***This is an excerpt from the Guidance document that specifically applies to ISS Templates provided for your convenience.***

## V. ISS template

### 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:

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| **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 the *current* Est # if it is different from the original Est #. Enter any *current* 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. |

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| **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** | 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. |

## B. Subsequent page(s)

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

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| **Study Type** | Enter Efficacy or Safety. |
| **Pertaining to** | • Enter the agent against which efficacy is being demonstrated. For influenza products, include the influenza strain by WHO nomenclature (e.g., A/California/04/2009(H1N1).<br>• For BVD products, enter the type (e.g. Type 1, Type 2).<br>• For PCV products, enter the genotype (e.g. 2).<br><br>Enter ALL for safety studies. |
| **Study Purpose** | Be succinct and non-technical, using plain language.<br>Examples:<br>• To demonstrate efficacy against diarrhea in piglets nursing vaccinated sows<br>• To demonstrate efficacy against respiratory disease one year after vaccination<br>• To demonstrate safety under field conditions<br>• To demonstrate safety in pregnant animals |
| **Product Administration** | Include the number of doses, interval between doses, and the route of administration.<br>If the product administered is a platform product, include the identity of the inserted gene for the serial used in the study. |
| **Study Animals** | Include the animal species, age at first product administration, and number of animals per treatment group.<br>For efficacy studies, the number of animals per treatment group should be the number included in the final study analysis.<br>For field safety trials, all animals enrolled in the study should be represented. State an age range indicating the number of animals at the minimum age. |

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| **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.)<br>• Bovine Virus Diarrhea Virus-state the type, subtype, and strain.<br>• Infectious Bronchitis Virus-state the type.<br>• Infectious Bursal Disease Virus-state the type.<br>• Influenza Virus-state the subtype and strain. Designate the strain according to accepted standards of influenza virus nomenclature.<br>• Newcastle Disease Virus-state the strain.<br>• Porcine Circovirus-state the type and subtype.<br>• Rabies Virus-state the strain.<br><br>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. |
| **Results** | *****See the following section of this document for data formatting requirements.*****<br><br>Efficacy: Focus on results that provided the primary basis for regulatory acceptance. Avoid myriad unremarkable secondary findings.<br><br>Define any complex case definitions and indicate when the test was conducted according to a codified Standard Requirement. Explain scientific/medical terms in plain language.<br><br>If multiple dose concentrations or different routes of administrations were tested, present only the data for the formulation/route that was approved for licensure.<br><br>Safety: Account for all enrolled animals by adverse event observed.<br><br>Presentation:<br>If a table or graphical presentation does not fit easily in the Results block of the ISS template, append additional pages to the template and refer the user to the added pages. If the data fit better on 8.5 x 11" pages in landscape view, it is permissible to rotate the data sideways on portrait-oriented pages. (Example ISS #9 contains rotated text.) Do not rotate individual pages within the Word document, however, as this creates problems during the CVB's automated compilation of a Product Compilation Summary. |

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| | If data were presented in tabular format in the study report, the same table may be copied/pasted into the ISS, provided there is adequate resolution to retain readability. |