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OMB Approved  
0579-0013  
Exp Date: xx/xxxx

This application may be submitted to request authorization to ship experimental biological product, as specified in 9CFR 103.3. **INSTRUCTIONS: See reverse side.**

U.S. DEPARTMENT OF AGRICULTURE ANIMAL AND PLANT HEALTH INSPECTION SERVICE VETERINARY SERVICES, CENTER FOR VETERINARY BIOLOGICS <b>APPLICATION FOR AUTHORIZATION TO SHIP EXPERIMENTAL                  VETERINARY BIOLOGICAL PRODUCTS</b>	1. NAME AND FULL MAILING ADDRESS OF APPLICANT
2. U.S. VET. EST. NO. (if applicable)	3. APPLICATION TYPE: <input type="checkbox"/> NEW <input type="checkbox"/> AMENDMENT TO SUBMISSION DATED _____ AND/OR PRIOR CVB MAIL LOG ID _____

**4. PRODUCT(S) TO BE SHIPPED (CHECK HERE  IF ADDITIONAL PRODUCT INFO APPENDED)**

A. BIOLOGICAL PRODUCT TRUE NAME OR DESCRIPTION (INCLUDING ANY INTERNAL IDENTIFIER IF THE PRODUCT DOES NOT HAVE AN APHIS PRODUCT CODE)	B. APHIS PROD CODE	C. SERIAL/LOT ID(S)	D. MAX QTY (DS OR ML)
	<input type="checkbox"/> UNL <input type="checkbox"/> LIC		
	<input type="checkbox"/> UNL <input type="checkbox"/> LIC		

**5. RECIPIENT(S) (CHECK HERE  IF ADDITIONAL RECIPIENT INFO APPENDED)**

A. NAME AND SHIPPING ADDRESS	B. LOCATION OF PRODUCT USE (IF DIFFERS FROM 6A)

**CHECKLIST FOR SUPPORTING MATERIAL**

ITEM	DESCRIPTION	A. WITH THIS APPLICATION ("X")	B. DATE OR CVB MAIL LOG ID OF PREV SUBMISSION
6. METHOD OF PRODUCTION	<input type="checkbox"/> OUTLINE OF PRODUCTION (9CFR 114.9) <input type="checkbox"/> SIMILAR INFO		
7. PRODUCT TEST RESULTS	<input type="checkbox"/> APHIS FORM 2008 <input type="checkbox"/> OTHER		
8. PERMIT OR LETTER OF PERMISSION FROM AUTHORITIES IN EACH STATE/FOREIGN COUNTRY	LIST STATE(S) OR FOREIGN COUNTRY:		
9. STUDY PROTOCOL NO. _____	<input type="checkbox"/> PIVOTAL USDA LICENSING STUDY <input type="checkbox"/> EXPLORATORY <input type="checkbox"/> FOR INTERNATIONAL REGISTRATION		
10. DISTRIBUTION OF PRODUCT AMONG MULTIPLE RECIPIENTS (if applicable)			
11. EXPERIMENTAL LABELS (2 copies)			
12. DATA TO DEMONSTRATE WHOLESOMENESS OF MEAT (if applicable)			
13. OTHER			
14. BIOSECURITY OF STUDY FACILITY: <input type="checkbox"/> BSL 1 <input type="checkbox"/> BSL 2 <input type="checkbox"/> BSL 3 <input type="checkbox"/> FIELD STUDY/ UNSPECIFIED BIOCONTAINMENT			
15. DISPOSITION OF UNUSED PRODUCT: <input type="checkbox"/> DESTROY ONSITE <input type="checkbox"/> RETURN TO APPLICANT <input type="checkbox"/> OTHER (describe) _____			
16. DISPOSITION OF ANIMALS: <input type="checkbox"/> ONSITE DISPOSAL <input type="checkbox"/> RETURN TO OWNER <input type="checkbox"/> SLAUGHTER NO LESS THAN _____ DAYS AFTER FINAL PRODUCT USE <input type="checkbox"/> OTHER (describe) _____			

*I agree to ship this experimental product in accordance with 9CFR 103.3 and conduct the study according to the filed protocol, also observing any additional conditions imposed by the State or foreign country in which the study will be conducted. I agree to furnish, upon request, additional information concerning meat animals prior to moving these animals from the test premises. Upon conclusion of the studies, I agree to summarize the results and submit them to APHIS.*

17. PRINTED NAME AND TITLE OF APPLICANT	18. SIGNATURE OF APPLICANT	19. DATE SUBMITTED
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**FOR VETERINARY BIOLOGICS USE ONLY**

*The applicant is authorized to ship the above experimental product to the designated recipients to conduct the specified study, with any Exceptions that may be attached (i.e., if there is a check in the box in item 20). In the event the product is compromised prior to use, one repeat shipment may be made. This authorization is effective for one year from the date in Item 21. If a pivotal USDA licensing study protocol was submitted with this application, comments on the study may be returned under separate cover. Other protocols are filed for information only, unless CVB comments are explicitly requested.*

20. APPLICATION APPROVED BY (Signature)	<input type="checkbox"/> CVB EXCEPTIONS ATTACHED <input type="checkbox"/> DATE-STAMPED LABELS ENCLOSED	21. DATE APPROVED	22. CVB MAIL LOG NO.
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#### **INSTRUCTIONS FOR COMPLETING APHIS FORM 2071:**

Submit one copy of the form. Enclose one copy of each supporting document, except for labels (Line Item 12). If additional space is needed, attach additional sheets and refer to Item No.

If APHIS's Center for Veterinary Biologics (CVB) approves the request, the CVB will complete items 20-22 and return the form to the applicant.

#### **1. NAME AND FULL MAILING ADDRESS OF APPLICANT**

Enter the establishment name and complete mailing address (street, city, state, ZIP) of the applicant. The processed form will be returned to this address.

#### **2. U.S. VETERINARY ESTABLISHMENT NUMBER**

Enter the veterinary biologics establishment number assigned by APHIS, if one has been assigned.

#### **3. APPLICATION TYPE**

Indicate whether this is a new request or an amendment to a prior authorization. If it is an amendment, enter the submission date and, if known, the CVB mail log number of the prior submission. The CVB mail log number appears in Item 22 of all processed forms.

#### **4. PRODUCT TO BE SHIPPED**

- A. True Name or Description: Enter the True Name designated by APHIS, if applicable. Otherwise provide a clear description of the product; avoid acronyms. Specify any in-house codes that may assist in identifying this product.
- B. APHIS Product Code: Enter the Product Code assigned by APHIS, if applicable. Otherwise, enter NA. (Enter internal working codes in item 4A.) Check whether the product is currently licensed by the USDA (LIC). Select UNL if the product is currently in the USDA licensing process, is not yet under consideration for licensure, or is not intended for licensure.
- C. Serial or Lot Number: Enter the unique lot identification for the product batch being shipped. If more than one lot of the same product is being shipped, it is permissible to enter more than one identification per line.
- D. Maximum Quantity to be Shipped: Enter the maximum quantity of each serial to be shipped. Indicate whether the quantity is expressed in mL or doses.

#### **5. RECIPIENT**

- A. Name and Shipping Address: Enter the name, affiliation, and complete shipping address of each recipient of the experimental product.
- B. Location of Product Use: If the study location differs from the shipping address, specify the study location(s). Otherwise, enter NA.

#### **CHECKLIST OF SUPPORTING MATERIAL**

Items 6-11 and 14-16 in the checklist should be addressed for every application. Items 12-13 should be provided as applicable. If supporting information is attached to, or provided concurrently with, the application, place an X in column A of the corresponding item. If the information was provided previously, it is permissible to cite the submission date and/or CVB Mail Log Number of the previous submission in lieu of providing another copy.

#### **6. METHOD OF PRODUCTION**

Clearly explain how the experimental product was made. The most efficient means is to provide an Outline of Production, formatted according to 9CFR 114.9. If an Outline is not available, ensure that the document provided covers the same general production points found in Outline sections I-IV.

#### **7. PRODUCT TEST RESULTS**

The minimum testing required is sterility or purity testing; additional tests may be required by APHIS depending on the nature of the product and the study purpose. If the product is licensed or in the USDA licensing process, provide the results of tests described in Section V of the Outline of Production. Ideally submit these results on APHIS Form 2008, but an alternative document is acceptable. For exploratory studies unrelated to product licensing, provide a summary of preliminary research work.

#### **8. PERMIT OR LETTER OF PERMISSION FROM AUTHORITIES IN EACH STATE/FOREIGN COUNTRY**

Authorization must be obtained from each state and foreign country described in Items 5A and 5B. Attach a copy of each State authorization or acknowledgement letter. Attach a copy of the import permit for each foreign country. If no import permit is required, attach a document stating this.

#### **9. STUDY PROTOCOL**

Attach a study design/protocol for the *in vivo* work to be performed with the experimental product.

If the protocol has a unique study identifier, enter it in the blank indicated. Check whether the study is a pivotal USDA licensing study, an exploratory (non-pivotal) study, or is being conducted solely to support international registration. The CVB conducts in-depth reviews and provides comments on pivotal USDA licensing study protocols. Unless otherwise requested, exploratory and international registration study protocols are filed for information without return comments.

#### **10. DISTRIBUTION OF PRODUCT AMONG MULTIPLE RECIPIENTS**

If the experimental product is to be distributed among multiple recipients, attach a document listing the quantity of each serial(s) to be provided to each recipient.

**11. EXPERIMENTAL LABELS**

Submit two copies of each of the labels that will be affixed to the experimental product. Format the labels according to 9CFR 103.3(d). Avoid acronyms and abbreviations in the product name.

**12. DATA TO DEMONSTRATE WHOLESOMENESS OF MEAT**

If the study is being conducted in meat animals and the study animals will be sent to slaughter for human consumption after participating in the study, attach information (such as residue clearance data) to demonstrate that the meat from the study animals should be wholesome.

**13. OTHER**

APHIS may request additional information to support applications for certain products or to conduct certain types of studies. If applicable, briefly describe the purpose of the additional information in the line provided and attach supporting documentation.

**14. BIOSAFETY OF STUDY FACILITY**

Indicate whether the facility meets the requirements of a biosafety level (BSL) described in *Biosafety in Microbiological and Biomedical Laboratories* published by, and available from, the Centers for Disease Control ([www.cdc.gov](http://www.cdc.gov)). Otherwise, describe the biocontainment features the facility has.

**15. DISPOSITION OF UNUSED PRODUCT**

Specify how the recipient will dispose of unused product when the study is completed.

**16. DISPOSITION OF STUDY ANIMALS**

Specify how surviving study animals will be handled at the conclusion of the study.

**17. PRINTED NAME AND TITLE OF APPLICANT**

If the applicant has been assigned a U.S. veterinary biologics establishment number, the APHIS primary or alternate liaison should serve as the applicant.

**18. SIGNATURE OF APPLICANT**

Self-explanatory

**19. DATE SUBMITTED**

This date should correspond to the date the application is mailed. This will be the submission date cited in all return correspondence.

**THE FOLLOWING ITEMS ARE FOR VETERINARY BIOLOGICS USE ONLY**

**20. APPLICATION APPROVED BY**

Signature of the APHIS-CVB official approving the application. If APHIS identifies any exceptions or special circumstances regarding the authorization to ship samples, they will be noted on an attached document. If the application is not approved, the form will not bear a signature in this item and reasons for denial will be attached. If APHIS attaches documents to the return form, a check will appear in the appropriate box(es) in this item.

**21. DATE APPROVED**

Self-explanatory. Shipment of experimental product should not occur prior to this date.

**22. CVB MAIL LOG NUMBER**

The application is assigned a unique tracking number when received by APHIS. For improved efficiency, cite this number in future communications regarding this application.