

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   
  Clin Path Laboratory   
  Distributer   
  Human Patient  
 Licensed Partner   
  Medical Physician   
  NOS Other   
  Owner/Producer/Employee

2. First Name	3. Last Name	4. Contract Number	5. Submitter's Case Number
6. Date First Received (MM/DD/YYYY)	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   
  Field Safety Study   
  Human Exposure   
  Inquiry   
  Product Problem Only

11. Problem Type

- Adverse Reaction   
  Eco-toxicity   
  Extra Label Use   
  Human Exposure - Asymptomatic  
 Human Exposure - Symptomatic   
  Inquiry   
  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
Manufacturer				
Serial/Lot Number				
Expiration Date				
Was product used as per label instructions?	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Not Applicable <input type="checkbox"/> Unknown to Company <input type="checkbox"/> Unknown to Reporter	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Not Applicable <input type="checkbox"/> Unknown to Company <input type="checkbox"/> Unknown to Reporter	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Not Applicable <input type="checkbox"/> Unknown to Company <input type="checkbox"/> Unknown to Reporter	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Not Applicable <input type="checkbox"/> Unknown to Company <input type="checkbox"/> Unknown to Reporter
Off-label use type				
Has patient received this product before	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Not Applicable <input type="checkbox"/> Unknown to Company <input type="checkbox"/> Unknown to Reporter	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Not Applicable <input type="checkbox"/> Unknown to Company <input type="checkbox"/> Unknown to Reporter	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Not Applicable <input type="checkbox"/> Unknown to Company <input type="checkbox"/> Unknown to Reporter	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Not Applicable <input type="checkbox"/> Unknown to Company <input type="checkbox"/> Unknown to Reporter
Has patient experienced AEs from this product before?	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Not Applicable <input type="checkbox"/> Unknown to Company <input type="checkbox"/> Unknown to Reporter	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Not Applicable <input type="checkbox"/> Unknown to Company <input type="checkbox"/> Unknown to Reporter	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Not Applicable <input type="checkbox"/> Unknown to Company <input type="checkbox"/> Unknown to Reporter	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Not Applicable <input type="checkbox"/> Unknown to Company <input type="checkbox"/> Unknown to Reporter
Route of Administration				
Site of Administration				
Duration of Treatment/Exposure	Start Date    End Date	Start Date    End Date	Start Date    End Date	Start Date    End Date
Dose Amount				
Who administered the product?				
Attending veterinarian's level of suspicion				

**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"/> Other        | <input type="checkbox"/> Reproductive              |

## 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"/> Not Applicable      | <input type="checkbox"/> Recovered          | <input type="checkbox"/> Remains Under Treatment | <input type="checkbox"/> Unknown       |

Enter case narrative:

**SUSPECTED ADVERSE EVENT DATE(S):**

- |  |                                 |  |  |
|--|---------------------------------|--|--|
| 1. Date of Onset of AE<br>(MM/DD/YYYY) | APX<br><input type="checkbox"/> | 2. Duration of Suspected Adverse Event | 3. Time Between Administration and Event |
|--|---------------------------------|--|--|

**ANIMAL INFORMATION**

- |   |  |   |               |
|---|--|---|---------------|
| 1. Number of Animals Exposed<br>Estate <input type="checkbox"/>   | 2. Number of Animals Reacted<br>Estate <input type="checkbox"/>  | 3. Number of Dead Animals<br>Estate <input type="checkbox"/>  |               |
| 4. Animal Condition Prior to Treatment<br><input type="checkbox"/> Critical <input type="checkbox"/> Fair <input type="checkbox"/> Good <input type="checkbox"/> Not Applicable <input type="checkbox"/> Poor <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"/> Clin Path Laboratory <input type="checkbox"/> Distributor <input type="checkbox"/> Human Patient <input type="checkbox"/> Licensed Partner <input type="checkbox"/> Medical Physician <input type="checkbox"/> NOS Other <input type="checkbox"/> Owner/Producer/Employee |               |          |
| 2. First Name   | 3. Last Name  |          |
| 4. Address(include ZIP Code and country)  |               |          |
| 5. Phone Number   | 6. Fax Number | 7. Email |

**Other Report**

- |   |               |          |
|---|---------------|----------|
| 1. Sender<br><input type="checkbox"/> Attending Veterinarian <input type="checkbox"/> Clin Path Laboratory <input type="checkbox"/> Distributor <input type="checkbox"/> Human Patient <input type="checkbox"/> Licensed Partner <input type="checkbox"/> Medical Physician <input type="checkbox"/> NOS Other <input type="checkbox"/> Owner/Producer/Employee |               |          |
| 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@aphis.usda.com](mailto:cvb@aphis.usda.com)

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