



Centers for Disease Control  
and Prevention (CDC)  
Atlanta GA 30333

December 9, 2011

Mr. Tony Maida, Senior Counsel  
DHHS Headquarters OIG  
330 Independence Ave. SW Room 55227  
Washington, DC 20201-0002

Subject: Rocky Mountain Laboratories (Registration #C20090508-0835)

Dear Mr. Maida:

I am forwarding for your review documents that we believe show that [REDACTED] conducted "restricted experiments" that involve utilizing recombinant DNA to deliberately transfer a drug resistance trait to a select agent not known to acquire the trait naturally, and that such transfer could compromise the use of the drug to control disease agents in humans. See 42 C.F.R. § 73.13. Specifically, [REDACTED] introduced genetic elements encoding for tetracycline, gentamicin and chloramphenicol resistance to *Yersinia pestis* (see 42 C.F.R. § 73.13(b)(1)) without obtaining prior approval from the Centers for Disease Control and Prevention (CDC), Division of Select Agents and Toxins (DSAT) (see 42 C.F.R. § 73.13(a)).

On October 12, 2010, DSAT informed the Responsible Official (RO) for Rocky Mountain Laboratories that [REDACTED] work involving the introduction of genes conferring kanamycin resistance to *Yersinia pestis* was approved as long as the work did not confer resistance to gentamicin (see attachment #6, "Request for Review of Experiments" letter dated October 12, 2010).

While preparing for an inspection of the Rocky Mountain Laboratories in late October 2011, Dr. Benjamin Hasselbring, DSAT Lead Inspector who conducted the inspection of this entity, identified the attached two publications that indicated that [REDACTED] may have conducted restricted experiments (see attachments #1 and #2). After the November 15 through November 17, 2011 inspection, a report from the Rocky Mountain Laboratories RO verified that [REDACTED] had been in possession of antibiotic resistant strains for which he did not have DSAT authorization or the entity's approval to conduct this work (see attachment #8). The Rocky Mountain Laboratories RO confirmed that she, during a September 22, 2011 internal inspection, identified in [REDACTED] long-term inventory the presence of *Y. pestis* strains containing elements encoding for chloramphenicol and tetracycline resistance, which were engineered under the direction of [REDACTED]. The Rocky Mountain Laboratories RO informed [REDACTED] on September 27, 2011 that he needed to destroy any strains containing genes that resulted in resistance to tetracycline or chloramphenicol. The Rocky Mountain Laboratories RO informed DSAT that the relevant strains were destroyed on October 3, 2011. It should be noted that DSAT inspectors discovered an additional restricted strain (the chloramphenicol resistant *Y. pestis*) of which the Rocky Mountain Laboratories RO was unaware (see attachment #9, observation #8). According to the Rocky Mountain Laboratories RO, the restricted strain was not identified during the Rocky Mountain Laboratories RO's September 2011 inventory inspection due to the omission of the relevant strain information in [REDACTED] inventory log. The Rocky Mountain Laboratories RO confirmed that this strain was destroyed on November 22, 2011. With regard to the DSAT inspectors' identification of the construction of gentamicin-resistant intermediate strains, the Rocky Mountain Laboratories RO informed DSAT that [REDACTED] confirmed that these were intermediate strains in the

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mutant construction process which had not been saved. DSAT plans to resolve this notification of apparent violation with the entity and the Rocky Mountain Laboratories RO through other means than a referral to HHS OIG.

██████████ failed to comply with the provisions set forth in 42 C.F.R. § 73.16. Specifically, DSAT received the attached report (refer to Attachment #7) from the Rocky Mountain Laboratories RO in which she describes an unauthorized transfer whereby ██████████ received on May 16, 2007 an international shipment of *Y. pestis* from ██████████ of the Pasteur Institute in Paris, France without obtaining prior approval from DSAT to receive the material. The attachment includes documentation that Dr. ██████████ imported the material for his inventory. It should be noted that during the period of 2006 and 2007, ██████████ conducted 5 transfers of select agents (see attachments #3 and #4 for the transfer history for the entity) and used the APHIS/CDC Form 2 that contain guidance on how to import a select agent or toxins (see attachment #5 for the APHIS/CDC Form 2; expiration date 12/31/08).

██████████ is a Principal Investigator for Rocky Mountain Laboratories, 903 South 4<sup>th</sup> Street Hamilton, MT 59840. Their Responsible Official is ██████████ and she may be contacted at ██████████

To assist with understanding any technical information regarding this referral, DSAT has identified the following individuals: Dr. Denise Gangadharan, DSAT Acting Associate Director for Science and Dr. Benjamin Hasselbring, the Lead Inspector who conducted the inspection of this entity. Lori Bane, DSAT Associate Director for Policy, will assist with any coordination of schedules.

This information is sensitive, has been marked "Sensitive But Unclassified (SBU)" and should be handled accordingly. The attached material is the property of the Division of Select Agents and Toxins, Centers for Disease Control and Prevention. Its transfer to another agency is not authorized without the express prior approval of the Division of Select Agents and Toxins and release of this material is subject to the provisions of section 351A(h) of the Public Health Security and Bioterrorism Preparedness and Response Act of 2002 (42 U.S.C. 262a(h)). While this material is retained by your agency, it should be safeguarded in a manner that will prohibit its unauthorized disclosure. Review of this material should be limited to those persons whose official duties require it.

Please contact ██████████ if you have additional questions regarding this correspondence.

Robbin Weyant, PhD, RBP (ABSA)  
Captain, USPHS (Ret.)  
Director, Division of Select Agents and Toxins  
Office of Public Health Preparedness and Response

Enclosure

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- Attachment 1: [REDACTED]  
Role of the Yersinia pestis Ail Protein in Preventing a Protective Polymorphonuclear Leukocyte Response during Bubonic Plague. Infect and Immun. 79(12):4984
- Attachment 2: [REDACTED] Differential  
Control of Yersinia pestis Biofilm Formation In Vitro and in the Flea Vector by Two c-di-GMP Diguanylate Cyclases. PLoS ONE 6(4): e19267.
- Attachment 3: APHIS/CDC Form 2 Transfer History of Rocky Mountain Laboratories as Transferor
- Attachment 4: APHIS/CDC Form 2 Transfer History of Rocky Mountain Laboratories as Requestor
- Attachment 5: APHIS/CDC Form 2 (Request to Transfer Select Agents and Toxins) expiration date 12/31/08.

Attachment 6 - 8 is a communication summary between Division of Select Agents and Toxins (DSAT) and Rocky Mountain Laboratories (RML):

- Attachment 6: On 10/12/10, DSAT sent RML the "Request for Review of Experiments" letter.
- Attachment 7: On 11/6/11, RML informed DSAT of the unauthorized transfer that was conducted on 5/16/07.
- Attachment 8: On 11/23/11, RML informed DSAT of the restricted experiments and provided DSAT with 2 emails from [REDACTED] to the Responsible Official regarding the incidents (email dated 11/16/11 and 11/17/11).
- Attachment 9: On 11/23/11, DSAT sent RML facility inspection report.