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.