INSTRUCTIONS:				Т	ITLE OF INFORMA	TION COLLECT	ION DOCUMEN	Т	OME	3 NO.
					ıs-Sarum-Tavin	ED	0579-0013			
						Virus-Serum-Toxin Act and Regulations in 9 CFR, Subchapter E, Parts 101-124				
					·		August 27, 2018			
IDENTIFICATION	OF REPORTING OR RECORDKEEPING REQUIREMENT					ANNUAL B	URDEN			
				_	REPORTS				RECORDS	
SECTION OF REGS	DESCRIPTION	FORM NO's (if none, so state)	NO. OF RESPONDENTS	NO. OF RESPONSES PER RESPONDENT	TOTAL ANNUAL RESPONSES	HOURS PER RESPONSE	TOTAL HOURS	NO. OF RECORD- KEEPERS	ANNUAL HOURS PER RECORD- KEEPER	RECORD- KEEPING HOURS
(A)	(B)	(C)	(D)	(E)	(Col. D x E) (F)	(G)	(Col. F x G) (H)	(I)	(J)	(Col. I x J) (K)
9 CFR 102.1, 108.2	Application for U.S. Veterinary Biologics Establishment License (includes plot plants and blueprints) (Business)	APHIS 2001	20	1	20	1.000	20			
102.1, 108.2	CVB Inspection and Compliance Facility Document Submission Worksheet (Business) (New)	APHIS 2009	1	1	1	0.150	1			
102.1	Application for U.S. Veterinary Biologics License (Business)	APHIS 2003	25	3	75	1.000	75			
102.4	Certificate of Licensing and Inspection (Business)	APHIS 2046, 2046S, 2047, 2047S	100	35	3,500	0.333	1,166			
102.4, 114.7	Qualifications of Veterinary Biologics Personnel (Business)	APHIS 2007	90	8	720	0.200	144			
102.5	Request for Restriction on Distribution and Use of a Veterinary Biological Product (Business)	none	1	1	1	1.000	1			
102.6	Petition for Reissue of Conditional License (Business)	none	10	1	10	1.000	10			
103.1	Application to Produce Experimental Products (Business)	none	50	1	50	0.500	25			
103.3	Application for Authorization to Ship Experimental Veterinary Biological Products (Business)	APHIS 2071	45	8	360	1.000	360			
SUBTOTAL					4,737		1,802	0		0
	TOTAL OF ALL PAGES		10,183		298,820,111		64,071	690		58,927
	TOTAL COLUMNS F + I = OMB 831, 13b COLUMNS H + K = OMB 831, 13c				298,820,801		122,998			

INSTRUCTIONS:			Т	ITLE OF INFORMA	OMB NO.						
				\ /:	o Comuna Tavia	ED.	0579-0013 DATE PREPARED				
					is-Serum-Toxin ا Subchapt	rk,					
					Casonapi	or E, r arto re	71 121		August 27, 2018		
				L		ANNUAL B	URDEN		<u>.</u>		
IDENTIFICATION	I OF REPORTING OR RECORDKEEPING REQUIREMENT				REPORTS				RECORDS		
SECTION OF REGS	DESCRIPTION	FORM NO's (if none, so state)	NO. OF RESPONDENTS	NO. OF RESPONSES PER RESPONDENT	TOTAL ANNUAL RESPONSES	HOURS PER RESPONSE	TOTAL HOURS	NO. OF RECORD- KEEPERS	ANNUAL HOURS PER RECORD- KEEPER	RECORD- KEEPING HOURS	
(A)	(B)	(C)	(D)	(E)	(Col. D x E) (F)	(G)	(Col. F x G) (H)	(1)	(J)	(Col. I x J) (K)	
104.5	Applications for U.S. Veterinary Biologics Product Permit (Business)	APHIS 2005	220	1	220	1.000	220				
105.4	Show Intent to Resume Production (Business)	none	50	1	50	1.000	50				
107.2, 114.2	State notifies APHIS of each Establishment and Product License Issued or Terminated (State)	none	1	1	1	1.000	1				
112.1, 112.2	Package Labeling (Business) (Third Party Disclosure) (New)	none	100	2,987,637	298,763,700	0.000028	8,365				
112.2, 112.5, 112.9, 113.3, 113.47, 114.9	Transmittal of Labels and Circulars or Outlines, Reporting (Business) (Merger)	APHIS 2015	100	48	4,800	0.050	240				
112.2, 113.3	Written Authorization Statement, Reporting (Foreign Government) (Merger)	none	100	8	800	0.050	40				
112.5	List of Approved Labels Currently Being Used (Business)	none	48	1	48	0.250	12				
	Official Export Certificate for Animal Biological Products (Business)	APHIS 2017	100	10	1,000	1.000	1,000				
	Request for Reference, Reagent, or Reagent Seed Material (Business)	APHIS 2018	200	2	400	0.100	40				
113.3	Shipment and Receipt of Biologics Samples (Business)	APHIS 2020	100	115	11,500	0.300	3,450				
113.3, 113.6	Application for Authorization to Ship Biological Product Samples for Confirmatory Testing (Business)	APHIS 2072	48	1	48	1.000	48				
	SUBTOTAL				298,782,567		13,466	0		0	

INSTRUCTIONS:			Т	ITLE OF INFORMA	OMB NO.						
					Camura Tarria	ED.	0579-0013				
				VIIC	ıs-Serum-Toxin Subchant	er E, Parts 10		rk,	DATE PREPARED August 27, 2018		
					Guberiapi	or E, r arts re	71 124				
				I.		ANNUAL B	URDEN				
IDENTIFICATION	OF REPORTING OR RECORDKEEPING REQUIREMENT				REPORTS				RECORDS		
SECTION OF REGS	DESCRIPTION	FORM NO's (if none, so state)	NO. OF RESPONDENTS	NO. OF RESPONSES PER RESPONDENT	TOTAL ANNUAL RESPONSES	HOURS PER RESPONSE	TOTAL HOURS	NO. OF RECORD- KEEPERS	ANNUAL HOURS PER RECORD- KEEPER	RECORD- KEEPING HOURS	
(A)	(B)	(C)	(D)	(E)	(Col. D x E) (F)	(G)	(Col. F x G) (H)	(1)	(J)	(Col. l x J) (K)	
113.5,.68,.69, .70,.71, 114.17, 116.7	Veterinary Biologics Production and Test Report (Business)	APHIS 2008 & 2008A	100	160	16,000	1.000	16,000	V	(4)	(' '	
114.18	Request for Reprocessing and Rebottling for a Serial or Subserial (Business)	APHIS 2008 & 2008A	30	1	30	1.000	30				
113.52, 113.100, 113.200, 113.300	Application for Authorization to Ship Master Seed or Cell Samples for Confirmatory Testing by APHIS (Business)	APHIS 2070	60	2	120	1.000	120				
113.113	Request for Authorization to Prepare an Autogenous Biologic for Use in Herds Adjacentto the Herd of Origin (Business)	none	20	1	20	0.250	5				
113.113	Request to Use an Isolate Beyond the Time Limit Prescribed (Business)	none	20	1	20	0.500	10				
113.113	Protocol and Additional Testing Requirements for Autogenous Biologics (Business)	none	1	1	1	1.000	1				
114.14	Request for Extension of Expiration Date for a Serial or Subserial (Business)	none	50	10	500	1.000	500				
115.2	Notify Wholesalers (Licensee and Permittees) (Business)	none	5	1	5	0.167	1				
115.2(b)(3)	Accounting of Inventory (Licensees and Permittees) (Business)	none	5	1	5	1.000	5				
115.2(b)(4)	Accounting of Inventory (Wholesalers, Jobbers, etc.) (Business)	none	50	1	50	2.000	100				
116.5	Reports on Activities [Center for Vet Biologics, Inspection and Compliance E-Submission form] (Business)	APHIS 2048	25	1	25	0.500	13				
	SUBTOTAL				16,776		16,785	0		0	

INSTRUCTIONS:				Т	TITLE OF INFORMA	TION COLLECT	ION DOCUMEN	Т	OMB	NO.	
				Viru	ıs-Serum-Toxin	Act and Regu	lations in 9 Cl	FR	0579-	-0013	
				Virus-Serum-Toxin Act and Regulations in 9 CFR, Subchapter E, Parts 101-124					DATE PREPARED		
					·	•			August 27, 2018		
IDENTIFICATION	LOS DEPORTINO OR DECORDIZEDINO DECLUREMENT					ANNUAL B	URDEN				
IDENTIFICATION	OF REPORTING OR RECORDKEEPING REQUIREMENT				REPORTS				RECORDS	S RECORD- KEEPING HOURS (Col. I x J) (K) 33 15 00 1	
SECTION OF REGS	DESCRIPTION	FORM NO's (if none, so state)	NO. OF RESPONDENTS	NO. OF RESPONSES PER RESPONDENT	TOTAL ANNUAL RESPONSES	HOURS PER RESPONSE	TOTAL HOURS	NO. OF RECORD- KEEPERS	ANNUAL HOURS PER RECORD- KEEPER	RECORD- KEEPING HOURS	
(A)	(B)	(C)	(D)	(E)	(Col. D x E) (F)	(G)	(Col. F x G) (H)	(1)	(J)		
116.5	Reports on Activities [Veterinary Biologics Regulation E-Submission form Policy, Evaluation, and Licensing] (Business)	APHIS 2049	25	1	25	0.500	13	V	.,,	,	
124.10, 124.20	Patent Term Restoration Letter of Application for Extending the Term of a Veterinary Biologic Patent (Business)	none	1	1	1	1.000	1				
124.22	Request for Revision of the Regulatory Review Period (Business)	none	1	1	1	1.000	1				
124.30	Due Dilligence Petition and Certification Statement of True and Complete Copy (Business)	none	1	1	1	1.000	1			0	
124.30	Due Dilligence Petition and Certification Statement of True and Complete Copy (Individual)	none	1	1	1	1.000	1			0	
124.31	Applicants Response to Petition (Business)	none	1	1	1	1.000	1			0	
124.40	Request for Due Dilligence Hearing (Business)	none	1	1	1	1.000	1			0	
124.40	Request for Due Dilligence Hearing (Individual)	none	1	1	1	1.000	1			0	
103.2	Records of Disposition of Test Animals (Business)				0		0	44	0.333	15	
107.1	Records of Exempt Biologics (Business)				0		0	1	1.000	1	
109.2	Sterilization and Pasteurization Records (Business)				0		0	100	9.500	950	
	SUBTOTAL				32		20	145		966	

INSTRUCTIONS:		TITLE OF INFORMATION COLLECTION DOCUMENT					OMB NO.				
				Virus-Serum-Toxin Act and Regulations in 9 CFR,						0579-0013	
				V C	Subchapt	DATE PREPARED					
					·		0579	-0013			
IDENTIFICATION	OF REPORTING OR RECORDKEEPING REQUIREMENT					ANNUAL B	URDEN				
IDENTII IOATION	OF REFORMED ON REGONDREEF ING REGONEINEN				REPORTS				RECORDS		
SECTION OF REGS	DESCRIPTION	FORM NO's (if none, so state)	NO. OF RESPONDENTS	NO. OF RESPONSES PER RESPONDENT	TOTAL ANNUAL RESPONSES	HOURS PER RESPONSE	TOTAL HOURS	NO. OF RECORD- KEEPERS	ANNUAL HOURS PER RECORD- KEEPER	RECORD- KEEPING HOURS	
(A)	(B)	(C)	(D)	(E)	(Col. D x E) (F)	(G)	(Col. F x G) (H)	(1)	(J)	(Col. I x J) (K)	
113.5, 113.6	Records of All Tests (Business)				0		0	100	172.000	17,200	
113/15	Records of Antiserum or Serum Pasteurized (Business)				0		0	20	46.000	920	
114.5	Identity of the Microorganism (Business)				0		0	25	0.500	13	
114.5	Records of Microorganisms Used (Business)				0		0	100	143.000	14,300	
	Records of Production of Product, Inventory and Disposition (Business)				0		0	100	5.250	525	
112.2, 112.5, 112.9, 113.3, 113.47, 114.9, 116.3	Label Records (Business)				0		0	100	250.000	25,000	
116.6, 117	Animal Records (Business)				0		0	100	0.033	3	
116.9	Adverse Event Report (Business) (merger)	APHIS 2080	3,333	1	3,333	2	6,666	0	0.000	0	
116.9	Adverse Event Report (State) (merger)	APHIS 2080	3,333	1	3,333	2	6,666	0	0.000	0	
116.9	Adverse Event Report (Individual) (merger)	APHIS 2080	3,333	1	3,333	2	6,666	0	0.000	0	
	Adverse Event Report Followup (Business) (merger)	APHIS 2081	2,000	1	2,000	2.000	4,000	0	0.000	0	
SUBTOTAL					11,999		23,998	545		57,961	

INSTRUCTIONS:				Т	ITLE OF INFORMA	TION COLLECT	ION DOCUMEN	Т	OME	3 NO.		
					Virus-Serum-Toxin Act and Regulations in 9 CFR,					0579-0013		
					Subchapt	ΓK,	DATE PREPARED					
									0579-0013			
IDENTIFICATION	OF REPORTING OR RECORDKEEPING REQUIREMENT					ANNUAL B	URDEN					
				1	REPORTS				RECORDS	1		
SECTION OF REGS	DESCRIPTION	FORM NO's (if none, so state)	NO. OF RESPONDENTS	NO. OF RESPONSES PER RESPONDENT	TOTAL ANNUAL RESPONSES	HOURS PER RESPONSE	TOTAL HOURS	NO. OF RECORD- KEEPERS	ANNUAL HOURS PER RECORD- KEEPER	RECORD- KEEPING HOURS		
(A)	(B)	(C)	(D)	(E)	(Col. D x E) (F)	(G)	(Col. F x G) (H)	(1)	(J)	(Col. I x J) (K)		
116.9	Adverse Event Report Followup (State) (merger)	APHIS 2081	2,000	1	2,000	2.000	4,000	0	0.000	0		
116.9	Adverse Event Report Followup (Individual) (merger)	APHIS 2081	2,000	1	2,000	2.000	4,000	0	0.000	0		
	SUBTOTAL				4,000		8,000	0		0		