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.

**WHAT ARE MCMs?**

Prevent, protect against, treat or diagnose diseases or health effects caused by CBRN threat agents.

**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

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

**EXAMPLES OF FDA’s MCM ROLES**

1. FDA assesses the safety & effectiveness of MCMs for FDA approval

2. FDA works with partners to advance development & availability of MCMs to prepare for & respond to emerging threats

3. FDA can issue Emergency Use Authorizations to enable to access 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.

**LEARN MORE OR ASK US**

www.fda.gov/medicalcountermeasures
AskMCMi@fda.hhs.gov

*Number includes approved MCMs listed in the MCMi annual program update in fiscal years 2012-2019*