Est. Name

Version B

Site(s): City, State

ADMINISTRATIVE INSPECTION REVIEW AIR- -

Section 1 - Verification of reports from the Center for Veterinary Biologics (CVB) - Licensing, Serial Release, Testing and Inspection System and other CVB databases.

Directions:
Please initial and date each page in the lower right corner upon review and verification. Indicate any discrepancies by pen-and-ink corrections. Please sign and date in the space provided on the last page of each list once verification is complete.

Part	List Title	9 CFR Reference	VS Memo/CVB Notice
A	APHIS Approved Labels with Trade Names	116.3(a), 112.5(f) 102.5(c)(3)	800.80, Notice 03-17 800.76
B	Establishment Employees by Site or Establishment (APHIS Form 2007s)	114.7(a)	800.63
C	Prelicensing Activity	102.5	800.200
D	Potency References	113.8(c)	800.92
E	Establishment Contact Information		
F	Combination Product Relationships with the Individual Product Codes	114.9(d)	Notice 01-04

Section 2 - General information of the firm's licensed sites:
Directions:
Please answer the following questions. Indicate the parts that are site specific by identifying each licensed site involved. Only provide documentation that is requested. **Authenticate** by signing and dating each page.

Please attach extra sheets if necessary.

A. Does the firm have a World Wide Web (www) site? Yes ☐ No ☐

1. If yes, please provide: www.

Signature Date

USDA APHIS

B. Who are the contacts that assess or respond to adverse event reports?

1. What is the contact telephone number for adverse event reports?

Title	9 CFR Reference	VS Memo/CVB Notice
Process for documentation and review of Adverse Event Reports	116.5	

C. Who is involved in the annual Outline of Production and Special Outline review for each licensed site?

1. Please explain how employees involved with the preparation of licensed product participate in the review process.

2. Provide the date of the last review for each of the firm's Outlines of Production.

3. Provide a list of Special Outlines with the date of the last review.

Title	9 CFR Reference	VS Memo/CVB Notice
Outline of Production review	114.8(d) / 114.8(e)	

D. Please use the provided list of your firm's licensed products to demonstrate expiration date confirmation. For each product, list the date the CVB approved the expiration date confirmation. If this has not been completed yet, then enter the date the stability study was completed or the date the final report was submitted to the CVB (if not yet approved).

*Note: If your firm is currently working with your CVB Reviewer on expiration date confirmation, please reference any related correspondence for each product in the Comments field.

Title	9 CFR Reference	VS Memo/CVB Notice
Expiration Date Confirmation	114.13	800.206

Signature Date

Version B

Est. ☐ Name ☐

AIR- ☐ - ☐

E. Does the firm have any licensed product that is manufactured at multiple sites? Yes ☐ No ☐

1. If yes, list all sites (by street address and city) where product is prepared in the first row.

2. Indicate the stage of production or manufacturing that occurs at each site by checking the applicable boxes for each corresponding site.

Prepare or preparation. Sometimes referred to as manufacture or produce, means the steps and procedures used in the processing, testing, packaging, labeling, and storing of a biological product. - 9CFR 101.2

Title	9 CFR Reference	VS Memo/CVB Notice
Multiple Site Preparation	102.4	800.87

	Site A	Site B	Site C	Site D	Site E
Address:					
Virus Production	☐	☐	☐	☐	☐
Bacteria Production	☐	☐	☐	☐	☐
Animal Testing	☐	☐	☐	☐	☐
Laboratory Testing	☐	☐	☐	☐	☐
Labeling / Packaging	☐	☐	☐	☐	☐
Filling	☐	☐	☐	☐	☐
Storage of Final Product	☐	☐	☐	☐	☐

This form should be printed, signed and dated by the firm's designated representative. Please submit this form, or the version mailed to you, by the assigned deadline with your firm's Administrative Inspection Review packet from the CVB.

Signature Date

USDA APHIS