According to the Paperwork Reduction Act of 1995, an agency may not conduct or sponsor, and a person is not required to respond to a collection of information unless it displays a valid OMB control number. The valid OMB control number for this information collection is 0579-0013. The time required to complete this information collection is estimated to average 1 hour per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information.

OMB Approved
0579-0013
EXP DATE xx/xxxx

This application may be submitted to request authorization to ship biological product samples for confirmatory testing by APHIS.

INSTRUCTIONS: See reverse side.

U.S. DEPARTMENT OF AGRICULTURE
ANIMAL AND PLANT HEALTH INSPECTION SERVICE
VETERINARY SERVICES, CENTER FOR VETERINARY BIOLOGICS (CVB)

APPLICATION FOR AUTHORIZATION TO SHIP BIOLOGICAL PRODUCT SAMPLES FOR CONFIRMATORY TESTING BY APHIS

1. NAME AND FULL MAILING ADDRESS OF APPLICANT

2. U.S. VET. EST. NO.

3. APPLICATION TYPE: ☐ NEW ☐ AMENDMENT
TO SUBMISSION DATED_____
AND/OR PRIOR CVB MAIL LOG NO_____

4. PURPOSE: ☐ PRE-LICENSE ☐ POST-LICENSE OUTLINE CHANGE ☐ OTHER (describe) _____

5. ITEM(S) TO BE SHIPPED **(CHECK HERE ☐ IF ADDITIONAL ITEM INFORMATION IS APPENDED)**

A.TRUE NAME OF PRODUCT	B. PRODUCT CODE	C. SERIAL NUMBER

CHECKLIST FOR SUPPORTING MATERIAL FOR CONFIRMATORY TESTING

ITEM	DESCRIPTION (SEE INSTRUCTIONS ON REVERSE FOR DETAILS)	A. WITH THIS APPLICATION ("X")	B. DATE AND/OR CVB MAIL LOG NO OF PRIOR SUBMISSION
6. ITEMIZATION OF SERIAL RELEASE TESTING, VALIDITY CRITERIA, REQUIREMENTS FOR RELEASE	SECTION V OF OUTLINE OF PRODUCTION (9CFR 114.9) IN FINAL FORMAT		
7. STEPWISE PROTOCOLS FOR EACH ASSAY IN SECTION V OF OUTLINE OF PRODUCTION	☐ OUTLINE OF PRODUCTION (9CFR 114.9) ☐ SPECIAL OUTLINE		
8. ASSAY VALIDATION REPORT(S)	TO BE SUBMITTED *PRIOR TO* REQUESTING AUTHORIZATION TO SUBMIT SAMPLES		
9. DILUTION OF PRESERVATIVE STUDY	9CFR 113.25(d)		
10. RESULTS OF TESTING CONDUCTED BY APPLICANT	APHIS FORM 2008		
11. OTHER			

12. BY DEFAULT, ALL CVB COMMUNICATIONS ARE DIRECTED TO THE APHIS LIAISON FOR THE ESTABLISHMENT. IF YOU WISH TO DESIGNATE A LABORATORY CONTACT TO HANDLE COMMUNICATIONS FOR THIS CONFIRMATORY TESTING, LIST THIS INDIVIDUAL BELOW.

A. CONTACT NAME	B. PHONE	C. EMAIL

I agree to ship this product in accordance with 9CFR 113.3, under cover of APHIS Form 2020, and to provide any test reagents requested by the CVB. I agree to provide the CVB with an anticipated shipping date for reagents. Once shipped, I will provide tracking information.

13. OTHER COMMENTS

14. PRINTED NAME AND TITLE OF APPLICANT	15. SIGNATURE OF APPLICANT	16. DATE SUBMITTED

FOR CENTER FOR VETERINARY BIOLOGICS USE ONLY

The applicant is authorized to ship the above product(s) to the CVB, with any Exceptions that may be attached (i.e., if there is a check in the box in item 20). The CVB Laboratory Coordinator (item 18) will contact the APHIS liaison or, if applicable, the designated Contact (item 12) to discuss needed reagents. Ship the requested quantity of samples and/or reagents under cover of APHIS Form 2020, noting the test authorization in the Remarks section. Ship to the CVB address listed above, addressed to the attention of the CVB Laboratory Coordinator.

17. TEST AUTHORIZATION NO

18. CENTER FOR VETERINARY BIOLOGICS LABORATORY COORDINATOR	19. COORDINATOR'S EMAIL

20. APPLICATION APPROVED BY (Signature) ☐ CVB EXCEPTIONS ATTACHED	21. DATE APPROVED	22. CVB MAIL LOG NO.

INSTRUCTIONS FOR COMPLETING APHIS FORM 2072:
Submit one copy of the form. Enclose two copies of each supporting document, except for electronic files. 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 4E and 14-21 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.

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 21 of processed forms.

4. PURPOSE
Indicate whether the confirmatory testing is for a prelicense product or a licensed product with a proposed change in manufacture (Outline of Production change). If testing is being conducted for another purpose, please describe.

5. ITEMS TO BE SHIPPED
Applicants should submit samples in accordance with 9CFR 113.3. Indicate the True Name, USDA Product Code, and serial number of the product(s) to be shipped. It is permissible to enter more than one serial number on a single line.

CHECKLIST OF SUPPORTING MATERIAL
The checklist includes items that must be satisfactorily reviewed by the CVB prior to authorizing submission of product samples for confirmatory testing. 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 prior submission in lieu of providing another copy.

6. Itemization of Serial Release Testing: Section V of the Outline of Production (9CFR 114.9) should be in its expected final format with regard to tests conducted, validity criteria, and requirements for a satisfactory serial.

7. Stepwise Protocols for tests: Stepwise assay protocols, with sufficient detail for the CVB laboratory to replicate the assay, should be provided either in Section V of the Outline of Production or Special Outlines.

8. Assay validation reports: All non-codified assays must be validated for use in serial release testing. Please submit validation reports *prior to* submitting an application to ship product samples. Assays must be validated before the CVB conducts confirmatory testing.

9. Dilution of preservative study: Testing per 9CFR 113.25(d) must be conducted to determine the appropriate volume of diluent for sterility and purity testing (9CFR 113.26 or 113.27).

10. Results of Testing Conducted by the Applicant: All Section V testing must be conducted by, or under the oversight of, the applicant prior to requesting confirmatory testing. Submit all results on APHIS Form 2008. See Veterinary Services Memorandum 800.53 for additional guidance on completing APHIS Form 2008.

11. Other: The CVB may request other data to support an application to submit samples for confirmatory testing. Any such requirements will be communicated by the CVB licensing reviewer for the applicant.

12. APPLICANT'S LABORATORY CONTACT
By default, the CVB communicates through the APHIS liaison for the applicant establishment. The applicant, however, may designate a Laboratory Contact to serve as the point of contact for all communications regarding the testing of this product. Provide the contact's name, phone number, and email address. If all communications should go through the APHIS liaison, enter NA (not applicable).

13. OTHER COMMENTS
Enter any other pertinent information here.

14. PRINTED NAME AND TITLE OF APPLICANT
The APHIS primary or alternate liaison for the establishment should serve as the applicant.

15. SIGNATURE OF APPLICANT
Self-explanatory

16. 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 CENTER FOR VETERINARY BIOLOGICS USE ONLY

17. TEST AUTHORIZATION NO
The CVB will issue a Test Authorization Number for the Product(s). Include this number in the Remarks section of the APHIS Form 2020 that accompanies the samples, as well as any other communications regarding the testing.

18-19. CENTER FOR VETERINARY BIOLOGICS LABORATORY COORDINATOR AND PHONE NUMBER
The CVB designates a Laboratory Coordinator for confirmatory testing. This contact serves as the laboratory point of contact for interactions with the applicant and the CVB licensing reviewer.

20. APPLICATION APPROVED BY
Signature of 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 box in this item.

21. DATE APPROVED
Self-explanatory. Shipment of product should not occur prior to this date.

22. CVB MAIL LOG NUMBER
The application is assigned a unique tracking number when received by the CVB. For improved efficiency, cite this number in future communications regarding this application.