

V. ISS template

Every page of an ISS must be in portrait mode. It is permissible to rotate text on a page, but not the page itself.

A. First page

The first page of the ISS template contains a table with identifying information that will not be included when this ISS is incorporated into a PCS by the CVB. PCSs will have their own cover page containing appropriate identifying information for the Product. To facilitate computerized assembly of the PCS by the CVB, the table on page 1 of an ISS template must be the only item on Page 1 of the completed document.

First page table:

| | |
|---|---|
| Original Establishment Number | Enter the Est # from which the study was submitted, even if (as in the case of split manufacture or acquisition/merger) the study may pertain to another Establishment's final-use product |
| Original Product Code | Enter the original code(s) of the product under which the study was submitted. |
| Current Product Codes | Enter any <i>current</i> codes to which the study applies. We realize this may not agree with the original code if the product has been subject to acquisitions and mergers. |
| Study Identifier | The CVB strongly encourages applicants to create a unique ID for studies. Enter the identifier, if one was created. The CVB recognizes there may not be a unique ID for certain historical studies. |
| Date Study Submitted | Enter the date the efficacy/safety study was submitted to the CVB (not the submission date for the Individual Study Summary if it is submitted after the study was reviewed) |
| CVB Mail Log ID containing study | <p>For historical studies, the CVB Mail Log (ML) ID of the full study submission will differ from the ML assigned to the individual study summary because they are being submitted separately. In many cases, the ML ID assigned to the full study report may not be known to the firm. The CVB may add this information later if we can trace the ML # in our records. Some studies may pre-date any kind of CVB Mail Log.</p> <p>As we move forward, however, we encourage firms to submit a full study report and a proposed individual study summary together so that they are filed under the same ML #. In this scenario, the CVB will complete this field once a ML # has been assigned.</p> |

B. Subsequent page(s)

The following table, to begin on page 2 of a completed ISS, will appear in PCSs.

| | |
|--|--|
| Study Type | Enter Efficacy or Safety. |
| Pertaining to | Enter the agent against which efficacy is being demonstrated. Enter ALL for safety studies. |
| Study Purpose | Be succinct and non-technical, using plain language. Examples: <ul style="list-style-type: none"> • To demonstrate efficacy against diarrhea in piglets nursing vaccinated sows • To demonstrate efficacy against respiratory disease one year after vaccination • To demonstrate safety under field conditions • To demonstrate safety in pregnant animals |
| Product Administration | Include the number of doses, interval between doses, and the route of administration. If the product administered is a platform product, include the identity of the inserted gene for the serial used in the study. For influenza products, include the influenza strain by WHO nomenclature (e.g., A/California/04/2009(H1N1)). |
| Study Animals | Include the animal species, age at first product administration, and number of animals per treatment group. For efficacy studies, the number of animals per treatment group should be the number included in the final study analysis. For field safety trials, all animals enrolled in the study should be represented. |
| Challenge Description | Include the challenge agent and time interval between the last product dose and challenge. If the challenge agent is a generally recognized strain (e.g., Singer strain of BVD1 or Rickard strain of FeLV), please indicate it. Specify influenza strains by WHO nomenclature.). Enter “Not applicable” for safety studies. |
| Interval observed after challenge | Specify how long, and how frequently, animals were monitored for safety studies and after challenge for efficacy studies. |