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## The FDA and the Fight Against Terrorism

By Michelle Meadows

The FDA has adopted five broad strategies for counterterrorism:

- Awareness: Increasing awareness through collecting, analyzing, and spreading information and knowledge.
- Prevention: Identifying specific threats or attacks that involve biological, chemical, radiological or nuclear agents.
- Preparedness: Developing and making available medical countermeasures such as drugs, devices, and vaccines.
- Response: Ensuring rapid and coordinated response to any terrorist attacks.
- Recovery: Ensuring rapid and coordinated treatment for any illness that may result from a terrorist attack.

Minutes after two hijacked airliners crashed into the World Trade Center on the morning of Sept. 11, 2001, the Federal Aviation Administration stopped all flights from U.S. airports. It marked the first time that air traffic came to a halt nationwide. Soon after, a third plane crashed into the Pentagon, and a fourth plane thought to be headed for another target in Washington, D.C., crashed into a field in Somerset County, Pa.

All told, more than 3,000 people died. Experts from the Food and Drug Administration immediately became involved. They ensured that blood could be collected quickly from people living near the disaster sites to help the injured survivors. Other agency experts evaluated burn wound dressings that could be used to treat victims and checked on reserves of drugs and medical supplies.

And while the country was still reeling from these tragedies, terrorists launched more attacks through the mail in October 2001. Letters containing anthrax spores (*Bacillus anthracis*) were mailed to U.S. senators and members of the media. The Centers for Disease Control and Prevention (CDC) recorded 22 cases of anthrax. There were 11 cases of cutaneous (skin-based) anthrax and 11 cases of inhalational anthrax. Among the inhalational cases, there were five deaths.

A key challenge for public health workers was the fact that early inhalational anthrax symptoms are similar to those of common illnesses such as the flu. Lung infections with anthrax can rapidly become fatal unless appropriate antibiotic treatment is started very soon after symptoms develop.

Two postal workers at the Brentwood mail facility in Washington, D.C., were among those who died from exposure to inhalational anthrax. They initially presented with non-specific symptoms and were diagnosed as having common infections that did not require hospitalization. Their doctors considered the possibility of anthrax only after they became aware of media reports about other postal workers with inhalational anthrax. Experts from the National Institutes of Health, the Johns Hopkins Schools of Medicine and Public Health, and area hospitals published a report on the two anthrax-related deaths in the Nov. 28, 2001, issue of the *Journal of the American Medical Association*. The authors concluded that rapid communication of information between public health agencies and health care professionals is needed in the event of a serious infectious disease outbreak.

At the time of the terrorist attacks, the FDA had already approved the drug Cipro (ciprofloxacin) to prevent the progression of anthrax following inhalation of anthrax spores under the FDA's accelerated approval regulations. In November 2001, the agency clarified that two more drugs--doxycycline and procaine penicillin G--also were approved to treat inhalational anthrax. The FDA initiated public education about the treatments, which included providing dosing regimens and answering questions about the use of antibiotics in children and pregnant or nursing women.

The FDA worked closely with blood banks in anthrax-affected areas to determine whether people incubating this disease may have donated. This enabled the removal of potentially unsafe blood from the blood supply.

Later, when operators of some Web sites seeking to capitalize on the threat sold unapproved foreign-made Cipro over the Internet, the FDA issued warnings and reminded consumers that only FDA-approved products can be legally marketed in the United States.

### **Preparing for Emergencies**

The FDA's Office of Crisis Management (OCM) is responsible for preparing the agency for a range of possible terrorist events. This office maintains round-the-clock coverage for the agency and coordinates emergency response activities in the five FDA centers and the Office of Regulatory Affairs. OCM activities include leading the agency in emergency response drills, maintaining the physical security of FDA buildings, ensuring that the agency can continue its mission in a time of crisis, and educating employees on handling sensitive information.

### **A Comprehensive Approach**

"It was always our job to protect the public health," says Jeff Shuren, M.D., J.D., assistant commissioner for policy at the FDA. "But in an environment of heightened security, we are applying even more resources to counterterrorism in all areas of the agency."

This means safeguarding all products that the agency regulates, including food, drugs, medical devices, cosmetics, and animal feed. The FDA also works to speed the development of medical countermeasures--human and animal drugs, vaccines and other biologics, blood and blood products, diagnostic tests, and devices that can prevent, diagnose, and treat illnesses related to a terrorist attack. FDA Commissioner Mark B. McClellan, M.D., Ph.D., has identified counterterrorism as one of his strategic priorities.

The FDA's Office of Regulatory Affairs (ORA) is responsible for ensuring that all FDA-regulated products are in compliance with laws and regulations that the FDA is charged with enforcing. The agency responds rapidly to emergencies and redirects efforts when necessary to respond to incidents of product tampering and other unforeseen events. The FDA's Office of Criminal Investigations (OCI), part of ORA, maintains relationships with domestic and foreign law enforcement agencies and serves as the FDA's liaison with the intelligence community.

To bolster the FDA's counterterrorism efforts, McClellan appointed Margaret Glavin, one of the nation's foremost food safety experts, to the new position of Assistant Commissioner for Counterterrorism Policy in October 2003. In addition to serving as the Commissioner's senior adviser on counterterrorism, Glavin oversees the newly established Office of Counterterrorism Policy.

"We're implementing a comprehensive, integrated counterterrorism program that can only be done by working closely with other agencies and industry," Glavin says. "Of course, working with the FDA centers to prevent a terrorist attack against food and medical supplies will be a major part of our efforts, but we are also working on other key priorities that the Commissioner has laid out." Glavin also coordinates with other agencies within the U.S. Department of Health and Human Services (HHS), such as the CDC and the National Institutes of Health (NIH), as well as the U.S. Department of Defense (DoD), the White House Homeland Security Council, and the Department of Homeland Security (DHS).

The FDA is working with the NIH, CDC, DoD, industry, and foreign governments to ensure the availability of drugs

and vaccines through the Strategic National Stockpile (SNS), which is intended for deployment in response to national emergencies. The SNS is a stockpile of antibiotics, antitoxins, vaccines, medical supplies, medications and surgical items.

Emergency drug packages known as Push Packs are strategically located in warehouses across the country and can be sent to any destination in the United States within 12 hours of a federal decision to deploy them. In addition, under pending legislation called BioShield, promising new products that have not been approved, licensed, or cleared by the FDA could be used temporarily under new emergency authorization procedures if alternatives are not available to cope with a terrorist attack.

A top priority is relaying information about counterterrorism to the public quickly. The FDA's Web site ([www.fda.gov](http://www.fda.gov)) is a primary way the agency communicates with consumers. A section of the site is devoted to counterterrorism, along with links to other government agencies and tips on how to avoid bogus counterterrorism products. For more information, visit [www.fda.gov/oc/opacom/hottopics/bioterrorism.html](http://www.fda.gov/oc/opacom/hottopics/bioterrorism.html).

### Protecting Animal Health

The FDA's Center for Veterinary Medicine (CVM) regulates drugs, devices, and food additives that are given to or used on millions of poultry, cattle, pigs, and minor animal species such as birds and rabbits. There has been considerable testing of feed and feed ingredients to avert diseases such as "mad cow disease," and the agency is working on bio-security awareness guidance for the feed industry. The FDA is collaborating with Iowa State University to set up a database that involves all veterinary labs and provides a rapid response network for animal- or feed-related terrorism. Counterterrorism priorities for CVM include:

- Working with other agencies to lower risk of terrorist attack on feed for animals raised for human consumption
- Helping to identify labs that can test feed and animal tissues for the presence of chemicals and biological agents
- Protecting pets from terrorist attacks and developing veterinary drug products to meet emergency needs
- Partnering with the USDA's Food Safety and Inspection Service to monitor drug and chemical residues in meat and poultry.

## Food Safety and Security

Food safety and security fall under the jurisdiction of several centers and offices within the FDA, including the Center for Food Safety and Applied Nutrition and the National Center for Toxicological Research, which conducts scientific research to support the agency's regulatory needs. The FDA's Center for Veterinary Medicine has authority over food additives and drugs given to animals, including food-producing animals.

In the past, food safety concerns centered on accidental and natural food contamination that could occur. But now, there is concern that biological, chemical, or radiological agents could be intentionally introduced into our food supply.

Several recent incidents in other countries highlight the importance of the FDA's watchdog role in food security. In 2002, a restaurant owner in China added chemicals to a competitor's food, killing dozens of people and sending hundreds to the hospital. In another incident in 2002, three people were arrested in Jerusalem for allegedly planning a mass poisoning of patrons at a cafe. And in January 2003, several people were arrested in London for plotting to add a deadly poison called ricin to the food supply on a British military base.

The FDA is responsible for the safety of about 80 percent of the U.S. food supply. FDA oversight includes the safe production, processing, storage and holding of domestic and imported food. The exceptions are meat, poultry and processed egg products, which are under the jurisdiction of the U.S. Department of Agriculture (USDA).

If a terrorist-related outbreak occurred in the United States, the FDA would work closely with federal, state, and local authorities to identify the problem, investigate, and get the contaminated products off the market quickly. Here are some examples of how the FDA works to safeguard the food supply:

**Prevention and Surveillance:** After Sept. 11, 2001, the FDA conducted food supply vulnerability assessments. The FDA also issued guidance documents on security measures that the food industry can take to minimize the risk that food will be subject to tampering or other criminal actions. The guidances are aimed at food producers, processors, transporters, importers, retailers, food service establishments, and cosmetic processors. The agency has also issued guidance for the milk industry.

The FDA is working with the USDA and other federal and state agencies on the Electronic Laboratory Exchange Network (eLEXNET), the first integrated, Web-based data exchange system for sharing food testing information. It allows multiple agencies engaged in food safety activities to compare and coordinate findings of laboratory analyses.

A critical component of controlling threats from deliberate foodborne contamination is the ability to rapidly test large numbers of samples of potentially contaminated foods for a variety of biological, chemical and radiological agents. The FDA has worked closely with the CDC and the USDA to establish the Food Emergency Response Network (FERN)--a national network of laboratories ready to respond to a food security emergency.

**Protecting Imports:** The FDA is improving its efforts to ensure the safety of the nearly 6 million food shipments that arrive in the United States each year. With additional funding for counterterrorism, the FDA has hired more than 655 new field inspectors to monitor imports. The addition of these field employees has resulted in increased surveillance of imported foods and enhanced laboratory analysis capacity.

Within the last two years, the number of ports that have an FDA presence has more than doubled from about 40 ports in 2001 to about 90 ports by the end of 2002. In addition, the agency has increased by more than sixfold the number of food import exams conducted at the border, from 12,000 in fiscal year 2001 to more than 78,000 in fiscal year 2003.

The agency has also updated its labs to handle the increased number of food samples that may be contaminated by terrorism. There are more than 90 active FDA research projects on the development of tests and sampling methods to quickly detect contaminated food. A major focus is on developing rapid test kits that can be used to quickly inspect food at ports of entry to the United States.

**Four Major Regulations:** Under the authority of the Public Health Security and Bioterrorism Preparedness and Response Act of 2002, signed by President Bush in June 2002, the FDA developed four new regulations that address provisions of the law.

- **Registration of food facilities.** This regulation became effective in December 2003. It requires owners and operators of foreign or domestic food facilities that manufacture or process, pack, or hold food for human or animal consumption in the United States to submit information to the agency about the facility and emergency contacts. More than 400,000 facilities are expected to register through the FDA's new electronic registration system, which went online in October 2003.
- **Prior notification of imported food shipments.** This regulation, which became effective in December 2003, requires the FDA to receive prior notice of imported food shipments before the food arrives at a U.S. port. The FDA expects to receive about 25,000 notifications about incoming shipments every day.
- **Establishment and maintenance of records.** Manufacturers, processors, packers, importers, and others are required to keep records that identify the source from which they receive food and where they send it.
- **Administrative detention.** The agency has new authority to detain any food for up to 30 days for which there is credible evidence that the food poses a serious threat to humans or animals.

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### Keeping the Blood Supply Safe

Any time there are large emergencies or outbreaks of diseases, the blood supply is threatened. In the case of mass vaccinations, sometimes people who receive vaccinations containing live viruses can't be blood

donors because of the potential to transmit the vaccine virus. The FDA's Center for Biologics Evaluation and Research (CBER) has issued guidances on reducing the risk of transmitting diseases through blood donated by people who may be infected, either by vaccination or by exposure to a bioterrorist agent. There are also other FDA programs to evaluate the effects of other possible disaster scenarios. The FDA has made recommendations for national emergency planning to assure that vaccination campaigns consider blood supply. CBER scientists are also researching ways to detect bioterrorist agents in blood donations.

According to the American Association of Blood Banks (AABB), a disaster would include an act of terrorism that requires a much larger amount of blood than usual, one that temporarily restricts blood collection, testing, and distribution, or one that creates a sudden influx of donors requiring accelerated drawing of blood. The AABB has a disaster operations handbook on coordinating the nation's blood supply during disasters and biological events and serves as the coordinator for the Interorganizational Task Force on Domestic Disasters and Acts of Terrorism. This task force will assist HHS in emergency situations to assure an adequate blood supply. The FDA is an active member of this task force, and helps assure that blood donations would remain safe and plentiful in times of disaster. Other members of the task force include the CDC, the American Association of Tissue Banks, the American Hospital Association, and the American Red Cross.

## Medical Countermeasures

Ensuring that safe and effective medical products are available for diagnosing, treating, and preventing illness due to terrorist agents is the responsibility of the FDA's Center for Drug Evaluation and Research, the Center for Devices and Radiological Health, and the Center for Biologics Evaluation and Research. Biologics are medical products derived from living sources. These products include vaccines, blood and blood derivatives, and cells and tissues for transplantation.

The FDA works with other health agencies and manufacturers to identify promising research and to encourage the development of new products. The FDA supports clinical research to find out whether products approved for one indication could be used for an indication related to counterterrorism. In some cases, the FDA conducts research on its own.

Under a new regulation known as "the animal efficacy rule," the FDA can approve medical treatments against terrorist agents based on effectiveness data from animal studies when human studies are unethical and not feasible. Studies demonstrating the safety of the new product in humans are still required.

The FDA also publishes guidance for using medical countermeasures in special groups such as the first responders in an emergency, people in the military, people who live near nuclear facilities, pregnant women, children, and people with compromised immune systems.

As part of national policy, the FDA places high priority on Category A agents, a designation the CDC gives to the greatest threats to public health. Category A agents include the organisms that cause anthrax, plague, smallpox, tularemia and viral hemorrhagic fevers, as well as botulinum toxin. Here are some examples of areas in which the FDA works on medical countermeasures:

**Anthrax:** Anthrax is an infectious disease caused by the spore-forming bacterium *Bacillus anthracis*. There are three forms of anthrax infection: skin (cutaneous), gastrointestinal, and inhalational.

Cutaneous anthrax can be acquired when spores enter cuts or abrasions in the skin. It is marked by a sore that progresses from a red raised area on the skin to an ulcer with a black center. Gastrointestinal anthrax can result from ingesting food that contains *B. anthracis* spores. It can cause fever, loss of appetite, nausea, and vomiting, which can progress to vomiting of blood and severe, often bloody, diarrhea and abdominal pain.

Inhalational anthrax, which is associated with the highest death rates, occurs when spores are inhaled and cause infection in the lungs. Initial symptoms are similar to a cold or the flu, but the illness worsens over several days and a high fever typically develops.

The treatment for all types of anthrax is antibiotics. The antibiotics approved by the FDA are Cipro (ciprofloxacin),

drugs in the tetracycline class such as doxycycline, and some drugs in the penicillin class such as procaine penicillin G.

The anthrax vaccine is primarily given to people in the military and is only recommended for individuals considered to be at high risk, such as scientists who handle anthrax bacteria in a research lab. During the anthrax attacks in 2001, the FDA made one type of anthrax vaccine, Anthrax Vaccine Adsorbed, available under an investigational new drug application (IND) for people who are not in the military and who had been exposed to inhalational anthrax. An IND allows a treatment to be made available before final FDA approval of the drug. These individuals also received antibiotics.

The FDA is part of an interagency working group, together with NIH, CDC, DoD, and HHS, that is focused on encouraging the development of new generation recombinant anthrax vaccines intended to prevent inhalational anthrax both before and after exposure.

The genetic makeup of anthrax is being studied to help improve vaccines and treatments. FDA scientists are studying a weakened infectious strain of bacteria as a possible carrier to stimulate antibodies against anthrax. They also are evaluating whether small, non-infective pieces of anthrax bacteria potentially could be used as safe and effective vaccines. The FDA and CDC are studying the possibility that anthrax immune globulin (AIG) may be useful in prevention or treatment of anthrax.

In August 2003, the agency granted fast-track designation to an IND for ABthrax, an antibody that is being evaluated for the prevention and treatment of anthrax infections. The FDA also issued guidance to the drug industry on developing antimicrobial drug products for inhalational anthrax. There is also research underway on an investigational device that tests for the presence of *B. anthracis*.

**Smallpox:** The last confirmed case of smallpox in the United States was in 1949, and the last naturally occurring case in the world was recorded in Somalia in 1977. The World Health Organization has declared the illness eradicated, but if one case were intentionally introduced, the result could be a public health emergency. Caused by the variola virus, smallpox is highly contagious and can be spread by close contact with a person who has smallpox symptoms--high fever, fatigue, headaches, backaches, vomiting, rash, and pus-filled blisters. There is no proven treatment. The death rate in the past was about 30 percent, and death rates can be higher for infants and young children.

Smallpox can be prevented through vaccination. Dryvax (smallpox vaccine, dried, calf lymph type), made by Wyeth Laboratories of Marietta, Pa., is the only smallpox vaccine currently licensed by the FDA. In October 2002, the FDA approved a license supplement for a 100-dose kit of Dryvax with a new supply of diluent, which is the liquid that's mixed with dried vaccine before it's administered. Before this supplement, Dryvax was only available for use in clinical investigations under an IND.

In December 2002, President Bush announced a voluntary national plan to contain a smallpox outbreak through vaccinating smallpox response teams across the country. These teams are made up mostly of health care workers. Part of the plan involved developing a national stockpile of the vaccine. The FDA's work with manufacturers and the CDC has boosted the stockpile of investigational smallpox vaccine by hundreds of millions of doses. In addition, under CDC-sponsored INDs, the FDA has approved the use of various investigational smallpox vaccines. The FDA has also approved INDs for Vaccinia Immune Globulin (VIG), which is used to treat some rare but life-threatening complications of the smallpox vaccine. The FDA's research laboratories have developed two new methods to test and monitor the strength of VIG preparations.

In the spring of 2003, the CDC and DoD reported several types of cardiac problems among some people who had recently received the smallpox vaccine. The FDA is working with other agencies on the ongoing evaluation of these events. Although it's unknown if smallpox vaccine causes atherosclerotic cardiovascular disease, the Advisory Committee on Immunization Practices recommends that people with underlying heart disease or three or more known cardiac risk factors (hypertension, diabetes, and smoking, for example) not be vaccinated. Also, a link between the smallpox vaccine and inflammatory heart disease appears to be likely.

The FDA made appropriate changes to the Dryvax package insert to reflect these findings. Several smallpox vaccines that are related to the same vaccine strain used in Dryvax but grown in cell culture are being developed. FDA scientists are pursuing studies that may support development of safer smallpox vaccines.

**Plague:** Plague is caused by the bacterium *Yersinia pestis*. Bubonic plague is the most common type of naturally occurring plague. It is transmitted through the bite of an infected flea or exposure through a cut. Symptoms of bubonic plague include swollen, tender lymph nodes, headache, fever, and chills. If untreated, bubonic plague may result in death.

In pneumonic plague, the lungs are infected with the plague bacterium. People with pneumonic plague can transmit plague to other people, whereas bubonic plague cannot be spread from person to person. Antibiotics approved by the FDA to treat plague are streptomycin, doxycycline, and other drugs in the tetracycline class.

The FDA has requested grant applications for clinical trials for plague treatments, and in conjunction with the CDC, the FDA is funding research on evaluating rapid diagnostic test kits for plague. The FDA, along with the NIH and DoD, has funded studies investigating the safety and effectiveness of gentamicin and other antibiotics for plague. There is no plague vaccine available in the United States. The originally licensed whole-cell plague vaccine is no longer being manufactured and there is no vaccine inventory remaining. Given the potential threat, the FDA is accepting applications for newly developed plague vaccines that could be licensed.

**Nerve Agents:** These chemical agents interfere with nerve function, causing paralysis, suffocation, and seizures. The FDA worked with the U.S. Army to approve pyridostigmine bromide for combat use to protect people in the military from soman, a nerve gas that can kill in 15 minutes. Evidence of pyridostigmine bromide's effectiveness was obtained primarily from studies in monkeys and guinea pigs. It was the first drug approved under the animal efficacy rule.

In January 2002, the FDA also approved ATNAA (atropine/pralidoxime) autoinjector to treat nerve gas intoxication. And in June 2003, the agency approved new dosage forms of AtroPen (atropine) autoinjectors for use in children and adolescents exposed to nerve agents.

In March 2003, the FDA cleared Reactive Skin Decontamination Lotion for use by the military to remove or neutralize chemical warfare agents and T-2 fungal toxin from the skin.

**Radioactive Contamination:** Radioactive material could be introduced into the food or water supply or with explosives that spread radioactive materials.

In 2001, the FDA collaborated with the NIH to issue a final guidance applying to children and adults on the use of potassium iodide (KI) in radiation emergencies. When given in the recommended dose, KI reduces the risk of thyroid cancer in people at risk for inhaling or ingesting radioiodines. KI floods the thyroid with non-radioactive iodine and prevents the thyroid's uptake of radioactive molecules.

In September 2002, the FDA approved ThyroSafe Tablets (potassium iodide) as a thyroid-blocking agent for use in radiation emergencies. This drug underwent fast review, and the dosage form can be used in children because it's half the strength of formulations that were previously approved.

Normally, a drug or device company collects data on a new product and submits it to the agency. But in two instances, the FDA found the data on its own, and then called for manufacturers to submit applications. The first example is Prussian blue, a substance that has been used as a pigment for artists since 1704. The substance can treat people exposed to radioactive cesium or radioactive and non-radioactive thallium. Radioactive cesium could be used in a "dirty bomb" or other terror device. Prussian blue traps thallium or cesium in the intestine so that they can be passed out of the body in the stool rather than reabsorbed into the body. This reduces the amount of radiation in the body. In March 2003, the FDA received its first marketing application for Prussian blue in response to the agency's call for applications. On Oct. 2, 2003, this application was approved, giving the nation the first drug that can be used as a medical countermeasure to the threat of radioactive cesium.

The FDA also determined conditions under which pentetate calcium trisodium (Ca-DTPA) and pentetate zinc sodium (Zn-DTPA) are safe and effective for treating certain kinds of radiation exposure. The agency then encouraged submission of new drug applications for these products. Ca-DTPA and Zn-DTPA are usually given intravenously, and have been used as investigational drugs for 40 years.

The FDA determined the drugs can be safe and effective for treating internal contamination with plutonium,

americium, or curium, substances that can be found in the fallout from the detonation of nuclear weapons and waste from nuclear power plants. Ca-DTPA and Zn-DTPA work by increasing the rate of elimination of these substances from the body.

### **Examples of Medical Countermeasures**

<b>Product</b>	<b>Indication</b>	<b>Approved/Cleared</b>
Redline Alert Test	Used with other tests to determine whether a person has anthrax disease.	Dec. 9, 2003
AtroPen Autoinjector (atropine)	Exposure to nerve agents or insecticides. Has been approved since 1973 for adults. Approved for children and adolescents.	June 19, 2003
Reactive Skin Decontamination Lotion	Used by the military to remove or neutralize chemical warfare agents and fungal toxin from the skin.	March 29, 2003
Pyridostigmine Tablets	Treat soman nerve gas poisoning. First drug approved under the animal efficacy rule.	Feb. 5, 2003
HemCon Bandage	Temporary control of severely bleeding wounds. For military battlefield treatment.	Nov. 4, 2002
Smallpox Vaccine (Dryvax)	Prevention of smallpox infection. An amendment to the license for a 100-dose kit of Dryvax with a new supply of diluent and needles.	Oct. 25, 2002
ThyroSafe Tablets, 65 mg (potassium iodide)	Thyroid blocking agent for use in radiation emergencies. For adults and children.	Sept. 10, 2002
QuickClot	Emergency use as temporary treatment for wounds. For military use.	May 29, 2002
Anthrax Vaccine	Prevention of anthrax infection. An amended license for manufacturing changes.	Jan. 31, 2002
ATNAA (atropine/pralidoxime)	One injection of the two products, for poisoning by nerve agents.	Jan. 17, 2002
Nucleic Acid Amplification Assay for Anthrax	An assay that tests for presence of anthrax, made available under an investigational device exemption.	Dec. 21, 2001
Ciprofloxacin (Cipro)	Inhalational anthrax post-exposure in adults and children.	Aug. 30, 2000
Skin Exposure Reduction Paste Against Chemical Warfare Agents	Protecting skin from contact with chemical warfare agents (blister and nerve agents).	Feb. 2000

Source: FDA

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