Emergency Use Authorization for MCMs

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MCM Portfolio

- BARDA’s portfolio includes medical countermeasures (MCMs) to respond to a variety of “CBRN” threats:
  - CHEMICAL
  - BIOLOGICAL
  - RADIOLOGICAL
  - NUCLEAR

- BARDA’s portfolio expands to incorporate new MCMs in response to various emerging threats....
CBRN...Z?
Get A Kit | Make A Plan
Be Prepared

emergency.cdc.gov
Before an Outbreak

There have been only limited accounts of people showing zombie-like illness
Pre-Emergency Use Authorization

• Engage with FDA in non-emergency scenarios to:
  ▪ Allow time for review/feedback from FDA for a robust submission
  ▪ Expeditious review during an emergency
• Part of the USG’s preparedness plans for MCMs that BARDA seeks to procure for inclusion in the Strategic National Stockpile
What a Pre-EUA/EUA IS and IS NOT

**IS**

A legal mechanism that allows use of an unapproved medical product or unapproved use of an approved medical product during a CBRN emergency or when there is a potential for a CBRN emergency.

**IS NOT**

A regulatory milestone or stopping point.

For additional FDA information about the EUA authority, see final guidance (2017):
https://www.fda.gov/regulatoryinformation guidances/ucm125127.htm
Pre-EUA & EUA Process

• Predicated on the understanding of what is needed for FDA to authorize an EUA in an emergency:
  ▪ Serious or life-threatening disease or condition
  ▪ Evidence of effectiveness
  ▪ Risk-benefit analysis
  ▪ No alternatives
RoMero Inc. has developed zombicillin as treatment for the zombie virus (ZomV)

- Regulatory status:
  - Phase II/III studies
  - BARDA is supporting RoMero Inc. for advanced development of zombicillin
  - BARDA engaged with RoMero Inc. to acquire zombicillin
- Zombicillin meets an unmet medical need:
  - There are no other approved, available, alternative MCMs to treat ZomV
Pre-EUA Activities

• BARDA requests the following documentation from RoMero Inc. at least 3 months* prior to the submission:
  ▪ Letter of Cross Reference Authorization
  ▪ Investigator’s Brochure
  ▪ Information to support use of the product:
    ✓ Final study reports or summaries of safety/efficacy data or preliminary data from nonclinical and clinical studies
    ✓ Protocols/tabular summaries for nonclinical and clinical studies
    ✓ Published studies and/or other publications

* In a non-emergency scenario, more time is available to develop the Pre-EUA
Content of Pre-EUA

- Unmet medical need
- Risk/benefit analysis
- Safety and effectiveness
Content of Pre-EUA

- Why take zombicillin for ZomV
- How to take zombicillin
- Risks/side effects
- Benefits
- Instructions for certain populations
Submit the Pre-EUA for zombicillin to FDA

FDA provides comments and feedback*

Work with RoMero Inc. to address FDA’s comments

*Note – for Pre-EUAs, these are not PDUFA submissions and there is no review clock for FDA

GOAL

FDA provides a “no further comments” notification
Who, What, Where, When...

- Under the Pre-EUA, zombicillin is brought into SNS
- RoMero Inc., continues development of zombicillin
  - Provides updated product information
- Pre-EUA is revised with the most up-to-date information
Then... if the most feared day becomes a reality.....
An Outbreak Happens
BARDA Responds!

GOAL

FDA authorizes the EUA

Submit EUA for zombicillin to FDA

FDA reviews EUA
Thank You

No more zombies have returned from the grave! A successful response!