

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 (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

- 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)*