

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 | Product2 | 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