United States Department of Agriculture
Center for Veterinary Biologics

Standard Operating Policy/Procedure

Investigation and Processing of Alleged Violations of the Virus-Serum-Toxin Act

Date: **June 27, 2011**

Number: ICSOP0016.02

Supersedes: ICSOP0016.01, August 14, 2007

Contact: Daniel C. Coyle, (515) 337-6178

Approvals:

/s/Steven A. Karli Date: 05Jul11
Steven A. Karli, Director
Inspection and Compliance
Center for Veterinary Biologics

/s/Rebecca L.W. Hyde Date: 06Jul11
Rebecca L.W. Hyde, Section Leader
Quality Management
Center for Veterinary Biologics

United States Department of Agriculture
Animal and Plant Health Inspection Service
P. O. Box 844
Ames, IA 50010

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1. Purpose and Scope

This document describes the responsibilities, duties and processes associated with a Center for Veterinary Biologics-Inspection and Compliance (CVB-IC) Veterinary Biologics Investigation (VBI). Veterinary Services Memorandum 800.1 delegates authority to the IC Director to direct investigations of the Virus-Serum-Toxin Act (VSTA) and regulations (Code of Federal Regulations, Title 9 [9 CFR], Parts 101-121).

2. Investigative Responsibilities

2.1 Center for Veterinary Biologics-Inspection and Compliance

Inspection and Compliance is responsible for investigating alleged violations of the VSTA and regulations by licensees, permittees, and foreign manufacturers involving licensed or permitted products. In addition, the IC Director may request the assistance of the Regional Director, Investigative and Enforcement Services, Animal and Plant Health Inspection Service (APHIS), in the investigation of alleged violations of the VSTA and regulations. For investigations of violations of the VSTA or regulations by unlicensed entities, IC is responsible for monitoring and coordinating these investigations with IES. Furthermore, IC will recommend to IES the action to be taken as a result of investigations conducted by IES.

2.2 The Regional Director/Investigation and Enforcement Services (RD/IES)

As requested by IC, the RD/IES where the alleged violation occurred will conduct investigations of unlicensed manufacturers. Inspection and Compliance will provide technical and investigative support to IES as appropriate. In addition, IC may request through the RD/IES assistance for investigations involving a licensed product that has been illegally handled by an unlicensed person. All IES cases will be presented to the IC Director for review prior to any IES action be taken.

2.3 Center for Veterinary Biologics-Policy, Evaluation, and Licensing

CVB-Policy, Evaluation, and Licensing (PEL) may assist IC and IES in investigations.

3. Violations

Investigation of alleged violations of the VSTA involving veterinary biologics can be divided into two categories.

3.1 Violation of the VSTA by an unlicensed entity

This is the preparation, selling, bartering, exchanging or shipping of products by a person firm or corporation not federally licensed, the importing into the United States of an unlicensed product intended for the treatment of domestic animals or the adulteration of licensed product by an unlicensed person.

3.2 Violation of the VSTA or the promulgated regulations by a licensed entity

This is the act of a person, firm or corporation that violates the VSTA or the promulgated regulations in the 9 CFR, Parts 101 through 118.

The following are examples of some typical, but not all, violations which may require investigation:

- Distribution of known defective product
- Shipment of unlicensed veterinary biologics
- Importation of any biological product without a permit
- Use of an unlicensed premise for any step in production of a licensed product
- Submitting official reports to APHIS without adequate supporting documentation
- Falsification of production or test records of a licensed product (falsifying official government records)
- False or misleading advertising for a veterinary biological product
- False labeling or adulteration of labels
- Failure to immediately report concerns regarding product purity, potency, safety, or efficacy
- Rabies Vaccine efficacy concerns (rabies in vaccinated animals)

4. Procedures

When aware of a violation, IC is responsible for initiating the process, and when necessary, involving IES.

4.1 IC Director Responsibilities

The IC Director has delegated responsibilities associated with investigations of alleged violations of the VSTA to the Compliance Section Leader.

The IC Director assures that proper disposition of all investigations is accomplished.

The IC Director signs the APHIS Form 7060, Official Warning, Violation of Federal Regulations.

4.2 Compliance Section Leader Responsibilities

The Compliance Section Leader:

- Reviews all investigations when opened and when closed for completeness.
- Reviews all proposed regulatory actions to assure that actions taken are appropriate and in accord with all applicable regulations.
- Coordinates all investigations and recommends cases for prosecution.
- Acts as a liaison with the IES, the Office of General Counsel (OGC) and the Department of Justice (DOJ) on case development and litigation.
- Provides assistance and guidance to IES personnel and Biologics Specialists (Specialists) and will provide summary reports on all investigations to the IC Director as required.

4.3 Investigation Manager Responsibilities

The Investigation Manager:

- Assists the Compliance Section Leader and Specialists in investigations.
- Provides assistance and guidance to IES personnel and Specialists and will provide summary reports on all investigations to the IC Director or Compliance Section Leader as required.
- See the current version of **ICSOP0001** for delegation of authorities.

4.4 Biologics Compliance Inspector (BCI) Responsibilities

The BCI:

- Sets up the investigation case files.
- Maintains the investigation database.
- Assists in investigations as requested.

- Provides administrative reviews of investigations to ensure completeness and proper disposition.

4.5 Specialist Responsibilities

The Specialist:

- Directs the investigation, if it is IC jurisdiction or coordinates the investigation, if it is IES jurisdiction.
- Maintains a current investigation file within a chain of custody.
- Forwards information to PEL on alleged violations of advertising or labels for PEL advice and consultation.
- Reviews the evidence and reports submitted concerning the investigation.
- Consults with PEL and other Veterinary Services personnel and requests CVB testing as required.
- Disseminates information among people involved in the case in order to successfully complete the investigation.
- Prepares investigation summaries for internal and external dissemination.
- Prepares the closing memorandum and submits with recommended disposition to the IC Director after review by the Compliance Section Leader.
- Only discusses information regarding the investigation with those individuals on a need to know basis.

5. Processing an Investigation

Upon receipt of the alleged violation, the information is given to the Compliance Section Leader, or the Investigation Manager, who:

- Reviews the violation for validity.
- Assigns a unique number to the investigation.
- Assigns the VBI to a Specialist.

- A VBI folder is issued to the Specialist which includes a Summary Sheet with #1-11 filled in. See **Appendix I**.

Special Considerations

When IC receives information on a possible violation from a second party (i.e., whistle blower, competitor, etc.) the following steps are taken:

- The Compliance Section Leader or Investigation Manager is notified as soon as possible.

- An acknowledgement letter, drafted by the Specialist, is sent to the person who reported the alleged violation, expressing our concern and our intent to investigate the matter. The letter should be signed by the Compliance Section Leader or Investigation Manager.

- If the person requests anonymity, advise them that we will do our best but we can not guarantee anonymity. Plainly note in the investigation file that the person wishes to remain anonymous so that the FOIA office can make that determination, if the case is requested under the FOIA. If the case goes to court, the name can not be withheld.

- If it cannot be determined who submitted the information, and there is enough information to follow through with an investigation, the process of initiating an investigation is still performed.

6. Veterinary Biological Investigations Scope

The scope of a veterinary biological investigation is to investigate and prove or disprove a violation of the VSTA or its promulgated regulations, such as:

- Prove the product being investigated to be a veterinary biological product.

- Prove whether the product being investigated is federally licensed.

- Prove production and distribution of an unlicensed product has taken place.

- Prove importation of veterinary biological products or components thereof has taken place without prior approval and appropriate permit(s) having been issued.

- Prove that unknown master seed or seed virus has been stored or used within a federally licensed facility without prior approval or authorization to do same.
- Prove that falsification of required production or related test records associated with a licensed product has taken place in a licensed production facility

- Prove that a defective product produced by a licensed firm has been distributed to users.

7. Investigation Techniques

(b) (2)

7.1 Evidence Chain of Custody

(b) (2)

7.2 Documentary Evidence

(b) (2) [redacted]

7.3 Purpose of the Investigation

(b) (2) [redacted]

7.4 Investigative Procedures

(b) (2) [redacted]

(b) (2) [redacted]

[redacted]

[redacted]

[redacted]

[redacted]

[redacted]

[redacted]

7.5 Rules of Evidence

7.5.1 Evaluating the evidence

If the results of an investigation appear to sustain the Allegation, the evidence must be obtained and presented in a manner that will stand up under the Federal Rules of Evidence (88 Stat 1926-1949 28 USC App).

7.5.2 Relevance

The evidence must relate to the matter at issue and tend to prove the alleged violation. Irrelevant facts and those that are not essential to the issue should be omitted.

7.5.3 Hearsay

"Hearsay" is secondhand information or knowledge. Hearsay testimony is usually not allowed as evidence.

7.5.4 Original Document

(b) (2) [redacted]

7.5.5 Exclusionary Rule

In criminal proceedings, all evidence secured in violation of the U.S. Constitution is inadmissible.

7.6 Statements

(b) (2) [redacted]

Three Divisions of a Statement

1. Introduction

Be sure the following information is given:

- The name and identity of the interviewee
- The name and identity of the interviewer
- The date and place of the interview
- That the statements are voluntary.

2. The Statement Proper

Present the facts, circumstances, or events concisely in chronological order whenever possible. Preserve the actual words the interviewee uses. The words of the interviewer may be more accurate and correct, but they may not say what the interviewee wants to say. Stress interviewee's personal knowledge of material facts.

3. Conclusion

Indicate that the interviewee has a clear understanding of the contents of the statement and of the truth and correctness of what is in the statement. Ask them to sign the statement in the presence of the interviewer. Ask for initials if they are unwilling to sign their full name. If they are unwilling to sign or initial, add a paragraph to the effect that the interviewee has read the statement and is unwilling to sign. Ask for that to be initialed.

7.7 Affidavits

An affidavit is a written statement made under oath or affirmation before a person specifically authorized to take affidavits or before a notary public. Note that IES will train IC personnel to take affidavits; the IC Director will maintain a current list of all CVB personnel trained in the affidavit process.

(b) (2) [redacted]

[redacted] Warn the person making the false statements that knowingly giving false information under oath can be a commission of perjury under 19 USC 1001. See **Appendix III**.

7.8 The Interview

(b) (2)

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7.9 Miranda Rule

(b) (2)
[redacted]

(b) (2) [redacted]

8. Reporting the Investigation

(b) (2) [redacted]

8.1 Common Errors

- (b) (2) [redacted]

8.2 Analysis of the Case

(b) (2) [redacted]

- (b) (2)
- [redacted]
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(b) (2) [redacted]

9.1 Infraction Notice

This type of letter is used to notify a firm that holds a U.S. Veterinary Biologics Establishment License that we have evidence to support a violation of the VSTA or promulgated regulations. We inform the firm that subsequent violations of a similar nature could result in further actions by this Agency. See the current template in the Inspection and Compliance Manual or located on the CVB Quality Management SharePoint site and 9 CFR 105.2

9.2 Warning Letter

This type of letter is used when it has been determined that a firm may be producing and distributing a veterinary biologics without holding a U.S. Veterinary Biologics Establishment or Veterinary Product License. The letter's purpose is to warn the firm that it is unlawful under the VSTA for any firm to ship a veterinary biological product without have a U.S Veterinary Biologics Establishment or Veterinary Product License. The letter also directs the addressee on whom to contact for information regarding licensure. See the current template in the Inspection and Compliance Manual or located on the CVB Quality Management SharePoint site.

9.3 APHIS Mandated Stop Distribution and Sale

See 9 CFR 105.3 and 115.2

9.4 APHIS Form 7060, Official Warning, Violation of Federal Regulations.

(b) (2) [redacted]

9.5 Detention, Seizure and Condemnation

See 9 CFR 118

9.6 Formal Administrative Procedures without a hearing

See 9 CFR 105.1 (b), 105.3 (a)
See 9 CFR 122.4 (b)

9.7 Formal Administrative Procedures with a hearing

See 9 CFR 105.1 (a)
See 9 CFR 114.8 (f)
See 9 CFR 122.4 (a)

9.8 Prosecuting Apparent Violations

There are two avenues of prosecution for apparent violations:

- Criminal prosecution in U.S. District Courts, as recommended by OGC.
- Formal administrative hearings before USDA Administrative Law Judges. See 9 CFR Part 123.

9.9 Criminal Proceedings

(b) (2) [redacted]

9.9.1 Courtroom Testimony

(b) (2) [redacted]

- [redacted]
- [redacted]
- [redacted]

- (b) (2)

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- [redacted]
- [redacted]

[redacted]

10. Closure of VBI

Once the issue has been resolved to the satisfaction of the Agency and the case has been closed by IES (if involved in the investigation), the Specialist will prepare the draft closing memo and submit it along with the VBI folder to the Compliance Section Leader for review and approval. The Compliance Section Leader forwards the final memo to the IC Director for review.

The file is officially closed when Section 16 of the VBI Summary Sheet is signed off by the Compliance Section Leader.

11. Summary of Revisions

- The Contact information has been updated.
- **7.2:** Clarification of document identification has been added.
- **9:** The location of template letters has been updated.
- **Appendix I:** The Chronology of Events has been updated.

Investigation and Processing of Alleged Violations of the Virus-Serum-Toxin Act

Appendix I

VETERINARY BIOLOGICS INVESTIGATION SUMMARY SHEET

1. FILE NUMBER: ***VBI – NUMBER***	2. IC-SPECIALIST:
3. IES NUMBER:	4. IES INVESTIGATOR:
5. DATE OPENED:	6. OTHER REFERENCE(S): ***CONSUMER COMPLA NTS, ETC.***
7. WHO SUBMITTED THE INFORMATION: ***PERSON WHO MADE THE ALLEGED VIOLATION***	8. PERSON/FIRM INVOLVED ST. NO.) ***WHO THE ALLEGED VIO TION IS AGAINST***
9. NAME OF CONTACT, TITLE, ETC.: ***NAME OF PERSON AT THE FIRM***	10. PRODUCT( ) INVO D: (CODE) ***PRODUC NAME OR*** ***PRODUC CODE, IF LICENSED***
11. DESCRIPTION OF ALLEGED VIOLATION: ***SHORT DESCRIPTION O THE VIOLAT N***	
12. VSTA OR 9 CFR REFERENCE(S): ***VSTA OR CFR SECTIONS***	13. DAT LOSED BY IN IGATOR:
14. DISPOSITION: ***SHORT DESCRIPTION OF W THE CASE WAS CLOSED***	
15. REMARKS: ***ANY OTHER PERTINENT INFORMATION*** ***e.g., Significant Items, Infraction es etc.***	16. REVIEW: SECTION LEADER, COMPLIANCE _____ _____ OPEN DATE CLOSE DATE

OPENING AN INVES GATION: --COMPLETE ITEMS 1 HROUGH 12 ABOV --GIVE TO SECTION LEADER, COMPLIANCE **WHEN NOT WORKING ON FILE** **KEE IN TIONS FILE CABINENT or MAINTAIN * LOSING AN INVESTIG TION: --COMPLETE ITEMS 13 THROUGH 15 --GIVE TO SECTION LEADER, COMPLIANCE FOR REVIEW	USE OF TABS IN THE INVESTIGATION FOLDER: TAB A – INVESTIGATION SUMMARY SHEETS TAB B – CORRESPONDENCE, PHONE LOGS, ETC. TAB C – IES INVESTIGATION REPORTS, OTHER REPORTS TAB D – TEST REQUESTS, TEST RESULTS

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CHRONOLOGY OF EVENTS

DATE (D/M/YR)	ACTION	Specialist Initials	Entry Number
DATE ACTION	***DESCRIPTION OF ACTION IN FILE***	***SPECIALIST'S***	***Number Pages entered into file***
OCCURED		***INITIALS***	

VETERINARY BIOLOGICS INVESTIGATION SUMMARY SHEE CONTIN TION

FILE NUMBER: VBI -	CVB-IC CO DINATOR:

CHRONOLOGY OF EVENTS

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Appendix II

EVIDENCE IDENTIFICATION

CASE NO._____
ITEM NO._____

NAME_____

_____

WHERE
OBTAINED_____

_____

_____

HOW
OBTAINED_____

_____

OBTAINED
BY_____

WITNESSED
BY_____

DATE
RECEIVED_____

DESCRIPTION OF
EVIDENCE_____

_____

_____

_____

_____

CUSTODIAN	DATE IN	DATE OUT	INITIAL

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Appendix III

Privacy Act Notice on Reverse

AFFIDAVIT

Before me, Gilbert R. Love , an employee of the United States Department
Agriculture designate by the Secretary of Agriculture under authority of section 1 of the Act of Congress app ed
January 31, 1925 (43 Stat. 803; 7 U.S.C. 2217), personally appeared
John M. Smith , who depos and says:

I, John M. Smith, hereby make the following free and voluntary statement to Gilbert R. L who has identif d
himself as an employee of the United States Department of Agriculture. I h en advise f my legal rights that
I may remain silent, that any statements I make can be used against me in court, that I have right to have a
lawyer present during this interview. No threats or promises have be made to m o give this st nt.

I am a Veterinary Biologics Distributor. I have been dealing in Veterinary iologics for more than 20 years. I have
a distributorship for Superb Biologics, Inc., St. Cloud, Minne ta. My addre s Rt. #1, Denton, Texas.

On September 10, 199X, I received a shipment of 500 1,000 d se tles of Marek Disease Vaccine from Superb
Biologics, Inc. of St. Cloud, Minnesota via United Airlines air freigh

I was not aware that Superb Biologics was not ensed to sell thi product me in Texas. Mr. Undholm of Superb
Biologics told me that he could provide me with th ine at regular inter als if I could sell it in my area.

I have read the above statement and it is true and corr ct.

SIGNATURE OF AFFIANT

Subscribed an before me at Rt. #1, Denton, Texas
on this 12th day eptember , 19 9X .

DESIGNATED PURSUANT TO LAW TO
ADMINISTER OATHS, AFFIDAVITS,
AND AFFIRMATIONS, AUTHORITY NO.

VS F M 3-59G
(MAY 77) Previous editions obsolete.

Investigation and Processing of Alleged Violations of the Virus-Serum-Toxin Act

Appendix IV

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FIELD INVESTIGATION REPORT BIOLOGICS PROGRAM APHIS, USDA	Name of Firm and Location of Main Premises	Dates of Field Investigation
		License Number (If Applica)
		V vestigation Number IES Cas Number (If Appl able)

Other Locations Investigated:

INVESTIGATOR(S):

PURPOSE:

ATTACHMENT(S):

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Original: V terinary Biologics nvestigation File

ignature of Investigator	Name and Title	Date Signed

APHIS:VS:CVB IC:

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FIELD INVESTIGATION REPORT (Continued) Page of XX

Firm	License Number	Investigation Dates	VBI Number	Investigator
INVESTIGATION CATEGORIES		INVESTIGATION FINDINGS		

I. BACKGROUND