According to the Paperwork Reduction Act of 1995, an agency may not conduct or sponsor, and a p	person is not required to respond to a	OMB APPROVED
collection of information unless it displays a valid OMB control number. The valid OMB control number for this information collection is 0579-0036. The time required to complete this information collection is estimated to average 5 hours per response, including the time for		0579-0036
reviewing instructions, searching existing data sources, gathering and maintaining the data needed collection of information.	, and completing and reviewing the	Interagency Report Control No. 0180-DO A-AN
		Fiscal year: 2020-2021
UNITED STATES DEPARTMENT OF AGRICULTURE ANIMAL AND PLANT HEALTH INSPECTION SERVICE Annual Report of Research Facility Column E Explanation		
	OR PRINT)	
This information is required by law (7 U.S.C. 2143 and 9 C.F.R. §2.36 cease	 Failure to report accordin and desist. 	ng to the regulations can result in an order to
1. REGISTRATION NUMBER	2. Research Facil	lity Headquarters address
32-R-0053	Elanco Animal Health 2500 Innovation Way Greenfield, IN 46140	
3. Number of animals used in the study.	4. Species (common name) of animals used in the study.	
2 Dogs		
(b) (4) These two dogs exhibited several days of vomiting, diarrhea and dehydration and due to the duration of signs, potentially experienced pain/distress, despite that they both started to recover before study end.		
6. Provide the scientific justification for not providing the appropriate anesthetics, analgesics, or tranquilizing drugs during procedures where the animal experienced accompanying pain or distress greater than momentary or slight.		
Both the USDA and the European Union require efficacy of ^{(b) (4)} to be demonstrated in the host animal. Therefore, clinical signs are assessed over time to prevent disease.		
7. What, if any, Federal regulations require this procedure? Cite the agency, the Code of Federal Regulations (CFR) title number, and the specific section number (e.g., APHIS, 9 CFR 113, 102):		
Agency CFR		CEP

According to the Paperwork Reduction Act of 1995, an agency may not conduct or sponsor, at	nd a person is not required to respond to a	OMB APPROVED
According to the Paperwork Reduction Act of 1995, an agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a valid OMB control number. The valid OMB control number for this information collection is 0579-0036. The time required to complete this information collection is estimated to average .5 hours per response, including the time for		0579-0036
reviewing instructions, searching existing data sources, gathering and maintaining the data ne collection of information.	eded, and completing and reviewing the	Interagency Report Control No. 0180-DOA-AN
		Fiscal year: 2020-2021
Column	EALTH INSPECTION of Research Faci E Explanation	SERVICE
	YPE OR PRINT)	
This information is required by law (7 U.S.C. 2143 and 9 C.F.R. §	2.36). Failure to report accordines and desist.	ng to the regulations can result in an order to
1. REGISTRATION NUMBER	2. Research Faci	lity Headquarters address
32-R-0053	Elanco Animal Health 2500 Innovation Way Greenfield, IN 46140	
3. Number of animals used in the study. 1	4. Species (common name) of animals used in the study. Rabbit	
6. Provide the scientific justification for not or tranquilizing drugs during procedures wh distress greater than momentary or slight. Systemic analgesics have not been assessed a	nere the animal exper	rienced accompanying pain or
7. What, if any, Federal regulations require the Federal Regulations (CFR) title number, and 113, 102): Procedure described in section (d) (2) Safety	the specific section	
Agency APHIS - CVB and Notice 11-18		CFR 9CFR113.209

According to the Paperwork Reduction Act of 1995, an agency may not conduct or sponsor, and a	person is not required to respond to, a	OMB APPROVED
collection of information unless it displays a valid OMB control number. The valid OMB control number for this information collection is 0579-0036. The time required to complete this information collection is estimated to average .5 hours per response, including the time for		0579-0036
reviewing instructions, searching existing data sources, gathering and maintaining the data neede collection of information.	d, and completing and reviewing the	Interagency Report Control No. 0180-DO A-AN
		Fiscal year: 2020-2021
Column E		SERVICE
This information is required by law (7 U.S.C. 2143 and 9 C.F.R. §2.36). Failure to report according to the regulations can result in an order to cease and desist.		
1. REGISTRATION NUMBER	2. Research Facil	ity Headquarters address
32-R-0053	Elanco Animal Health 2500 Innovation Way Greenfield, IN 46140	
3. Number of animals used in the study.	4. Species (common name) of animals used in the study.	
2381	Hamsters	
5. Explain the procedure producing pain and	distress	
additional daily welfare checks.		
6. Provide the scientific justification for not providing the appropriate anesthetics, analgesics, or tranquilizing drugs during procedures where the animal experienced accompanying pain or distress greater than momentary or slight. Additional welfare checks are part of the oversight of these animals in order to identify moribund animals for humane euthanasia, however due to the rapid progression of disease, these animals were		
7. What, if any, Federal regulations require this procedure? Cite the agency, the Code of Federal Regulations (CFR) title number, and the specific section number (e.g., APHIS, 9 CFR 113, 102): Testing in accordance with section (c) Potency for QC testing.		
Agency AHIS: CVB		CFR 9CFR-101 thru -104
AIIIO. OVD		501 10-101 ullu -104

0079-0000, The time regulard complete his indomained to alreage 3 hours get response, fielding holding to the field of the set of the	According to the Paperwork Reduction Act of 1995, an agency may not conduct or sponsor, and a p collection of information unless it displays a valid OMB control number. The valid OMB control numb		OMB APPROVED	
Fiscal year: 2020-2021 Fiscal year: 2020-2021 UNITED STATES DEPARTMENT OF AGRICULTURE ANIMAL AND PLANT HEALTH INSPECTION SERVICE Annual Report of Research Facility Column E Explanation (rmec/mattion (rmec/mattion Annual Report of Research Facility Column E Explanation (rmec/mattion (rmec/mattion (rmec/mattion 140 State Colspan="2">Colspan="2">Common name) of animals used in the study. Rabbit State Colspan= Colspan="2">Colspan= Colspan="2">Colspan="2">Colspan= Colspan="2">Colspan= Colspan="2">Colspan= Colspan="2">Colspan= Colspan="2">Colspan= Colspan= Colspan="2">Colspan= Colspan="2">Colspan= Colspan="2">Colspan= Colspan="2">Colspan= Colspan="2">Colspan= Colspan="2">Colspan= Colspan="2">Colspan= Colspan="2">Colspan= Colspan="2">Colspan="2">Colspan= Colspan="2">Colspan= Colspan="2">Colspan="2">Colspan= Colspan="2">Colspan= Colspan="2">Colspan= Colspan="2">Colspan= Colspan="2">Colspan= Colspan="2">Col	0579-0036. The time required to complete this information collection is estimated to average .5 hour reviewing instructions, searching existing data sources, gathering and maintaining the data needed,	s per response, including the time for		
UNITED STATES DEPARTMENT OF AGRICULTURE ANIMAL AND PLANT HEALTH INSPECTION SERVICE Annual Report of Research Facility Column E Explanation (PPE OR PRIMO) This information is required by law (? U.S.C. 2143 and 9 C.R. § 236). Failure to report according to the regulations can result in an order to cease and desist. Interinformation is required by law (? U.S.C. 2143 and 9 C.R. § 236). Failure to report according to the regulations can result in an order to cease and desist. 1. REGISTRATION NUMBER 32-R-0053 Colspan="2">Control of Research Facility Headquarters address Elanco Animal Health 2500 Innovation Way Greenfield, IN 46140 3. Number of animals used in the study. 140 State study. Rabbit These rabbits evaluate the serological response to Design and distress. These rabbits evaluate the serological response to Design and its receive a large volume of vaccine with adjuvant as an intramuscular injection which resulted in reluctance to move and lameness in the limb, which are clinical signs suggesting pain. 6. Provide the scientific justification for not providing the appropriate anesthetics, analgesics, or tranquilizing during procedures where the animal experienced accompanying pain or distress greater than momentary or slight. Systemic analgesics have not been assessed and could impact test outcomes. 7. What, if any, Federal regulations require this procedure? Cite t	collection of information.		a de la companya de la	
This information is required by law (? U.S.C. 2143 and 9 C.F.R. §2.36). Falure to report according to the regulations can result in an order to compare according to the regulations can result in an order to compare according to the regulations can result in an order to compare according to the regulations can result in an order to compare according to the regulations can result in an order to compare according to the regulations can result in an order to compare according to the regulations can result in an order to compare according to the regulations can result in an order to compare according to the regulations can result in an order to compare according to the regulations can result in an order to compare according to the regulations can result in an order to compare according to the regulations can result in an order to compare according to the regulations and results. 3. Number of animals used in the study. 2. Research Facility Headquarters address 140 4. Species (common name) of animals used in the study. 140 Rabbit 5. Explain the procedure producing pain and distress. These rabbits evaluate the serological response to the study. Rabbit 6. Provide the scientific justification for not providing the appropriate anesthetics, analgesics, or tranquilizing drugs during procedures where the animal experienced accompanying pain or distress greater than momentary or slight. Systemic analgesics have not been assessed and could impact test outcomes. 7. What, if any, Federal regulations require this procedure? Cite the agency, the Code of Federal Regulations (CFR) title number, and the specific section number (e.g., APHIS, 9 CFR 113, 102): </td <td colspan="4">UNITED STATES DEPARTMENT OF AGRICULTURE ANIMAL AND PLANT HEALTH INSPECTION SERVICE</td>	UNITED STATES DEPARTMENT OF AGRICULTURE ANIMAL AND PLANT HEALTH INSPECTION SERVICE			
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140 Rabbit 5. Explain the procedure producing pain and distress. These rabbits evaluate the serological response to 101 (d) These rabbits evaluate the serological response to 101 (d) For vaccine test release. These animals receive a large volume of vaccine with adjuvant as an intramuscular injection which resulted in reluctance to move and lameness in the limb, which are clinical signs suggesting pain. 6. Provide the scientific justification for not providing the appropriate anesthetics, analgesics, or tranquilizing drugs during procedures where the animal experienced accompanying pain or distress greater than momentary or slight. Systemic analgesics have not been assessed and could impact test outcomes. 7. What, if any, Federal regulations require this procedure? Cite the agency, the Code of Federal Regulations (CFR) title number, and the specific section number (e.g., APHIS, 9 CFR 113, 102): Volumes given are in accordance with the regulatory requirements described below. Agency CFR	3. Number of animals used in the study.			
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113, 102): Volumes given are in accordance with the regulatory requirements described below. Agency CFR				
Agency CFR	113, 102):			
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reviewing instructions, searching existing data sources, gathering and maintaining the data needed callection of information.		Interagency Report Control No. 0180-DOA-AN
		Fiscal year: 2020-2021
UNITED STATES DEPARTMENT OF AGRICULTURE ANIMAL AND PLANT HEALTH INSPECTION SERVICE Annual Report of Research Facility		
	Explanation	,
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1. REGISTRATION NUMBER	2. Research Facil	ity Headquarters address
32-R-0053	Elanco Animal Health 2500 Innovation Way Greenfield, IN 46140	
3. Number of animals used in the study.	4. Species (common name) of animals used in the study.	
4 Rabbits		
6. Provide the scientific justification for not providing the appropriate anesthetics, analgesics, or tranquilizing drugs during procedures where the animal experienced accompanying pain or distress greater than momentary or slight.		
Systemic analgesics have not been assessed for impact to titers, and potential results.		
7. What, if any, Federal regulations require this procedure? Cite the agency, the Code of Federal Regulations (CFR) title number, and the specific section number (e.g., APHIS, 9 CFR 113, 102): Code of Federal Reguations: 9CFR113.9 with Standard Outline SO-098		
Agency		CFR
APHIS: CVB		9CFR113.9

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		Interagency Report Control No. 0180-DOA-AN
Constant of a formation.		Fiscal year: 2020-2021
UNITED STATES DEPARTMEN ANIMAL AND PLANT HEALTH II Annual Report of Rese Column E Expla (TYPE OR PRINT) This information is required by law (7 U.S.C. 2143 and 9 C.F.R. §2.36). Failure	NSPECTION earch Faci anation	SERVICE
1. REGISTRATION NUMBER 2. Re	<u> </u>	ity Headquarters address
Elanc 32-R-0053 2500	Elanco Animal Health 2500 Innovation Way Greenfield, IN 46140	
	4. Species (common name) of animals used in the study.	
5. Explain the procedure producing pain and distress		
deemed to have experienced pain/distress.		
6. Provide the scientific justification for not providing or tranquilizing drugs during procedures where the a distress greater than momentary or slight.		
Dogs had defined criteria to meet the case definition (b) (4 exhibited non-specific clinical signs and intervention woul confounding the study.	d obscure sy	or humane euthanasia. This dog mptoms of disease, thus
7. What, if any, Federal regulations require this proce Federal Regulations (CFR) title number, and the spec 113, 102):		