

INSTRUCTIONS:			TITLE OF INFORMATION COLLECTION DOCUMENT					OMB NO.		
			Virus-Serum-Toxin Act and Regulations in 9 CFR, Subchapter E, Parts 101-124					0579-0013		
			DATE PREPARED							
			August 27, 2018							
IDENTIFICATION OF REPORTING OR RECORDKEEPING REQUIREMENT			ANNUAL BURDEN							
			REPORTS					RECORDS		
SECTION OF REGS	DESCRIPTION	FORM NO's (if none, so state)	NO. OF RESPONDENTS	NO. OF RESPONSES PER RESPONDENT	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)	RECORD-KEEPING HOURS (Col. I x J) (K)
(A)	(B)	(C)	(D)	(E)	(F)	(G)	(H)	(I)	(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			
112.47, 112.69, 112.71	Official Export Certificate for Animal Biological Products (Business)	APHIS 2017	100	10	1,000	1.000	1,000			
113, 114.4, 114.8, 114.9	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

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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			
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 Adjacent...to 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

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116.5	Reports on Activities [Veterinary Biologics Regulation E-Submission form Policy, Evaluation, and Licensing] (Business)	APHIS 2049	25	1	25	0.500	13			
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

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113.5, 113.6	Records of All Tests (Business)				0		0	100	172.000	17,200
113.45	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
114.6, 115.1, 116.1, .2, .5, .8	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
116.9	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

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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