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**TITLE OF INFORMATION COLLECTION DOCUMENT**  
**VIRUS-SERUM-TO XIN ACT AND REGULATIONS IN 9 CFR, SUBCHAPTER E, PARTS 101-124**

**OMB NO.**  
 0579-0013

**DATE PREPARED**  
 February 28, 2011

IDENTIFICATION OF REPORTING OR RECORDKEEPING REQUIREMENT			ANNUAL BURDEN							
SECTION OF REGS. (A)	DESCRIPTION (B)	FORMS NO (S) (If "none" so state) (C)	REPORTS					RECORDS		
			NO. OF RESPONDENTS (D)	NO OF RESPONSES PER RESPONDENT (E)	TOTAL ANNUAL RESPONSES (Col. D x E) (F)	HOURS PER RESPONSE (G)	TOTAL HOURS (Col. F x G) (H)	NO. OF RECORD-KEEPERS (I)	ANNUAL HOURS PER RECORD-KEEPER (J)	TOTAL RECORD-KEEPING HOURS (Col. I x J) (K)
102.3, 108.2, .7	Application for US Veterinary Biologics Establishment License (includes plot plants and blueprints)(Business)	APHIS 2001	20	1.00	20	1.00	20			0.00
102.3	Application for US Veterinary Biologics License (Business)	APHIS 2003	25	3.00	75	1.00	75			0.00
102.4, 114.7	Qualifications of Veterinary Biologics Personnel (Business)	APHIS 2007	120	2.00	240	0.16	38			0.00
112.2,,9, 113.3,,47	Transmittal of Labels and Circulars or Outlines (Business)	APHIS 2015	100	40.00	4,000	0.05	200			0.00
112.47,,71,,69	Official Export Certificate for animal Biological Products (Business)	APHIS 2017	35	1.00	35	1.00	35			0.00
.113,114.4, .8, .9	Request for Reference, Reagent, or Reagent Seed Material (Business)	APHIS 2018	200	2.00	400	0.10	40			0.00
	<b>SUBTOTAL</b>				4,770		408	0.00		0.00
	<b>TOTAL OF ALL PAGES</b>				18,599		7,332	705.00		67,054

<b>TOTAL - COLUMNS "F" AND "I" = OMB 831, 13 b; COLUMNS "H" AND "K" = OMB 831, 13c</b>		202		19,304		74,386			
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104.6, .6	Applications for US Veterinary Biologics Product Permit (Business)	APHIS 2005	200	1.00	200	1.00	200			0.00
113.3	Shipment and Receipt of Biologics Samples (Business)	APHIS 2020	100	75.00	7,500	0.30	2,250			0.00
113.5,.68,.69,.70,.71,114.17,116.7	Veterinary Biologics Production and Test Report (Business)	APHIS 2008 &2008a	100	50.00	5,000	0.73	3,630			0.00
114.8	Certificate of Licensing and Inspection (Business)	APHIS 2046, 2046s, 2047, 2047s	100	3.00	300	0.33	100			0.00
	List of Licensed Biological Products (Business)	none	10	1.00	10	0.30	3			0.00
102.5	Request for restriction on distribution and use of a veterinary biological product (Business)	none	1	1.00	1	1.00	1			0.00
<b>SUBTOTAL</b>					13,011		6,184	0		0.00

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102.6	Petition for reissue of Conditional License (Business)	none	10	1.00	10	1.00	10.00			0.00
103.1	Application to Produce Experimental Products (Business)	none	50	1.00	50	0.50	25.00			0.00
103.3	Request for authorization to ship unlicensed biological products for experimental field studies in US (Business)	none	35	3.00	105	1.00	105.00			0.00
105.4	Show intent to resume production or not (Business)	none	50	1.00	50	1.00	50.00			0.00
107.2	State shall notify APHIS of each establishment and product issued or terminated (State)	none	1	1.00	1	1.00	1.00			0.00
112.5	List of approved labels currently being used (Business)	none	4	1.00	4	0.25	1.00			0.00
<b>SUBTOTAL</b>					220		192.00	0		0.00

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113.113	Request for authorization to prepare an autogenous biologic for use in herds adjacent and not adjacent to the herd of origin (Business)	none	10	2.00	20	0.25	5			0.00
113.113	Request to use an isolate beyond the time limit prescribed (Business)	none	20	1.00	20	0.50	10			0.00
113.113	Protocol & additional testing requirements for autogenous biologics (Business)	none	1	1.00	1	1.00	1			0.00
114.14	Request for extension of expiration date for a serial or subserial (Business)	none	50	10.00	500	1.00	500			0.00
116.5	Reports on activities (Business)	none	50	1.00	50	0.50	25			0.00
124.10, .20	PATENT TERM RESTORATION Letter Application to PTO (Business)		1	1.00	1	1.00	1			0.00
<b>SUBTOTAL</b>					592		542	0		0.00

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124.22	Request for revision of the regulatory review period (Business)	none	1	1.00	1	1.00	1			0.00
124.30	Due dilligence petition and certification statement of True and Completed Copy (Business)	none	1	1.00	1	1.00	1			0.00
124.30	Due dilligence petition and certification statement of True and Completed Copy (Individual)	none	1	1.00	1	1.00	1			0.00
124.31	Applicants response to petition (Business)	none	1	1.00	1	1.00	1			0.00
124.40	Request for due dilligence hearing (Business)	none	1	1.00	1	1.00	1			0.00
124.40	Request for due dilligence hearing (Individual)	none	1	1.00	1	1.00	1			0.00
103.2	Records of disposition of test animals (Business)				0		0	44	0.350	15
<b>SUBTOTAL</b>					6		6	44		15

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107.1	Records of exempt biologics (normal business records) (Business)				0.00			0.00	1	1.00	1
109.2, 116.4	Sterilization and Pasteurization Records (Business)				0.00			0.00	114	9.50	1,083
113.450	Records of antiserum or serum pasteurized (Business)				0.00			0.00	20	46.00	920
113.5	Records of all tests (Business)				0.00			0.00	114	172.00	19,608
116.6, .117	Animal records (Business)				0.00			0.00	20	0.03	1
113.113	Identity of the microorganism-recordkeeping (Business)				0.00			0.00	50	0.50	25
<b>SUBTOTAL</b>					0.00			0.00	319		21,638

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114.5	Records of microorganism used (Business)				0.00			0.00	114	143.00	16,302
114.6, 115.1, 116.1,,2,,5,8	Records of Production of product, inventory and disposition (Business)				0.00			0.00	114	5.25	599
116.3	Label records (Business)				0.00			0.00	114	250.00	28,500
					0.00			0.00			0
					0.00			0.00			0
					0.00			0.00			0
	<b>SUBTOTAL</b>				0.00			0.00	342		45,401