Definition of a 2049 "Submission"

Why is it important to define a "Submission"?

The CVB tries to create one mail log record for items that deal with a single issue and for which our CVB response is likely to be communicated in a single letter. Currently, this sometimes means breaking up large packages that arrive under a single cover letter or, less frequently, combining several small, highly related documents into a single tracking record.

Your electronic submissions will be most efficient if you attempt to define submission in the same manner. The goal is **[1 submission] = [1 mail log ID] = [1 CVB response letter]**. Each submission needs its own 2049 form.

Rules of thumb for items being submitted on the same day

- **Separate reports and/or protocols having distinct purposes into individual submissions, even if they pertain to the same product.**
  - Examples: 1) a field safety study and an efficacy study; 2) efficacy studies for different product fractions; 3) validation work for two different potency assays
- **Combine "sub" reports that the CVB will review together in support of a larger, single objective.**
  - Examples: 1) Individual reports for each study site of a field safety study; 2) Optimization and verification reports to validate one new assay; 3) Multiple duration of immunity (DOI) studies for a single product fraction, the only difference being the timing of the challenge—all to be considered together to determine the best estimate of DOI
- **Separate reports for pivotal licensing studies (requiring full review) from proof-of-concept studies (meriting only cursory review, filed only for information).**
- **Combine all studies being submitted solely for information (i.e., proof-of-concept studies or invalid/terminated studies) if they pertain to the same product(s).**
- **Only one Outline of Production or Special Outline per submission. Do not combine Outlines/SOs with reports, even if they contain updates supported by data in the report. Instead, cross reference such submissions in the Brief Description.**
- **If submitting labels, multiple labels for the same product may be combined in a single submission.**
- **Do not combine license/permit applications (APHIS 2001, 2003, 2005) with any other documents to be reviewed. This is necessary because the license application must remain open until the license/permit is issued.**