

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/2020

Read all instructions carefully before submitting the form to either APHIS Agriculture Select Agent Services or CDC Division of Select Agents and Toxins, through the Federal Select Agent Program electronic information system or email. Instructions are available at https://www.selectagents.gov/form5.html

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 H-21-7

Atlanta, GA 30329 FAX: 404-718-2096 E-mail: lrsat@cdc.gov

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:
6. Applicant First: MI:	Last:	7. Title:		
8. Telephone #:		9. E-mail address:		
10. FDA IND/INAD/IDE number:	11. FDA product name:	12. This product has been appr trials by FDA:	oved for Phas	
13. Date of the IND/INAD/IDE application subm FDA Center/Review Office:		ite:		
14. USDA veterinarian product code number:	15. USDA veterinarian product name:	16. This product has been teste trials by USDA:	ed and approv	
17. Investigational product (Give select agent n	ame and characterization):			
18. Federal act that authorizes investigational u	ise of this product:			
19. Provide a detailed justification to request ar (attach additional sheets if necessary):				
I hereby certify that the information contained statement on any part of this form, or its attact Part 331, 9 CFR Part 121, or 42 CFR Part 73 investigational product that is, bears, or conta INAD, or IDE, and agree that such confirmatic Trade Secrets Act (18 U.S.C. § 1905).	hments, I may be subject to criminal fines may result in civil or criminal penalties, inc ins select agents or toxin, I authorize FDA	and/or imprisonment. I further un- cluding imprisonment. For exempt to confirm for APHIS or CDC the	derstand that tion requests t existence and	violations of 7 CFR that involve the d status of the IND,
Signature of Investigational Product Exemptio	n Applicant:	Da	ate:	

Public reporting burden: Public reporting burden of this collection of information is estimated to average 30 minutes per response, including 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).