

## **Investigation Procedures Following a Report of Potential Lack of Efficacy Report for a Rabies Vaccine**

Due to human health concerns, any notification of a potential lack of efficacy of a USDA licensed rabies vaccine is classified as an urgent report and will be investigated by the Center for Veterinary Biologics-Inspection and Compliance (CVB-IC).

1. When a potential lack of efficacy notification is received, the person receiving the report should complete an Adverse Event Report form. If there is possible human exposure, the person taking the call should get as much information concerning the exposure as possible.
2. The CVB-IC Compliance Section Leader, Investigation Manager, or other member (or acting member) of the Inspection and Compliance Management Team (ICMT) should be informed within 2 hours of the report.
3. An investigation will be opened following procedures described in **ICSOP0016**, *Investigation and Processing of Alleged Violations of the Virus-Serum-Toxin Act*.
4. The CVB-IC Compliance Section Leader, Investigation Manager, or their designated Acting, will notify by email the following people:

Operational Director, CVB  
Director, Inspection and Compliance  
Director, Policy, Evaluation, and Licensing (PEL)  
Section Leader, Virology  
Supervisory Microbiologist, Virology  
Section Leader, Compliance  
Investigation Manager

CDC Contacts: Currently (Human Exposure cases only)

Dr. Tom Gomez - [REDACTED] (Veterinary Services liaison stationed at CDC)

Dr. Emily Pieracci: [REDACTED]

Jesse Blanton: [REDACTED]

Ryan Wallace: [REDACTED]

5. The notification should detail:

Veterinary Biologics Investigation (VBI) number

Product involved: True Name, Code, Serial No.

Manufacturing establishment

Alleged violation: 9 CFR 113.209 – Potential lack of efficacy with human exposure

Species and number of animals involved

Human exposure (How many? any treatment [if known])

Details at this time

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Serial status and expiration date  
Biologics Specialist assigned to VBI  
Plan of action

6. Assigned Biologics Specialist duties:
  - A. If report came from the public, contact the official liaison of the manufacturer and inform them of the situation. The firm should be contacted the same day as the report.
  - B. The following must be requested when in contact with the manufacturer:
    - a) Request verbally and in writing from the manufacturing firm a summary of all adverse events;
    - b) Request potency test bench records for the serial involved – include mouse acquisition records;
    - c) Request all production records associated with the serial;
    - d) Request all production records associated with common bulks used in the serial;
    - e) Request all adverse events with bulk lots associated with this adverse event.
  - C. Request from the Biologics Epidemiologist copies of any adverse events reports that CVB has received for the serial in question and file these in the VBI folder.
  - D. The Specialist assigned must run a serial stat from LSRTIS to determine if the serial is still within dating. If the serial is still within dating, a potency test may be requested after consultation with an IC Program Section Leader and the Section Leader, Virology. In an effort to save resources, testing should not commence until there is a laboratory confirmation of rabies. Preferably this confirmation should come from the CDC. If it is decided that the serial should be tested for potency, follow the procedures described in **CVBSOP0101**, *Tests Requested to Assist Investigations – Processes and Responsibilities*. If the serial has expired, no testing will be conducted.
  - E. Prior to testing being initiated by CVB, the Biologics Specialist will notify the manufacturer in writing to inform them that the serial will be tested and will be put at risk. To expedite this, verbal communication to the official liaison of the firm is acceptable if followed by a letter.
  - F. Place a copy of the released APHIS Form 2008 (and any CVB-PEL laboratory test reports) in the VBI folder.

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### 7. Closure

#### A. If testing was conducted:

1. And the serial was tested satisfactory, the results are provided to the firm and the VBI is closed following **ICSOP0016**, *Investigation and Processing of Alleged Violations of the Virus-Serum-Toxin Act*;
  2. And the serial was tested unsatisfactory, immediately contact an ICMT member for further guidance.
- B. For investigations in which no testing was conducted, consult with the Investigation Manager and/or Compliance Section Leader on appropriate steps.