

## U.S. Food and Drug Administration: Medical Countermeasures Initiative

In recognition of our Nation's vulnerability to deliberate chemical, biological, radiological, and nuclear (CBRN) threats, as well as emerging infectious diseases, President Obama announced a bold Medical Countermeasures (MCM) Initiative in his 2010 State of the Union Address: "[W]e are launching a new initiative that will give us the capacity to respond faster and more effectively to bioterrorism or an infectious disease – a plan that will counter threats at home and strengthen public health abroad."

On August 19, 2010, HHS Secretary Kathleen Sebelius released a report of an extensive review of the Federal government's system to develop MCMs, which includes drugs, vaccines, diagnostic tests, and other equipment and supplies needed to respond to a public health emergency. These products include, for example, MCMs for anthrax, smallpox, and radiological/nuclear agents, among others.

The review identified FDA as one of the most critical components of the Nation's MCM Enterprise. FDA is responsible for evaluating product safety and efficacy; as a result, FDA has significant understanding of the steps required for successful product development. The development and regulatory review of these products requires specialized knowledge and scientific expertise. FDA's engagement will help to accelerate MCM development towards approval, establish clear regulatory pathways based on the most advanced scientific foundations available, and realize the promise of new technologies for flexible, rapidly scalable development and manufacturing of vaccines and other MCMs.

To bolster FDA's involvement in helping to facilitate the development of high-priority MCMs and strengthen the MCM Enterprise, FDA developed an Action Plan based on a three-pillar strategy:

- 1. Enhance the review process for MCMs by establishing Public Health and Security Action Teams.** To advance high priority Enterprise MCMs and related technologies, FDA will establish multidisciplinary Action Teams that will tackle the range of regulatory, scientific and policy issues facing MCM development and approval. They will ensure consistent regulatory approaches and efficient implementation of best regulatory review practices while fostering proactive communication with sponsors and U.S. Government partners. These teams will also allow FDA to anticipate challenges that inevitably emerge during product development and appropriately resolve them to avoid unnecessary delays in MCM development.
- 2. Advance regulatory science for MCM development and evaluation.** FDA's MCM regulatory science program will be implemented through internal and collaborative research, as well as through partnerships with academia, U.S. government agencies, and industry to explore solutions to complex scientific regulatory problems and to identify situations in which the application of new science could simplify or speed product development and/or the regulatory process.
- 3. Optimize the legal, regulatory, and policy framework for effective public health response.** To assure that laws and policies adequately support preparedness and response, FDA will conduct a review of the strengths and weaknesses of existing legal and policy approaches to MCM development, distribuion, administration and use. Where changes are needed to better protect public health, FDA will work with its partners to develop and propose new approaches.

FDA is essential to the success and strength of the MCM Enterprise and will immediately begin implementing this Action Plan to help the Enterprise safeguard the public's health.

