

UNITED STATES DEPARTMENT OF AGRICULTURE  
ANIMAL AND PLANT HEALTH INSPECTION SERVICE  
VETERINARY SERVICES

CENTER FOR VETERINARY BIOLOGICS  
1920 DAYTON AVENUE  
AMES, IOWA 50010

## ADVERSE EVENT REPORT

See reverse side for Privacy Act notice

1. Information Reported By

- Attending Veterinarian     
  Clinical Pathology Laboratory     
  Distributer     
  Human Patient  
 Medical Physician     
  Owner/Producer/Employee     
  Other

2. First Name	3. Last Name	4. Contact Number	5. Submitter's Case Number
6. Date First Received <i>(MM/DD/YYYY)</i>	7. Report <input type="checkbox"/> Initial <input type="checkbox"/> Follow-up	8. Submitted to Manufacturer <input type="checkbox"/> Yes <input type="checkbox"/> No	9. Country of Occurrence

10. Case Type

- Animal Complaint     
  Human Exposure     
  Product Problem Only

11. Problem Type

- Adverse Reaction     
  Eco-toxicity     
  Extra Label Use     
  Human Exposure - Asymptomatic  
 Human Exposure - Symptomatic     
  Lack of Efficacy     
  Product Problem

### PRODUCT INFORMATION

Product Number	Brand Name/Trade Name	Generic Name/Active Ingredient(s)
1		
2		
3		
4		

	Product 1		Product 2		Product 3		Product 4	
<b>Manufacturer</b>								
<b>Serial/Lot Number</b>								
<b>Expiration Date</b>								
<b>Was product used as per label instructions?</b>	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Not Applicable <input type="checkbox"/> Unknown to Reporter		<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Not Applicable <input type="checkbox"/> Unknown to Reporter		<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Not Applicable <input type="checkbox"/> Unknown to Reporter		<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Not Applicable <input type="checkbox"/> Unknown to Reporter	
<b>Off-label use type</b>								
<b>Has patient received this product before</b>	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Not Applicable <input type="checkbox"/> Unknown to Reporter		<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Not Applicable <input type="checkbox"/> Unknown to Reporter		<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Not Applicable <input type="checkbox"/> Unknown to Reporter		<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Not Applicable <input type="checkbox"/> Unknown to Reporter	
<b>Has patient experienced AEs from this product before?</b>	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Not Applicable <input type="checkbox"/> Unknown to Reporter		<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Not Applicable <input type="checkbox"/> Unknown to Reporter		<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Not Applicable <input type="checkbox"/> Unknown to Reporter		<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Not Applicable <input type="checkbox"/> Unknown to Reporter	
<b>Route of Administration</b>								
<b>Site of Administration</b>								
<b>Duration of Treatment/Exposure</b>	Start Date	End Date	Start Date	End Date	Start Date	End Date	Start Date	End Date
<b>Dose Amount</b>								
<b>Who administered the product?</b>								
<b>Attending veterinarian's level of suspicion</b>								

**DETAILED DESCRIPTION OF EVENT (narrative)**

Event Category

- |   |                                     |                                       |  |
|---|-------------------------------------|---------------------------------------|--|
| <input type="checkbox"/> Anaphylaxis - Hypersensitivity | <input type="checkbox"/> Autoimmune | <input type="checkbox"/> Birth Defect | <input type="checkbox"/> Lack of Expected Efficacy |
| <input type="checkbox"/> Local                          | <input type="checkbox"/> Neoplasia  | <input type="checkbox"/> Reproductive | <input type="checkbox"/> Other                     |

What was the final outcome?

- |  |  |   |  |
|--|--|---|--|
| <input type="checkbox"/> Alive with Sequelae | <input type="checkbox"/> Death (All Causes)      | <input type="checkbox"/> Euthanasia     | <input type="checkbox"/> Natural Death |
| <input type="checkbox"/> Recovered           | <input type="checkbox"/> Remains Under Treatment | <input type="checkbox"/> Not Applicable | <input type="checkbox"/> Unknown       |

Enter case narrative (if necessary, continue on page 3):

**SUSPECTED ADVERSE EVENT DATE(S)**

- |                                     |  |  |
|-------------------------------------|--|--|
| 1. Date of Onset of AE (MM/DD/YYYY) | 2. Duration of Suspected Adverse Event | 3. Time Between Administration and Event |
|-------------------------------------|--|--|

**ANIMAL INFORMATION**

- |   |  |   |               |
|---|--|---|---------------|
| 1. Number of Animals Exposed  | 2. Number of Animals Reacted   | 3. Number of Dead Animals   |               |
| 4. Animal Condition Prior to Treatment<br><input type="checkbox"/> Critical <input type="checkbox"/> Fair <input type="checkbox"/> Good <input type="checkbox"/> Poor <input type="checkbox"/> Not Applicable <input type="checkbox"/> Unknown                      |  |   |               |
| 5. Animal Name  | 6. Gender<br><input type="checkbox"/> Female <input type="checkbox"/> Male <input type="checkbox"/> Mixed <input type="checkbox"/> Not Applicable <input type="checkbox"/> Unknown |   |               |
| 7. Species<br><input type="checkbox"/> Cat <input type="checkbox"/> Cattle <input type="checkbox"/> Chicken <input type="checkbox"/> Dog <input type="checkbox"/> Goat <input type="checkbox"/> Horse <input type="checkbox"/> Human <input type="checkbox"/> Other |  |   |               |
| 8. Mixed Breed<br><input type="checkbox"/>  | Mixed with   | 9. Status<br><input type="checkbox"/> Intact <input type="checkbox"/> Neutered <input type="checkbox"/> Not Applicable <input type="checkbox"/> Unknown |               |
| 10. Age From  | 11. Age To   | 12. Weight From   | 13. Weight To |

**REPORTER INFORMATION**

**Primary Report**

- |  |               |          |
|--|---------------|----------|
| 1. Sender<br><input type="checkbox"/> Attending Veterinarian <input type="checkbox"/> Clinical Pathology Laboratory <input type="checkbox"/> Distributor <input type="checkbox"/> Human Patient <input type="checkbox"/> Medical Physician <input type="checkbox"/> Owner/Producer/Employee <input type="checkbox"/> Other |               |          |
| 2. First Name  | 3. Last Name  |          |
| 4. Address (include ZIP Code and country)  |               |          |
| 5. Phone Number  | 6. Fax Number | 7. Email |

Additional Information

- |   |  |  |
|---|--|--|
| Save and submit via email to:<br><br><a href="mailto:cvb@aphis.usda.com">cvb@aphis.usda.com</a> | Print form and mail to:<br><br>Pharmacovigilance, USDA,<br>Center for Veterinary Biologics,<br>1920 Dayton Avenue,<br>Ames, IA 50010 | Print and fax it to:<br><br>515-337-6120 |
|---|--|--|

**PRIVACY ACT NOTICE**

The information requested on this form will not be retrieved from our files by using your name or personal identifier and is therefore, in the opinion of this agency, not subject to provisions of the Privacy Act of 1974. However, in keeping with the spirit and intent of the Privacy Act we are informing you of the following:

**Authority:** 9 CFR Section 114.7.

**Purpose:** That compliance with the Act and applicable regulations be under supervision of person(s) competent in the preparation of biological products.

**Routine uses:** To determine that the responsible person(s) producing biological products are qualified by training and experience and have demonstrated fitness to produce such products in compliance with the Act.

**CONTINUATION SHEET**

*(use this page to continue any item on this form)*