FORM APPROVED
OMB NO. 0579-0213
OMB NO. 0920-0576
EXP DATE 05/31/2005

GUIDANCE DOCUMENT FOR REQUEST FOR EXEMPTION OF SELECT AGENTS AND TOXINS

INTRODUCTION

The "Public Health Security and Bioterrorism Preparedness Response Act of 2002" (Public Law 107-188) signed into law on June 12, 2002, requires that the United States improve its ability to prevent, prepare for, and respond to bioterrorism and other public health emergencies. It necessitates that individuals possessing, using or transferring agents or toxins deemed a threat to public, animal or plant health, or to animal or plant products, notify either the Secretary of the Department of Health and Human Services (HHS) or the Secretary of the Department of Agriculture (USDA). Subsequent to enactment of this law, requirements for possession, use, and transfer of select agents and toxins were published by HHS (42 CFR 73) and by USDA (9 CFR 121 and 7 CFR 331).

Responsibility for providing guidance on this form was designated to the Centers for Disease Control and Prevention (CDC) by the Secretary, HHS, and to the Animal and Plant Health Inspection Service (APHIS) by the Secretary, USDA. In order to minimize the reporting burden to the public, HHS/CDC and the USDA/APHIS have developed a common reporting form for this data collection. This form is designed to assist entities in complying with this legal obligation.

This form should be used to apply for exemption from the requirements of 42 CFR 73, 9 CFR 121, or 7 CFR 331 in cases of: (a) Use of an investigational product, or, (b) Due to public health or agricultural emergency. This exemption request should be sent to either CDC or APHIS, as appropriate, for exemption consideration. For HHS agents and toxins, the applicant should contact CDC (telephone: 404-498-2255; facsimile: 404-498-2265). For HHS/USDA overlap agents, the applicant should contact either APHIS or CDC. For USDA agents and toxins, the applicant should contact APHIS (telephone: 301-734-5960; facsimile: 301-734-3652). A listing of HHS select agents and toxins is available at http://www.cdc.gov/od/sap. A listing of USDA animal agents and toxins is available at http://www.aphis.usda.gov/vs/ncie/bta.html. The list of plant agents and toxins is available at http://www.aphis.usda.gov/ppq/permits.

This form is not for use when applying for an exclusion. To apply for an exclusion, an applicant must submit a letter to the HHS Secretary (see 42 CFR 73.21) or to the USDA Secretary (9 CFR 121, 7 CFR 331) that provides information that establishes that it is eligible for exclusion. Information in the letter should include at a minimum: strain, how strain was derived; how it is ascertained that it does not pose a severe threat to public health or to animal or plant health or to animal or plant products, and all citation or pertinent data to support your request.

INSTRUCTIONS

Entities may apply for an exemption from the requirements of 42 CFR 73, 9 CFR 121, or 7 CFR 331 using this form (1) If the entity possesses, uses, or transfers investigational or experimental products (IND) that are, bear, or contain select agents or toxins; or (2) In order to respond to a domestic or foreign public health or agricultural emergency.

All applicants must complete Section 1. Section 2 should be completed for those entities that wish to request an exemption due to investigational use of select agents or toxins. Section 3 should be completed for those entities that wish to apply for an exemption due to a public health or agricultural emergency. Applicants must sign and date the form.

OBTAINING EXTRA COPIES OF THIS FORM

To obtain additional copies of this form, contact the CDC at (404) 498-2255 or APHIS at (301) 734-5960. This guidance document and form are also available at http://www.cdc.gov/od/sap, http://www.aphis.usda.gov/vs/ncie/bta.html and http://www.aphis.usda.gov/ppq/permits.

WHERE TO SEND THE COMPLETED FORM

For HHS agents, return completed forms to: Centers for Disease Control and Prevention, Select Agent Program, 1600 Clifton Road NE, Mailstop E-79, Atlanta, GA 30333.

For USDA agents, return completed forms to: Agricultural Select Agent Program, 4700 River Road Unit 2, Mailstop 22, Cubicle 1A07, Riverdale, MD 20737.

For HHS/USDA overlap select agents, return forms to: either CDC or APHIS at the addresses provided.

This form shall not be disclosed under the Freedom of Information Act. Under Public Law 107-188, information derived from this form is also protected from release.

FORM APPROVED
OMB NO. 0579-0213
OMB NO. 0920-0576
EXP DATE 05/31/2005

REQUEST FOR EXEMPTION OF SELECT AGENTS AND TOXINS

Read all instructions carefully before completing the form. Answer all items completely and type or print in ink. The form must be signed. For HHS agents, submit document to: Centers for Disease Control and Prevention, Select Agent Program, 1600 Clifton Rd NE, Mailstop E-79, Atlanta, GA 30333. For HHS/USDA overlap agents submit the form to either CDC or APHIS. For USDA agents, submit document to: Agricultural Select Agent Program, 4700 River Road Unit 2, Mailstop 22, Cubicle 1A07, Riverdale, MD 20737.

SECTION 1 – TO BE COMPLETED BY ALL APPLICANTS

Entity name			Entity registration number (if applicable)	
Entity address (NOT a post office address)		City	State	Zip code
Applicant	Title	Telephone	FAX	E-mail
Business Address (NOT a post office address)		City	State	Zip Code

Are you the:
☐ Laboratory Director ☐ Responsible Official ☐ Other (specify):

SECTION 2 – TO BE COMPLETED FOR INVESTIGATIONAL/ EXPERIMENTAL PRODUCT EXEMPTION

FDA IND number	FDA product name	This product has been approved for Phase I clinical trials by FDA: ☐ Yes ☐ No
USDA veterinarian product code number	USDA veterinarian product name	This product has been tested and approved for field trials by USDA: ☐ Yes ☐ No

Investigational/ Experimental product (Give select agent name and characterization)

Federal act that authorizes investigational use of this product

Provide a detailed justification for exemption from registration for select agents and toxins due to investigational use. Provide sufficient detail to argue that applying additional regulation under 42 CFR 73, 9 CFR 121, or 7 CFR 331 (as applicable) would not be necessary to protect public health and safety (attach additional sheets if necessary):

SECTION 3 – TO BE COMPLETED FOR PUBLIC HEALTH OR AGRICULTURAL EMERGENCY EXEMPTION

INFORMATION ON PUBLIC HEALTH OR AGRICULTURAL EMERGENCY

Name of person most familiar with public health or agricultural emergency	Telephone number

Description of select agent(s) involved in public health or agricultural emergency

Description of disease caused by select agent(s):

Date of first confirmed cases	Number of cases biweekly	How diagnosis was made

Laboratory that confirmed original diagnosis	Name, address and phone of laboratory director

Describe circumstances of public health/ agricultural emergency (attach additional sheets if necessary):

INFORMATION ON SELECT AGENTS AND TOXINS INVOLVED

Location where work with specimens will be conducted: Building: Room:

Biosafety level of laboratory	Name of Principal Investigator

Type of specimens that will be received:

- ☐ Clinical/diagnostic (Specify from which species): _____
- ☐ Isolates (Specify how and when they will be characterized): _____
- ☐ Environmental (Specify): _____
- ☐ Other (Specify): _____

Is this source expected to provide additional specimens? ☐ Yes ☐ No

Anticipated quantity of specimens to be received:

Anticipated time period to receive specimen (give estimated 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 42 CFR 73, 9 CFR 121 or 7 CFR 331 may result in civil or criminal penalties, including imprisonment.

Signature of Applicant: _____ Typed or printed name of Applicant: _____

Title of Applicant: _____ Date: _____