

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: 03/2027

This application must be submitted for issuance of a United States Veterinary Biologics Establishment License. The information will assist in determining the qualifications of the establishment to prepare biological products (9 CFR 102).

UNITED STATES DEPARTMENT OF AGRICULTURE  
ANIMAL AND PLANT HEALTH INSPECTION SERVICE  
VETERINARY SERVICES, CENTER FOR VETERINARY BIOLOGICS

*LEAVE BLANK FOR INITIAL APPLICATIONS*

USDA ESTABLISHMENT LICENSE NUMBER

**APPLICATION FOR  
UNITED STATES VETERINARY BIOLOGICS ESTABLISHMENT LICENSE**

1. TYPE OF APPLICATION ("X" one) <input type="checkbox"/> INITIAL <input type="checkbox"/> CHANGE OF LICENSE <small>(specify reason in block 2)</small>	2. IF CHANGE OF LICENSE, SPECIFY REASON	3. DATE SUBMITTED
4. NAME AND COMPLETE ADDRESS OF APPLICANT		5. ADDRESS FOR OFFICIAL MAIL FROM VETERINARY BIOLOGICS (IF DIFFERENT FROM BLOCK 4.)
6. TYPE OF ORGANIZATION ("X" one) <input type="checkbox"/> INDIVIDUAL PROPRIETORSHIP <input type="checkbox"/> PARTNERSHIP <input type="checkbox"/> CORPORATION    STATE IN WHICH INCORPORATED _____		
7. NAME AND LOCATION OF SUBSIDIARIES TO OPERATE IN THE ESTABLISHMENT		8. NAME OF EACH MARKETING DIVISION
9. LIST THE LOCATION OF ALL PREMISES TO BE USED FOR PREPARATION, TESTING, AND INITIAL SHIPPING (if different from block 4)		

**10. PRINCIPAL OFFICERS OR PARTNERS**

A. NAME	B. TITLE	C. BUSINESS ADDRESS

**CHECKLIST OF SUPPORTING MATERIAL**

ITEM	INSTRUCTIONS	A. WITH THIS APPLICATION (X)	B. DATE OR CVB MAIL LOG ID OF PREVIOUS SUBMISSION
11. APHIS FORM 2003 FOR AT LEAST ONE PRODUCT	INITIAL APPLICATIONS ONLY		
12. ARTICLES OF INCORPORATION, INCLUDING FOR EACH SUBSIDIARY			
13. LETTER(S) OF APPROVAL SIGNED BY AUTHORIZED OFFICER OF EACH SUBSIDIARY			
14. WATER QUALITY STATEMENT			
15. FACILITY DOCUMENTS (9 CFR 108)	SUBMIT TO VET BIOLOGICS-INSPECTION AND COMPLIANCE		
16. 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 maintain an establishment for the preparation of animal biological products for the use in the treatment of domestic animals. If a license is issued by the United States Department of Agriculture under this application, the licensee expressly agrees to comply with the provision of the said Act, and all rules, regulations, and orders of the Department of Agriculture issued pursuant thereto relating to the operation of such establishment and the preparation, testing, and distribution of animal biological products prepared therein, and that the animal biological products will not be labeled or advertised so as to mislead or deceive the purchaser in any particular.*

17. SIGNATURE OF AUTHORIZED OFFICIAL	18. TITLE	19. DATE SIGNED
--------------------------------------	-----------	-----------------

## INSTRUCTIONS FOR APHIS FORM 2001

Submit one copy of the form. If additional space is needed, attach additional sheets and refer to Item No.

### 1. TYPE OF APPLICATION

Specify whether this is an initial application for an establishment license or a change in regulatory information associated with an existing license. If it is a change, also enter the assigned USDA establishment license number in the unnumbered block above block 3.

### 2. REASON FOR CHANGE IN LICENSE

If a Change in License was selected in block 1, indicate the reason for the change.

### 3. DATE SUBMITTED

Enter the date this application was mailed or electronically submitted to Center for Veterinary Biologics.

### 4. NAME AND COMPLETE ADDRESS OF APPLICANT

Enter the establishment name and complete legal address (*street, city, state, ZIP Code*) of the applicant. If the applicant is a corporation, enter the name and address listed in the Articles of Incorporation.

### 5. ADDRESS FOR OFFICIAL MAIL FROM VETERINARY BIOLOGICS

Enter a single address to which official correspondence should be mailed, if different from that entered in block 4.

### 6. TYPE OF ORGANIZATION

Self-explanatory.

### 7. NAME AND LOCATION OF SUBSIDIARIES TO OPERATE IN THE ESTABLISHMENT

A *Subsidiary* is defined as a corporation in which a corporate licensee owns in excess of 50 percent of the voting stock. List only those subsidiaries that will be used in the preparation and marketing of veterinary biologics.

### 8. NAME OF EACH MARKETING DIVISION

A *Division* is defined as a marketing unit established by the licensee, which may be named on labels, advertisements, and promotional material in addition to the name and address of the producer (*licensee*).

### 9. LOCATION OF ALL PREMISES TO BE USED FOR PREPARATION, TESTING, AND INITIAL SHIPPING

Enter the street address, city, state, and ZIP Code of all premises to be used.

### 10. PRINCIPAL OFFICERS OR PARTNERS

Enter the name, title, and business address of each officer/partner in the applicant's organization.

## CHECKLIST OF SUPPORTING MATERIAL

The following checklist is intended to ensure that APHIS has adequate information to review an establishment license application. If supporting material was not submitted previously, ensure that it is provided with this application.

### 11. APHIS FORM 2003 FOR AT LEAST ONE PRODUCT

A Veterinary Biologics Establishment License is issued concurrently with a license(s) for product(s) to be prepared in the establishment. Thus, the applicant is expected to apply for a product license concurrently with the establishment license.

### 12. ARTICLES OF INCORPORATION, INCLUDING FOR EACH SUBSIDIARY

Self-explanatory.

### 13. LETTER(S) OF APPROVAL FROM EACH SUBSIDIARY

Subsidiaries appearing on an establishment license must provide informed consent, acknowledging they accept the regulatory responsibilities involved.

### 14. WATER QUALITY STATEMENT

Per 9 CFR 108, applicants must file a document verifying that the *effluent waste* (not incoming water) for the facility meets local regulatory standards. Some municipalities or rural areas do not have specific regulations regarding effluent waste. In such cases, the applicant should submit a letter from the appropriate local authority stating that the area has no regulations in this regard.

### 15. FACILITY DOCUMENTS

Submit facility documents, prepared in accordance with 9 CFR 108, for each premises listed in Item 9.

### 16. OTHER

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

### 17. 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.

### 18. TITLE

Enter the title of the individual signing in block 17.

### 19. DATE SIGNED

Self-explanatory.