

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

See reverse side for Privacy Act notice

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>	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
 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	
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 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	
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 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	
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 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	
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"/> 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, continue 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
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ANIMAL INFORMATION

1. Number of Animals Exposed	2. Number of Animals Reacted	3. Number of Dead Animals	
4. Animal Condition Prior to Treatment <input type="checkbox"/> Critical <input type="checkbox"/> Fair <input type="checkbox"/> Good <input type="checkbox"/> Poor <input type="checkbox"/> Not Applicable <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"/> Clinical Pathology Laboratory <input type="checkbox"/> Distributor <input type="checkbox"/> Human Patient <input type="checkbox"/> Medical Physician <input type="checkbox"/> Owner/Producer/Employee <input type="checkbox"/> 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@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
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PRIVACY ACT NOTICE

The information requested on this form will not be retrieved from our files by using your name or personal identifier and is therefore, in the opinion of this agency, not subject to provisions of the Privacy Act of 1974. However, in keeping with the spirit and intent of the Privacy Act we are informing you of the following:

Authority: 9 CFR Section 114.7.

Purpose: That compliance with the Act and applicable regulations be under supervision of person(s) competent in the preparation of biological products.

Routine uses: To determine that the responsible person(s) producing biological products are qualified by training and experience and have demonstrated fitness to produce such products in compliance with the Act.

CONTINUATION SHEET

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