GUIDANCE DOCUMENT FOR 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

INTRODUCTION

The U.S. Departments of Health and Human Services (HHS) and Agriculture (USDA) published final rules (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) setting forth the requirements for possession, use, and transfer of select agents and toxins. The select agents and toxins identified in the final rules have the potential to pose a severe threat to public health and safety, to animal and plant health, or to animal and plant products. Responsibility for providing guidance on this form was designated to the Centers for Disease Control and Prevention (CDC) by the HHS Secretary and to the Animal and Plant Health Inspection Service (APHIS) by the USDA Secretary. In order to minimize the reporting burden to the public, APHIS and CDC have developed a common reporting form for this data collection.

An entity may apply for an exemption from the requirements of 7 CFR 331, 9 CFR 121, or 42 CFR 73 in order to: (a) use an investigational product that is, bears, or contains select agents or toxins, or, (b) provide a response to a public health or agricultural emergency. This exemption request (APHIS/CDC Form 5) should be sent to either APHIS or CDC for consideration:

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 exemptions:

1. For exemption requests that involve the investigational product that is, bears, or contains select agents or toxins, 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.
2. For the response to an extraordinary public health or agricultural emergency(ies).

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.
   a. For applying for an exemption of an investigational product that is, bears, or contains select agents or toxins, complete section 1.
   b. For applying for an exemption to respond to a public health or agricultural emergency, complete section 2.
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.

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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
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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. Are you the: ☐ Facility Director ☐ Responsible Official ☐ Other (specify):				
13. FDA IND/INAD/IDE number:	14. FDA product name:	15. This product has been approved for Phase I clinical trials by FDA: ☐ No ☐ Yes		
16. 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:				
17. USDA veterinarian product code number:	18. USDA veterinarian product name:	19. This product has been tested and approved for field trials by USDA: ☐ No ☐ Yes		
20. Investigational product (Give select agent name and characterization):				
21. Federal act that authorizes investigational use of this product:				
22. 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: _____

SECTION 2 – TO BE COMPLETED FOR PUBLIC HEALTH OR AGRICULTURAL EMERGENCY EXEMPTION

23. Entity name:		24. Entity registration number (if applicable):	
25. Entity address (NOT a post office address):	26. City:	27. State:	28. Zip code:
29. Applicant First: MI: Last:		30. Title:	
31. Telephone #:	32. FAX #:	33. Email address:	
34. Are you the: ☐ Facility Director ☐ Responsible Official ☐ Other (specify):			
35. Name of person most familiar with public health or agricultural emergency First: MI: Last:		36. Title:	
37. Name of entity (if different than Block 23):		38. Telephone #:	
39. Address (NOT a post office address):	40. City:	41. State:	42. Zip Code:
43. Description of select agent(s) involved in public health or agricultural emergency:			
44. Describe public health or agricultural emergency including historical, clinical, and epidemiological details of emergency:			

45. Date of first confirmed case:	46. Date reported on APHIS/CDC Form 4:	47. Number of cases biweekly:	48. How diagnosis was made:
49. Name of laboratory that confirmed original diagnosis (if different than Blocks 23 or 37):			50. Telephone #:
51. Address (NOT a post office address):	52. City:	53. State:	54. Zip Code:

55. Provide a detailed justification to request an exemption in response to a public health or agricultural emergency (attach additional sheets if necessary):

INFORMATION ON SELECT AGENTS AND TOXINS INVOLVED

56. Location where laboratory testing will be conducted Building: Room:	57. Biosafety level (BSL) of laboratory or PPQ containment designation:
58. Name of Principal Investigator First: MI: Last:	
59. Type of specimens that will be received: ☐ Clinical/diagnostic specimens ☐ Environmental specimens ☐ Isolates ☐ Other (specify): _____	
60. Is this source expected to provide additional specimens? ☐ Unknown ☐ No ☐ Yes If yes, give the anticipated quantity and end date: _____	

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.

Signature of Emergency 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).