

TITLE OF INFORMATION COLLECTION REQUEST Virus-Serum-Toxin Act and Regulations	OMB CONTROL NO.
	0579-0013
	DATE PREPARED
	February 3, 2022

	OPM PAY TABLE	FRINGE BENEFITS	OVERHEAD COST FACTOR	TOTAL FEDERAL GOVERNMENT COSTS
	(A)	(B)	(C)	
	2022-DM	0.613	0.139	\$2,606,101

ACTIVITY DESCRIPTION (incl form number)	TOTAL ANNUAL RESPONSES (D)	AVG TIME PER RESPONSES (E)	TOTAL HOURS PER YEAR (F)	SALARY		TOTAL COSTS (1+B+C) X F X H
				GRADE (G)	WAGE (Step 4) (H)	
Application for U.S. Veterinary Biologics Establishment License (APHIS 2001)	22	1.000	22	14	58.94	\$ 2,272
CVB Inspection and Compliance Facility Document Submission Worksheet (APHIS 2009)	46	0.500	23	13	49.88	\$ 2,010
Application for U.S. Veterinary Biologics License (APHIS 2003)	88	1	88	14	58.94	\$ 9,087
Certificate of Licensing and Inspection (APHIS 2046/S and 2047/S)	1,240	1	620	13	49.88	\$ 54,182
Qualifications of Veterinary Biologics Personnel (APHIS 2007)	1,170	0	293	13	49.88	\$ 25,605
Request for Restriction on Distribution and Use of a Veterinary Biological Product	1	1	1	13	49.88	\$ 87
Petition for Reissue of Conditional License	24	1	24	14	58.94	\$ 2,478
Application to Produce Experimental Products	112	1	56	14	58.94	\$ 5,783
Application for Authorization to Ship Experimental Veterinary Biological Products (APHIS 2071)	315	0	79	14	58.94	\$ 8,158
Application for U.S. Veterinary Biologics Product Permit (APHIS 2005)	540	1	540	14	58.94	\$ 55,762
Show Intent to Resume Production	9	1	9	14	58.94	\$ 929
Transmittal of Labels and Circulars or Outlines, Reporting (APHIS 2015)	156	0	16	14	58.94	\$ 1,652
Written Authorization Statement, Reporting	2,475	0	248	14	58.94	\$ 25,609

ACTIVITY DESCRIPTION (incl form number)	TOTAL ANNUAL RESPONSES	AVG TIME PER RESPONSES	TOTAL HOURS PER YEAR	SALARY		TOTAL COSTS
				GRADE	WAGE (Step 4)	
List of Approved Labels Currently Being Used	83	1	42	13	49.88	\$ 3,670
Official Export Certificate for Animal Biological Products (APHIS 2017)	1,860	1	1,860	13	49.88	\$ 162,545
Request for Reference, Reagent, or Reagent Seed Material (APHIS 2018)	352	0	88	13	49.88	\$ 7,690
Shipment and Receipt of Biologics Samples (APHIS 2020)	13,500	0	4,455	13	49.88	\$ 389,321
Application for Authorization to Ship Biological Product Samples for APHIS Confirmatory Testing (APHIS 2072)	32	0	8	13	49.88	\$ 699
Veterinary Biologics Production and Test Report (APHIS 2008 and 2008A)	16,300	1	16,300	13	49.88	\$ 1,424,453
Request for Reprocessing and Rebottling for a Serial or Subserial (APHIS 2008 and 2008A)	12	1	12	13	49.88	\$ 1,049
Application for Authorization to Ship Master Seed or Cell Samples for APHIS Confirmatory Testing (APHIS 2070)	14	0	4	14	58.94	\$ 413
Request to Use an Isolate Beyond the Time Prescribed	20	1	10	13	49.88	\$ 874
Protocol and Additional Testing Requirements for Autogenous Biologics	1	1	1	13	49.88	\$ 87
Request for Extension of Expiration Date for a Serial or Subserial	33	1	33	13	49.88	\$ 2,884
Wholesaler Notification (Licensees and Permittees)	1	10	10	14	58.94	\$ 1,033
Accounting of Inventory (Licensees and Permittees)	1	10	10	14	58.94	\$ 1,033
Accounting of Inventory (Wholesalers, Jobbers, etc.,)	1	10	10	14	58.94	\$ 1,033
Reports on Activities (CVB Inspection and Compliance E-Submission Form, APHIS 2048)	900	1	450	13	49.88	\$ 39,325
Reports on Activities (CVB Regulations/Policy, Evaluation, and Licensing E-Submission Form, APHIS 2049)	6,930	1	3,465	14	58.94	\$ 357,806
Patent Term Restoration; Letter of Application for Extending the Term of a Veterinary Biologic Patent	1	1	1	13	49.88	\$ 87

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				GRADE	WAGE (Step 4)	
Request for Revision of the Regulatory Review Period	1	1	1	14	58.94	\$ 103
Due Diligence Petition and Certification Statement	2	1	2	14	58.94	\$ 207
Applicant's Response to Petition	1	1	1	14	58.94	\$ 103
Request for Due Diligence Hearing	2	1	2	14	58.94	\$ 207
Adverse Event Report	345	1	173	14	58.94	\$ 17,864