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OMB Control No.  
0579-0013

No U.S. Veterinary Biological Product License may be issued until product labeling and an outline of production have been reviewed (9 CFR 102, 112, and 114).

U.S. DEPARTMENT OF AGRICULTURE  
ANIMAL AND PLANT HEALTH INSPECTION SERVICE  
VETERINARY SERVICES  
CENTER FOR VETERINARY BIOLOGICS  
AMES, IOWA 50010

**TRANSMITTAL OF LABELING  
OR OUTLINES**

1. NAME AND FULL MAILING ADDRESS OF SUBMITTER (Include ZIP Code)

2. DATE OR CVB MAIL LOG NO. OF PRIOR RELATED CORRESPONDENCE

3. VET BIOLOGICS ESTABLISHMENT NO.

4. DATE SUBMITTED

5. NAME OF PRODUCT OR SPECIAL OUTLINE (Use separate form for each product or special outline)

6. PRODUCT CODE (or Special Outline number)

7. "X" IF PRELICENSE

**8. LABELING SUBMITTED (COMPLETE ONE LINE FOR EACH ITEM)**

A. Type	B. No. Copies	C. Item on File Being Replaced (Give Number(s))	D. Use Remaining Inventories of Replaced Label (X)	E. Comments	F. Assigned Label No (APHIS Use)

**OUTLINE OF PRODUCTION OR SPECIAL OUTLINE SUBMITTED (Do not submit with same form covering Labeling)**

9. NUMBER COPIES	10. TYPE OF SUBMISSION <input type="checkbox"/> New Outline <input type="checkbox"/> Complete Revision <input type="checkbox"/> Pages Amended <input type="checkbox"/> Pages Added	11. PAGE NUMBERS AMENDED OR ADDED	12. DATE OR CVB MAIL LOG NO. OF LAST COMPLETE REVISION
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13. COMMENTS

14. SIGNATURE OF ESTABLISHMENT REPRESENTATIVE

15. PRINTED NAME AND TITLE

**REVIEW BY VETERINARY BIOLOGICS**

*In the absence of any attached applicable Exceptions (as noted by a checkmark in the box in Item 16), remaining inventories of replaced labels may be used through the last day of the twelfth month after the Return Date in Item 18, provided that ongoing use was requested in Item 8D.*

16. REVIEWED BY

CVB EXCEPTIONS ATTACHED

17. DATE RETURNED

18. CVB MAIL LOG NO.

## INSTRUCTIONS FOR APHIS FORM 2015

This form is intended as a cover page for paper submissions of labeling materials, an Outline of Production, or a Special Outline. It is not needed for submissions via the NCAH Portal. Submit one copy of this form for each paper Outline, Special Outline, or group of labeling intended for one product. Use separate forms for Outlines and labeling.

### 1. NAME AND FULL MAILING ADDRESS OF SUBMITTER

Enter the establishment name and complete mailing address (street, city, state, ZIP) of the submitter. The processed form will be returned to official mailing address on file for the establishment.

### 2. DATE OF RELATED PRIOR CORRESPONDENCE

Enter the submission date of the last related Outline or labeling submission (as applicable) for this product.

### 3. VETERINARY BIOLOGICS ESTABLISHMENT NUMBER

Enter the veterinary biologics establishment number assigned by APHIS.

### 4. DATE SUBMITTED

Self-explanatory. For complete revisions of Outlines of Production, this date should agree with the date on the revised cover page of the Outline. For page amendments, the date should agree with the date on the new page(s). If the Outline is not mailed on this date, enter the date mailed in Item 13, Comments.

### 5. NAME OF PRODUCT OR SPECIAL OUTLINE

Enter the True Name of the product, as assigned by APHIS. If no True Name has yet been assigned, list the components of the product. If the submission is a Special Outline, enter the title of the Special Outline.

### 6. PRODUCT CODE OR SPECIAL OUTLINE NUMBER

Enter the Product Code assigned by APHIS. If no Product Code has yet been assigned, enter "Unassigned." If the submission is a Special Outline, add the unique identifier assigned by your Establishment to the Special Outline.

### 7. PRELICENSE (X)

If the product has not yet been licensed at the time of this submission, place an "X" in this box.

### 8. LABELING SUBMITTED

Complete one line for each piece of labeling submitted.

#### A. Type

Specify whether the item is a Container, Box, or Shipping label; Circular (insert); or Other.

#### B. No. Copies

Specify the number of identical copies being submitted (minimum = 2). Each copy will be stamped by APHIS, and all but one copy will be returned for the submitter's records.

#### C. Item on File Being Replaced

If the current submission is intended to replace previously submitted labeling, specify the Label Number(s) assigned by APHIS to the previous submission(s). The Label Number is added to the bottom right corner of the label mounting sheet during processing.

#### D. Use Remaining Inventories of Replaced Items

Place a check ("X") in this box if you wish to obtain permission to use the existing inventories of the labeling being replaced. The default period to use existing inventories is 1 year, adjusted to the last day of the month, from the date the replacement label was approved. (Example: If the replacement label was processed on July 15, 2012, the superseded label may be used through July 31, 2013.) Longer intervals may be requested, with justification, in the Comments column (8E). If this item is not checked, the replaced labeling will be inactivated and archived by APHIS immediately upon approval of the replacement.

#### E. Comments

Optional. Explanatory comments or requests specific to an individual piece of labeling may be added here.

#### F. Assigned Label Number

For APHIS Use Only. When the label is processed, it is assigned an APHIS label number, which will be noted here.

## OUTLINE OF PRODUCTION OR SPECIAL OUTLINE SUBMITTED

### 9. NO. COPIES

Enter the number of identical copies being submitted. The minimum is two, each with original signatures. Each copy will be stamped by APHIS upon processing, and all but one copy will be returned for the submitter's records.

### 10. TYPE OF SUBMISSION

Check all boxes that apply.

- New Outline: No prior versions of this Outline have been submitted to APHIS.
- Complete Revision: A previously filed Outline is being replaced in its entirety.
- Pages Amended: Only selected pages, and not a complete Outline, are being submitted for replacement.
- Pages Added: Additional text or repagination necessitates the addition of new pages to a previously filed Outline. Only affected pages are being submitted.

### 11. PAGES AMENDED OR ADDED

Specify the page numbers being amended or added. Leave this item blank for a Complete Revision.

### 12. DATE OF LAST COMPLETE REVISION

Enter the submission date of the last Complete Revision of this Outline. Do not include the date of individual page amendments that may have been submitted subsequent to the last Complete Revision. Do not cite the date APHIS processed the last revision.

### 13. COMMENTS

Optional. Explanatory comments or requests may be added here.

### 14. SIGNATURE OF ESTABLISHMENT REPRESENTATIVE

This form should be signed by the APHIS liaison or an alternate liaison.

### 15. PRINTED NAME AND TITLE

Add the printed name and position title of the person signing in Item 14.

## THE FOLLOWING ITEMS ARE FOR CENTER FOR VETERINARY BIOLOGICS USE ONLY

### 16. REVIEWED BY

Signature of CVB official reviewing the submission. If APHIS identifies any exceptions or special circumstances regarding the submission, they will be noted on an attached document. If APHIS attaches documents to the return form, a check will appear in the box in this item.

### 17. DATE RETURNED

This is the date the submission is processed and corresponds to the date stamped on each label mounting sheet or approved Outline page.

### 18. CVB MAIL LOG NUMBER

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