# Next Steps: Biosafety and Biosecurity at the Food and Drug Administration (FDA)

## Summary

On August 18, 2014 Assistant to the President for Homeland Security and Counterterrorism Lisa Monaco and Assistant to the President for Science and Technology John Holdren issued a memorandum, titled, *"Enhancing Biosafety and Biosecurity in the United States,"* which urged all United States Government departments and agencies that work with infectious agents to take immediate and long-term steps to enhance safety and security of research to minimize the potential for future incidents. All United States Government departments and agencies that possess, use, or transfer human, animal, or plant infectious agents or toxins were urged to perform a Safety Stand-Down, to include an immediate sweep of their facilities to verify that all Biological Select Agents and Toxins in their possession were appropriately registered, stored, and disposed of in accordance with applicable regulations.

In July 2014, the Food and Drug Administration (FDA) initiated a careful and deliberate review of its biosafety and biosecurity protocols and implemented a series of measures to improve laboratory safety practices across the agency, including a comprehensive search of laboratory and associated spaces to identify Biological Select Agents and Toxins (BSAT) and ensure their proper registration, safe stewardship, and secure storage or disposal, among other measures. These measures also fulfill the immediate and long-term steps called for in the August 18, 2014 memorandum.

## Overview of Process

Between July 10 and September 30, 2014, FDA scientists performed a vial-by-vial visual inspection of all specimens held in FDA laboratories to identify any inappropriately stored, potentially hazardous biological agents and toxins. This included an inspection of approximately 670,000 specimens across seven FDA centers and offices with laboratories located in the Washington, DC metropolitan area and around the country. This comprehensive sweep followed an initial search of all shared cold storage areas to identify any improperly stored hazardous materials, which was completed July 17, 2014.

## Overall Findings

FDA's lab sweep was initiated after the July 1, 2014 identification of vials of variola (smallpox virus) and other pathogens in an FDA laboratory building located on the campus of the National Institutes of Health (NIH) in Bethesda, Maryland. These vials were sealed and there was no evidence that lab workers were exposed to the contents of these vials or that there was a risk to public health. Upon identification of the vials of variola, CDC's Division of Select Agents and Toxins (DSAT) was immediately notified and the vials containing smallpox virus were transferred to CDC's high containment laboratories in Atlanta, Georgia for analysis. The vials containing other pathogens were moved to a select agent laboratory in the metropolitan Washington, DC area.

| Entity | Discovery Date | Discovered Agent or Toxin | Quantity | Resolution of Sample | Indication of Human Exposure Prior to or During BSAT Discovery |
|---|---|---|---|---|---|
| FDA | 7/15/2014 | Staphylococcal enterotoxin | 8 mg | Destroyed | No |
| FDA | 9/7/2014 | *Clostridium botulinum* | 3 vials | Destroyed | No |

In addition to the variola finding, two additional instances of hazardous biological materials stored in locations not registered with CDC's DSAT were found during the laboratory sweep (see table above).

In no case was there an indication of human exposure, including staff or the general public, to any of these agents or toxins. After notifying CDC's DSAT, the inappropriately stored vials were destroyed.

## Additional FDA Actions

*Plans for Sustained Inventory Monitoring*

FDA will be developing and implementing a new data management system to facilitate automated inventory of long-term stored biological materials, creating a uniform inventory system at FDA that will document and monitor specimens maintained by FDA laboratories.

*Comprehensive Review of Current Biosafety and Biosecurity Protocols*

FDA has established an agency-wide Laboratory Safety Policies and Practices Workgroup (LSPPW) to (a) conduct a comprehensive review of laboratory safety and security policies and procedures, including inventory management (b) identify and address any gaps in policies and procedures and (c) standardize safety and security practices across the agency's laboratories. This group was also responsible for overseeing the vial-by-vial inspection.

In addition, FDA participated in the review of government-wide laboratory safety policies and regulations performed by the multi-agency Federal Experts Security Advisory Panel (FESAP) at the request of the National Security Staff and Office of Science and Technology Policy

*Opportunities for Improving Research Safety*

FDA also organized a Biosafety Stewardship Month during September and October 2014, featuring a series of events and training activities to raise awareness and highlight the importance of laboratory safety and security among FDA scientists.

*Next Steps*

FDA has also initiated engagement with the External Advisory Group (EAG) on laboratory safety established in August 2014 through the Centers for Disease Control and Prevention (CDC) Director's Advisory Board. The EAG is scheduled to examine the adequacy of FDA's laboratory safety and security enterprise, identify gaps, and provide recommendations for improvements as indicated.

For a summary of the U.S. Government-wide Safety Stand-Down, click here:
*http://www.fda.gov/downloads/NewsEvents/Newsroom/FactSheets/UCM427035.pdf*

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