According to the Paperwork Reduction Act of 1995, an agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a valid OMB control number. The valid OMB control number for this information is 0579-0209. The time required to complete this information collection is estimated to average .33 hours per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information.

OMB Approved 0579-0209 EXP. XX/XXXX

UNITED STATES DEPARTMENT OF AGRICULTURE ANIMAL AND PLANT HEALTH INSPECTION SERVICE VETERINARY SERVICES

CENTER FOR VETERINARY BIOLOGICS 1920 DAYTON AVENUE AMES, JOWA 50010

ADVERSE EVENT REPORT

4 Information Dans	AIVIES, IOVVA 50010									
1. Information Repo	rted By									
Attending Veterinarian		Clin	Path Laboratory	/	Distributer		Human Patient			
Licensed Partner		Med		☐ NOS Otl		Owner/Producer/Employee				
2. First Name		3. Last N	ame		4. Contract I	Number	5. Submitter's Case Number			
6. Date First Receiv (MM/DD/YYYY)	ed	7. Report			8. Submitted to Manufacturer		9. Country of Occurrence			
(IVIIVI/DD/TTTT)		Initial	Follow-u	J p	Yes No					
10. Case Type										
						roblem Only				
11. Problem Type								_		
Adverse Reacti	on	Eco-	toxicity	Extra Label Use				uman Exposure symptomatic	-	
Human Exposur	re -	☐ Inqu	iry	Lack of Efficacy			Product Problem			
			Р	RODUCT IN	IFORMATI	ON				
Product Number		Brar	nd Name/Trade	Name		Generic N	Name/Activ	ve Ingredient(s)	
1										
2										
3										
4										
	<u>I</u>	Prod	uct 1	Proc	luct2	Product 3	3	Prod	uct 4	
Manufacturer										
Serial/Lot Number										
Expiration Date										
	as ner	Yes No	Not Applicable	Yes No	■ Not Applicable	Yes No No No	t Applicable	Yes No	Not Applicable	
Was product used label instructions?		Yes No Unknown to Company	Not Applicable Unknown to Reporter	Yes No Unknown to Company	Not Applicable Unknown to Reporter		t Applicable Unknown to Reporter	☐ Yes ☐ No ☐ Unknown to Company	Not Applicable Unknown to Reporter	
Was product used		Unknown to	Unknown to	Unknown to	☐ Unknown to	Unknown to	Unknown to	Unknown to	Unknown to	
Was product used label instructions?		Unknown to Company	Unknown to	Unknown to	☐ Unknown to	Unknown to Company	Unknown to	Unknown to Company	Unknown to	
Was product used label instructions? Off-label use type		Unknown to Company	Unknown to Reporter	Unknown to Company Yes No Unknown to	Unknown to Reporter	Unknown to Company Yes No No	Unknown to Reporter	Unknown to Company	Unknown to Reporter	
Was product used label instructions? Off-label use type Has patient receive product before Has patient experie	ed this	Unknown to Company Yes No Unknown to Company Yes No	Unknown to Reporter Not Applicable Unknown to Reporter Not Applicable	Unknown to Company Yes No Unknown to Company Yes No	Unknown to Reporter Not Applicable Unknown to Reporter Not Applicable	Unknown to Company Yes No No Unknown to Company Yes No No	Unknown to Reporter t Applicable Unknown to Reporter t Applicable	Unknown to Company Yes No Unknown to Company Yes No	Unknown to Reporter Not Applicable Unknown to Reporter Not Applicable	
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DETAILED DESCRIPTION OF EVENT (narrative):												
Event Category			_									
Anaphylaxis - Hypersensitivity	Autoimi	mune	Birth Defect	Lack	of Expected Efficacy							
Local	☐ Neopla	sia	Other	Repro	oductive							
What was the final outcome?												
☐ Alive with Sequelae		All Causes)	L Euthanasia	= =	al Death							
Not Applicable	Recove	red	Remains Under	reatment Unkno	own							
Enter case narrative:												
SUSPECTED ADVERSE EVENT DATE(S):												
1. Date of Onset of AE APX (MM/DD/YYYY)	2. Duration	of Suspected Advers	e Event	B. Time Between Administra	ation and Event							
(IVIIVI/DD/1111)												
			IFORMATION									
Number of Animals Exposed		2. Number of Anima		3. Number of Dead An								
	Estate		Estate		Estate							
4. Animal Condition Prior to Treatment												
Critical Fair		Good		☐ Poor	Unknown							
5. Animal Name	6. Gende	_	□		🗖							
7 Chaolina	Fema	ale Male	e Mixed	☐ Not Applica	able Unknown							
7. Species												
Cat Cattle	Chicker	n 🔲 Dog	☐ Goat ☐] Horse Hu [Other							
				man								
8. Mixed Breed Mixed with		9. Status										
		☐ Intact	Neutered	Not Applicable	Unknown							
10. Age From	11. Age To	1	12. Weight From	13. Weigh	nt To							
		REPORTER	INFORMATION									
Primary Report 1. Sender												
Attending Clin Path	Distributor	☐ Human ☐	Licensed Medic	al 🗆 NOS 🗀	Owner/Producer/							
☐ Veterinarian ☐ Laboratory ☐	DISTIDUTO	☐ Patient ☐	Partner Physic	ian U Other U	Employee							
2. First Name			3. Last Name									
A Address (include ZID Code and cour	4 m . 1											
4. Address (include ZIP Code and coun	try)											
5. Phone Number	6. Fax Num	ber	7.Email									
Other Report 1. Sender												
Attending Clin Path	Distributor	☐ Human ☐	Licensed Medic	al 🖂 NOS 🖂	Owner/Producer/							
☐ Veterinarian ☐ Laboratory ☐	Distributor	☐ Patient ☐	Partner U Physic	ian 🗀 Other 🗀	Employee							
2. First Name			3. Last Name									
4. Address(include ZIP Code and Cour	ntry)											
5. Phone Number	6. Fax Num	ber	7.Email									
Additional Information												
Save and submit via email to:		Print form and mail	.O.	Print and fax it to:								
Gave and Submit via Email 10.		T THE TOTAL AND HIGH	ю.	ו ווווג מווט ומג וג נט.								
cvb@aphis.usda.com			ovigilance, USDA,	515-337-612	0							
			Veterinary Biologics, ton Avenue,									
		Ames, IA										