

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

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>	<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, use continuation sheet on page 3)*:

**SUSPECTED ADVERSE EVENT DATE(S)**

- |  |  |  |
|--|--|--|
| 1. Date of Onset of AE <i>(MM/DD/YYYY)</i> | 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

- Critical   
  Fair   
  Good   
  Poor   
  Not Applicable   
  Unknown

5. Animal Name

6. Gender

- Female   
  Male   
  Mixed   
  Not Applicable   
  Unknown

7. Species

- Cat   
  Cattle   
  Chicken   
  Dog   
  Goat   
  Horse   
  Human   
  Other

8. Mixed Breed

Mixed with

9. Status

- Intact   
  Neutered   
  Not Applicable   
  Unknown

10. Age From

11. Age To

12. Weight From

13. Weight To

**REPORTER INFORMATION**

**Primary Report**

1. Sender

- Attending Veterinarian   
  Clinical Pathology Laboratory   
  Distributor   
  Human Patient   
  Medical Physician   
  Owner/Producer/Employee   
  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:

CVB@usda.gov

Print form and mail to:

Pharmacovigilance, USDA,  
Center for Veterinary Biologics,  
1920 Dayton Avenue,  
Ames, IA 50010

Print and fax it to:

515-337-6120

**CONTINUATION SHEET**

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