

# **Emergency Use of Medical Countermeasures**

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# Project BioShield Act of 2004

- Signed into law 7/21/04.
- Amends the Federal Food, Drug and Cosmetic Act (FD&C Act)
- Section 4 provides for emergency use of “investigational” countermeasures not yet approved, licensed or cleared by the FDA where a heightened risk of attack on the U.S. public or a potential for such exists that would affect national security (Emergency Use Authorization -- EUA)

# **Why Allow for EUAs?**

- **Informed consent may not be practicable during a rapidly progressive public health emergency.**
- **Consent process may limit ability to respond and contain the disease/illness.**

# Emergency Use Authorization

- **Allows for the use of unapproved products and unapproved uses of approved products as the result of an incident involving a chemical, biological, or radiological/nuclear (CBRN) agent.**
  - **Drugs, devices and biological products**
  - **Not yet approved, cleared or licensed for the intended emergency use.**

# **Emergency Use Authorization**

- **Secretary of HHS can declare an emergency after Secretary of Defense, Homeland Security, or HHS determines an emergency (or potential for) exists.**
- **Secretary of HHS must issue a declaration of emergency justifying an EUA before FDA can issue an EUA for any product.**
  - **Law does not allow for “pre-authorization.”**
- **Secretary of HHS has delegated the ability to authorize use of a product under an EUA to the FDA Commissioner.**
- **EUA is granted for up to 1 year, or until termination of declaration or revocation; can be renewed.**

# Post Declaration of an Emergency

- **FDA Regulatory Center makes a case-by-case evaluation of whether an EUA can be issued for a particular product(s).**
- **Conditions to be met to authorize use of a product:**
  - **Circumstances of the emergency as set out in the HHS Secretary's declaration;**
  - **CBRN agent is responsible for or causes a serious, life-threatening disease/condition;**

# Post Declaration of an Emergency

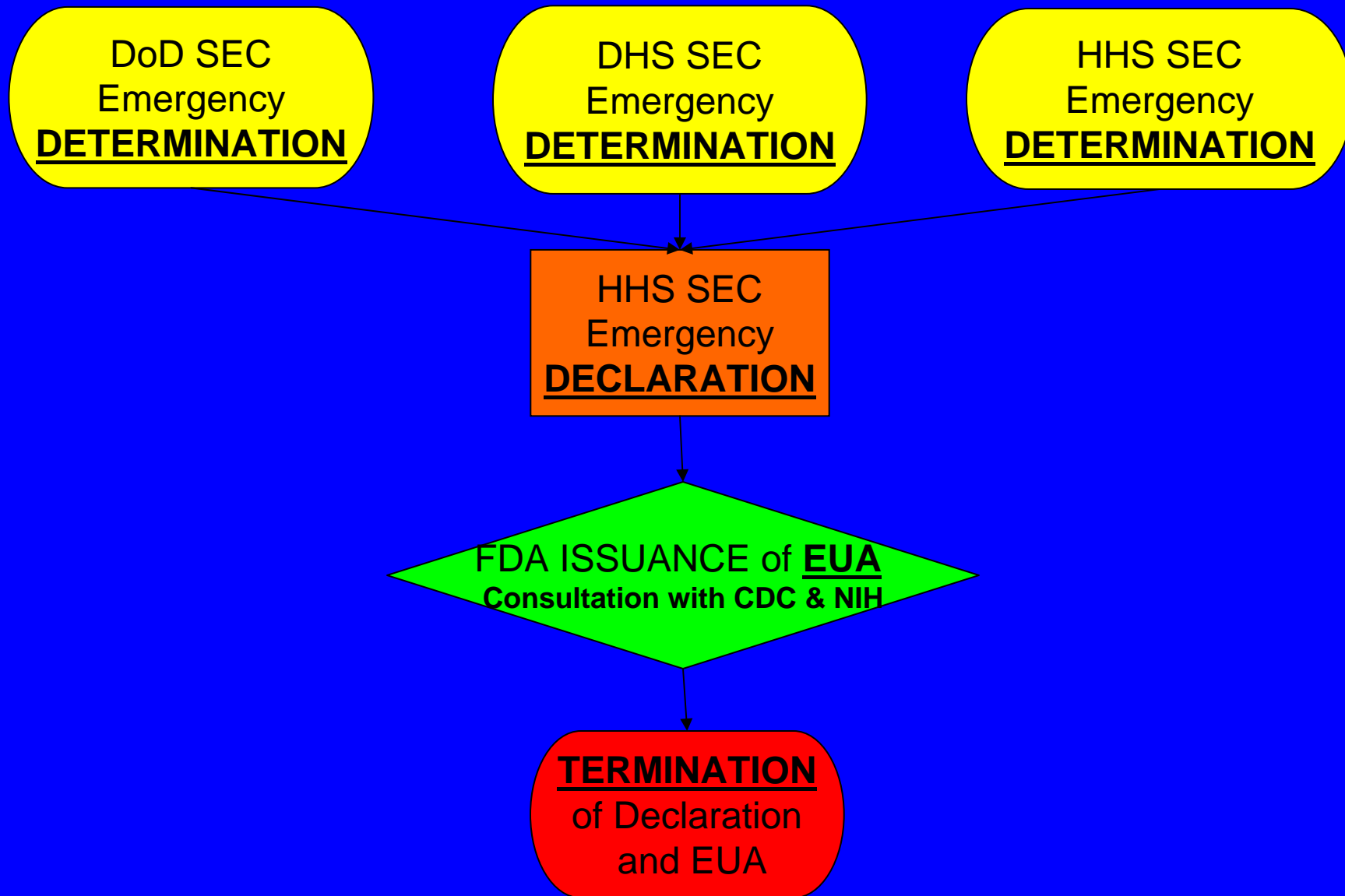
- **Conditions on the decision to authorize an EUA, ability to determine:**
  - It is reasonable to believe that the product **MAY BE EFFECTIVE** in diagnosis, treatment, or prevention of disease;
  - Known and potential benefits of the product, when used to diagnose, prevent, or treat such a disease or condition, *outweigh* the known and potential risks of use of the product; and,
  - There is no adequate, approved, and available alternative product.

# **EUA – Conditions of Authorization**

- **Inform health care workers or recipients, if feasible:**
  - **Product authorized for emergency use;**
  - **Significant known and potential risks and benefits, extent to which unknown;**
  - **Alternative products; and**
  - **Option to accept or refuse the product.**
- **Appropriate conditions for monitoring and reporting AEs, record keeping and reporting use and outcomes.**
- **Can be additional conditions on use, e.g., who may distribute, administer, or be offered the product, collection and analysis of information.**



# EUA PROCESS



# **General Data/Information Supportive of Potential Use**

- **Product Quality data:**
  - **Validated manufacturing process;**
  - **Manufactured according to cGMPs;**
  - **Consistently manufacture product that meets specifications; and,**
  - **Stability of product.**

# **General Data/Information Supportive of Potential Use**

- **Clinical and Nonclinical data:**
  - **Product-specific nonclinical data;**
  - **Demonstration of safety in humans;**
  - **Demonstration of efficacy in humans or an appropriate animal model(s) if it is unethical or not feasible to study in human clinical trials – efficacy data should be representative of the intended emergency use (PEP, treatment, etc.);**

# **General Data/Information Supportive of Potential Use**

- **Clinical and Nonclinical data (cont.):**
  - **Data should be representative of the population product is intended for use in (adults, special populations, etc.); and,**
  - **Data should be derived from product that meets product quality expectations.**



# What if the MCM Lacks Data to Support an EUA

- **Facilitated implementation of protocols (contingency use) under Investigational New Drug (IND) for use of investigational products in an emergency.**
  - **Protocols also provide the supportive data to use an investigational product in a case-by-case scenario under an emergency IND.**
- **Also, absent a declared emergency, products have the potential to be used under an IND protocol.**

# Conclusions

- **Data/information needed to support potential use of a product under an EUA is very product and circumstance specific.**
- **Communication regarding what is known about an EUA product is critical to maintain public confidence.**

# Thanks!

- **CBER's CT page:**

<http://www.fda.gov/cber/ctrbio/ctrbio.htm>

- **OCTMA phone – (301) 827-2000**

- **Manufacturer's assistance:**

<http://www.fda.gov/cber/manufacturer.htm>

- **C. Kelley phone – (301) 827-0636**

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