Business Rules for CVB Submittal Template

Submission-specific Folder ID on submitted electronic media (if more than one submission on a single disk)	This is required ONLY if you have more than one submission on a single piece of electronic media, so that we can match up which files go with which cover page. Format is left to submitter preference.
Related Prior Open Submission	If the current submission corrects/clarifies/provides an addendum to a prior submission that is *still under review at the CVB,* list the prior submission here. Cite by ML number if possible, otherwise by Submission Date. The new documents will be added to the *existing* ML.
USDA Establishment Number	Self-explanatory
All applicable Product Code(s)	Enter UNASGN if the product is not yet coded, but it is helpful to append any internal identifiers to keep UNASGN products distinct. If not product-related, enter NOTAPP.
Special Outline No.	Self-explanatory
Submission Type	Choose from picklist. --Protocol is for pre-study review. --Report is for data of any kind, whether formatted as a formal report or simply a summary appended to a letter. --Outline/SO/labels are for items accompanied by APHIS Form 2015, and is currently out of scope for electronic submission. (If an Outline or label is not submitted with a 2015—such as FDA-EREA items-- pick Correspondence.) --Use Correspondence only if other values do not apply.
Submission Subtype	Choose from picklist. Enter one or more values, as appropriate. See following page for explanation of individual subtype values.
Date Submitted	Self-explanatory
Brief Description	Purpose of submission. Include study numbers, but be succinct. Maximum 200 characters, and most entries should not need that many.
Tags	See following section for Tag definitions.
Direct submission to	Select name of CVB reviewer to whom this submission should be routed
Also notify	Optional. List any CVB employees who should be notified that this submission has arrived (equivalent to those you previously would have provided a cc copy)
Related Prior Completed Submissions	List any <u>directly</u> related prior reviewed/completed submissions if this submission is a follow-up to a CVB response or if there are precedents that need to be considered. Cite by ML number if possible, otherwise by Submission Date.
Count of electronic files, by folder, provided in this submission	Provide total count of the files *for this submission* on the disposable media so we can validate we received all of the expected files. Separate counts by folder into Core Documents, Statistical Data Files, and Sequence Data Files.

Tag Definitions

Tag Value	Description
Paperless	Use this tag for all submissions that are ONLY provided in electronic form.
Critical Path Agreement	For items submitted per CVB Notice 11-12
Firm's Licensing Plan	For submissions where you are sending us your anticipated list of submissions needed for licensure, for CVB concurrence. See CVB Notice 11-12 for details.
Firm's Priority	Use this tag if the submission is high priority for processing. Use with discretion!
Forward 2007/2008 to CVB-IC	Add this tag when your submission includes APHIS Form 2007 for a liaison/alternate liaison OR *final* APHIS Form 2008 for a prelicense product serial (but not for 2008s that may be submitted for experimental product or seeds/cells, or for preliminary 2008s containing only partial testing, or for routine post-license 2008s sent directly to IC)

Submission Subtype Value	Description
103.3/other movements	For authorizations to move product under 9CFR 103.3 or to move items into production facilities or other locations
Administrative/license maintenance	For routine letters about license termination/inactivation or special outline inactivation.
Assay validation	For initial assay validation or to support changes in assay architecture/format
Assay reagent change	For submissions supporting the change to new reagent lots in a previously validated assay
Cell	Submissions pertaining to Master Cells
CVB Testing	Request confirmatory testing by the CVB
Diagnostic field study	Ruggedness studies for kits
Diagnostic spec-sens	Specificity/sensitivity studies for kits
Efficacy-component compatibility	Lack of interference studies
Efficacy-pivotal or DOI	Both short- and long-term pivotal efficacy studies
Efficacy-proof of concept/other	For exploratory studies, challenge model development, and other miscellaneous studies
Efficacy-reference qualification	Qualification or requalification studies (not stability monitoring data)
Establishment issue	Submissions pertaining to an establishment license, including corporate acquisitions and mergers
Exemption	Exemption requests
FDA-EREA	Submissions regarding products to be exported under the Food and Drug Administration's Export Reform and Enhancement Act of 1996
Jurisdiction/Licensability	Issues regarding regulatory jurisdiction or other concerns regarding whether something is licensable.
Labeling	Non-2015 submissions pertaining to labeling statements or label maintenance
Manufacturing Process (Mfr Proc)	Proposals to change manufacturing methods. Equivalency studies (not efficacy) when changing formulations or processes
Personnel	Liaison designations or withdrawals
Residue clearance	Slaughter withdrawal, adjuvant clearance
Safety-backpassage	Reversion to virulence studies
Safety-field	Typical field safety, per VSM 800.204
Safety-overdose	Overdose studies
Safety-shed/spread/tropism	Shed/spread studies and non-target safety
Safety-special claims	Such as safe in pregnant cows or some other special condition not adequately addressed in a normal field safety study
Seed	Submission pertaining to Master Seeds
SIF/Risk Analysis	SIFs and other risk-related documents
Stability-confirm dating	Confirming product dating, per 9CFR 114.13
Stability-reference monitoring	Per VSM 800.211