FDA-REGULATED MEDICAL PRODUCTS

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/certain masks
  - Gowns

EXAMPLES OF FDA’S MCM ROLES

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

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

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

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
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* Number includes approved MCMs listed in the MCMI annual program update in fiscal years 2012-2021