Emergency Use of Medical Countermeasures

Debra A. Yeskey, Pharm. D.
Director, Regulatory & Quality Affairs Division
HHS/ASPR/BARDA
Mechanisms to use Medical Countermeasures

• “Contingency Use” protocols under Investigational New Drug (IND)
  — Same requirements as 21 CFR 312
• Emergency IND: 21 CFR 312.36
  — Requires IRB approval- 72 hours post use
  — Case by case basis
• Emergency Use Authorization (EUA)
  — Requires Declaration of Emergency
Contingency Use” IND Protocol

• Purpose:
  — An application for exemption from the Food, Drug, and Cosmetic Act
  — Permits distribution of a product during an investigational period
  — A mechanism to obtain safety and efficacy information

• Requirements
  — Sponsor Responsibilities
  — IRB approval
  — Informed Consent
  — Patient Parameters
  — Record Keeping
  — Follow-up
Emergency IND

• Purpose
  — Exemption from FD&CA and allows distribution
  — **Individual** patient access for serious disease
  — Need for an investigational drug may arise in an emergency situation that does not allow time for submission of an IND in accordance with 21 CFR 312.23 or 312.34
  — FDA may authorize shipment of the drug for a specified use in advance of submission of an IND

• Requirements
  — A request for such authorization may be transmitted to FDA by telephone or other rapid communication means
  — Provide 1572 and IRB approval within 72 hours of authorization
  — Record keeping
Emergency Use Authorization

• Purpose
  — Mechanism to use
    • an unapproved product,
    • an approved product for an unapproved indication, or
    • an approved product with other circumstances

• Requirements
  — Declaration of Emergency
  — Adequacy of the data – known and potential benefits must outweigh the known and potential risks
  — Information sheets for healthcare providers and recipients
  — Conditions of Authorization
Emergency Use During Product Development

Adapted from the FDA Critical Path Report (March 2004)
Products Authorized for Use Under an EUA

• January 2005
  — Department of Defense- AVA Vaccine- expired

• October 2008- Currently Authorized
  — Department of Health and Human Services/BARDA
    • Home Antibiotic Kits for USPS

• April/May 2009- expired
  — Department of Health and Human Services/Centers of Disease Control and Prevention
    • Antivirals
    • N-95 masks
    • PCR kits
Practical Aspects of a pre-EUA/EUA

• USG will *likely* be the sponsor of any pre-EUA/EUA
• Formulating the “Request”
  — Cover letter
  — “Executive summary”
  — Fact sheets
  — Other documents requested
• Correspondence with FDA
• Conditions of Authorization
  — Clarity of Roles CDC, State and Local Public Health Authorities
Logistics of an EUA

• EUA route not a given
  — Depends on data
  — Depends on the nature of the incident/emergency
• MCMs in the Strategic National Stockpile
  — EUAs typically held by CDC
• Examples where BARDA holds the EUAs
  — Home Antibiotic Kits for US Postal Service workers under the Cities Readiness Initiative (CRI) – Authorized October 3, 2008
  — EUA’s to support the use of pre-pandemic vaccines
  — First Responder “medkit” (in conjunction with DHS)
Other EUA Considerations

• An EUA is NOT a regulatory endpoint
• Do not assume that your regulatory development pathway will be easy with FDA because you have an MCM
• Sharing of data with the USG is critical to support use in an emergency…the USG will decide on the best regulatory mechanism for use…IND, EIND, and/or EUA
• Work closely with BARDA, CDC, and FDA on your alternative labeling strategy…take the comments from these entities seriously…this is not a slam dunk – it will require work on your part.
Thank you!

Contact Information:
debra.yeskey@hhs.gov
Interfacing with BARDA

• [www.phe.gov](http://www.phe.gov)  
  — Program description, information, news, announcements

• [www.medicalcountermeasures.gov](http://www.medicalcountermeasures.gov)  
  — Portal to BARDA  
  — Register, request a meeting  
  — Tech Watch

• [www.fedbizopps.gov](http://www.fedbizopps.gov)  
  — Official announcements and detailed information about all government contract solicitations

[www.fbo.gov](http://www.fbo.gov)