Medical countermeasures, or MCMs, are FDA-regulated products that may be used in a public health emergency stemming from a terrorist attack with or accidental release of a biological, chemical, or radiological/nuclear agent, or a naturally occurring emerging infectious disease.

**EXAMPLES of MCMs**

**BIOLOGIC PRODUCTS**
- Vaccines
- Blood products
- Antibodies

**DRUGS**
- Antimicrobials
- Chemical threat antidotes
- Treatments for radiation injury

**DEVICES**
- Diagnostic tests
- Personal protective equipment (PPE)
  - Gloves
  - Respirators/masks
  - Gowns

**FDA’s MCM ROLES** [some examples]

FDA is responsible for assessing safety & effectiveness of MCMs for FDA approval.

FDA works with partners to advance development & availability of MCMs.

FDA CAN ISSUE EMERGENCY USE AUTHORIZATIONS TO ENABLE ACCESS TO MCMs PRIOR TO APPROVAL (OR FOR UNAPPROVED USES)

FDA MEDICAL COUNTERMEASURES INITIATIVE (MCMi)

MCMi is an FDA-WIDE initiative across FDA product centers (including CBER, CDER, and CDRH) and offices to coordinate MCM development, preparedness, and response, led by the Office of Counterterrorism and Emerging Threats, in the Office of the Chief Scientist.

**AVAILABILITY OF MCMs TO ENABLE ACCESS TO MCMs PRIOR TO APPROVAL (OR FOR UNAPPROVED USES)**

FDA ALSO HAS OTHER LEGAL AUTHORITIES TO FACILITATE EMERGENCY ACCESS TO MCMs

FDA IS RESPONSIBLE FOR ASSESSING SAFETY & EFFECTIVENESS OF MCMs FOR FDA APPROVAL

FDA WORKS WITH PARTNERS TO ADVANCE DEVELOPMENT & AVAILABILITY OF MCMs

ACTIVITIES INCLUDE:
- Review evidence for approval
- Regulatory science
- Policy & legal support
- Professional development

MCMs

PREVENT

TREAT

DIAGNOSE

DISEASES OR HEALTH EFFECTS CAUSED BY CBRN THREAT AGENTS

CHEMICAL

BIOLOGICAL

RADIOLOGICAL

NUCLEAR

EMERGING INFECTIOUS DISEASES

FDA also has other legal authorities to facilitate emergency access to MCMs since 2005.

121 MCMs approved since 2012*

60+ EUAs since 2005

FDA CAN ISSUE EMERGENCY USE AUTHORIZATIONS TO ENABLE ACCESS TO MCMs PRIOR TO APPROVAL (OR FOR UNAPPROVED USES)

TO PREPARE FOR & RESPOND TO EMERGING THREATS

FDA IS RESPONSIBLE FOR ASSESSING SAFETY & EFFECTIVENESS OF MCMs FOR FDA APPROVAL

FDA WORKS WITH PARTNERS TO ADVANCE DEVELOPMENT & AVAILABILITY OF MCMs

ACTIVITIES INCLUDE:
- Review evidence for approval
- Regulatory science
- Policy & legal support
- Professional development

FDA CAN ISSUE EMERGENCY USE AUTHORIZATIONS TO ENABLE ACCESS TO MCMs PRIOR TO APPROVAL (OR FOR UNAPPROVED USES)

TO PREPARE FOR & RESPOND TO EMERGING THREATS

FDA IS RESPONSIBLE FOR ASSESSING SAFETY & EFFECTIVENESS OF MCMs FOR FDA APPROVAL

FDA WORKS WITH PARTNERS TO ADVANCE DEVELOPMENT & AVAILABILITY OF MCMs

ACTIVITIES INCLUDE:
- Review evidence for approval
- Regulatory science
- Policy & legal support
- Professional development

FDA CAN ISSUE EMERGENCY USE AUTHORIZATIONS TO ENABLE ACCESS TO MCMs PRIOR TO APPROVAL (OR FOR UNAPPROVED USES)

TO PREPARE FOR & RESPOND TO EMERGING THREATS

*Number includes approved MCMs listed in the MCMi annual program update in fiscal years 2012-2017

LEARN MORE OR ASK US

www.fda.gov/medicalcountermeasures

AskMCMi@fda.hhs.gov

MCMi is an FDA-WIDE initiative across FDA product centers (including CBER, CDER, and CDRH) and offices to coordinate MCM development, preparedness, and response, led by the Office of Counterterrorism and Emerging Threats, in the Office of the Chief Scientist.

FDA MEDICAL COUNTERMEASURES INITIATIVE (MCMi)

MCMi is an FDA-WIDE initiative across FDA product centers (including CBER, CDER, and CDRH) and offices to coordinate MCM development, preparedness, and response, led by the Office of Counterterrorism and Emerging Threats, in the Office of the Chief Scientist.

FDA MEDICAL COUNTERMEASURES INITIATIVE (MCMi)

MCMi is an FDA-WID...