

REQUEST FOR EXEMPTION OF SELECT AGENTS AND TOXINS FOR AN INVESTIGATIONAL PRODUCT (APHIS/CDC FORM 5)

FORM APPROVED OMB NO. 0920-0576 EXP DATE: 01/31/2024

Answer all items completely and type or print in ink. Detailed instructions are available at https://www.selectagents.gov/form5.html. This form must be signed and submitted to either DASAT or DRSC:

Animal and Plant Health Inspection Service Division of Agricultural Select Agents and Toxins 4700 River Road Unit 2, Mailstop 22, Cubicle 1A07 Riverdale, MD 20737

FAX: (301) 734-3652 E-mail: <u>DASAT@usda.gov</u> Centers for Disease Control and Prevention Division of Regulatory Science and Compliance 1600 Clifton Road NE, Mailstop H21-4 Atlanta, GA 30329

FAX: (404) 718-2096 E-mail: lrsat@cdc.gov

Submit completed form only once by either eFSAP, fax, or email

SECTION 1 – TO BE COMPLETED FOR INVESTIGATIONAL PRODUCT EXEMPTION				
1. Entity name:				
2. Entity address (NOT a post office address):		3. City:	4. State:	5. Zip code:
	Last:	7. Title:		
8. Telephone #:		9. E-mail address:		
10. FDA IND/INAD/IDE number:	11. FDA product name:	12. This product has been approved for Phase I clinical trials by FDA: □ No □ Yes		
13. Date of the IND/INAD/IDE application subm FDA Center/Review Office:	itted to FDA including the name of the FD Da			
14. USDA veterinarian product code number:	15. USDA veterinarian product name:	16. This product has been tested and approved for field trials by USDA: □ No □ Yes		
17. Investigational product (Give select agent n	ame and characterization):			
18. Federal act that authorizes investigational u	se of this product:			
(attach additional sheets if necessary):				
I hereby certify that the information contained statement on any part of this form, or its attack Part 331, 9 CFR Part 121, or 42 CFR Part 73 investigational product that is, bears, or contai INAD, or IDE, and agree that such confirmatio Trade Secrets Act (18 U.S.C. § 1905).	nments, I may be subject to criminal fines may result in civil or criminal penalties, inc ns select agents or toxin, I authorize FDA	and/or imprisonment. I further und luding imprisonment. For exemption to confirm for APHIS or CDC the	erstand that on requests the existence and	violations of 7 CFR hat involve the d status of the IND,
Signature of Investigational Product Exemption	n Applicant:	Dat	e:	
Public reporting burden: Public reporting but	rden of this collection of information is est	mated to average 30 minutes per	response, inc	cluding the time for

reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. An agency may not conduct or sponsor, and a person is not required to respond to a collection of information unless it displays a currently valid OMB control number. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden to CDC/ATSDR Reports Clearance Officer; 1600 Clifton Road NE, MS D-74, Atlanta, Georgia 30329; ATTN: PRA (0920-0576).