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
Agriculture Select Agent Services
Riverdale, MD

July 23, 2020

TO: (b)(3):42 U.S.C. § 262a(h)(1)(E) Responsible Official
(b)(3):42 U.S.C. § 262a(h)(1)(E)

CC:

FROM: Federal Select Agent Program (FSAP)

RE: **Opportunity to show cause why the select agent and toxin registration of** National Animal Disease Center (Registration # (b)(3):42 U.S.C. § 262a(h)(1)(E) **should not be suspended or revoked.**

Dear (b)(3):42 U.S.C. § 262a(h)(1)(E)

Per section 8 of the select agents and toxins regulations [42 CFR Part 73 (HHS), 9 CFR Part 121 (USDA-VS)], an entity's registration may be suspended or revoked for failure to meet the requirements of the select agent regulations. [redacted] (b)(3):42 U.S.C. §), is being provided the opportunity to show cause why its registration for the possession, use, or transfer of select agents should not be suspended or revoked for failure to meet the requirements of the select agents regulations.

This action is based on failures of [redacted] o meet the requirements of the select agents and toxins regulations. Specifically [redacted] exhibited non-compliance with Section 12 (Biosafety), demonstrated by repetitive failures of and releases from (b)(3):42 U.S.C. § 262a(h)(1)(E) These failures and releases are outlined below (UIDs refer to specific observations in the eFSAP Inspection Module and TLR-F3 numbers refer to APHIS/CDC Form 3, Report of Theft, Loss, or Release of Select Agents and Toxins).

42 CFR § 73.12(b): Biosafety **UID: 42-12-38300**

On June 5, 2019, [redacted] Facilities and Engineering employees responded to three leak detection alarms for monitoring points located in (b)(3):42 U.S.C. § 262a(h)(1)(E) (b)(3):42 These alarms monitor the (b)(3):42 U.S.C. § 262a(h)(1)(C) hat feed into the [redacted] treatment plant - Building (b)(3) (b)(3):42 U.S.C. § 262a(h)(1)(E) (b)(3):42 U.S.C. § 262a(h)(1)(C) These (b)(3):42 operational design failures were subsequently evaluated by FSAP during the [redacted] June 2019 verification inspection (b)(3):42 and cited in the associated inspection report.

Initial responses to this UID did not adequately address FSAP's request of a timeline and schedule for double-walled drain line integrity testing, evaluation, and planned repairs. The (b)(3):42 initial responses to this UID, as well as additional information provided in May 2020, indicated that:

- A contract was awarded in Fall 2019 to repair and replace existing double-walled drain lines and install redundant drain lines in all sections where the double-walled drain line design failed. However, these efforts did not begin until April 2020 and only focused on double-walled drain lines between (b)(3):42 U.S.C. §

- (b)(3):42 U.S.C. § 262a(h)(1)(E); (b)(7)(C) were investigating methods to seal the (b)(3):42 U.S.C. § to ensure integrity. However, these efforts have not been further addressed and no results have been provided to FSAP.

- Evaluation of the root cause(s) for the failures of double-walled drain line integrity would be conducted at the time of repairs. However, repair efforts did not begin until April 2020 and no further updates have been provided to FSAP regarding the cause for failures in operational design.

9 CFR § 121.12(b): Biosafety **UID: 9-12-32300**

(b)(3):42 U.S.C. § 262a(h)(1)(E); (b)(3):42 U.S.C. § 262a(h)(1)(C)
(b)(3):42 U.S.C. § 262a(h)(1)(C)

These sensors were calibrated in 2009 upon commissioning of the system but have not been calibrated in an ongoing basis or annually. The NCAH/NADC response indicated that these operational design components would not be calibrated on an annual basis. Refer to the November 20, 2014 FSAP Policy Statement, *BSL-3/ABSL-3 Verification* for more information.

APHIS/CDC Form 3, Report of Theft, Loss, or Release of Select Agents and Toxins:

TLR-F3-000683 and TLR-F3-000690 **4/16/2020 and 5/3/2020**

(b)(3):42 U.S.C. § 262a(h)(1)(D); (b)(3):42 U.S.C. § 262a(h)(1)(C)

TLR-F3-000421 **6/5/2019**

(b)(3):42 U.S.C. § 262a(h)(1)(D)

Collectively, the deficiencies identified in repeated Form 3 reports and observed during the June 2019 (b)(3):42 verification inspection represent a failure of (b)(3):42 U.S.C. § 262a(h)(1)(E) s working as originally designed to maintain containment of select agent effluent waste materials. The continued, compounding failures within the (b)(3):42 U.S.C. § 262a(represent risk to the safety of agriculture and public health.

In lieu of taking steps to immediately suspend or revoke the (b)(3):42 U.S.C. § 262a(h)(1)(E) **certificate of registration** for the possession, use, or transfer of select agents, FSAP will allow the entity to participate in a Corrective Action Plan (CAP) program under the conditions listed below.

1. Within 10 business days of the date of this letter (July 23, 2020), (b)(3):42 must notify FSAP of its intention to participate in the CAP program and its agreement to meet the terms specified in sub-paragraph (2) below.
2. (b)(3):42 must notify FSAP immediately of any situation that impacts (b)(3):42 U.S.C. § ability to adhere to the above CAP or otherwise comply with the select agent regulations.

Should (b)(3):42 **decline to participate in the CAP program, all departures noted for Inspection** (b)(3):42 U.S.C. § 262a(h)(1)(E) **must be resolved**, and documentation of the resolution submitted, by **August 06, 2020**, stipulated in the eFSAP Inspection Module.

FSAP retains the authority to conduct announced or unannounced inspections at any time to ensure compliance with the select agent regulations (See Section 18). Resolution of all departures from the select agent regulations will be confirmed by onsite verification inspections by FSAP.

Contact (b)(6) with questions regarding this correspondence.

Sincerely,

Samuel S. Edwin

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

Jacek Taniewski, DVM
Director
Agriculture Select Agent Services
United States Department of Agriculture
Animal and Plant Health Inspection Service

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

United States Department of Agriculture
Animal and Plant Health Inspection Service (APHIS)
Agricultural Select Agent Program (AgSAS)
Riverdale, Maryland

July 18, 2019

(b)(3):42 U.S.C. § 262a(h)(1)(E) (Responsible Official)
U.S. Army Medical Research Institute of Infectious Disease (Registration (b)(3):42 U.S.C. § 262a(h)(1)(E)
1425 Porter Street
Fort Detrick, MD 21702
(b)(3):42 U.S.C. § 262a(h)(1)(E)

Subject: **Suspension of Registration**, **U.S. Army Medical Research Institute of Infectious Diseases (USAMRIID)**

Dear (b)(3):42 U.S.C. § 262a(h)(1)(E)

In accordance with Section 8 of the Select Agent Regulations, this letter serves as formal notice that he Federal Select Agent Program (FSAP) is suspending the U.S. Army Medical Research Institute of Infectious Diseases (USAMRIID) certificate of registration (Registration (b)(3):42 U.S.C. § for the possession, use and transfer select agents and toxins. FSAP implemented this suspension because USAMRIID does not currently meet the requirements of 42 CFR part 73, 9 CFR part 121, and 7 CFR 331. The suspension is effective July 12, 2019.

All activities with select agents and toxins must cease immediately at USAMRIID. All select agents and toxins in USAMRIID's possession must be securely stored to prevent theft, loss, or release. FSAP will consider granting specific limited exclusions from the suspension action for ongoing studies that prevent the immediate stoppage of select agent and toxin work. To be considered, USAMRIID must provide a list of ongoing studies, the expected duration of these studies, number of staff involved, and a summary of the means to ensure adequate internal oversight through the conclusion of these studies.

This suspension of registration is based on the continued failure of USAMRIID to meet the requirements of Section 12 (Biosafety) in that USAMRIID is not implementing the USAMRIID biosafety plan in a manner that safeguards select agents against release. This failure to implement biosafety practices resulted in an increased risk of exposure to USAMRIID personnel and the preventable releases of select agents and toxins from primary containment. Specifically:

Section 12 (Biosafety)

Recent FSAP inspections of USAMRIID in March 2019 and June 2019 revealed:

(b)(3):42 U.S.C. § 262a(h)(1)(D)

FSAP also noted significant departures from the regulatory requirements in the areas of training, security, and Responsible Official oversight. Specifically:

Section 15: Training

(b)(3):42 U.S.C. § 262a(h)(1)(C)

Section 11: Security

(b)(3):42 U.S.C. § 262a(h)(1)(C)

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 Federal Select Agent Program within 30 calendar days of receipt of this letter (Section 20). During the appeal, USAMRIID must halt all activities with select agents and toxins, and securely store all select agents and toxins in its possession to prevent theft, loss, or release.

FSAP will provide a detailed inspection report by July 23, 2019. The report will include the corrective actions that USAMRIID must implement for FSAP to consider restoration of the entity's registration. Additionally, USAMRIID must:

1. Adequately addresses all departures from the March 2019 inspection.
2. Provide the measures implemented to ensure the biosafety practices are sufficient to contain select agents and toxins given the work described on USAMRIID's APHIS/CDC Form 1.
3. Provide the measures implemented by the Responsible Official to ensure compliance with the requirements of the select agent and toxin regulations.
4. Demonstrate staff have been trained on the USAMRIID biosafety plan, and provide the means used to ensure staff understand the training.

Contact (b)(6), CDC Division of Select Agents and Toxins, at (b)(6) (b)(6) with any questions regarding this correspondence.

Sincerely,

Samuel S. Edwin

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

Jacek (Jack) Taniewski, DVM
National Director,
Agriculture Select Agent Services
Animal and Plant Health Inspection Service
United States Department of Agriculture

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
Agriculture Select Agent Services
Riverdale, MD

March 27, 2020

(b)(3):42 U.S.C. § 262a(h)(1)(E) PhD, RBP (Responsible Official)
U.S. Army Medical Research Institute of Infectious Disease (Registration # (b)(3):42 U.S.C. §)
1425 Porter Street
Fort Detrick, MD 21702

(b)(3):42 U.S.C. § 262a(h)(1)(E)

Subject: **Request to Begin third Cohort of Studies**, U.S. Army Medical Research Institute of Infectious Diseases (USAMRIID)

Dear (b)(3):42 U.S.C. § 262a(h)(1)(E)

The Federal Select Agent Program (FSAP) has reviewed the March 9, 2020 request to resume all work associated with storing biological select agents and toxins (BSAT), (b)(3):42 U.S.C. § 262a(h)(1)(E)

(b)(3):42 U.S.C. § 262a(h)(1)(E)

After reviewing information pertaining to your request and conducting on-site inspections at USAMRIID, **FSAP conditionally approves your request to resume full activities under your registration.**

Prior to resuming full activities and every two weeks following, USAMRIID must provide FSAP with written documentation to confirm:

- Each approved individual has completed the revised training curriculum relevant to their work duties prior to accessing BSAT.
- All training records are maintained as required under Section 15.
- All records required to be maintained under Section 17(a)(6) are complete.
- The HVAC system associated with each registered laboratory has been verified and documented to be operating as designed prior to resuming work with BSAT. For more guidance, see the FSAP Policy Statement, BSL-3/ABSL-3 HVAC Verification: https://www.selectagents.gov/regBSL3ABSL3policy.html.
- The effluent decontamination system is operating as designed.
- No mechanical failures in the registered space.

FSAP reserves the right to revoke this conditional approval, or suspend any activities with BSAT at USAMRIID, if actions at your entity are deemed insufficient to ensure the safe containment and security of the select agents in your possession. FSAP will continue to monitor USAMRIID's compliance with the federal select agent regulations in the future via remote and on-site inspections.

Contact (b)(6) CDC Division of Select Agents and Toxins, at (b)(6) with any questions regarding this correspondence.

Sincerely,

Samuel S. Edwin

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

Jacek Taniewski, DVM
Director
Agriculture Select Agent Services
United States Department of Agriculture
Animal and Plant Health Inspection Service

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
Agriculture Select Agent Services
Riverdale, MD

July 10, 2019

TO: (b)(3):42 U.S.C. § 262a(h)(1)(E) Responsible Official
(b)(3):42 U.S.C. § 262a(h)(1)(E)

cc: (b)(3):42 U.S.C. § 262a(h)(1)(E)

FROM: Centers for Disease Control and Prevention (CDC), Division of Select Agents and Toxins (DSAT)

Re: **Opportunity to show cause why the select agent and toxin registration** of (b)(3):42 U.S.C. § 262a(h)(1)(E) (Registration (b)(3):42 U.S.C. § 262a(h)(1)(E) **should not be suspended or revoked**

Dear (b)(3):42 U.S.C. § 262a(h)(1)(E)

Per Section 8 of the select agents and toxins regulations [42 CFR Part 73 (HHS)], an entity's registration may be suspended or revoked for failure to meet the requirements of the select agents and toxins regulations. (b)(3):42 U.S.C. § 262a(h)(1)(E) is being provided the opportunity to show cause why its registration for the possession, use, or transfer of select agents and toxins should not be suspended or revoked for failure to meet the requirements of the select agents and toxins regulations.

Specifically, during a May 21-23, 2019, inspection, representatives from the Federal Select Agent Program (FSAP) identified the following serious departures from the select agents and toxins regulations (the UID numbers refer to the specific observation in the eFSAP Inspection Module):

42 CFR § 73.9(a)(4): Responsible Official **UID: 42-09-00400**

(b)(3):42 U.S.C. § 262a(h)(1)(E) The Responsible Official failed to ensure compliance with the select agents and toxins regulations as evidenced by the following observations:

1. (b)(3):42 U.S.C. § 262a(h)(1)(E) failed to implement the (b)(3): 42 U.S.C. § 262a(h)(1)(E) security plan (see UID 42-11-00100).
2. (b)(3):42 U.S.C. § 262a(h)(1)(E) failed to provide adequate training to FSAP access-approved staff on the biosafety plan and the (b)(3): 42 U.S.C. § 262a(h)(1)(E) security plan (see UID 42-15-00400).
3. (b)(3):42 U.S.C. § 262a(h)(1)(E) failed to correct deficiencies identified during the 2017 and 2018 RO annual inspections (see UID 42-09-00600).
4. (b)(3):42 U.S.C. § 262a(h)(1)(E) failed to report the release of a Tier 1 select agent outside of the primary barriers of the biocontainment area. (see UID 42-19-00400).
5. (b)(3):42 U.S.C. § 262a(h)(1)(D) (b)(3):42 U.S.C. § 262a(h)(1)(D) (see UID 42-17-00200)

42 CFR § 73.9(a)(6): Responsible Official **UID: 42-09-00600**

The Responsible Official's annual inspections of each registered space where select agents or toxins are stored or used from November and December 2018 noted the following items as deficient:

1. (b)(3):42 U.S.C. § 262a(h)(1)(E) did not perform routine laboratory housekeeping tasks (also noted in the 2017 annual internal inspection), as required by (b)(3):42 U.S.C. § 262a(h)(1)(E) biosafety plan.

2. Disinfectant was expired or missing (also noted in the 2017 RO annual internal inspection).
3. Short-term inventory records were not updated as required by (b)(3):42 security plan.
4. Bags of waste were full and not autoclaved and/or not double bagged., and
5. (b)(3):42 U.S.C. § 262a(h)(1)(C)
6. The 2017 RO internal inspection of registered room noted that a dissection board used with select agent infected animals was stored in a drawer with needles held in it. There was no documented corrective action implemented for this item, which poses a needle stick/potential exposure hazard.

(b)(3):42 U.S.C. § 262a(h)(1)(E)

(b)(3):42 U.S.C. § 262a(h)(1)(E)

A follow up by the RO in February 2019 noted that several of these items had still not been corrected. Additionally, four months later FSAP inspectors noted these deficiencies during the May 2019 inspection of the registered laboratories.

Collectively, these observations represent a failure of to correct deficiencies, some identified by RO over 2 years ago.

(b)(3):42 U.S.C. § 262a(h)(1)(E)

42 CFR § 73.11(a): Security **UID: 42-11-00100**

(b)(3):42 U.S.C. § 262a(h)(1) failed to implement the following parts of the (b)(3): 42 security plan:

1. Attachment 3.000 K1, section 6.9.3 describes the record keeping procedures that each Principle Investigator (PI) must follow when working with materials that have been "checked out" from long-term storage. However, a review of the short-term inventory logs for PI (b)(3):42 showed that record keeping requirements described in the (b)(3): security plan were not followed. (b)(3): security plan procedures that were not followed include documenting of the unique identifier of the material that corresponds with the research notes, date materials were created, and date materials were used, disposed, or transferred.
2. Section 10.5 described the ability to administratively revoke access at any time in response to safety, security, or compliance concerns. (b)(3):42 U.S.C. § 262a(h)(1)(C); (b)(7)(C)
3. Attachment 3.000 E1, section 6.9 states that all visitors are individuals without a containment suite access card and are required to complete visitor training. However, in 2017 and 2018 there were 216 instances of FSAP access-approved individuals who did not possess a containment suite access card entering registered space under escort without any evidence of visitor training.

42 CFR § 73.11(c)(7): Security **UID: 42-11-01000**

Section 19 of the security plan requires all individuals with access approval understand and comply with the security procedures, but this provision is insufficient. Entity staff failed to follow the procedures and provisions in the security plan that describe short term inventory record keeping requirements (b)(3):42 U.S.C. § 262a(h)(1)(D) visitor training requirements, administrative revocation of access, and ongoing suitability assessments.

42 CFR § 73.15(c): Training **UID: 42-15-00400**

(b)(3):42 U.S.C. § instructs FSAP access approved personnel to review plans and take a quiz for refresher training. This training is ineffective as evidenced by:

1. Failure of personnel to follow the procedures and provisions described in the (b)(3):42 U.S.C. § security plan and biosafety plan (see UIDs 42-11-00100, 42-11-00200, and 42-12-38200).

(b)(3):42 U.S.C. §

(b)(3):42 U.S.C. §

2. Interviews with FSAP access approved personnel revealed that some had no knowledge of the (b)(3): suitability program and did not perform suitability assessments as required by the security plan. One staff member stated that it was not the individual's responsibility to know the federal regulations, only perform the work.

42 CFR § 73.12(b): Biosafety **UID: 42-12-44800**

Multiple laboratory groups at (b)(3): infect animals with select agents using an aerosol exposure system that is contained in a Class III biosafety cabinet (BSC). After the exposure procedures are completed, the interior of the Class III BSC is decontaminated using vaporized hydrogen peroxide, and the aerosol system tubing is flushed with water. These methods would not adequately decontaminate the tubing and internal parts of the aerosol generating equipment. Since 2016, (b)(3):42 U.S.C. § 262a(h)(1)(E)

(b)(3):42 U.S.C. § 262a(h)(1)(E)

(b)(3):42 U.S.C. § 262a(h)(1)(E)

Failure to decontaminate this equipment adequately between agents increases the risk of cross-contamination, potentially exposing animals to unintended select agents. Animals unknowingly infected with multiple select agents may present additional safety concerns for entity staff. Additionally, failure to decontaminate the aerosol equipment adequately presents a risk of exposure for persons performing maintenance tasks. [BMBL: (BSL-3) B7]

42 CFR § 73.19(a): Notification of Theft, Loss, or Release **UID: 42-19-00200**

(b)(3):42 U.S.C. § 262a(h)(1)(D)

42 CFR § 73.19(b): Notification of Theft, Loss, or Release **UID: 42-19-00400**

(b)(3):42 U.S.C. § 262a(h)(1)(D)

In lieu of taking steps to immediately suspend or revoke the (b)(3):4 certificate of registration for the possession, use, or transfer of select agents and toxins, FSAP will allow (b)(3): 42 U.S.C to participate in a Corrective Action Plan (CAP) program under the conditions listed below.

1. Within 14 business days of the date of this letter, July 30, 2019, (b)(3): must notify FSAP of its intention to participate in the CAP program and its agreement to meet the terms specified in sub-paragraphs (2) and (3) below.

2. (b)(3): must submit responses to all inspection observations and provide routine updates, as necessary, through the eFSAP Inspection Module. All departures must be resolved according to the due date listed in the eFSAP Inspection Module.

3. (b)(3):4 must notify FSAP immediately of any situation that impacts (b)(3): 42 U.S.C. ability to adhere to the above conditions.

(b)(3):42 U.S.C. § 262a(h)(1)(E)

Should decline to participate in the CAP program, all departures noted for Inspection 7113 must be resolved, and documentation of the resolution submitted, by the due date, August 21, 2019, stipulated in the eFSAP Inspection Module.

We note that the FSAP retains the authority to conduct announced or unannounced inspections at any time to ensure compliance with the select agents and toxins regulations (See Section 18). Resolution of all departures from the select agents and toxins regulations will be verified by onsite inspections by FSAP.

Contact (b)(6) with questions regarding this correspondence.

Sincerely,

Samuel S. Edwin

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

Jack Taniewski, DVM
Director
Agriculture Select Agent Services
Animal and Plant Health Inspection Service
Department of Agriculture

Department of Health and Human Services
Centers for Disease Control and Prevention
Division of Select Agents and Toxins
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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):42 U.S.C. § 262a(h)(1)(E) Responsible Official
(b)(3):42 U.S.C. § 262a(h)(1)(E) Registration # (b)(3):42 U.S.C. § 262a(h)(1)(E)
(b)(3):42 U.S.C. § 262a(h)(1)(E)

Subject: **Suspension of Registration**, (b)(3):42 U.S.C. § 262a(h)(1)(E)

Dear (b)(3):42 U.S.C. § 262a(h)(1)(E)

This letter serves as formal notice that the certificate of registration (Registration (b)(3):42 U.S.C. § 262a(h)(1)(E)) for the (b)(3):42 U.S.C. § 262a(h)(1)(E) 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):42 U.S.C. § 262a(h)(1)(E) **on February 1, 2021.** The report includes the corrective actions that (b)(3):42 U.S.C. § 262a(h)(1)(E) (b)(3):42 U.S.C. § 262a(h)(1)(E) 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):42 U.S.C. § 262a(h)(1)(E) (b)(3):42 U.S.C. § 262a(h)(1)(E) 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 (b)(6), or DASAT@usda.gov with any questions regarding this correspondence.

Sincerely,

Samuel S. Edwin

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
Animal and Plant Health Inspection Service
United States Department of Agriculture

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
Agriculture Select Agent Services
Riverdale, MD

July 23, 2020

TO: (b)(3):42 U.S.C. § 262a(h)(1)(E) Responsible Official
(b)(3):42 U.S.C. § 262a(h)(1)(E)

CC: (b)(3):42 U.S.C. § 262a(h)(1)(E)

FROM: Federal Select Agent Program (FSAP)

RE: **Opportunity to show cause why the select agent and toxin registration of** (b)(3):42 (b)(3):42 U.S.C. § 262a(h)(1)(E) (b)(3):42 **should not be suspended or revoked.**

Dear (b)(3):42 U.S.C. §

Per section 8 of the select agents and toxins regulations [42 CFR Part 73 (HHS), 9 CFR Part 121 (USDA-VS)], an entity's registration may be suspended or revoked for failure to meet the requirements of the select agents regulations (b)(3):42 U.S.C. § 262a(h)(1)(E) (b)(3):42 U.S.C. , within the (b)(3):42 U.S.C. § 262a(h)(1)(E) , is being provided the opportunity to show cause why its registration for the possession, use, or transfer of select agents and toxins should not be suspended or revoked for failure to meet the requirements of the select agents regulations.

This action is based on failures of (b)(3):42 to meet the requirements of the select agents and toxins regulations. Specifically (b)(3):42 exhibited non-compliance with Section 12 (Biosafety), demonstrated by repetitive failures of and releases from the effluent decontamination system (EDS). These failures and releases are outlined below (UIDs refer to specific observations in the eFSAP Inspection Module and TLR-F3 numbers refer to APHIS/CDC Form 3, Report of Theft, Loss, or Release of Select Agents and Toxins).

42 CFR § 73.12(b): Biosafety (b)(3):42 U.S.C. § 262a(h)(1)(E) **UID: 42-12-38300**

On June 5, 2019, Facilities and Engineering employees responded to three leak detection alarms for monitoring points located in (b)(3):42 U.S.C. § 262a(h)(1)(E) These alarms monitor the (b)(3):42 U.S.C. § 262a(h)(1)(E) that feed into the (b)(3):42 U.S.C. § 262a(h)(1)(E) These compromises in operational design were reported to the FSAP as release events (b)(3):42 U.S.C. § 262a(h)(1)(E) These operational design failures were subsequently evaluated by FSAP during the June 2019 renewal inspection and cited in the associated inspection report. (b)(3):42 U.S.C. § 262a(h)(1)(E) (b)(3):42 U.S.C. § 262a(h)(1)(E) (b)(3):42 U.S.C. § 262a(h)(1)(E) (b)(3):42 U.S.C. § 262a(h)(1)(E)

Initial responses to this UID did not adequately address FSAP's request of a timeline and schedule for double-walled drain line integrity testing, evaluation, and planned repairs. The (b)(3):42 U.S.C. § initial responses to this UID, as well as additional information provided in May 2020, indicated that:

- A contract was awarded in Fall 2019 to repair and replace existing double-walled drain lines and install redundant drain lines in all sections where the double-walled drain line design failed. However, these efforts did not begin until April 2020 and only focused on double-walled drain lines between F (b)(3):42 U.S.C. § .

(b)(3):42 U.S.C. § 262a(h)(1)(E) Facilities and Engineering staff were investigating methods to seal the (b)(3):42 U.S.C. § 262a(h)(1)(E) vaults to ensure integrity. However, these efforts have not been further addressed and no results have been provided to FSAP.

- Evaluation of the root cause(s) for the failures of double-walled drain line integrity would be conducted at the time of repairs. However, repair efforts did not begin until April 2020 and no further updates have been provided to FSAP regarding the cause for failures in operational design.

9 CFR § 121.12(b): Biosafety **UID: 9-12-32300**

(b)(3):42 U.S.C. § 262a(h)(1)(C)

APHIS/CDC Form 3, Report of Theft, Loss, or Release of Select Agents and Toxins:

TLR-F3-000684 and TLR-F3-000691 **4/16/2020 and 5/3/2020**

(b)(3):42 U.S.C. § 262a(h)(1)(D); (b)(3):42 U.S.C. § 262a(h)(1)(C)

TLR-F3-000474 **6/5/2019**

(b)(3):42 U.S.C. § 262a(h)(1)(D)

(b)(3):42 U.S.C. § 262a(h)(1)(A) Collectively, the deficiencies identified in repeated reports and observed during the June 2019 renewal inspection represent a failure of to ensure that the s working as originally (b)(3):42 U.S.C. § 262a(h)(1)(C) The continued, compounding failures within the (b)(3):42 U.S.C. § 262a(h)(1)(C) (b)(3):42 U.S.C. § 262a(h)(1)(E) (b)(3):42 U.S.C. § 262a(h)(1)(E) (b)(3):42 U.S.C. § 262a(h)(1)(E)

In lieu of taking steps to immediately suspend or revoke the (b)(3):42 U.S.C. § 262a(h)(1)(E) **certificate of registration** for the possession, use, or transfer of select agents, FSAP will allow the entity to participate in a Corrective Action Plan (CAP) program under the conditions listed below.

1. Within 10 business days of the date of this letter (July 23, 2020), (b)(3):42 U.S.C. § 262a(h)(1)(E) must notify FSAP of its intention to participate in the CAP program and its agreement to meet the terms specified in sub-paragraph (2) below.

2. (b)(3):42 U.S.C. § 262a(h)(1)(E) must notify FSAP immediately of any situation that impacts (b)(3):42 U.S.C. § 262a(h)(1)(E) ability to adhere to the above CAP or otherwise comply with the select agent regulations.

Should (b)(3):42 U.S.C. § 262a(h)(1)(E) **decline to participate in the CAP program, all departures noted for Inspection 7075 must be resolved**, and documentation of the resolution submitted, by **August 06, 2020**, stipulated in the eFSAP Inspection Module.

FSAP retains the authority to conduct announced or unannounced inspections at any time to ensure compliance with the select agent regulations (See Section 18). Resolution of all departures from the select agent regulations will be confirmed by onsite verification inspections by FSAP.

Contact (b)(6) with questions regarding this correspondence.

Sincerely,

Samuel S. Edwin

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

Jacek Taniewski, DVM
Director
Agriculture Select Agent Services
United States Department of Agriculture
Animal and Plant Health Inspection Service

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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

July 23, 2021

(b)(3):42 U.S.C. § 262a(h)(1)(E) Responsible Official
(b)(3):42 U.S.C. § 262a(h)(1)(E)
(Registration (b)(3):42 U.S.C. § 262a(h)(1)(E)

Subject: **Status of Registration** (b)(3):42 U.S.C. § 262a(h)(1)(E)

Dear (b)(3):42 U.S.C. § 262a(h)(1)(E)

Thank you for your responses on April 23, May 28, and July 9, 2021 to the suspension of registration (Registration (b)(3):42 U.S.C. § 262a(h)(1)(E)

Based upon these responses, the Federal Select Agent Program (FSAP) agrees that (b)(3):42 has addressed the observations of noncompliance and compliance concerns initially noted in the March 11, 2021 suspension letter. As a result, **the FSAP hereby reinstates the registration for** (b)(3):42 is permitted to possess, use and transfer select agents and toxins in accordance with the entity's approved FSAP registration.

Please be reminded that in accordance with 9 CFR 121.18, 42 CFR. 73.18, and 7 CFR. 331.18, the FSAP may at any time conduct an inspection to ensure compliance with the select agent and toxin regulations.

(b)(3):42 U.S.C. § 262a(h)(1)(E) registration is valid only for the select agents and toxins listed, the specified activities at the locations described in your application, and for the conditions that were approved under 9 CFR. Part 121, 42 C.F.R. Part 73, and 7 C.F.R. Part 331, to possess, use, or transfer select agents or toxins.

Contact (b)(6) 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
United States Department of Agriculture

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

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

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Animal and Plant Health Inspection Service
Division of Agricultural Select Agent and Toxins
Riverdale, MD

March 11, 2021

(b)(3):42 U.S.C. § 262a(h)(1)(E) Responsible Official
(Registration # (b)(3):42 U.S.C. § 262a(h)(1)(E)
(b)(3):42 U.S.C. § 262a(h)(1)(E)

FROM: Federal Select Agent Program (FSAP)

Re: **Suspension of Registration**, (b)(3):42 U.S.C. § 262a(h)(1)(E)

Dear (b)(3):42 U.S.C. § 262a(h)(1)(E)

This letter serves as formal notice that the certificate of registration (Registration # (b)(3):42 U.S.C. §) for (b)(3):42 U.S.C. § to possess, use, and transfer select agents and toxins is **suspended**, effective **March 11, 2021.**

(b)(3):42 U.S.C. § 262a(h)(1)(E)

All activities with select agents and toxins must cease immediately at (b)(3):42 U.S.C. § 262a(h)(1)(E) ~~All select agents and toxins in~~ 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 of certificate of registration is based on (b)(3):42 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, (b)(3):42 U.S.C. § 262a(h)(1)(D) 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 were not accurate to the final disposition of vials, nor the quantity of vials stored and/or transferred between inventories.

(b)(3):42 U.S.C. § 262a(h)(1)(E)

As described in more detail below, the (b)(3):42 U.S.C. § 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

(b)(3):42 U.S.C. § 262a(h)(1)(E)

(b)(3):42 U.S.C. § 262a(h)(1)(E)

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

- **TLR-F3-000312** – (b)(3):42 U.S.C. § 262a(h)(1)(D)

(b)(3):42 U.S.C. § 262a(h)(1)(D)

- **TLR-F3-000806** – (b)(3):42 U.S.C. § 262a(h)(1)(D)

(b)(3):42 U.S.C. § 262a(h)(1)(D)

- **Inventory discrepancy report** – On November 12, 2020, (b)(3):42 reported to the DASAT Point of Contact and Compliance Officer via email of the discovery of inaccuracies in the documentation of the March 2020 transfer of (b)(3):42 between registered laboratories. The transfer involved 24 vials from two different stocks. At the time of the transfer, (b)(3) believed 16 vials were of one stock and 8 vials were of another stock. However, (b)(3):4 discovered that the correct number of vials transferred was 17 vials of one stock and 7 vials of the other stock. Because all vials were accounted for and no vials were missing or stolen, no APHIS/CDC Form 3 was submitted.

- **TLR-F3-000853** – (b)(3):42 U.S.C. § 262a(h)(1)(D)

(b)(3):42 U.S.C. § 262a(h)(1)(D)

(b)(3):42 U.S.C. § 262a(h)(1)(E)

This letter includes the immediate actions must take and the corrective actions must implement for FSAP to consider restoration of the registration. Regardless of any suspension appeal, immediate actions listed below must be followed.

(b)(3):42 U.S.C. § 262a(h)(1)(E)

(b)(3):42 U.S.C. § 262a(h)(1)(E)

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

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

(b)(3):42 U.S.C. § 262a(h)(1)(E)

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 [redacted] are securely stored **by March 18, 2021**.

FSAP will consider restoration of [redacted] certificate of registration when [redacted] 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 [redacted] 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 [redacted] certificate of registration.

Pursuant to section 20 of the select agent and toxin regulations (9 CFR 121.20; 42 CFR 73.20), [redacted] may appeal the suspension of a certificate of registration. The appeal must be in writing and state the factual basis for the appeal. [redacted] 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 [redacted] possession must be securely stored to prevent theft, loss, or release.

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

Contact [redacted] 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
United States Department of Agriculture

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

Department of Health and Human Services
Centers for Disease Control and Prevention
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U.S. Department of Agriculture
Animal and Plant Health Inspection Service
Division of Agricultural Select Agent and Toxins
Riverdale, MD

August 27, 2021

(b)(3):42 U.S.C. § 262a(h)(1)(E)
Responsible Official

(b)(3):42 U.S.C. § 262a(h)(1)(E)

RE: **Federal Select Agent Program Registration:** (b)(3):42 U.S.C. § 262a(h)(1)(E)
(Entity Registration Number: (b)(3):42 U.S.C. § 262a(h)(1)(E))

(b)(3):42 U.S.C. § 262a(h)(1)(E) request to withdraw its registration with the Federal Select Agent Program (FSAP) for the approved possession, use, and transfer of select agents and toxins became effective on August 27, 2021.

Be advised that all records created under the select agent regulations, 7 CFR Part 331, 9 CFR Part 121, and 42 CFR Part 73, **must be maintained for 3 years** from the date of their creation.

If you have questions, contact APHIS at 301-851-2070 or dasat@usda.gov.

Sincerely,

(b)(6)

Technical Unit Director
Division of Agricultural Select Agents and Toxins
Emergency and Regulatory Compliance Services
Animal and Plant Health Inspection Service
United States Department of Agriculture