

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 12/31/2018

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 Program 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 E-mail: <u>lrsat@cdc.gov</u>

SECTION 1 – TO BE COMPLETED FOR INVESTIGATIONAL PRODUCT EXEMPTION				
1. Entity name:		2. Entity registration number (if applicable):		
2. Entity address (NOT a past office address).		4 City	E Ctoto	4. Zin anda.
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. E-mail address:		
12. FDA IND/INAD/IDE number:	13. FDA product name:	14. This product has been approved for Phase I clinical trials by FDA: ☐ No ☐ Yes		
15. Date of the IND/INAD/IDE application submitted to FDA including the name of the FDA center and review office				
FDA Center/Review Office: 16. USDA veterinarian product code number: 17. USDA veterinarian product name: 18. This product has been tested and approved for field trials				
16. USDA veterinarian product code number:	17. USDA veterinarian product name:	by USDA:	n tested and approv	
19. Investigational product (Give select agent na	ame and characterization):			
20. Federal act that authorizes investigational use of this product:				
21. Provide a detailed justification to request an exemption for the use of an investigational product that is, bears, or contains select agents or toxins				
(attach additional sheets if necessary):				
,				
I hereby certify that the information contained statement on any part of this form, or its attact 331, 9 CFR 121, or 42 CFR 73 may result in c product that is, bears, or contains select agent and agree that such confirmation will not violal Act (18 U.S.C. § 1905).	nments, I may be subject to criminal fines ivil or criminal penalties, including imprisc is or toxin, I authorize FDA to confirm for a	and/or imprisonment. I furt nment. For exemption requ APHIS or CDC the existenc	her understand that uests that involve the e and status of the I	violations of 7 CFR e investigational ND, INAD, or IDE,
Signature of Investigational Product Exemption	n Applicant:		Date:	
Public reporting burden: Public reporting bur reviewing instructions, searching existing data information. An agency may not conduct or sp	sources, gathering and maintaining the d	ata needed, and completing	g and reviewing the	collection of

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 (11/30/2018)