

INSTRUCTIONS FOR COMPLETING THE CENTER FOR VETERINARY BIOLOGICS INSPECTION AND COMPLIANCE FACILITY DOCUMENT SUBMISSION WORKSHEET

BACKGROUND:

One outcome from the Facility Document Business Process Improvement project of FY2017 was the use of the Center for Veterinary Biologics Inspection and Compliance Facility Document Submission Worksheet (FDS). It is not required for licensee/permittees to use the FDS. But this form streamlines the review and response process, so if the licensee/permittee does not submit facility documents using this form, the Export Document Examiner (EDE) will be filling out this form for the submission.

The FDS will be document type "Outgoing Correspondence".

PROCESS

A. The form can be found XXXXXXXXXXXXXXXXXXXX, CompleteDraftFormFDS
This is a fillable pdf form.

B. The EDE fills out the FDS Form based on the submission.

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. A site is not equal to an address. For example, Biomune has one site in Lenexa and one site in Anniston. An FDS form would be required for the Lenexa site, not each individual address listed on the establishment license for Lenexa. Another FDS form would be needed for the Anniston 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 (cover letter)
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

**INSTRUCTIONS FOR COMPLETING THE CENTER FOR VETERINARY BIOLOGICS INSPECTION
AND COMPLIANCE FACILITY DOCUMENT SUBMISSION WORKSHEET**

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

For use by Biologics Compliance Assistants (BCAs) to review submission against the FDS form.

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] or for listing extra documents if you run out of room (rather than opening a new FDS). The type of document is entered in the left side block and further identification is entered in the right side block. If additional room is needed, use an additional form and place "Page x/y" in the comments of each form.

6. Comments

Type "Form not submitted by establishment – cover letter signed by (name)"

7. Submitter Signature

[A] Signature left blank

[B] Date – same as date submitted, see Block 3

8. Enter Mail Log (ML) Number

- C. The EDE saves the completed FDS XXXXXXXXXX folder as EST FDS ML XXXXXX.

NOTE: If more than one form is used due to space constraints, append "part X" to the name of the saved forms.

- D. The EDE prints a hard copy of the FDS and files with the facility document submission in the pending drawer.
- E. The EDE attaches the FDS to the ML as Document Type "Incoming Submission" (along with the scanned cover letter).
- F. The EDE fills out a reference slip using **ICTEM0048** Word document.
1. Replace "(date)" with the submission date and "(number)" with the corresponding ML number.
 2. The liaison address should be placed in the "To:" field.
 3. Save the completed reference slip in the same folder with corresponding FDS Form as EST **ICTEM0048** ML XXXXXX.
- G. The EDE attaches the reference slip to the ML as Document Type "Internally Routed" and moves it forward to Initial Facility Document Review Pool.
- H. The BCA self-assigns ML – See **ICWI0081**, *Preliminary Review of Facility Documents (BCA)*.