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			VIRUS-SERUM-TO XIN ACT AND REGULATIONS IN 9 CFR, SUBCHAPTER E, PARTS 101-124					0579-0013		
								DATE PREPARED		
								July 1, 2013		
IDENTIFICATION OF REPORTING OR RECORDKEEPING REQUIREMENT			ANNUAL BURDEN							
SECTION OF REGS. (A)	DESCRIPTION (B)	FORMS NO (S) (If "none" so state) (C)	REPORTS					RECORDS		
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102.3, 108.2	Application for U.S. 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 U.S. Veterinary Biologics License (Business)	APHIS 2003	25	3.00	75	1.00	75			0.00
104.6	Applications for U.S. Veterinary Biologics Product Permit (Business)	APHIS 2005	220	1.00	220	1.00	220			0.00
102.4, 114.7	Qualifications of Veterinary Biologics Personnel (Business)	APHIS 2007	90	8.00	720	0.20	144			0.00
112.2, 112.9, 113.3, 113.47	Transmittal of Labels and Circulars or Outlines (Business)	APHIS 2015	100	40.00	4000	0.05	200			0.00
112.47, 112.71, 112.69	Official Export Certificate for Animal Biological Products (Business)	APHIS 2017	100	10.00	1000	1.00	1000			0.00
SUBTOTAL					6,035		1,659	0		0
TOTAL OF ALL PAGES					38,980		19,456	690		58,926
TOTAL - COLUMNS "F" AND "I" = OMB 831, 13 b; COLUMNS "H" AND "K" = OMB 831, 13c			220		39,670		78,382			

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113,114.4, 114.8, 114.9	Request for Reference, Reagent, or Reagent Seed Material (Business)	APHIS 2018	200	2.00	400	0.10	40			0.00
113.3	Shipment and Receipt of Biologics Samples (Business)	APHIS 2020	100	115.00	11,500	0.30	3,450			0.00
113.5, .68, .69, .70, .71, 114.17, 116.7	Veterinary Biologics Production and Test Report (Business)	APHIS 2008 & 2008a	100	160.00	16,000	0.73	11,680			0.00
114.18	Request for reprocessing and rebottling for a serial or subserial (Business)	2008	30	1.00	30	0.73	22			0.00
114.8	Certificate of Licensing and Inspection (Business)	APHIS 2046, 2046s, 2047, 2047s	100	35.00	3,500	0.33	1,155			0.00
103.3	Application for Authorization to Ship Experimental Veterinary Biological Products (Business)	APHIS 2071	45	8.00	360	1.00	360			0.00
SUBTOTAL					31,790		16,707	0		0.00

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			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	2.00	120	1.00	120
113.3, 113.6	Application for Authorization to Ship Biological Product Samples for Confirmatory Testing (Business)	APHIS 2072	48	1.00	48	1.00	48			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
102.6	Petition for Reissue of Conditional License (Business)	none	10	1.00	10	1.00	10			0.00
SUBTOTAL					169		169	0		0.00

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(A)	(B)	(C)	(D)	(E)	(F)	(G)	(H)	(I)	(J)	(K)
103.1	Application to Produce Experimental Products (Business)	none	50	1.00	50	0.50	25			0.00
105.4	Show Intent to Resume Production (Business)	none	50	1.00	50	1.00	50			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			
112.5	List of Approved Labels Currently Being Used (Business)	none	48	1.00	48	0.25	12			0.00
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	20	1.00	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
SUBTOTAL					368		282	0		0.00

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			113.113	Protocol & Additional Testing Requirements for Autogenous Biologics (Business)	none	1	1.00	1	1.00	1
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, 124.20	Patent Term Restoration; Letter of Application to PTO (Business)	none	1	1.00	1	1.00	1			0.00
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 Complete Copy (Business)	none	1	1.00	1	1.00	1			0.00
124.30	Due Dilligence Petition and Certification Statement of True and Complete Copy (Individual)	none	1	1.00	1	1.00	1			0.00
SUBTOTAL					555		530	0		0

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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
105.3 (C) 115.2 (b) (2)	This section is being merged from 0579-0318. Notify Wholesalers (Licensees and Permittees) - (Business)	none	5	1.00	5	0.16	1			0.00
115.2 (b)	This section is being merged from 0579-0318. Accounting of Inventory (Licensees and Permittees) - (Business)	none	5	1.00	5	1.00	5			0.00
115.2 (b) (4)	This section is being merged from 0579-0318. Accounting of Inventory (Wholesalers, Jobbers, Dealers, etc.) - (Business)	none	50	1.00	50	2.00	100			0.00
SUBTOTAL					63		109	0		0

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103.2	Records of Disposition of Test Animals (Business)				0.00			0.00	44	0.33	15
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	100	9.50	950
113.45	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	100	172.00	17,200
116.6, 117	Animal Records (Business)				0.00			0.00	100	0.03	3
SUBTOTAL					0.00			0.00	365		19,089

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			113.113	Identity of the Microorganism (Business)				0.00		0.00
114.5	Records of Microorganism Used (Business)				0.00		0.00	100	143.00	14,300
114.6, 115.1, 116.1,.2,.5,.8	Records of Production of Product, Inventory and Disposition (Business)				0.00		0.00	100	5.25	525
116.3	Label Records (Business)				0.00		0.00	100	250.00	25,000
					0.00		0.00			0.00
					0.00		0.00			0.00
	SUBTOTAL				0.00		0.00	325		39,838