

Distribution and Dispensing of Medical Countermeasures

FDA Regulatory Mechanisms

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Overview

- FDA's Mission
- Regulatory mechanisms facilitating development and availability of radiation medical countermeasures
- Emergency Use Authorization (EUA)
 - Statutory Criteria for issuance
 - EUA Process
 - Conditions of Authorization
 - Duration/Termination

FDA's Mission

- Responsible for **protecting the public health by assuring the safety, efficacy, and security** of human and veterinary drugs, biological products, medical devices, our nation's food supply, cosmetics, and products that emit radiation

FDA's Counterterrorism Mission

1. **Facilitate development and availability of medical countermeasures (MCMs).**
2. Protect the safety and security of regulated medical products.
3. Enhance emergency preparedness and response capabilities.
4. Implement comprehensive food security strategy.
5. Ensure safety and security of agency assets.

Facilitate Development and Availability of MCMs

- Research and Development
 - Early engagement with product developers and the scientific community
- Regulatory Tools/Approaches
 - Fast Track Designation
 - Priority Review
 - Accelerated Approval through surrogate markers
 - Animal Efficacy Rule

Emergency Use of Unapproved Products

- Emergency Use IND
- Treatment Use IND, IDE
 - Single patient use or limited populations
 - Submitted by IND sponsor of a clinical investigation or licensed practitioner
 - Must meet sponsor and investigator responsibilities
 - Informed Consent, IRB review, record keeping

NOTE: In these slides the acronym IND refers to an Investigational New Drug Application, not Improvised Nuclear Device

Emergency Use Authorization

- Project Bioshield Act Signed into law 7/21/04
 - Amended section 564 of the Food Drug and Cosmetic Act.
 - Sec. 4 provides for emergency use of “investigational” products not yet approved, licensed or cleared by the FDA intended to diagnose, treat, or prevent a serious or life-threatening disease or condition caused by a chemical, biological, radiological or nuclear (CBRN) agent.
 - Significant potential to affect national security.

EUA Key Concepts

- HHS SEC must issue a declaration of emergency justifying an EUA before FDA can issue an EUA
 - Based on one of three emergency determinations
 - 4 Statutory criteria must be met
 - Law doesn't allow for a “pre-authorization”
- FDA makes a case-by-case evaluation of whether an EUA can be issued
 - Safety and efficacy data supporting intended indication
 - Circumstances of emergency justifying an authorization (as set out in the HHS SEC declaration)
- FDA establishes conditions on an EUA

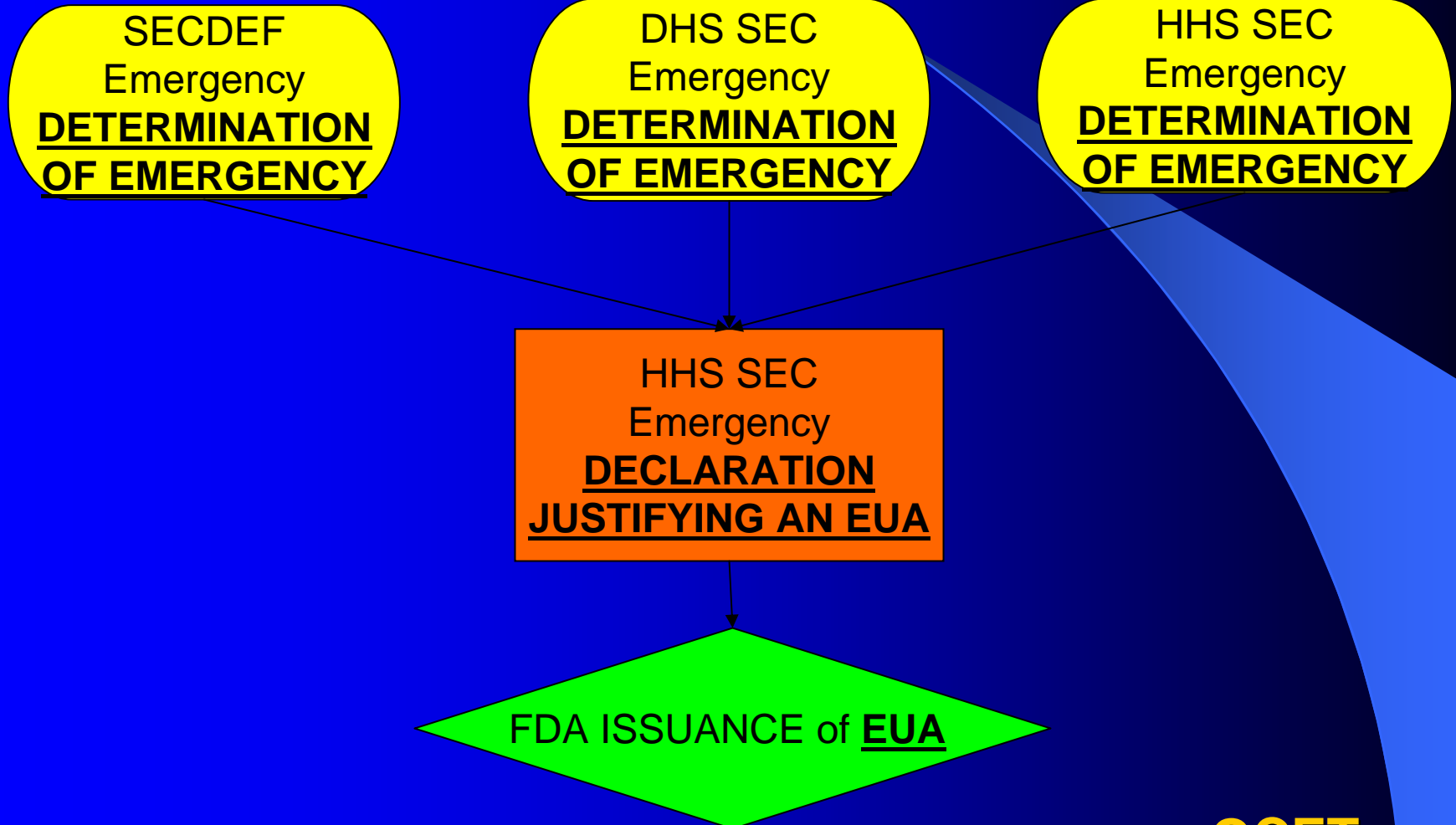
Eligible products for an EUA

- Vaccines and other biologics, drugs, and medical devices
- Unapproved products or unapproved uses of approved products
- Used to diagnose, treat, or prevent a serious or life-threatening disease or condition caused by CBRN agent or caused by an approved or authorized countermeasure for the CBRN agent

Statutory Criteria for EUA

1. Agent causes serious or life-threatening illness or condition
2. Reasonable to believe the product may be effective against agent
3. Known/potential benefits outweigh known/potential risks of use
4. No approved, adequate, and available alternatives

The EUA Process



Step One: Determination of Emergency

- **SECDEF--military emergency** (or significant potential) involving heightened risk to U.S. military forces of attack w/ specified CBRN agent
- **SEC DHS--domestic emergency** (or significant potential) involving a heightened risk of attack w/ specified CBRN agent
- **SEC HHS--public health emergency** (PHS Act) that affects or has a significant potential to affect **national security** (FD&C Act)

Step Two: Declaration of Emergency Justifying an EUA

- Issued by the HHS SEC based on Determination of Emergency
- Specifies the CBRN agent and justifies an EUA
- Issued under section 564 of the Federal Food, Drug, and Cosmetic Act
- Is different than a Declaration of Public Health Emergency under section 319 of the Public Health Service Act

Step Three: Issuance of Authorization

- FDA review of EUA request
- Law requires FDA to consult with Directors of NIH and CDC (or their delegees) before issuing an EUA
 - To the extent feasible and appropriate given the circumstances of the emergency involved
- Scope of the authorization
 - For product; no “sponsor”
 - Can specify population, age range, etc.

Conditions of Authorization

- Information for Health Care Practitioners/Authorized Dispensers
- Information for Recipients
- Adverse Event Reporting/Monitoring
- Recordkeeping/Access
- Restrictions on Distribution/Administration
- Restrictions on Advertising
- Data Collection/Analysis
- Compliance with GMPs

Termination/Revocation

- Declaration of Emergency in effect for 1 year from date of issuance, unless renewed
- EUA runs for duration of the emergency declaration, unless it is revoked because the criteria for issuance are no longer met or where revocation is appropriate to protect the public health or safety

EUA Resources

- Guidance Emergency Use Authorization of Medical Products (July 2007)

<http://www.fda.gov/oc/guidance/emergencyuse.html>

- FDA Center and Offices
 - OCET, CBER, CDER, CDRH
- HHS EUA Working group