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OMB Approved 0579-0013 EXP. 02/2022

## 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 f	or Privacy	Act ı	notice				
1. Information Rep	-										
Attending Veterinarian		rian [	n Clinical Pathology Laboratory				Distributer	□н	Human Patient		
Medical Physician		2.1.55	Owner/Producer/Employee				Other	F 0		li ina la a n	
2. First Name		3. Last	3. Last Name				umber	5. Sur	omitter's Case N	lumber	
6. Date First Rece	eived	7. Repo	7. Report				to Manufacture	er 9. Cou	untry of Occurre	nce	
(MM/DD/YYYY)			nitial	ow-up 📗 Ye		es	☐ No		•		
10. Case Type				<u> </u>							
☐ Animal Co	omnlaint	□ Hur	nan Exposure	☐ Prod	uct Problem	n Onl	V				
11. Problem Type	•		nan Exposure		4001 10010111		· ·				
Adverse Reaction			☐ Eco-toxicity				ra Label Use		Human Exposure - Asymptomatic		
Human E		-	Lack of E		_	- 1 pro	oduct Problem		Asymptomati	l C	
Sympton	natic										
	1			PRODUCT II	NFORMA	ATIC	ON				
Product Number	Brand Name/Trade			Name			Generic Name/Active Ingredient(s)				
1											
2											
3											
4											
		Prod	uct 1	Product 2			Prod	uct 3	Product 4		
Manufacturer											
Serial/Lot Number	er										
Expiration Date											
Was product use	d ac nor	☐ Yes ☐ No	☐ Not Applicable	Yes No	☐ Not Applica	able	☐ Yes ☐ No	☐ Not Applicable	☐ Yes ☐ No	☐ Not Applicable	
Was product used as per label instructions?		Unknown to Reporter		Unknown to Reporter			Unknown to F		Unknown to Reporter		
Off lobal use time											
Off-label use type											
product before		Yes No Not Applicable				able	l <u> </u>		1 <u> </u>		
		Unknown to Reporter		Unknown to Reporter			Unknown to Reporter		Unknown to Reporter		
Has patient experienced AEs from this product before?		Yes No Not Applicable		Yes No Not Applicab		able	Yes No Not Applicable				
		Unknown to Reporter		Unknown to Reporter			Unknown to F	Reporter	Unknown to Reporter		
Route of Administration											
Site of Administr	ation										
Duration of Treatment/Exposure		Start Date	End Date	Start Date	End Date	;	Start Date	End Date	Start Date	End Date	
Dose Amount											
Who administere product?	d the										
Attending vetering											

		DETAI	LED DESCR	IPTIO	N OF EVENT (	narra	ative)			
Event Category								_		
Anaphylaxis -	Hypersensitivity	☐ Autoimm	une		Birth Defect		Lack of Expected Efficacy			
Local		☐ Neoplasia	1		Reproductive		☐ Other			
What was the fina										
Alive with Sec	quelae		II Causes)		Euthanasia	∐ Natural Death				
Recovered			Jnder Treatment		☐ Not Applicable		Unknown			
Enter case narrati	VE (if necessary, continu	e on page 3):								
SUSPECTED ADVERSE EVENT DATE(S)										
1. Date of Onset of	of AE (MM/DD/YYYY)		2. Duration of S	Suspect	ted Adverse Event		3. Time Between Administration and Event			
ANIMAL INFORMATION										
1. Number of Anir	nals Exposed		2. Number of A	Animals	Reacted		3. Number of Dead Animals			
	on Prior to Treatme	nt .			_				_	
Critical	☐ Fair		Good		Poor		☐ Not Applicable ☐ Unknown			
5. Animal Name		6. Gender							_	
		☐ Fema	ıle 📙	Male	☐ Mix	ed		Not Applicable	e 📙 Unknown	
7. Species	□ Co#lo	Chieles	Dog		□ Cost		Horos	□ Uuman	n 🗌 Other	
8. Mixed Breed	<u> </u>						I U Otner			
	WILLIAM WILLI		☐ Intact		☐ Neutered	1	Пи	ot Applicable	Unknown	
10. Ago From		11. Age To	П ппаст	☐ IIIIaci				│ Not Applicable │ Unknown │ 13. Weight To		
10. Age From	l	11. Age 10	1		12. Weight From			is. Weight it	, 	
			DEDODI		IFORMATION					
- Darlan and Darrand			REPORT	EK IN	IFORMATION					
Primary Report  1. Sender										
☐ Attending	d	Pathology _	J 5:	<b>-</b>	5 "	Med	ical —	Owner/Produ	cer/ 🗖 🔐	
☐ Veterinar			Distributor _	Hu	man Patient U		sician $\Box$	Employee	Other	
2. First Name 3. Last Name										
4 Address (1 )									_	
4. Address (include	ZIP Code and country)									
5. Phone Number 6. Fax Nu			nber		7.Email					
A 1 1111										
Additional Informa	ation									
Save and submit	rint form and ma	il to:			Print and	fax it to:				
cvb@aphis.usda.com					ice, USDA,		515-337-6120			
			Center to 1920 Day		inary Biologics,					
			Ames, IA							
			PRIVA	CY AC1	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										
			ot the Privacy Ac	ct of 197	4. However, in kee	eping v	with the spir	it and intent of	the Privacy Act we	
are informing you of the following:										
Authority:	prity: 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.

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. Routine uses:

## **CONTINUATION SHEET**

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

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