



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

U.S. Department of Agriculture
Animal and Plant Health Inspection Service
Division of Agricultural Select Agent and Toxins
Riverdale, MD



February 19, 2021

(b)(3)

Subject: **Suspension of Registration** (b)(3)

Dear (b)(3)

This letter serves as formal notice that the certificate of registration (b)(3) for the (b)(3) to possess, use and transfer select agents and toxins is **suspended**, effective **February 19, 2021**.

This suspension of registration is based on the failure to comply with the regulatory requirements specified in sections 7 (Registration and Restricted Experiments), 9 (Responsible Official and Theft, Loss or Release), 11 (Security), 12 (Biosafety-General), 14 (Incident Response), 15 (Training), and 17 (Records) of the select agent regulations (9 CFR Part 121 and 42 CFR Part 73) observed during the January 19 – 22, 2021 inspection.

The Federal Select Agent Program (FSAP) provided the inspection report to (b)(3) on February 1, 2021. The report includes the corrective actions that (b)(3) must implement for FSAP to consider restoration of the entity's registration.

A suspension of registration would not impact the diagnostic work performed by (b)(3) as long as the entity meets all the provisions outlined under Sections 5 and 6 of the select agent regulations (9 CFR 121 and 42 CFR 73).

An entity may appeal the suspension of a certificate of registration. The appeal must be in writing and state the factual basis for the appeal. Submit the appeal to the Secretary of the U.S. Department of Agriculture through the Division of Agricultural Select Agent and Toxins within 30 calendar days of receipt of this letter (9 CFR 121.20). During the appeal, all activities with select agents and toxins must be halted, and all select agents in possession must be securely stored to prevent theft, loss, or release.

Contact Dr. Narda Huyke, Technical Unit Director, at 301-851-2070, or DASAT@usda.gov with any questions regarding this correspondence.

Sincerely,

Samuel S. Edwin, Ph.D
Director
Division of Select Agents and Toxins
Centers for Disease Control and Prevention
Department of Health and Human Services

Jacek Taniewski, DVM
Director
Division of Agricultural Select Agent and Toxins
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