Guidance Document for Completing the Request for Exemption of Select Agents and Toxins for an Investigational Product

Please review this guidance document in its entirety before completing and submitting your request for investigational product exemption to Federal Select Agent Program (either Animal and Plant Health Inspection Service (APHIS) or Centers for Disease Control and Prevention (CDC)).

An entity may apply for an exemption from the requirements of 9 CFR Part 121 or 42 CFR Part 73 in order to use an investigational product that is, bears, or contains select agents or toxins. The APHIS/CDC Form 5 should be sent to either APHIS or CDC for consideration.

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Section 1 – Investigational Product Exemption

For a request for exemption that involve the investigational **or experimental** 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 **or experimental** product that is, bears, or contains a select agent or toxin.

Block 1, Entity Name

- Please provide the complete name of your entity (corporation, partnership, sole proprietorship, etc.) under which the business conducts its operations (e.g., Animal and Plant Health Inspection Service instead of APHIS).
- Please do not abbreviate the organization name.

Block 2, Entity Registration Number

- For entities registered with APHIS or CDC, please enter the registration number exactly as it appears on your entity's current certificate of registration. The registration number is a 13 digit number which begins with an A or C and is not the entity application number (e.g. A00000000-0000 *or* C00000000-0000).
- Non-registered entities should leave this field blank.

Blocks 3-6, Entity Address

- For entities registered with APHIS or CDC, please provide your entity's complete address, exactly as it appears on your current certificate of registration.
- For non-registered entities, please provide the complete physical address of your entity and not a P.O. Box address.
- Zip Code – please provide only the five digit zip code.

Block 7, Applicant

- Please provide the full name of the applicant (i.e., the individual completing the form on behalf of the entity (e.g., Responsible Official or Facility Director)).
    - For the purposes of completing the Request for Exemption form, the term "full name" refers to an individual's first name, middle initial(s), and last name or surname, without use of nicknames.

Block 8, Title

- Please provide the title of the Applicant listed in *Block 7* (i.e., Responsible Official, Facility Director, Laboratory Supervisor).

Block 9, Telephone Number

- Please provide the direct dial 10-digit telephone number for the Applicant listed in *Block 7*; include an extension, if required.

Block 10, Fax Number

- Please provide the 10-digit facsimile number for the Applicant listed in *Block 7*.

Block 11, Email Address

- Please provide the email address for the Applicant listed in *Block 7*.
- Please print or type clearly; and ensure that you include the email domain (e.g., .org, .gov, .edu, .com, .net).

Block 12, Are you the:

- Please indicate the role of the individual listed in *Block 7*.
  - For the purposes of the APHIS/CDC Form 5, the term "Facility or Laboratory Director" refers to the chief person responsible for the operation of the laboratory and who ensures that quality standardized testing methods provide accurate and reliable results.
  - "Responsible Official" refers to the individual designated by an entity that is registered with APHIS or CDC with the authority and control to ensure compliance with the regulations in 7 CFR Part 331, 9 CFR Part 121, and 42 CFR Part 73.

Block 13, FDA IND/INAD/IDE Number

- Please provide the Investigational New Drug Application (IND), Investigational New Animal Drug file (INAD), or Investigational Device Exemption number (IDE) that was provided by U.S. Food and Drug Administration (FDA).

Block 14, FDA Product Name

- Please provide the product name that bears or contains the select agent or toxin that was listed on the application for IND, INAD or IDE.

Block 15, Phase I Approval

- Please indicate whether this product has been approved for Phase I clinical trials by FDA.

Block 16, FDA Center and IND/INAD/IDE Application Date

- Please indicate the date when the IND/INAD/IDE application submitted to FDA.
- Please provide the name of the FDA center (e.g., Center for Biologics Evaluation and Research (CBER), Center for Drug Evaluation and Research (CDER), Center for Devices and Radiological Health (CDRH), or Center for Veterinary Medicine (CVM)) where the application for the IND, INAD, or IDE was submitted and the review office name.

Block 17, USDA Product Code Number

- Please provide the product code number that was provided by U.S. Department of Agriculture (USDA).

Block 18, USDA Veterinarian Product Name

- Please provide the product name that bears or contains the select agent or toxin that was listed on the application submitted to USDA.

Block 19, Tested and Approved for Field Trials

- Please indicate whether this product has been tested and approved for field trials by USDA.

Block 20, Investigational Product

- Please list the select agent or toxin contained in the investigational product and any characteristics of the agent (e.g., *Bacillus anthracis* (Ames strain)).

Block 21, Federal Act Authorization

- Please indicate the Federal Act(s) that authorizes investigational use of this product (e.g., Federal Food, Drug, and Cosmetic Act, Section 351 of the Public Health Service Act pertaining to biological products, Act commonly known as the Virus-Serum-Toxin Act, or Federal Insecticide, Fungicide, and Rodenticide Act).

Block 22, Exemption Justification

- Provide a detailed justification to request an exemption for the use of an investigational product that is, bears, or contains select agents or toxins (e.g., human clinical trials).

Signature of Investigational Product Exemption Applicant

IMPORTANT NOTE: By signing and submitting the completed *Request for Exemption of Select Agents and Toxins for Investigational Product* to APHIS or CDC, the applicant is certifying that the information contained on the form is true and correct to the best of their knowledge. Additionally, the applicant is acknowledging that any false statement made in the signed/submitted application may subject them to criminal penalties pursuant to *18 U.S.C. 1001*. The applicant is also acknowledging that violations of 9 CFR Part 121 or 42 CFR Part 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, the applicant is also authorizing FDA to confirm for APHIS or CDC the existence and status of the IND, INAD, or IDE, and is agreeing 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 (REQUIRED)

- The Applicant listed in *Section 1*, *Block 7* must sign the completed exemption request form.

Date Signed

- Please enter the date the Applicant signs the completed form.

Document Change History

Version	Date	Summary of Changes
1.0	October 2011	Initial Release
1.1	January 2012	Added links and updated footer