Instructions

Answer all items completely and type or print in ink. Questions concerning the completion of this form can be directed to the respective agency listed below:

Division of Agricultural Select Agents and Toxins
Telephone: (301) 851-2070
Email: DASAT@usda.gov

Division of Regulatory Science and Compliance
Telephone: (404) 718-2000
Email: lrsat@cdc.gov

This form must be signed and submitted to either:

Division of Agricultural Select Agents and Toxins
4700 River Road Unit 2, Mailstop 22, Cubicle 1A07
Riverdale, MD 20737
FAX: (301) 734-3652
Email: DASAT@usda.gov

Division of Regulatory Science and Compliance
1600 Clifton Road NE, Mailstop H21-4
Atlanta, GA 30329
FAX: (404) 718-2096
Email: lrsat@cdc.gov

Section 1 – Investigational Product Exemption

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.

Block 1 – Entity Name:

- 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 2-5 – 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.

Block 6 – Applicant Name:

- Provide the full name of the applicant (i.e., the individual completing theform on behalf of the entity (e.g., Responsible Official or Facility Director)).
  - For the purposes of completing the Exemption Request 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 7 – Title:

- Provide the title of the individual listed in Block 6 (i.e., Responsible Official, Facility Director, Laboratory Supervisor).
  - For the purposes of the APHIS/CDC Form 5, the term 'Facility or Laboratory Director' refers to the person with overall responsibility for the operation of the laboratory and who ensures that quality standardized testing methods provide accurate and reliable results.
  - 'Responsible Official' is the individual designated by a registered entity as the responsible official.

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- ‘Laboratory Supervisor’ refers to the individual who is responsible for the supervision of a laboratory department and its procedures.

Block 8 – Telephone Number:

- Provide the direct dial 10-digit telephone number for the Applicant listed in Block 6; include an extension, if required.

Block 9 – Email Address:

- Provide the email address for the Applicant listed in Block 6.
- Print or type clearly; and ensure that you include the email domain (e.g., .org, .gov, .edu, .com, .net).

Block 10 – FDA IND/INAD/IDE Number:

- 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 11 – FDA Product Name:

- 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 12 – Phase I Approval:

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

Block 13 – FDA Center and IND/INAD/IDE Application Date:

- Indicate the date when the IND/INAD/IDE application was submitted to FDA.
- 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 14 – USDA Veterinarian Product Code Number:

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

Block 15 – USDA Veterinarian Product Name:

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

Block 16 – Tested and Approved for Field Trials:

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

Block 17 – Investigational Product:

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

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Block 18 – 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 19 – 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:

- The Applicant listed in Block 6 must sign the completed exemption request form.
- Enter the date the Applicant signs the completed form.