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 2 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, IOWA 50010

ADVERSE EVENT REPORT

Information Reported By									
Attending Veterinarian		Clin Path Laboratory		Distributer			Human Patient		
Licensed Partner		Medical Physician		NOS Other			Owner/Producer/Employee		
2. First Name		3. Last Name		4. Contract Number		5. Submitter's Case Number			
6. Date First Received		7. Report		8. Submitted to Manufacturer		9. Country of Occurrence			
(MM/DD/YYYY)		☐ Initial ☐ Follow-	Yes No						
10. Case Type									
					roblem Only				
11. Problem Type								_	
Adverse Reaction	on	☐ Eco-toxicity		Extra Label Use			Human Exposure - Asymptomatic		
Human Exposure - Symptomatic		☐ Inquiry		Lack of Efficacy			Product Problem		
- Jpiomaio		P	RODUCT IN	IFORMAT	TIOI	N			
Product Number		Brand Name/Trade					ame/Activ	ve Ingredient(s	s)
1									
2									
3									
4									
Product 1			Product 2		Product 3		Prod	luct 4	
Manufacturer									
Serial/Lot Number									
Expiration Date									
Was product used as per		Yes No Not Applicable	Yes No	Not Applicable		Yes No Not	Applicable	Yes No	Not Applicable
label instructions?		Unknown to Unknown to Company Reporter	Unknown to Unknown to Company Reporter				Inknown to Reporter	Unknown to Company	Unknown to Reporter
Off-label use type									
Has patient received this product before		Yes No Not Applicable				Applicable	Yes No	☐ Not Applicable	
		Unknown to Unknown to Company Reporter	Unknown to Company	Unknown to Reporter			Inknown to Reporter	Unknown to Company	Unknown to Reporter
Has patient experienced		Yes No Not Applicable	Not Applicab	Yes No Not	Applicable		Not Applicable		
AEs from this product before?		Unknown to Company Unknown to Reporter Unknown to Company		Unknown to Unknown to Company			Inknown to Reporter	Unknown to Company	Unknown to Reporter
Route of Administration									
Site of Administration									
Duration of Treatment/Exposure		Start Date End Date	Start Date	End Date		Start Date Er	nd 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	Autoimi	mune	Birth Defect	Lack of Expected Efficacy								
Local	☐ Neopla	sia	Other	Reproductive								
What was the final outcome?												
Alive with Sequelae	Death (All Causes)		L 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	ime Between Administration and Event								
			IFORMATION									
Number of Animals Exposed		2. Number of Anima	_	3. Number of Dead Animals								
	Estate		Estate	Estate								
4. Animal Condition Prior to Treatment		□ 。 .										
Critical Fair	C Canala	Good	Not Applicable	☐ Poor ☐ Unknown								
5. Animal Name	6. Gende			I D Not Applicable D Halmann								
7. Species	Fema	ale Male	e Mixed	Not Applicable Unknown								
7. Species												
☐ Cat ☐ Cattle	Chicker	n 🔲 Dog	Goat [Horse Human Other								
		1 = =:										
8. Mixed Breed Mixed with		9. Status										
		☐ Intact	Neutered	Not Applicable Unknown								
10. Age From	11. Age To	Í	12. Weight From	13. Weight To								
L		DEDORTED	INFORMATION									
REPORTER INFORMATION Primary Report												
1. Sender												
Attending Clin Path	Distributor	☐ Human ☐	Licensed Medic									
U Veterinarian U Laboratory U 2. First Name	Diotributor	☐ Patient ☐	Partner Physi	cian U Other U Employee								
2. Filst Name			3. Last Name									
4. Address(include ZIP Code and coun	try)											
4. Addiese (molade Zii Code diid oodii	u y /											
5 Dhara Nasahan	0 F N	h	1 7 5 1									
5. Phone Number	6. Fax Num	per	7.Email									
Other Report												
1. Sender												
☐ Attending ☐ Clin Path ☐	Distributor	☐ Human ☐	Licensed Medi									
U Veterinarian U Laboratory U 2. First Name	Biotributor	☐ Patient ☐	Partner Phys 3. Last Name	cian U Other U Employee								
2. First Name			3. Last Name									
4. Address(include ZIP Code and Cour	otry)											
4. Address (melade 211 Code and Codi	na y)											
	T =		T = = "									
5. Phone Number	6. Fax Number		7.Email									
A delition of Laterana Con												
Additional Information												
Save and submit via email to:		Print form and mail	to:	Print and fax it to:								
		Pharmacovid	gilance, USDA,									
cvb@aphis.usda.com		Center for V	eterinary Biologics,	515-337-6120								
		1920 Daytor										
		Ames, IA 50	UIU									