



## INSTRUCTIONS FOR COMPLETING THE CENTER FOR VETERINARY BIOLOGICS INSPECTION AND COMPLIANCE FACILITY 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 site 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.