

OMB CONTROL NO. 0579-0013	TITLE OF INFORMATION COLLECTION REQUEST Virus-Serum-Toxin Act and Regulations	DATE PREPARED February 3, 2022
TYPE OF REQUEST Renewal		PUBLIC COMMENT DOCKET NO. APHIS 2021-0035
POINT OF CONTACT Bonnie Coyle		FEDERAL REGISTER NOTICE 86 FR 40446
TELEPHONE NO. (515) 337-6561		FEDERAL REGISTER DATE July 28, 2021

PART I - SUMMARY

TOTAL RESPONDENTS 478	TOTAL ANNUAL RESPONSES 435,797,533	% ELECTRONIC 80%	RESPONSES PER RESPONDENT 911,710	TOTAL BURDEN HOURS 43,072	HOURS PER RESPONSE 0.00010	% SMALL ENTITIES 95%
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PART II - LIST OF ACTIVITIES

TYPE OF CHANGE	TYPE OF RESPONDENT	FIRST OCCURENCE	TYPE OF RESPONSE	AUTHORITY (U.S.C., CFR, or Manual)	ACTIVITY DESCRIPTION (title, respondent type, and type of change if discretionary)	FORM NO.	FORMAT	ESTIMATED ANNUAL NUMBER OF RESPONDENTS or RECORDKEEPERS	ESTIMATED TOTAL ANNUAL RESPONSES	ESTIMATED HOURS PER RESPONSE or ANNUAL HOURS PER RECORDKEEPER	ESTIMATED TOTAL ANNUAL BURDEN HOURS
(A)	(B)	(C)	(D)	(E)	(F)	(G)	(H)	(I)	(J)	(K)	(L)
E	P1		I	9 CFR 102.1, 108.2	Application for U.S. Veterinary Biologics Establishment License	APHIS 2001	Info system	22	22	1.000	22
E	P1		I	9 CFR 102.1, 108.2	CVB Inspection and Compliance Facility Document Submission Worksheet (includes plot plans and blueprints)	APHIS 2009	Info system	23	46	0.150	7
E	P1		I	9 CFR 102.1	Application for U.S. Veterinary Biologics License	APHIS 2003	Info system	22	88	1.000	88
E	P1		I	9 CFR 102.4	Certificate of Licensing and Inspection	APHIS 2046, 2046S, 2047, and 2047S	Info system	20	1,240	0.333	413
E	P1		I	9 CFR 102.4, 114.7	Qualifications of Veterinary Biologics Personnel	APHIS 2007	Info system	90	1,170	0.200	234

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E	P1		I	9 CFR 102.5	Request for Restriction on Distribution and Use of a Veterinary Biological Product	None	Info system	1	1	1.000	1
E	P1		I	9 CFR 102.6	Petition for Reissue of Conditional License	None	Info system	12	24	1.000	24
E	P1		I	9 CFR 103.1	Application to Produce Experimental Products	None	Info system	14	112	0.500	56
E	P1		I	9 CFR 103.3	Application for Authorization to Ship Experimental Veterinary Biological Products	APHIS 2071	Info system	35	315	1.000	315
E	P1		I	9 CFR 104.5	Application for U.S. Veterinary Biologics Product Permit	APHIS 2005	Info system	60	540	1.000	540
E	P1		I	9 CFR 105.4	Show Intent to Resume Production	None	Info system	3	9	1.000	9
E	P1		TP	9 CFR 112.1, 112.2	Package Labeling	None	Info system	27	435,749,193	0.000	12,201
E	P1		I	9 CFR 112.2, 112.5, 112.9, 113.3, 113.47, 114.9	Transmittal of Labels and Circulars or Outlines, Reporting	APHIS 2015	Paper	6	156	0.050	8
E	FG	X	I	9 CFR 112.2, 113.3	Written Authorization Statement, Reporting	None	Info system	45	2,475	0.050	124

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E	P1		I	9 CFR 112.5	List of Approved Labels Currently Being Used	None	Info system	83	83	0.250	21
E	P1		I	9 CFR 112.2(e)(2)	Official Export Certificate for Animal Biological Products	APHIS 2017	Info system	20	1,860	1.000	1,860
E	P1		I	9 CFR part 113 9 CFR 114.4, 114.8, 114.9	Request for Reference, Reagent, or Reagent Seed Material	APHIS 2018	Info system	88	352	0.100	36
E	P1	X	I	9 CFR 113.3	Shipment and Receipt of Biologics Samples	APHIS 2020	Info system	100	13,500	0.330	4,455
E	P1		I	9 CFR 113.3, 113.6	Application for Authorization to Ship Biological Product Samples for APHIS Confirmatory Testing	APHIS 2072	Info system	8	32	1.000	32
E	P1		I	9 CFR 113.5, 113.68, 113.69, 113.70, 113.71, 114.17, 116.7	Veterinary Biologics Production and Test Report	APHIS 2008 and 2008A	Info system	100	16,300	1.000	16,300
E	P1		I	9 CFR 114.18	Request for Reprocessing or Rebottling for a Serial or Subserial	APHIS 2008 and 2008A	Info system	6	12	1.000	12
E	P1		I	9 CFR 113.52, 113.100, 113.200, 113.300	Application for Authorization to Ship Master Seed or Cell Samples for APHIS Confirmatory Testing	APHIS 2070	Info system	7	14	1.000	14
E	P1		I	9 CFR 113.113	Request to Use an Isolate Beyond the Time Prescribed	None	Info system	20	20	0.500	10

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E	P1		I	9 CFR 113.113	Protocol and Additional Testing Requirements for Autogenous Biologics	None	Info system	1	1	1.000	1
E	P1		I	9 CFR 114.14	Request for Extension of Expiration Date for a Serial or Subserial	None	Info system	11	33	1.000	33
E	P1		TP	9 CFR 115.2	Wholesaler Notifications (Licensees and Permittees)	None	Paper	1	1	1.000	1
E	P1		I	9 CFR 115.2(b)	Accounting of Inventory (Licensees and Permittees)	None	Paper	1	1	2.000	2
E	P1		I	9 CFR 115.2(b)	Accounting of Inventory (Wholesalers, Jobbers, etc.)	None	Paper	1	1	2.000	2
E	P1		I	9 CFR 116.5	Reports on Activities (Center for Veterinary Biologics, Inspection and Compliance E-Submission Form)	APHIS 2048	Info system	90	900	0.500	450
E	P1		I	9 CFR 116.5	Reports on Activities (Center for Veterinary Biologics, Regulation and Policy, Evaluation, and Licensing E-Submission Form)	APHIS 2049	Info system	90	6,930	0.500	3,465
E	P1		I	9 CFR 124.10, 124.20	Patent Term Restoration - Letter of Application for Extending the Term of a Veterinary Biologic Patent	None	Paper	1	1	1.000	1
E	P1		I	9 CFR 124.22	Request for Revision of the Regulatory Review Period	None	Paper	1	1	1.000	1

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E	P1		I	9 CFR 124.30	Due Diligence Petition and Certification Statement of True and Complete Copy	None	Paper	1	1	1.000	1
E	I		I	9 CFR 124.30	Due Diligence Petition and Certification Statement of True and Complete Copy	None	Paper	1	1	1.000	1
E	P1		I	9 CFR 124.31	Applicant's Response to Petition	None	Paper	1	1	1.000	1
E	P1		I	9 CFR 124.40	Request for Due Diligence Hearing	None	Paper	1	1	1.000	1
E	I		I	9 CFR 124.40	Request for Due Diligence Hearing	None	Paper	1	1	1.000	1
E	P1		I	9 CFR 116.9	Adverse Event Report	APHIS 2080	Info system	11	11	0.330	4
E	I	X	I	9 CFR 116.9	Adverse Event Report	APHIS 2080	Info system	332	332	0.330	110
E	S1	X	I	9 CFR 116.9	Adverse Event Report	APHIS 2080	Info system	1	1	0.330	1
E	P1		R	9 CFR 103.2	Records of Disposition of Test Animals	None	Info system	44	44	0.330	15

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E	P1		R	9 CFR 107.1	Records of Exempt Biologics	None	Info system	1	1	1.000	1
E	P1		R	9 CFR 109.2	Sterilization and Pasteurization Records	None	Info system	61	61	4.000	244
E	P1		R	9 CFR 113.5, 9 CFR 113.6	Records of All Tests	None	Info system	88	88	2.000	176
E	P1		R	9 CFR 113.450	Records of Antiserum or Serum Pasteurized	None	Info system	1,172	1,172	0.500	586
E	P1		R	9 CFR 114.5	Identity of the Microorganism	None	Info system	26	26	0.500	13
E	P1		R	9 CFR 114.5	Records of Microorganisms Used	None	Info system	95	95	5.000	475
E	P1		R	9 CFR 114.6, 115.1, 116.1, 116.2, 116.5, 116.8	Records of Production of Product, Inventory, and Disposition	None	Info system	88	88	3.000	264
E	P1		R	9 CFR 112.1, 112.5(e), 116.3	Label Records	None	Info system	88	88	3.000	264
E	P1		R	9 CFR 116.6, 9 CFR part 117	Animal Records	None	Info system	88	88	2.000	176