

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

FORM APPROVED OMB NO. 0579-0213 OMB NO. 0920-0576 EXP DATE XX/XX/XXXX

Read all instructions carefully before completing the form. Answer all items completely and type or print in ink. The form must be signed and submitted to either APHIS or CDC:

Animal and Plant Health Inspection Service Agriculture Select Agent Services 4700 River Road Unit 2, Mailstop 22, Cubicle 1A07 Riverdale, MD 20737

FAX: 301-734-3652

E-mail: AgSAS@aphis.usda.gov

Centers for Disease Control and Prevention Division of Select Agents and Toxins 1600 Clifton Road NE, Mailstop A-46 Atlanta, GA 30329

FAX: 404-718-2096 Email: <a href="mailto:lrsat@cdc.gov">lrsat@cdc.gov</a>

SECTION 1 – TO BE COMPLETED FOR INVESTIGATIONAL PRODUCT EXEMPTION				
1. Entity name:		2. Entity registration number (if applicable):		
3. Entity address (NOT a post office address):		4. City:	5. State:	6. Zip code:
7. Applicant		8. Title:		
First: MI: Last:				
9. Telephone #:	10. FAX #:	11. Email address:		
12. FDA IND/INAD/IDE number:	13. FDA product name:	14. This product has been approby FDA:	oved for Phase	
15. Date of the IND/INAD/IDE application sul FDA Center/Review Office:		DA center and review office ate:		
16. USDA veterinarian product code number:	17. USDA veterinarian product name:	18. This product has been tested by USDA:	d and approve □ No □ Ye	
19. Investigational product (Give select agent	name and characterization):			
20. Federal act that authorizes investigational	use of this product:			
21. Provide a detailed justification to request (attach additional sheets if necessary):				
I hereby certify that the information contained statement on any part of this form, or its atta- 331, 9 CFR 121, or 42 CFR 73 may result in product that is, bears, or contains select age and agree that such confirmation will not viol Act (18 U.S.C. § 1905).	chments, I may be subject to criminal fines civil or criminal penalties, including impriso nts or toxin, I authorize FDA to confirm for	and/or imprisonment. I further und nment. For exemption requests th APHIS or CDC the existence and s	derstand that value the status of the line	violations of 7 CFR investigational ND, INAD, or IDE,
Signature of Investigational Product Exempti	on Applicant:		Date:	
Public reporting burden: Public reporting be reviewing instructions, searching existing date information. An agency may not conduct or searching existing the conduct or searching existing the conduct or search and conduc	ta sources, gathering and maintaining the d	ata needed, and completing and re	eviewing the c	collection of

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).

APHIS/CDC FORM 5 (XX/XX/XXXX)