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OMB Approved 0579-0013 EXP. 03/2027

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

Information Reported By Attending Veterinarian		_	Clinical Pathology Laboratory			Distributor		Liuman Dationt		
☐ Medical Physician		an Clinical Pathology Laboratory Owner/Producer/Employee			☐ Distributer ☐ Other		□ н	☐ Human Patient		
2. First Name		3. Last Name			4. Contact Number		5. Sub	5. Submitter's Case Number		
6. Date First Received (MM/DD/YYYY)		☐ Initial ☐ Follow-up			8. Submitted to Manufacturer Yes No		er 9. Cou	9. Country of Occurrence		
10. Case Type										
Animal Co	omplaint	☐ Hun	nan Exposure	☐ Produ	ct Problem C	Only				
11. Problem Type						_	☐ Human Exposure -			
Adverse I			☐ Eco-toxicity			Extra Label Use	L	Asymptomatic		
Human E Symptom		-	Lack of E	fficacy	□ F	Product Problem				
			F	PRODUCT IN	IFORMAT	ION				
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2										
3										
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		Product 1 Pro				uct 2 Product 3				
		Prod	luct 1	Produ	ict 2	Prod	luct 3	Prod	luct 4	
Manufacturer		Prod	luct 1	Produ	ict 2	Prod	luct 3	Prod	luct 4	
Manufacturer Serial/Lot Numbe	r	Prod	luct 1	Produ	ict 2	Prod	luct 3	Prod	luct 4	
	r	Prod	luct 1	Produ	ict 2	Prod	luct 3	Prod	luct 4	
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	DETA	VILED DESCRIPTION	ON OF EVENT <i>(narr</i>	rative)	
Event Category	_				
Anaphylaxis - Hypersensitivity	Autoimmune		Birth Defect	Lack of Expected Efficacy	
Local	☐ Neoplas	sia	Reproductive	☐ Other	
What was the final outcome?		A.II. Q			
☐ Alive with Sequelae	Death (All Causes)		Euthanasia	☐ Natural Death	
Recovered	Remains Under Treatment		Not Applicable	Unknown	
Enter case narrative (if necessary, use co	ntinuation sheet o	n page 3):			
	S	USPECTED ADVE	RSE EVENT DATE(S)	
1. Date of Onset of AE (MM/DD/YYYY)		2. Duration of Suspe	•	3. Time Between Administration and Event	
,		'			
		ANIMAL IN	FORMATION	l l	
Number of Animals Exposed		2. Number of Anima		3. Number of Dead Animals	
4. Animal Condition Prior to Treatme	nt				
Critical Fair		Good	Poor	☐ Not Applicable ☐ Unknown	
5. Animal Name	6. Gend		_	_	
	☐ Fem	nale	☐ Mixed	☐ Not Applicable ☐ Unknown	
7. Species Cattle	☐ Chic	ken 🔲 Dog	☐ Goat ☐	Horse ☐ Human ☐ Other	
8. Mixed Breed Mixed with		9. Status		Tioise Tidillali Ottlei	
		☐ Intact	☐ Neutered	☐ Not Applicable ☐ Unknown	
10. Age From	11. Age To	-	12. Weight From	13. Weight To	
	11.7.90 10		12. Wolght Folli	lo. Wolgik 16	
			 		
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Primary Report		REPORTER	NFORMATION		
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CONTINUATION SHEET

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

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