20, 2011; renewed July 20, 2012)

Doxycycline Mass Dispensing EUA

- Issued on July 21, 2011
- Covers all oral formulations of doxycycline (i.e., capsule, tablet, & liquid formulations) for PEP of inhalational anthrax
- Facilitates stakeholders' preparedness and response activities, which may otherwise violate FD&C Act provisions, such as:
  - Dispensing without a prescription
  - Providing minimum elements of information for flexibility in developing fact sheets for health care professionals and recipients
  - Pre-event storing or distributing of doxycycline packaged or repacked for emergency distribution
  - Dispensing of a partial supply of doxycycline (e.g., 10 days) of full 60-day dosage regimen

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Silver Spring, MD 20993

July 21, 2011

Thomas R. Frieden, M.D., M.P.H.
Director
Centers for Disease Control and Prevention
1600 Clifton Road, MS D-14
Atlanta, GA 30333

Dear Dr. Frieden:

This letter is in response to your May 5, 2011, submission[1] requesting that the Food and Drug Administration (FDA) issue an Emergency Use Authorization (EUA) for the emergency use of oral formulations of doxycycline products for the post-exposure prophylaxis (PEP)[2] of inhalational anthrax during a public health emergency involving aerosolized *Bacillus anthracis* (*B. anthracis*), pursuant to section 564 of the Federal Food, Drug, and Cosmetic Act (the Act) (21 U.S.C. § 360bbb-3).

In 2004, the Secretary of the Department of Homeland Security (DHS) issued a Material Threat Determination indicating that *B. anthracis*, the biological agent that causes anthrax disease, presents a material threat against the population of the United States sufficient to affect national security. On September 23, 2008, pursuant to section 564(b)(1)(A) of the Act (21 U.S.C. § 360bbb-3(b)(1)(A)), the Secretary of DHS determined that there is a significant potential for a domestic emergency involving a heightened risk of attack with a specified biological, chemical, radiological, or nuclear agent or agents—in this case, *B. anthracis*.[3] On October 1, 2008, pursuant to section 564(b) of the Act (21 U.S.C. § 360bbb-3(b)), and on the basis of such determination, the Secretary of Health and Human Services (HHS) then declared an emergency justifying the authorization of the emergency use of doxycycline hyclate tablets for PEP accompanied by emergency use information subject to the terms of any authorization issued under section 564(a) of the Act (21 U.S.C. § 360bbb-3(a)), and on October 1, 2009, and on October 1, 2010, renewed that declaration.[4] On July 20, 2011, the Secretary of HHS renewed and

Doxycycline Mass Dispensing EUA

- Who are the “stakeholders”? This EUA specifically defines them as:
  - “the **public agency or its delegate that has legal responsibility and authority** for responding to an incident, based on political or geographical (e.g., city, county, tribal, State, or Federal boundary lines) or functional (e.g., law enforcement or public health) range or sphere of authority to prescribe, administer, deliver, distribute, or dispense doxycycline in an emergency situation”

Doxycycline Mass Dispensing EUA:
Fact Sheets

- Fact sheets for health care professionals & for recipients
  - Example fact sheets are provided with the EUA
  - These fact sheets may be modified by stakeholders, but only if the new versions include all of the minimum elements of information specified in the EUA
  - CDC has developed a modified version of the recipient fact sheet—it is available on the SNS Extranet
- Fact sheets for children & adults unable to swallow pills
  - These fact sheets (1-page & 2-page versions) may not be modified by stakeholders
  - FDA will make available to stakeholders any applicable updated versions of these fact sheets, if necessary

Doxycycline EUA Fact Sheet for Recipients

You are receiving doxycycline because you may have been exposed to the anthrax germ, which can be deadly. You do not have to take this drug, but taking doxycycline to treat anthrax will reduce your risk of getting sick and dying. If possible, you may want to discuss with a health care professional the benefits and risks described in this fact sheet, or any available alternatives.

The full course of treatment is usually 60 days. If you have received a partial supply, public officials will announce where you can get the rest of the medicine.

What is anthrax?

Anthrax is a serious disease caused by the germ *Bacillus anthracis*. People who breathe in (inhale) anthrax germs are at risk of serious illness, ***including death***. However, you can't get anthrax from another person.

- First symptoms are cold-like or flu-like symptoms, e.g., a sore throat, mild fever, muscle aches.
- Later symptoms are cough, chest discomfort, shortness of breath, tiredness, muscle aches.

Symptoms usually occur within 7 days of inhaling anthrax germs, but can take up to 42 days to appear. See a doctor immediately if you have symptoms.

What is doxycycline?

Doxycycline is a prescription drug approved by the Food and Drug Administration (FDA) to prevent anthrax. Federal authorities have specially authorized certain uses of doxycycline,* including use ***without*** a prescription, for this emergency situation. If you take doxycycline as directed and begin to feel sick anyway, ***get medical care right away***.

How do I take doxycycline?

- Adults and those 8 years and older and children 89 lbs (40 kg) or more – take one pill (100 mg) in the morning and one pill in the evening on an empty stomach with a full glass of water.
- If you get an upset stomach or indigestion, take it with some food or milk. Be sure to drink lots of fluids.
- Children under 89 lbs (40 kg) and adults who can't swallow a pill – ***follow the directions provided to you on crushing and mixing doxycycline***.
- If you have received the liquid form, follow the directions on the bottle; you can store it at room temperature for up to 14 days.
- If you miss a dose, take only next scheduled dose – ***Do not take two doses at one time***.
- Doxycycline may not work as well when taken with some medicines. Take it 2 hours before or 2 hours after taking: antacids, multivitamins or supplements with calcium, iron
- Doxycycline may affect dosing of certain blood thinners or seizure medicines; call your doctor if you are on these medications.
- Keep the pills dry; store them between 68–77°F (20–25°C).
- Keep containers out of the reach of children and pets; call the poison control center if accidental ingestion occurs (1-800-222-1222).

Who should NOT take doxycycline?

STOP taking the medicine if you get any of these serious, but rare, side effects; get medical help right away (go to the Emergency Room or call 911):

- swelling of the tongue, hands, or feet
- closing of the throat
- trouble breathing
- severe itching or rash, especially hives and welts
- severe stomach cramps with high fever or bloody diarrhea
- yellowing of the eyes or skin or dark-colored urine
- pain when swallowing
- unusual bleeding or bruising
- severe headaches, dizziness, or double vision

Keep taking the medicine if you have:

- mild nausea or vomiting, upset stomach, loose stools
- vaginal yeast infection

Do not take doxycycline if you have had a severe allergic reaction to doxycycline or another tetracycline drug.

Are there other possible severe side effects?

- Serious liver problems (liver failure)
- Sensitivity to the sun
- Discolored teeth, poor tooth enamel in children under the age of 8 or when taken by their mothers during the last half of pregnancy or while nursing
- Slowed bone growth in children
- Birth control pills stop working. Use another form of birth control until you finish taking all of your doxycycline

What is unknown about the emergency use of doxycycline?

The benefit of providing you with emergency access to an initial supply of doxycycline is expected to outweigh the risks. However, it is unknown how well these emergency instructions will be used, how many individuals will receive the full, 60-day course of post-exposure prophylaxis (PEP), or what the impact of dispensing without an individual prescription will be.

How do I report side effects or errors?

In an Emergency:

How to Prepare Doxycycline for Children and Adults Who Cannot Swallow Pills

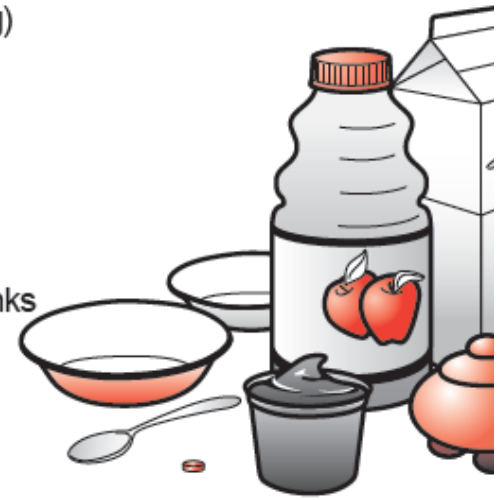
Mixing Doxycycline Hyclate 100mg Tablets with Food

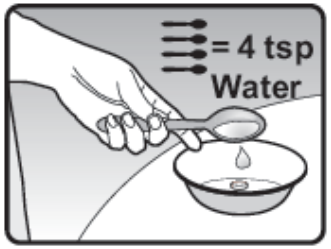
nce you have been notified by your federal, state or local authorities that you need to take doxycycline for a public health emergency, it may be necessary to prepare *mergency* doses of doxycycline for children and adults who cannot swallow pills.

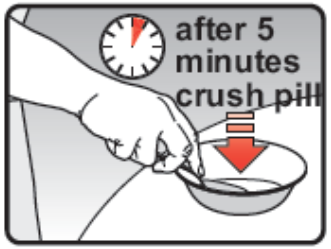
1 Supplies You Will Need

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

- 1 doxycycline pill (100 mg) *(Do not take doxycycline if you are allergic to tetracyclines)*
- a metal teaspoon
- 2 small bowls
- Water
- one of these foods or drinks to hide the bitter taste of crushed doxycycline:
  - milk or chocolate milk
  - chocolate pudding
  - apple juice and sugar







2 Crushing the Pill an Mixing with Water

1. Put 1 doxycycline pill in a small bo
2. Add 4 full teaspoons of water to th same bowl.
3. Let the pill soak in the water for 5 minutes so it will be soft.
4. Use the back of a metal teaspoon crush the pill in the water. Crush th until no visible pieces remain.
5. Stir the pill and water so it is well n

You have now made the Doxycycline and Water Mixture

Doxycycline Mass Dispensing EUA:
What must be done during an anthrax emergency?

- This EUA has already been issued and is currently in effect
  - It applies in all circumstances in which stakeholders reasonably believe there is a need to mass dispense authorized doxycycline products because of their constituent recipients' suspected or likely imminent exposure to *B. anthracis* spores
- Stakeholders would be responsible for such activities as:
  - Authorizing public and/or private entities acting as part of the public health response to dispense authorized doxycycline
  - Making available information (e.g., fact sheets) for health care professionals and recipients that includes the minimum elements of information specified in the EUA
  - Maintaining an inventory record of doxycycline distribution

Doxycycline Mass Dispensing EUA:
What must be done during an anthrax emergency?

- Stakeholders must ensure that any activities occurring under the EUA are in accordance with all terms and conditions that are outlined in the EUA
  - This includes instructing any public and/or private entities acting as part of the public health response about the terms and conditions of the EUA
- If any amendments to this EUA would be needed to address response needs during an anthrax emergency, FDA would work with its federal partners to amend the EUA and to keep stakeholders informed

Doxycycline Mass Dispensing EUA

- Letter of authorization
  - 76 Fed. Reg. 47197
  - http://www.fda.gov/downloads/EmergencyPreparedness/Counterterrorism/UCM264104.pdf
- Fact sheets
  - http://www.fda.gov/EmergencyPreparedness/Counterterrorism/ucm182568.htm
- HHS renewal of declaration justifying the authorization of emergency use of doxycycline
  - 77 Fed. Reg. 40060
  - http://www.gpo.gov/fdsys/pkg/FR-2012-07-06/pdf/2012-16588.pdf
- Doxycycline mass dispensing EUA questions and answers
  - http://www.fda.gov/EmergencyPreparedness/Counterterrorism/ucm269226.htm

National Postal Model (NPM) EUA

- In 2008, FDA issued an EUA for doxycycline hyclate tablets contained in individual workplace and household emergency antibiotic kits ("HAKs") for eligible USPS employee volunteers in CRI and their household members (*amended and reissued in 2009 & 2010*)

- In 2011, additional amendments were requested by ASPR/ BARDA to reflect programmatic changes

  – Issued on October 14, 2011

  – Covers HAKs for PEP of inhalational anthrax; limited to eligible USPS employee volunteers in NPM and their household members

  – Letter of authorization (76 Fed. Reg. 72935)
  http://www.fda.gov/EmergencyPreparedness/Counterterrorism/ucm182568.htm

Other Updates

- FDA currently has no plans to issue additional EUAs within a specific time frame. However, FDA:
  - Is engaged in a range of efforts to prepare for public health emergencies, such as through pre-EUA activities with its federal and other partners
  - Works closely with its federal government partners (e.g., CDC & ASPR) to provide technical assistance and regulatory feedback on preparedness issues related to EUAs
  - Would work closely with its federal partners during a public health emergency to facilitate (e.g., under an EUA) the availability of appropriate MCMs, if necessary for the response
- Reauthorization of Pandemic and All-Hazards Preparedness Act (PAHPA) (S. 1855 & H.R. 2405)

Additional Resources

- FDA State & Local Stakeholder Site
  - http://www.fda.gov/EmergencyPreparedness/Counterterrorism/ucm234336.htm
- EUA Questions & Answers
  - http://www.fda.gov/NewsEvents/PublicHealthFocus/ucm153297.htm
- EUA Guidance
  - http://www.fda.gov/RegulatoryInformation/Guidances/ucm125127.htm
- Current & Terminated (Archived) EUAs
  - http://www.fda.gov/EmergencyPreparedness/Counterterrorism/ucm182568.htm
- FDA Medical Countermeasures Initiative (MCMi)
  - www.fda.gov/medicalcountermeasures

Additional Resources

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THANK YOU!

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