

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 12/31/2011

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: <u>Agricultural.Select.Agent.Program@aphis.usda.gov</u>

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: Irsat@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.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 12/31/2011

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

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: <u>Irsat@cdc.gov</u>

	BE COMPLETED FOR INVESTIGA					
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 sub FDA Center/Review Office:	Da	DA center and review office ate:				
17. USDA veterinarian product code number:	·	19. This product has been tested by USDA:	d and approv ☐ No ☐ Y			
20. Investigational product (Give select agent	·					
21. Federal act that authorizes investigational	use of this product:					
22. Provide a detailed justification to request a (attach additional sheets if necessary):	an exemption for the use of an investigation	aal product that is, bears, or contai	ns select age	nts or toxins		
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 product that is, bears, or contains select ager and agree that such confirmation will not violated (18 U.S.C. § 1905).	chments, I may be subject to criminal fines a civil or criminal penalties, including imprison nts or toxin, I authorize FDA to confirm for A ate FDA's information disclosure regulations	and/or imprisonment. I further und nment. For exemption requests th APHIS or CDC the existence and s	lerstand that a at involve the tatus of the II	violations of 7 CFR investigational ND, INAD, or IDE,		
Signature of Investigational Product Exemption	on Applicant:		Date:			

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: 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: 37. Name of entity (if different than Block 23): 38. Telephone #:	SECTION 2 – TO BE COMPLETED FOR PUBLIC HEALTH OR AGRICULTURAL EMERGENCY EXEMPTION									
29. Applicant First: 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: 37. Name of entity (if different than Block 23): 38. Telephone #:										
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				38. Telephone #:						
39. Address (NOT a post office address): 40. City: 41. State: 42. Zip Code	39. Address (NOT a post office ad	ddress):	40. City:	40. City: 41. State: 42. Zip Code:			42. Zip Code:			
43. Description of select agent(s) involved in public health or agricultural emergency:	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 47. Number of cases 48. How diagnosis was made:	45. Date of first confirmed case: 46. Date reported on APHIS/CDC 47. Number of cases 48. How diagnosis was made:				de:					
Form 4: biweekly:	Form 4: biweekly:			<u>'):</u>	50. Telephone #:					
	-			,			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	•		,	or agricultu			·			
necessary):	necessary):									
INFORMATION ON SELECT AGENTS AND TOXINS INVOLVED										
56. Location where laboratory testing will be conducted Building: Som: 57. Biosafety level (BSL) of laboratory or PPQ containment designati		•	57. Biosaf	ety level (BS	SL) of laboratory	or PPQ contain	nment designation:			
58. Name of Principal Investigator First: MI: Last:	58. Name of Principal Investigator	r								
59. Type of specimens that will be received: ☐ Clinical/diagnostic specimens ☐ Environmental specimens ☐ Isolates ☐ Other (specify):	59. Type of specimens that will be	e received:	□ Isolato	s \square (Other (specify):					
60. Is this source expected to provide additional specimens?	60. Is this source expected to pro	vide additional specimens? ☐ Unk								
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 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 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).