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: XX/XXXX

This application must be submitted for issuance of a U.S. Veterinary Biological Product License (9 CFR 102). See instructions on reverse side for additional guidance.

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

APPLICATION FOR UNITED STATES VETERINARY BIOLOGICAL PRODUCT LICENSE

FOR VETERINARY BIOLOGICS USE ONLY

USDA PRODUCT CODE NUMBER

2. NAME AND ADDRESS OF APPLICANT (*Include No., Street, or RFD No., City, State, ZIP Code)*

1. VETERINARY BIOLOGICS ESTABLISHMENT NUMBER

3. ADDRESS OF PREMISES TO BE USED IF DIFFERENT FROM ITEM 2

4. BIOLOGICAL PRODUCT TRUE NAME

5. APPLICANT'S INTERNAL WORKING IDENTIFIER FOR PRODUCT (*if applicable*)

6. RELATIONSHIP OF NEW PRODUCT TO OTHER LICENSED, PRELICENSE, OR TERMINATED PRODUCTS FOR YOUR ESTABLISHMENT (*See instructions on reverse for detailed guidance*.)

7. OTHER COMMENTS

CHECKLIST FOR SUPPORTING MATERIAL

ITEMS SUBMITTED	DESCRIPTION	A. WITH THIS APPLICATION (X)	B. DATE OR CVB MAIL LOG ID OF PREVIOUS SUBMISSION
8. METHOD OF PRODUCTION	☐ OUTLINE OF PRODUCTION (*9 CFR 114.9*) ☐ SIMILAR INFORMATION		
9. PRIOR SUBMISSIONS (IF ANY) FOR THIS PRODUCT WHICH WERE PROCESSED BEFORE A USDA PRODUCT CODE WAS ASSIGNED			
10. OTHER (*specify*)			

CERTIFICATION

In accordance with the Act of Congress approved March 4, 1913 (37 Stat. 832-833: 21 U.S.C. 151-158) application is hereby made for a license to prepare the herein named animal biological product for use in the treatment of domestic animals. If a license is issued under this application, the licensee expressly agrees to comply with the provisions of the said Act, and all rules, regulations, and orders of the Department issued pursuant thereto governing the preparation, testing, and distribution of the animal biological product, and that the animal biological product will not be labeled or advertised so as to mislead or deceive the purchaser in any particular.

In case a product license is issued, it is further agreed that the biological product shall be subject to any additional requirements or restrictions stated therein.

11. SIGNATURE OF AUTHORIZED OFFICIAL	12. TITLE	13. DATE SIGNED

INSTRUCTIONS FOR APHIS FORM 2003:
Submit one copy of the form. If additional space is needed, attach additional sheets and refer to Item No.

1. VETERINARY BIOLOGICS ESTABLISHMENT NUMBER
Enter the veterinary biologics establishment number assigned by APHIS, if one has been assigned.

2. NAME AND ADDRESS OF APPLICANT
Enter the establishment name and complete mailing address (street, city, state, ZIP) of the applicant. If the applicant has been assigned a veterinary biologics establishment number by APHIS, enter the mailing address on file with APHIS.

3. INTENDED SITE(S) OF MANUFACTURE AND TESTING
List the intended site(s) of manufacture and testing for this product.

4. BIOLOGICAL PRODUCT TRUE NAME
The True Name includes all of the antigenic fractions of the product for which a label claim is intended. See the current catalog of licensed biological products (https://www.aphis.usda.gov/aphis/ourfocus/animalhealth/veterinary-biologics/ct_vb_licensed_products) for examples. The True Name listed by the applicant on this application should be considered preliminary. APHIS assigns True Names according to numerous established conventions intended to promote standardization, so the True Name under which the product is licensed may differ.

5. APPLICANT'S INTERNAL WORKING IDENTIFIER FOR PRODUCT
Manufacturers frequently designate working identifiers for new products prior to being assigned a USDA product code. If such an identifier exists, it may be entered here.

6. RELATIONSHIP OF NEW PRODUCT TO OTHER LICENSED, PRELICENSE, OR TERMINATED PRODUCTS FOR YOUR ESTABLISHMENT
To facilitate product classification and licensing plan development, describe the relationship of this new product with other products licensed, or under development, by your establishment. This may include, but is not limited to, describing whether the new product is:

- Prepared from new or previously approved Master Seeds/Cells
- Part of a product line (cite other products in the line, especially those already licensed)
- A modification of an existing product (e.g., adding or deleting an antigen, change in adjuvant/preservative/dose volume)
- Manufactured or tested with new technology for your establishment
- Part of a split manufacture agreement

7. OTHER COMMENTS
Optional field for miscellaneous comments not covered elsewhere.

CHECKLIST OF SUPPORTING MATERIAL
This checklist is intended to ensure that APHIS has adequate information to assign a Product Code and True Name to the new product. If supporting material was not submitted previously, ensure that it is provided with this application.

8. METHOD OF PRODUCTION
The most efficient means of describing how the product is made is to provide an Outline of Production, formatted according to 9 CFR 114.9. If an Outline is not yet available, provide the same general information captured in an Outline of Production.

9. LIST OF PRIOR SUBMISSIONS (IF ANY) FOR THIS PRODUCT WHICH WERE PROCESSED BEFORE A USDA PRODUCT CODE WAS ASSIGNED
Manufacturers may submit documentation, such as requests to ship experimental product or proof-of-concept studies, before submitting a formal license application and being assigned a USDA product code. If such submissions exist for this product, please list them so that these uncoded submissions may be transferred to the licensing file for this product.

10. OTHER
APHIS may request additional information to support initial applications for certain products. If this has been requested for your product, briefly describe the purpose of the additional information in the line provided and attach supporting documentation.

11. SIGNATURE OF AUTHORIZED OFFICIAL
The APHIS primary or alternate liaison for the establishment, if designated, should serve as the authorized official. If no liaison has yet been designated, an official authorized to assume responsibility for regulatory compliance on behalf of the establishment should sign.

12. TITLE
Enter the job title of the individual signing in Item 11.

13. DATE SIGNED
This date should correspond to the date the application is submitted. This will be the submission date cited in any return correspondence.