Clear Form

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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 (*MM/DD/YYYY*)	7. Report	8. Submitted to Manufacturer	9. Country of Occurrence
	☐ Initial ☐ Follow-up	☐ Yes ☐ No	

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?	☐ Yes ☐ No ☐ Not Applicable ☐ Unknown to Reporter	☐ Yes ☐ No ☐ Not Applicable ☐ Unknown to Reporter	☐ Yes ☐ No ☐ Not Applicable ☐ Unknown to Reporter	☐ Yes ☐ No ☐ Not Applicable ☐ Unknown to Reporter
Off-label use type				
Has patient received this product before	☐ Yes ☐ No ☐ Not Applicable ☐ Unknown to Reporter	☐ Yes ☐ No ☐ Not Applicable ☐ Unknown to Reporter	☐ Yes ☐ No ☐ Not Applicable ☐ Unknown to Reporter	☐ Yes ☐ No ☐ Not Applicable ☐ Unknown to Reporter
Has patient experienced AEs from this product before?	☐ Yes ☐ No ☐ Not Applicable ☐ Unknown to Reporter	☐ Yes ☐ No ☐ Not Applicable ☐ Unknown to Reporter	☐ Yes ☐ No ☐ Not Applicable ☐ Unknown to Reporter	☐ Yes ☐ No ☐ Not Applicable ☐ 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

☐ Anaphylaxis - Hypersensitivity ☐ Autoimmune ☐ Birth Defect ☐ Lack of Expected Efficacy
☐ Local ☐ Neoplasia ☐ Reproductive ☐ Other

What was the final outcome?

☐ Alive with Sequelae ☐ Death (All Causes) ☐ Euthanasia ☐ Natural Death
☐ Recovered ☐ Remains Under Treatment ☐ Not Applicable ☐ 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

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:	Print form and mail to:	Print and fax it to:
cvb@aphis.usda.com	Pharmacovigilance, USDA, Center for Veterinary Biologics, 1920 Dayton Avenue, Ames, IA 50010	515-337-6120

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)