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

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

INTRODUCTION

The U.S. Departments of Agriculture (USDA)and Health and Human Services (HHS) regulations (7 CFR 331, 9 CFR 121, and 42 CFR 73), which implement the provisions of the *Public Health Security and Bioterrorism Preparedness and Response Act of 2002* (Public Law 107-188) set forth the requirements for possession, use, and transfer of select agents and toxins. The select agents and toxins identified in the regulations have the potential to pose a severe threat to public health and safety, to animal and plant health, or to animal and plant products.

This exemption request (APHIS/CDC Form 5) should be sent to either APHIS or CDC:

Animal and Plant Health Inspection Service
Agricultural Select Agent Program
4700 River Road Unit 2, Mailstop 22, Cubicle 1A07
Riverdale, MD 20737
FAX: 301-734-3652
E-mail: Agricultural.Select.Agent.Program@aphis.usda.gov

Centers for Disease Control and Prevention
Division of Select Agents and Toxins
1600 Clifton Road NE, Mailstop A-46
Atlanta, GA 30333
FAX: 404-718-2096
Email: lrsat@cdc.gov

PURPOSE

The purpose of this form is to request an exemption for an investigational product that is, bears, or contains select agents or toxins when such product is being used in an investigation authorized under any federal Act listed in section 5(c) or section 6(c) of the above referenced select agent regulations. APHIS or CDC will confirm that the Food and Drug Administration (FDA) has accepted or approved, under the authority of the Food, Drug, and Cosmetics Act (21 U.S.C. 301 *et. seq.*), an Investigational New Drug application (IND), Investigational New Animal Drug (INAD) application or an Investigational Device Exemption (IDE) application for a clinical trial involving the use of an investigational product that is, bears, or contains a select agent or toxin.

A copy of the completed form and attachments must be maintained by the entity for three years.

This exemption form (APHIS/CDC Form 5) is not to be used if you are applying for an exclusion of an attenuated strain of a select agent or toxin. To apply for an exclusion, an applicant must submit a written request and supporting scientific information to APHIS or CDC (*See* 7 CFR § 331.3 (e), 9 CFR §§ 121.3(e) and 121.4(e), or 42 CFR §§ 73.3(e) and 73.4(e)).

INSTRUCTIONS

1. The applicant must complete, sign and date this form. For registered entities, the information provided for this form should match the information submitted for the entity's certificate of registration. For assistance in the completion of APHIS/CDC Form 5, please refer to the guidance document located at: http://www.selectagents.gov/ExemptionForm.html.
2. Fax, mail, or e-mail the form to APHIS or CDC.

OBTAINING EXTRA COPIES OF THIS FORM

To obtain additional copies of this form, contact APHIS at (301) 734-5960 or CDC at (404) 718-2000. This guidance document and form are also available at http://www.selectagents.gov, http://www.aphis.usda.gov/programs/ag_selectagent/index.html and http://www.cdc.gov/od/sap.

REQUEST FOR EXEMPTION OF SELECT AGENTS AND TOXINS FOR PUBLIC HEALTH OR AGRICULTURAL EMERGENCY OR 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
Agricultural Select Agent Program
4700 River Road Unit 2, Mailstop 22, Cubicle 1A07
Riverdale, MD 20737
FAX: 301-734-3652
E-mail: Agricultural.Select.Agent.Program@aphis.usda.gov

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Division of Select Agents and Toxins
1600 Clifton Road NE, Mailstop A-46
Atlanta, GA 30333
FAX: 404-718-2096
Email: lrsat@cdc.gov

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 First: MI: Last:		8. Title:		
9. Telephone #:	10. FAX #:	11. Email 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: Date:				
16. USDA veterinarian product code number:	17. USDA veterinarian product name:	18. This product has been tested and approved for field trials by USDA: ☐ No ☐ Yes		
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 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 on this form is true and correct to the best of my knowledge. I understand that if I knowingly provide a false statement on any part of this form, or its attachments, I may be subject to criminal fines and/or imprisonment. I further understand that violations of 7 CFR 331, 9 CFR 121, or 42 CFR 73 may result in civil or criminal penalties, including imprisonment. For exemption requests that involve the investigational product that is, bears, or contains select agents or toxin, I authorize FDA to confirm for APHIS or CDC the existence and status of the IND, INAD, or IDE, and agree that such confirmation will not violate FDA's information disclosure regulations, the Federal Food, Drug, and Cosmetic Act, or the Trade Secrets Act (18 U.S.C. § 1905).

Signature of Investigational Product Exemption Applicant: _____ Date: _____

Public reporting burden: Public reporting burden of this collection of information is estimated to average 1 hour 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 30333; ATTN: PRA (0920-0576).