

Obtaining Regulatory Guidance from FDA

**BARDA Industry Day
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U.S. Food and Drug Administration
Medical Countermeasures Initiative

Regulatory Guidance

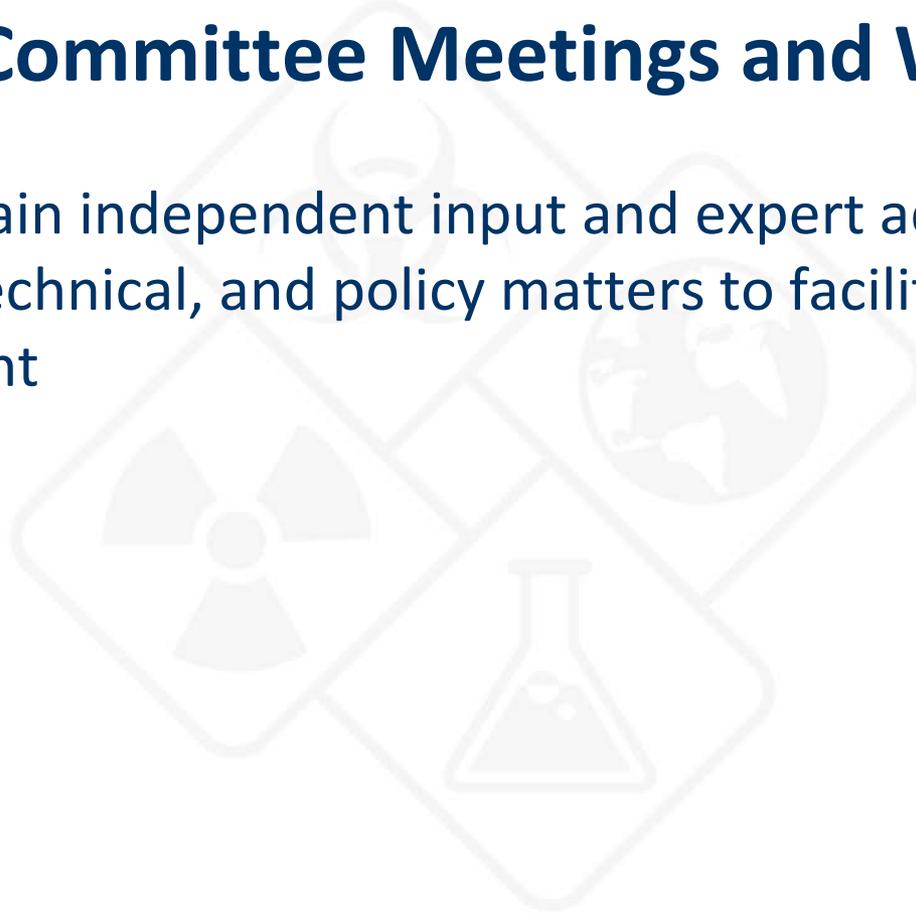
- FDA provides regulatory advice and guidance through a variety of mechanisms including:
 - issuing guidance documents
 - holding Advisory Committee meetings and public workshops
 - directly engaging with medical countermeasure sponsors and applicants

Guidance Documents

- Prepared for FDA staff, product applicants/sponsors, and the public
- Describe FDA's interpretation of or policy on a regulatory issue Include, but are not limited to, documents that relate to:
 - The design, production, labeling, promotion, manufacturing, and testing of regulated products;
 - the processing, content, and evaluation or approval of submissions;
 - and inspection and enforcement policies

Advisory Committee Meetings and Workshops

- Held to obtain independent input and expert advice on scientific, technical, and policy matters to facilitate product development



Formal Meetings

- Provide guidance relating to the development and review of investigational products
- Can be face-to-face, teleconference, or videoconference
- Held – as needed – at the request of a product sponsor or applicant and requests for meetings are granted unless there is a substantive reason for denying the request

Formal Meetings

- **CBER/CDER**
 - Type A - help an otherwise stalled product development program proceed
 - Type B - held at pivotal points during product development to help products move into and through clinical development to marketing application (i.e., pre-IND, certain end-of-phase 1, end-of-phase 2 and pre-phase 3, and pre-NDA/-BLA)
 - Type C - any meetings other than a Type A or Type B (e.g., discussions related to data requirements, scientific issues related product development and manufacturing, post-marketing commitments, etc.)

Formal Meetings

- CDRH
 - pre-Sub Meetings
 - Meeting to enable product sponsors to present an overview of ongoing device development to review teams without receiving feedback
 - Meetings to receive FDA feedback in response to specific questions related to product development
 - 510(k) /PMA Submission Issue Meetings
 - Meetings to discuss deficiencies identified during premarket review of device marketing applications and to provide clarification of FDA's questions or to discuss an approach to responding to any complex issues identified

What Makes MCMs Different?

- Regulatory and scientific complexities
- Response urgency, often combined with demand beyond capabilities of traditional pharmacy or medical models, might necessitate uses beyond an MCM's approved labeling (e.g., without a prescription, in different dosing regimens or age groups, with fact sheets)
- Risk-benefit analysis can support use of an investigational product as the most appropriate option for a particular emergency
- Requirements for clinical investigations or expanded access might not be possible to meet in emergency scenarios (e.g., mass dispensing)
- Need for pre-positioning/stockpiling flexibilities
- Stakeholder concerns about liability protections (e.g., PREP Act coverage)

FDA MCM Action Plan: 3 Pillars

1. Enhance the MCM Review Process
2. Advance MCM Regulatory Science
3. Optimize Legal, Regulatory, and Policy Approaches to MCM Development and Use

Objective:

FDA to strengthen regulatory evaluation and facilitate MCM development

Where to Start

- Refer to relevant guidance documents
- Contact appropriate center Counterterrorism Coordinator
 - CBER – Cindy Kelly
 - CDER – Rosemary Roberts
 - CDRH – Suzanne Schwartz
- Contact OCET
 - OCET (AskMCMi@fda.hhs.gov)

Stay Informed

- MCMi webpage - www.fda.gov/MedicalCountermeasures
- MCMi e-mail updates
- Twitter: [@FDA_MCMi](https://twitter.com/FDA_MCMi)



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Questions? AskMCMi@fda.hhs.gov



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