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 time required to complete this information collection is estimated to average 0.15 hours 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.

**DRAFT ONLY** 

## UNITED STATES DEPARTMENT OF AGRICULTURE ANIMAL AND PLANT HEALTH INSPECTION SERVICE VETERINARY SERVICES

# CENTER FOR VETERINARY BIOLOGICS (CVB) INSPECTION AND COMPLIANCE FACILITY DOCUMENT SUBMISSION WORKSHEET

All buildings, appurtenances, and equipment used in the preparation of biological products shall be in compliance with Title 9, Code of Federal Regulations, Part 108, Facility Requirements for Licensed Establishments. Completion of this worksheet facilitates review of facility documents submitted to CVB Inspection and Compliance.

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1. USDA VETERINARY BIOLOGICS ESTABLISHMENT NUMBER		2. ESTABLISHMENT SITE ADDRESS RELATED TO SUBMISSION	A. ESTABLISHMENT NAME  C. CITY		B. ADDRESS	B. ADDRESS			
					D. STATE	E. COUNTRY	JNTRY F. ZIP CODE		
3. DATE SUBMITTED									
			4. DOCUMENT	S SUBMITTED					
A. TYPE OF DOCUMENT				B. COMMENTS				CVB USE ONLY	
		5. MISCEL	LANEOUS DOCU	JMENT TYPE (not listed	labove)				
(Include pertinent information be maximum 200 characters. Do n information found elsewhere on	not repeat								
7. SUBMITTER SIGNATURE (or liaison/alternate liaison)  A. SIGNATURE						B. DA	TE		
			FOR CVB	USE ONLY					
8. MAIL LOG NUMBER									
9. CVB ACTION		A. DOCUMENTS FILED  B. DOCUMENTS FILED, REVISIONS REQUESTED  C. DOCUMENTS R					ENTS RET	JRNED	
10. APHIS REPRESENTATIVE SIGNATURE A. SIGNATURE.						B. DATE			

### INSTRUCTIONS FOR COMPLETING THE CENTER FOR VETERINARY BIOLOGICS INSPECTION AND COMPLIANCE FACILTY DOCUMENT SUBMISSION WORKSHEET (draft for pilot project)

The Center for Veterinary Biologics Inspection and Compliance Facility Document Submission Worksheet (FDS) must be submitted with each Establishment's submission of facility documents.

This is a fillable pdf form.

NOTE: Use a separate FDS form for each establishment <u>site</u> submission. This is relevant to establishments with multiple licensed premises and permittees regarding the international manufacturing site and the permittee/quarantine site

#### **Block** Required information

- 1. The U.S Veterinary Biologics Establishment number
- 2. The Establishment Site Address related to the Submission
  - [A] Establishment name for the site
  - [B] Establishment site street address
  - [C] Establishment site City
  - [D] Establishment site State
  - [E] Establishment site Country (international submissions)
  - [F] Establishment site Zip Code (domestic submissions)
- 3. The date the facility documents were submitted to the CVB
- 4. Documents Submitted
  - [A] Type of Document

This column has a pick list of different types of facility documents. Please choose the type that fits the document being submitted. Several documents may be submitted for one establishment site in a single submission. If you need to make more entries than one worksheet allows use an additional worksheet.

[B] Comments

This column is free text of up to 49 characters. Enter the identity of the building/floor/area related to the document listed in A. For legends, addendums, and summary of changes, include the page numbers. For example, a **Blueprint Legend** identified in column A would be further identified in column B as **Building X**, pages **1-10**.

[C] CVB USE ONLY

Do not mark any of the boxes in this column.

#### 5. Miscellaneous Document Type

This is for documents that don't match one of the types listed in the pick list under Section 4[A]. The type of document is entered in the left side block and further identification is entered in the right side block. Do not mark the boxes listed under the CVB USE ONLY column.

#### 6. Comments

Use this block to provide information formerly found in a cover letter with the facility document submission. It may also be used to add any other pertinent comments regarding the submission.

- 7. Submitter Signature the liaison or alternate liaison is considered the responsible firm official
  - [A] Digital signatures are not acceptable at this time
  - [B] Date of signature
- 8, 9, & 10 FOR CVB USE ONLY. **DO NOT** complete or mark in any of the boxes in these blocks.