Biological and Chemical Threats: FDA’s Public Health Challenge

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FDA Mission

To ensure the safety and effectiveness of drugs, biological products, medical devices, the food supply, cosmetics, and products that emit radiation.
FDA Priorities

Strong FDA
- Personnel, processes, infrastructure
- Enhance availability of new technologies

Risk Management

Decrease Medical Errors and AEs

Better informed constituents

Counterterrorism
Countering Terrorism

Goal: To Strengthen FDA’s Capability to Prepare for and Respond to Terrorist Threats and Incidents to Mitigate the Public Health Impact
Program Strategies

Facilitate development and availability of medical countermeasures

Ensure food safety and security

Ensure safety and security of medical products

Enhance the Agency’s emergency preparedness and response capabilities

Ensure the safety and security of FDA personnel, physical assets, and sensitive information
Facilitate Product Development and Availability

Identify gaps in medical countermeasures and gaps in knowledge needed to develop these.

Foster the development of novel and existing products for use as medical countermeasures.

Work with partners to facilitate the availability of an adequate inventory of products for emergency situations.
Facilitate Product Development and Availability

Encourage discussion with FDA before submitting an Investigational New Drug Application (IND) (so-called “pre-IND meeting”)

Frequent interaction during IND process helps assure that the data needed to evaluate the effectiveness, safety, and quality of manufacture are collected

“Streamlined INDs” for more wide-spread use of an investigational product in a public health emergency

Fast track designation
Facilitate Development and Availability

Tools to facilitate the approval of a new drug (NDA) or biological license application (BLA)

- Accelerated Approval – effectiveness based on surrogate endpoints likely to predict clinical benefit, but not yet established (confirmatory post-marketing studies needed)

- The “Animal Rule”- animal efficacy data in lieu of human data, when human efficacy trials not feasible or ethical
Recent Product Approvals and Development Efforts

Smallpox

- Approval of license supplements led to availability of millions of doses of smallpox vaccine
- Efforts to facilitate development of new smallpox vaccines
- Efforts to facilitate development of immune globulins and drugs to treat complications of smallpox vaccination and smallpox
Recent Product Approvals and Development Efforts (cont.)

Anthrax

Approval of license supplements led to availability of millions of doses of anthrax vaccine

Efforts to facilitate development of new anthrax vaccines and immune globulins

Drugs for post-exposure prophylaxis

- Ciprofloxacin: approval of supplement based on information submitted by manufacturer and USAMRIID
- Doxycycline, procaine penicillin G: FDA published finding of safety and efficacy for this indication
Recent Product Approvals and Development Efforts (cont.)

AtroPen Autoinjector (atropine): new dosage form approved for children and adolescents exposed to certain nerve agents and insecticides

Pyridostigmine Tablets: 1st product approved under Animal Rule – for prophylaxis against Soman nerve gas

Thyrosafe (KI): Approved to protect thyroid gland against radio-iodine
Ensuring food safety and security

The systems in place to reduce foodborne pathogens are the same systems that will assist in preventing or responding to a terrorist attack.

Rely on science-based approaches to solving public health problems.
FDA Activities: Food Safety

Anticipate
- Threat Assessments
- Intelligence Gathering

Deter
- Guidance to Industry
- Increased Focus on Imports
- Research Agenda
- Developing “Shields”
FDA Activities: Food Safety

Respond

- Emergency Response
- Lab Capacity/Surge Capacity
- Informing the Public
Conclusions

Proactively Facilitating Development of Medical Products and Devices

Increasing Vigilance in Food Safety and Security

The goal is to prepare for what is reasonably foreseeable and have the flexibility to respond swiftly and effectively to any public health crisis