

**United States Department of Agriculture  
Center for Veterinary Biologics**

**Standard Operating Policy/Procedure**

**Receiving Adverse Event Reports at the Center for Veterinary Biologics**

Date: **January 11, 2011**  
Number: ICSOP0017.04  
Supersedes: ICSOP0017.03, May 12, 2009  
Contact: Scott P. Taylor, (515) 337-6203  
Approvals:

/s/Steven A. Karli Date: 18Jan11  
Steven A. Karli, Director  
Inspection and Compliance

/s/Rebecca L.W. Hyde Date: 20Jan11  
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

**INTERNAL USE ONLY**

Mention of trademark or proprietary product does not constitute a guarantee or warranty of the product by USDA and does not imply its approval to the exclusion of other products that may be suitable.

**UNCONTROLLED COPY**

Receiving Adverse Event Reports at the Center for Veterinary Biologics

**Table of Contents**

- 1. Purpose and Scope**
- 2. Definitions**
- 3. Adverse Event Report Records**
- 4. Receipt of Report**
- 5. Procedures**
- 6. Review of AER Records**
- 7. Acknowledgement of Receipt of AERs**
- 8. Summary of Revisions**

## Receiving Adverse Event Reports at the Center for Veterinary Biologics

### 1. Purpose and Scope

This document establishes a uniform, recommended procedure for handling voluntary adverse event reports (AERs) received by the Center for Veterinary Biologics (CVB) personnel from the public associated with the use of veterinary biological products.

### 2. Definitions

**Adverse Event:** An adverse event is any observation in animals, whether or not considered to be product-related, that is unfavorable and unintended and that occurs after any use of a biological product (off-label and on-label uses). Included are events related to a suspected lack of expected efficacy. For products intended to diagnose disease, adverse events refer to anything that hinders discovery of the correct diagnosis.

**Veterinary Biological Product:** A veterinary biological product is any biological product with approved claim(s) to having a protective, therapeutic or diagnostic effect or to alter physiological functions when administered to or applied to an animal. The term applies to therapeutics, biologicals, diagnostics and modifiers of physiological function.

**Adverse Event Report:** An AER is a direct communication from an identifiable first-hand reporter that includes at least the following information: (1) an identifiable reporter; (2) an identifiable animal(s); (3) an identifiable biological product; and (4) one or more adverse events. The receipt, acknowledgement or recording of an AER does not necessarily have any implication regarding the veracity or authenticity of the AER nor does it imply any degree of causality.

### 3. Adverse Event Report Records

AER records should be reported on the CVB adverse event form and include:

- Product trade name and/or true name;
- The serial number(s) of the product(s), if available;
- Route and location of administration;
- Type of person that administered the product (i.e., veterinarian or veterinary staff or non-veterinarian);
- The date the product was administered;
- A description of the adverse event;
- Name of attending veterinarian or approved Specialist
- Attending veterinarian's or approved Specialist's level of suspicion (i.e., high, medium, low);
- The outcome of the adverse event (i.e., recovered without treatment, recovered with treatment, did not recover, died);

### Receiving Adverse Event Reports at the Center for Veterinary Biologics

- A description of the animal(s) involved including the number dead, number affected, number exposed to product, species, breed, age, sex and physiological status;
- Name and phone number of attending veterinarian;
- The identification of the person submitting the report and the submitter's phone number; and
- The date of the report.

## 4. Receipt of Report

AERs may be reported to CVB by:

- Telephone - (800) 752-6255 or through the main switchboard
- Mail - Pharmacovigilance  
United States Department of Agriculture  
Center for Veterinary Biologics  
1920 Dayton Avenue  
Ames, IA 50010
- Email - [cvb@aphis.usda.gov](mailto:cvb@aphis.usda.gov)
- Fax - (515) 337-6120
- Electronic - <https://web01.aphis.usda.gov/CVB/adverseeventreport.nsf/Adverse%20Event%20Report%20Form?OpenForm>

## 5. Procedures

### 5.1 AERs received by mail or fax:

- Date stamp and place in the "New AER" slot inside the Biologics Epidemiologist cubicle.

### 5.2 AERs received by email:

- Forward to the Biologics Epidemiologist.

### 5.3 AERs received by telephone:

- The receptionist should immediately forward the caller to the Program Coordinator (PC). A current list of PC daily/weekly assignments and respective phone extensions should be available to the receptionist.
- The PC should suggest that the caller contact the Firm's Veterinary Technical Support Group for further assistance if needed.

### Receiving Adverse Event Reports at the Center for Veterinary Biologics

- The PC should also state that the CVB is interested in collecting all pertinent information and offer to collect the adverse event information and submit an AER on the caller's behalf. In the event the caller wishes to submit an AER at a different time or in a different manner, the PC should suggest the caller report the event by:
  - using the website at <https://web01.aphis.usda.gov/CVB/adverseeventreport.nsf/AdverseEventReportForm>;
  - downloading an AER form from this website and faxing it to (515) 337-6120;
  - mailing a copy of the reporting form to the caller and having the caller return the completed form by mail or fax.
- If the PC records the AER information on paper at the time of the telephone call, the AER form should be used and the completed form placed in the "New AER" mailbox or slot in the Biologics Epidemiologist cubicle.
- Alternatively the PC may enter the AER electronically on the CVB website.
- If calls become too numerous or a particular call is perceived to be unusual, difficult, or unexpected, the call should be forwarded the Biologics Epidemiologist if available.

The PC may determine the identified product is not a biological product licensed by CVB and forward the caller to the appropriate agency.

- Pharmaceuticals: Report to FDA-CVM, 888-332-8387
- Chemicals or external use pesticides: Report to EPA, 800-858-7378,

#### 5.4 Suggested PC statements in response to AER inquiries

- The CVB encourages submission of AERs. Collecting this information supports ongoing surveillance of products we license under normal conditions of use.
- The CVB cannot determine causality from one independent report since so many known and unknown variables may be associated directly or indirectly with the event.
- The event should be reported by a first-hand reporter (case veterinarian, animal health technician, owner or owner's agent witnessing the event).

**Receiving Adverse Event Reports at the Center for Veterinary Biologics**

- The CVB does not discuss other individual events with the public. However, the CVB does evaluate the information collected to identify unexpected trends in either the number of events or seriousness of events and takes appropriate action(s) when warranted.
- The CVB does provide additional information on pharmacovigilance activities at APHIS and this may be accessed at the CVB website:  
[http://www.aphis.usda.gov/animal\\_health/vet\\_biologics/](http://www.aphis.usda.gov/animal_health/vet_biologics/)
- CVB encourages the caller to discuss the history of events for a specific product with the Firm.
- If the caller insists on receiving confidential business information from the CVB regarding AER records, suggest they contact FOIA,  
[http://www.aphis.usda.gov/footer\\_items/foia.shtml](http://www.aphis.usda.gov/footer_items/foia.shtml) or by calling (301)734-8296.
- The biological product has been licensed by CVB. This means before the license was issued, the product's manufacturer had to perform numerous procedures required by the regulations to prove the product was safe, pure, potent and efficacious. Upon meeting these requirements, a product license was issued. Furthermore, each lot or serial must be tested according to plan and satisfactory results must be reported prior to release of the lot for distribution or sale.
- Callers seeking scientific-based information about specific adverse event types (e.g., feline sarcoma) from experienced people should be advised to contact their practicing veterinarian, a veterinary teaching hospital, university faculty, a Firm's technical services group or a credible association or focus group specializing in the event type.
- Humans directly inoculated with or otherwise exposed to a biological product should be advised to contact their health care provider immediately. Additional information regarding treatment, prevention, and prognosis may be available by contacting the Firm.
- Offer the caller a copy of the Pharmacovigilance brochure (found on the CVB QM SharePoint site as Chapter 5.1.1 of the IC Manual).
  - Via email
  - Or by faxing this two-sided document,
  - Or by mailing this document

**Receiving Adverse Event Reports at the Center for Veterinary Biologics**

**6. Review of AER Records**

All AER records received are verified by a Biologics Compliance Assistant (BCA) for completeness and accuracy and then reviewed by the Biologics Epidemiologist. A record number is assigned and the appropriate product code(s) determined. The Biologics Epidemiologist then sees that the AER records are entered into the AER database. A hard copy of the report is produced and kept in the AER record files.

**7. Acknowledgement of Receipt of AERs**

In the case of AERs received electronically, an autoreply message acknowledging receipt of the AER will be generated and sent back to the submitter. AERs received by telephone and submitted by the PC or the Biologics Epidemiologist on behalf of the caller will be considered as acknowledged. For any AER received that is not confirmed, the submitter will be mailed an acknowledgement letter confirming receipt of the AER in a periodic mass mailing of such letters.

**8. Summary of Revisions**

**Version .04**

- The Contact information has been updated.
- Website addresses have been updated throughout the document.

**Version .03**

- The Contact has been changed from Timothy Frana to Scott Taylor.
- The website links throughout the document have been updated to current information.

**Version .02**

- The website addresses have been updated throughout the document.
- **7:** The information from the former Section 7 (Evaluation of AERs) is now included in the current version of ICSOP0040. This section now contains information on acknowledgement of receipt of AERs.