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

March 11, 2021

(b)(3) [redacted]

FROM: Federal Select Agent Program (FSAP)

Re: **Suspension of Registration**, (b)(3) [redacted]

Dear (b)(3) [redacted]

This letter serves as formal notice that the certificate of registration (b)(3) [redacted] for (b)(3) [redacted] to possess, use, and transfer select agents and toxins is **suspended**, effective **March 11, 2021.**

All activities with select agents and toxins must cease immediately at (b)(3) [redacted]
All select agents and toxins in (b)(3) [redacted] possession must be securely stored to prevent theft, loss, or release.

Pursuant to section 8 of the select agent and toxin regulations, FSAP may suspend an entity's certificate of registration if the entity does not meet the requirements of the select agent and toxins regulations. 9 CFR 121.8(a)(3); 42 CFR Part 73.8(a)(3). This suspension o (b)(3) [redacted] certificate of registration is based on (b)(3) [redacted] failure to comply with the regulatory requirements specified in sections 9 (Responsible Official), 15 (Training), and 17 (Records) of the select agent and toxin regulations (9 CFR Part 121 and 42 CFR Part 73) as observed in recent immediate notifications regarding inventory discrepancies and the subsequent reports, *Incident Notification and Reporting APHIS/CDC Form 3*s submitted to FSAP. The select agent and toxin regulations identified above require, among other things, the following:

- Section 9(a)(4) states that "the responsible official must ensure compliance with the requirements of this part;"
- Section 11(e)(3) states "Entities must conduct complete inventory audits of all affected select agents and toxins in long-term storage . . . in the event of a theft or loss of a select agent or toxin, all select agents and toxins under the control of that principal investigator;"
- Section 15(a)(1) states that "training must address the particular needs of the individual, the work they will do, and the risks posed by the select agents or toxins;" Training provided must cover entities procedures, including inventory procedures, and ensure that staff understand and follow the required procedures.
- Section 17(a)(1) states that an entity "must maintain complete records relating to the activities covered under this part. Such records must include an accurate, current inventory for each select agent . . . held in long-term storage." Inventory records held by (b)(3) [redacted] were not accurate to the final disposition of vials, nor the quantity of vials stored and/or transferred between inventories.

As described in more detail below, the APHIS/CDC Form 3 reports and notification of inventory discrepancies made in January 2019, October - November 2020, and most recently in January 2021, indicate systemic noncompliance with inventory record keeping and effective training requirements that would prevent these repeated occurrences. Despite written assurances by the Responsible Official (RO) after each aforementioned incident that staff had been retrained on inventory practices and reminded of

portance of proper communication continued to report inventory discrepancies. Specifically, systemic noncompliance with the ements of the select agent and toxin regulations are evidenced by the following:

- **TLR** – On Jan 10, 2019,
- **TLR** – On October 14, 2020,
- **Inventory discrepancy report** – On November 12, 2020, Because all vials were accounted for and no vials were missing or stolen, no APHIS/CDC Form 3 was submitted.
- **TLR** – On Jan 20, 2021

This letter includes the immediate actions must take and the corrective actions must implement for FSAP to consider restoratio the registration. Regardless o suspension appeal, immediate actions listed below e followed.

Upon receipt of this letter, must immediately do the following:

1. Stop all activities with select agents and toxins, except the vial-by-vial inventory described in more detail below, and

2. Provide attestation in eFSAP information system confirming that all work with select agents and toxins as described above has ceased and the select agents and toxins possessed by (b)(3) are securely stored **by March 18, 2021**.

FSAP will consider restoration of (b)(3) certificate of registration when (b)(3) has taken the following corrective actions. Confirm and provide documentation in eFSAP information system showing:

1. 100% vial-by-vial inventory has been completed for all select agents at (b)(3) (Section 11(e)(3)).
2. Updated inventory procedures in compliance with section 17(a)(1) of the select agent and toxin regulations.
3. Updated and improved quarterly inventory procedures to ensure that vials in storage match the quantity and description assigned to each storage container; (Sections 11 (e)(3) and 17 (a)(1)).
4. All FSAP approved staff members with access to select agents and toxins have been trained on the updated inventory procedures; and (Section 15)
5. Greater oversight and involvement by Responsible Official in inventory verification. (Section 9 (a)).

FSAP may perform an onsite verification of the above corrective actions prior to restoration of (b)(3) certificate of registration.

Pursuant to section 20 of the select agent and toxin regulations (9 CFR 121.20; 42 CFR 73.20) (b)(3) may appeal the suspension of a certificate of registration. The appeal must be in writing and state the factual basis for the appeal (b)(3) must submit the appeal to the Secretary of the U.S. Department of Health and Human Services, through the DSAT Director, or the Administrator of the Animal and Plant Health Inspection Service, through the DASAT Director within 30 calendar days of decision of this letter. During the appeal, all activities with select agents and toxins must be halted, and all select agents and toxins within (b)(3) possession must be securely stored to prevent theft, loss, or release.

(b)(3) must complete the above listed corrective actions **by August 11, 2021**. Failure to complete the corrective actions may result in revocation of the (b)(3) certificate of registration. If (b)(3) certificate of registration is revoked, all select agents and toxins a (b)(3) will need to be transferred to a registered facility or destroyed.

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

Sincerely,

Jacek Taniewski, DVM
Director
Division of Agricultural Select Agent and Toxins
Animal and Plant Health Inspection Service
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Samuel S. Edwin, Ph.D
Director
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