



**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>.

