



United States  
Department of  
Agriculture

June 27, 2013

Animal and Plant  
Health Inspection  
Service

Veterinary Services

National Center for  
Import and Export

4700 River Road,  
Unit 2, Mailstop 22,  
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Riverdale, MD 20737

(301) 851-3300, 1  
FAX (301) 734-3652

[Redacted]

Responsible Official  
Centers for Disease Control and Prevention  
Select Agent Compliance, Roybal Campus  
1600 Clifton Road NE, Mail Stop A-22  
Atlanta, Georgia 30333

[Redacted]

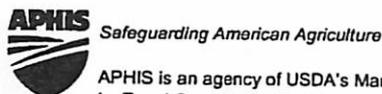
The Animal and Plant Health Inspection Service (APHIS), Agricultural Select Agent Program (ASAP) and the Centers for Disease Control and Prevention (CDC), Division of Select Agents and Toxins (DSAT) conducted an APHIS-Led CDC joint inspection January 14, 2013 to January 17, 2013, at the Centers for Disease Control and Prevention. ASAP and DSAT have completed the review of the Pox Branch facility inspection. ASAP does not have any questions at this time but DSAT requires additional information from you. Please provide this information to DSAT's office no later than 14 calendar days from receipt of this letter. Please see the CDC attached letter dated June 25, 2013.

If there are any questions or concerns in reference to this correspondence the DSAT letter states to contact Martin Smeltzer. Instead of [Redacted], please contact [Redacted] at [Redacted] with the Centers for Disease Control and Prevention, Division of Select Agents and Toxins for any questions. Thank you

Sincerely,

[Redacted Signature]

[Redacted Title]  
Staff Veterinary Medical Officer  
Agricultural Select Agent Program



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Department of Health and Human Services  
Centers for Disease Control and  
Prevention  
Division of Select Agents and Toxins  
Atlanta, Georgia

U.S. Department of Agriculture  
Animal and Plant Health Inspection Service  
Select Agent Program  
Riverdale, Maryland



June 25, 2013

[Redacted] (Responsible Official)  
Centers for Disease Control and Prevention  
1600 Clifton Road, NE, Mailstop A-22  
Atlanta, GA 30333  
FAX: (404) 639-0437

**RE: Entity Inspection Report: Centers for Disease Control and Prevention**

Pursuant to the Public Health Security and Bioterrorism Preparedness and Response Act of 2002, the United States Department of Health and Human Services (HHS) and the United States Department of Agriculture (USDA) have established regulatory requirements for the possession, use, and transfer of biological agents and toxins that have the potential to pose a severe threat to public health and safety, animal and plant health, and animal and plant products. These requirements can be found at 42 CFR Part 73 (HHS), 7 CFR Part 331 (USDA-PPQ), and 9 CFR Part 121 (USDA-VS). The Centers for Disease Control and Prevention's (CDC) Division of Select Agents and Toxins (DSAT) inspects entities to evaluate whether they meet the regulatory requirements set forth in 42 CFR Part 73, and the Animal and Plant Health Inspection Service (APHIS) Select Agent Program (ASAP) inspects entities to evaluate whether they meet the regulatory requirements set forth in 7 CFR Part 331 and 9 CFR Part 121. The above referenced regulations and supporting guidance information may be found at <http://www.selectagents.gov/>.

DSAT inspectors visited your facility located at 1600 Clifton Road, NE, Mailstop A-22 Atlanta, GA 30333 from January 14, 2013 to January 17, 2013. A list of laboratories inspected on these dates is on file with this letter at CDC.

The following personnel from the CDC and APHIS Select Agent Programs inspected the facility:

- [Redacted] Lead Inspector
- [Redacted] Inspector

Individuals from Centers for Disease Control and Prevention present during the inspection included:

- [Redacted] Support: Animal Care
- [Redacted] Laboratorian
- [Redacted] Laboratorian/PI
- [Redacted] PI
- [Redacted] Quality Assurance Associate
- [Redacted] Support Staff: Animal
- [Redacted] RO, Safety and Occupational Health Manager
- [Redacted] CCID Safety Manager
- [Redacted] SRP, Alternate Attending Veterinarian
- [Redacted] Support Staff: Animal Care

[REDACTED] Support: Admin  
[REDACTED] PI  
[REDACTED] Veterinary Medical Officer  
[REDACTED]  
[REDACTED] Laboratorian  
[REDACTED] Clinical Veterinarian  
[REDACTED] Support: Animal Care  
[REDACTED]  
[REDACTED] ARO, Safety and Occupational Health Manager

During the inspection, departures from regulatory requirements cited above were noted. Please address each of the items described in Attachment 1 (List of Entity Departures) and include in your response the specific actions or changes to be adopted to correct these departures. A detailed response should be received by this office not later than 14 calendar days from receipt of this letter. An electronic copy of your response should be sent to the lead inspector. Failure to fully respond may result in the initiation of proceedings for the withdrawal of your facility registration to possess, use, or transfer select agents and toxins.

If you have any questions concerning this correspondence please contact [REDACTED] at [REDACTED]

Sincerely,

[REDACTED]  
[REDACTED]

Director, Division of Select  
Agents and Toxins  
Department of Health and Human  
Services  
Centers for Disease Control and  
Prevention

[REDACTED]  
[REDACTED]

Director, Agriculture Select Agent  
Program  
United States Department of  
Agriculture  
Animal and Plant Health  
Inspection Service

Attachment 1:  
List of Entity Departures

**Attachment 1: Entity Departures**

Departures noted from January 14, 2013 to January 17, 2013 at Centers for Disease Control and Prevention (citations from 42 CFR Part 73 specifying each requirement are given in brackets).

- 1 Requirement:** The biosafety and containment procedures must be sufficient to contain the select agent or toxin (e.g., physical structure and features of the entity, and operational and procedural safeguards). [42 CFR 73.12(b)]. Equipment that may produce aerosols must be contained in devices that exhaust air through HEPA filtration before being discharged into the laboratory. [BMBL: (BSL-4) C(B)1]

**Observation:** At the time of inspection, it was not clear that all aerosol-producing equipment was properly protected. Please verify that all instruments and equipment that may produce infectious aerosol in laboratory spaces are equipped with HEPA filters. Please verify that all table top centrifuges have primary containment rotors or are placed in BSCs when used.

- 2 Requirement:** The biosafety and containment procedures must be sufficient to contain the select agent or toxin (e.g., physical structure and features of the entity, and operational and procedural safeguards). [42 CFR 73.12(b)]. These HEPA filters should be tested annually and replaced as needed. [BMBL: (BSL-4) C(B)1]

**Observation:** Please verify that all HEPA filters in aerosol producing equipment are tested or replaced annually.

[REDACTED]

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**From:** [REDACTED]  
**Sent:** Thursday, June 27, 2013 2:25 PM  
**To:** [REDACTED]  
**Cc:** [REDACTED]  
**Subject:** Review of the [REDACTED] Branch Facility  
**Attachments:** CDC030046 [REDACTED] Branch IR.pdf

Dear Ms. Jones,

Enclosed is the review of the [REDACTED] Branch Facility inspection conducted on January 14, 2013 to January 17, 2013. The Division of Select Agents and Toxins (DSAT) require additional information from you. Please provide this information to DSAT's office no later than 14 calendar days from receipt of this letter.

Best regards,

[REDACTED]  
Program Analyst  
APHIS Select Agent Program  
[REDACTED]