

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

ANIMAL INFORMATION

- | | | | |
|---|--|---|---------------|
| 1. Number of Animals Exposed
Estate <input type="checkbox"/> | 2. Number of Animals Reacted
Estate <input type="checkbox"/> | 3. Number of Dead Animals
Estate <input type="checkbox"/> | |
| 4. Animal Condition Prior to Treatment
<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
<input type="checkbox"/> Female <input type="checkbox"/> Male <input type="checkbox"/> Mixed <input type="checkbox"/> Not Applicable <input type="checkbox"/> Unknown | | |
| 7. Species
<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
<input type="checkbox"/> | Mixed with | 9. Status
<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
<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
<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

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