United States Department of Agriculture
Center for Veterinary Biologics

Standard Operating Policy/Procedure

Receiving Adverse Event Reports at the Center for Veterinary Biologics

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Approvals:

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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 Report Worksheets (found here: https://www.aphis.usda.gov/aphis/ourfocus/animalhealth/veterinary-biologics/adverse-event-reporting/ct_vb_adverse_event_forms) 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);
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- The outcome of the adverse event (i.e., recovered without treatment, recovered with treatment, did not recover, died);
- 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
- Mail - Pharmacovigilance
  Center for Veterinary Biologics
  1920 Dayton Avenue
  P.O. Box 844
  Ames, IA 50010
- Fax - (515) 337-6120

5. Procedures

5.1 Hard copy AERs received by mail or fax:

- Forward to appropriate Inspection and Compliance personnel who will enter them into the Pv-Works System.

5.2 AERs received by telephone:

- The Administrative Services Assistant should immediately forward the caller to the Inspection and Compliance Program Coordinator (PC). A current list of PC daily/weekly assignments and respective phone extensions should be available to the Administrative Services Assistant.
- The PC should suggest that the caller contact the Firm’s Veterinary Technical Support Group for further assistance, if needed.
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- 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:
  - downloading an AER worksheet from this website and faxing it to (515) 337-6120;
  - mailing a copy of the reporting worksheet to the caller and having the caller return the completed worksheet by mail or fax.

- If the PC records the AER information on paper at the time of the telephone call, the AER worksheet should be used and the completed worksheet given to the appropriate Insection and Compliance personnel.

- 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,

5.3 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).

- The CVB does not discuss other individual events with the public. However, the CVB does evaluate the information collected to identify unexpected trends.
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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: https://www.aphis.usda.gov/aphis/ourfocus/animalhealth/veterinary-biologics/adverse-event-reporting/ct_vb_adverse_event

- 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 through the website https://www.aphis.usda.gov/aphis/resources/foia/ct_foia, by calling (301) 851-4102, or by emailing foia.officer@aphis.usda.gov.

- 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.

6. Review of AER Records

All AER records received are verified by CVB Inspection and Compliance personnel for completeness and accuracy (see ICWI0117, Entering and Verifying Adverse Event Reports in PvWorks).

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.

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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 .05**

- The document has been updated to reflect current processes.
- Website addresses have been updated throughout the document.

**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.

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