	ol number. T onse, includi	Act of 1995, an agency may not conduct ('he valid OMB control number for this info ng the time for reviewing instructions, sea	ormation is 0579-020	9. The time required	to complete this information c	collection is estimated to	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, IOWA 50010				ADVERSE EVENT REPORT							
1. Information Reported By											
Attending Veter		Clin Path Laborator	Distribute		Human Patient						
Licensed Partne	er	Medical Physician 3. Last Name	4. Contract N		Owner/Producer/Employee 5. Submitter's Case Number						
6. Date First Receiv (<i>MM/DD/YYYY</i>)	6. Date First Received (<i>MM/DD/YYYY</i>)			8. Submitted	to Manufacturer	9. Country of Occurrence					
10. Case Type											
Animal Complai	int	Field Safety Study	🗌 Human E	xposure	Inquiry	Pro	duct Problem Only				
11. Problem Type	on	Eco-toxicity		Extra Lab	مالام	Human Ex					
					Asymptomatic						
Symptomatic Inquiry Lack of Efficacy Product Proble							Diem				
Product Number		Brand Name/Trade		NFORMATIO		ame/Active Ingree	dient(s)				
1		Brand Name, Had									
2											
3											
4											
						B Product 4					
		Product 1	Pro	duct2	Product 3		Product 4				
Manufacturer		Product 1	Pro	duct2	Product 3		Product 4				
Manufacturer Serial/Lot Number		Product 1	Pro	duct2	Product 3		Product 4				
		Product 1	Pro	duct2	Product 3		Product 4				
Serial/Lot Number		Yes No Not Applicable Unknown to Unknown to	Yes No	Not Applicable	Yes No Not	Jnknown to Unkn	No Not Applicable				
Serial/Lot Number Expiration Date Was product used		Yes No Not Applicable	Yes No	Not Applicable	Yes No Not	Jnknown to Unkn	No Not Applicable				
Serial/Lot Number Expiration Date Was product used label instructions?		Yes No Not Applicable Unknown to Unknown to	Yes No	Not Applicable	Yes No Not Unknown to Ves No Not Yes No Not Unknown to U	Applicable Unkn	No Not Applicable own to Unknown to ppany —				
Serial/Lot Number Expiration Date Was product used label instructions? Off-label use type Has patient received	ed this enced	Yes No Not Applicable Unknown to Company Yes No Not Applicable Unknown to	Yes No	Not Applicable Unknown to Reporter Not Applicable Unknown to Reporter	Yes No Not Unknown to U Company U Unknown to U Unknown to U Yes No Ves No Ves No Unknown to U Unknown to U Unknown to U Unknown to U Unknown to U	Applicable Version Con Reporter Version Con Applicable Version Con Applicable Version Con Applicable Version Con	No Not Applicable own to Unknown to Reporter				
Serial/Lot Number Expiration Date Was product used label instructions? Off-label use type Has patient receive product before Has patient experie AEs from this prod	ed this enced luct	Yes No Not Applicable Unknown to Company Yes No Not Applicable Unknown to Company Yes No Not Applicable Unknown to Company Yes No Not Applicable Unknown to Unknown	Yes No Unknown to Company Yes No Unknown to Company Yes No Unknown to Company Yes No Unknown to	Not Applicable Unknown to Reporter Not Applicable Unknown to Reporter Not Applicable Unknown to Reporter Not Applicable Unknown to	Yes No Not Unknown to U Company U Unknown to U Unknown to U Yes No Ves No Ves No Unknown to U Unknown to U Unknown to U Unknown to U Unknown to U	Applicable Version Con Reporter Version Con Applicable Version Con Applicable Version Con Applicable Version Con	No Not Applicable own to Unknown to Reporter				
Serial/Lot Number Expiration Date Was product used label instructions? Off-label use type Has patient receive product before Has patient experie AEs from this prod before?	ed this enced luct ration	Yes No Not Applicable Unknown to Company Yes No Not Applicable Unknown to Unknown to Unknown to Unknown to Company Yes No Not Applicable Unknown to Company Keporter Unknown to Company Keporter	Yes □ No Unknown to Company Yes □ No Unknown to Company Yes □ No Unknown to Company Yes □ No Unknown to Company	Not Applicable Unknown to Reporter Not Applicable Unknown to Reporter Not Applicable Unknown to Reporter Not Applicable Unknown to	Yes No Not Unknown to U Company U Unknown to U Unknown to U Company U Unknown to U Unknown to U Company U Unknown to U Onknown to U Company U	Applicable Share Con Reporter Con Applicable Share Con Applicable Share Con Applicable Share Con Applicable Share Con Applicable Share Con Reporter Con	No Not Applicable own to Unknown to npany Not Applicable own to Unknown to npany Unknown to No Not Applicable own to Unknown to npany Not Applicable own to Unknown to npany Not Applicable own to Unknown to npany Reporter				
Serial/Lot Number Expiration Date Was product used label instructions? Off-label use type Has patient receive product before Has patient experie AEs from this prod before? Route of Administr	ed this enced luct ration	Yes No Not Applicable Unknown to Company Yes No Not Applicable Unknown to Company Yes No Not Applicable Unknown to Company Yes No Not Applicable Unknown to Unknown	Yes No Unknown to Company Yes No Unknown to Company Yes No Unknown to Company Yes No Unknown to	Not Applicable Unknown to Reporter Not Applicable Unknown to Reporter Not Applicable Unknown to Reporter Not Applicable Unknown to	Yes No Not Unknown to U Company U Unknown to U Unknown to U Company U Unknown to U Unknown to U Company U Unknown to U Onknown to U Company U	Applicable Version Con Reporter Version Con Applicable Version Con Applicable Version Con Applicable Version Con	No Not Applicable own to Unknown to npany Not Applicable own to Unknown to npany Unknown to No Not Applicable own to Unknown to npany Not Applicable own to Unknown to npany Not Applicable own to Unknown to npany Reporter				
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Serial/Lot Number Expiration Date Was product used label instructions? Off-label use type Has patient receive product before Has patient experie AEs from this prod before? Route of Administrat Duration of Treatment/Exposur Dose Amount Who administered	ed this enced luct ration ion re the	Yes No Not Applicable Unknown to Company Yes No Not Applicable Unknown to Unknown to Unknown to Unknown to Company Yes No Not Applicable Unknown to Company Keporter Unknown to Company Keporter	Yes □ No Unknown to Company Yes □ No Unknown to Company Yes □ No Unknown to Company Yes □ No Unknown to Company	Not Applicable Unknown to Reporter	Yes No Not Unknown to U Company U Unknown to U Unknown to U Company U Unknown to U Unknown to U Company U Unknown to U Onknown to U Company U	Applicable Share Con Reporter Con Applicable Share Con Applicable Share Con Applicable Share Con Applicable Share Con Applicable Share Con Reporter Con	No Not Applicable own to Unknown to npany Reporter No Not Applicable own to Unknown to npany Reporter				

SEP 2015

DETAILED DESCRIPTION OF EVENT (narrative):								
Event Category								
Anaphylaxis - Hypersensitivity	Autoimmune	Birth Defect	Lack of Expected Efficacy					
Local	Neoplasia	Other	Reproductive					
What was the final outcome?								
Alive with Sequelae	Death (All Causes)	🗌 Euthanasia	Natural Death					
Not Applicable	Recovered	Remains Under Treatment	Unknown					
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			3. Ti	ne Betv	ween Ac	dministr	ation and Event	
(<i>IVIIVI/DD/YYYY</i>)													
ANIMAL INFORMATION													
1. Number of Animals Exposed	_	· · · · · · □	2. Number of	Anima	als Reacted		—	1	3. Num	ber of D	Dead Ar		
4. Animal Condition Prior to Treat	Estate Estate Estate Estate												
			Good			t Applie	rahle			or		Unknown	
5. Animal Name		6. Gender				і дрріі	Lable			01			
		Fema		Mal	е		Mixed	1		Not	t Applic	able 🗌 Unknowr	า
7. Species										Г	-		
Cat Cattle		Chicken	Dog		🗌 Go	at	Ľ	□н	orse	L H m	u [ian	Other	
8. Mixed Breed Mixed with			9. Status										
			Intac	t		Neut	ered			Not Ap	plicable	e 🗌 Unknown	
10. Age From		11. Age To			12. Wei	ght Fro	om			1:	3. Weig	ht To	
			REPOR	TER	INFORM	ATIC	N						
Primary Report													
1. Sender Attending Clin Path Veterinarian Laboratory	, 🗆	Distributor	Human Patient		Licensed Partner		Medic Physi			NOS Other] Owner/Producer/ Employee	/
2. First Name 3. Last Name													
4. Address (include ZIP Code and	l coun	try)											
5. Phone Number		6. Fax Numb	ber		7.Email								
Other Report													
1. Sender Attending Clin Path Veterinarian Laboratory	, 🗆	Distributor	Human Patient		Licensed Partner		Medio Physi			NOS Other] Owner/Producer, Employee	/
2. First Name	,				3. Last	Name				0.1101			
4. Address(include ZIP Code and Country)													
5. Phone Number		6. Fax Numl	ber		7.Email								
Additional Information													
Save and submit via email to:			Print form and	d mail	to:				Print ar	nd fax it	to:		
cvb@aphis.usda.com			Ce 192					515-337-6120			20		