

Product Study Summaries

Overview

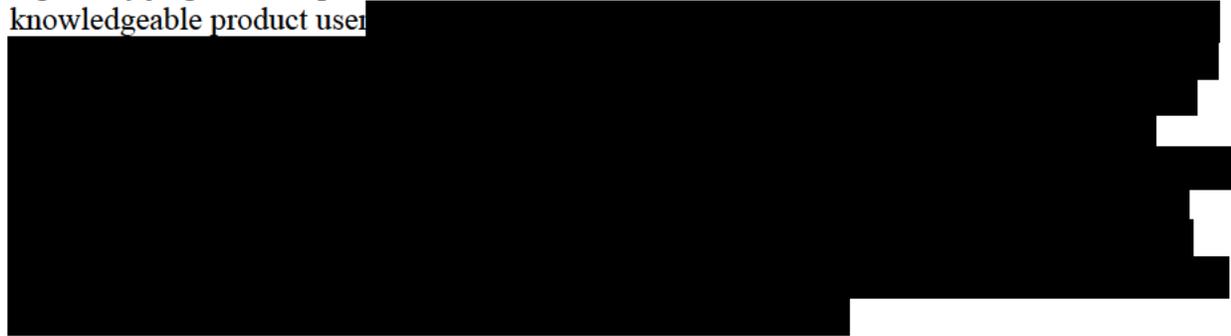
The Food and Drug Administration posts summaries of licensing studies on the internet for public information as part of the Freedom of Information Act (FOIA). See <http://www.fda.gov/AnimalVeterinary/Products/ApprovedAnimalDrugProducts/FOIADrugSummaries/default.htm> for examples. While the CVB does not have regulatory authority to post such summaries to the internet at this time, the information is useful for internal program reference. All reviewers are expected to complete an electronic summary of applicable studies at the time the study review is completed.

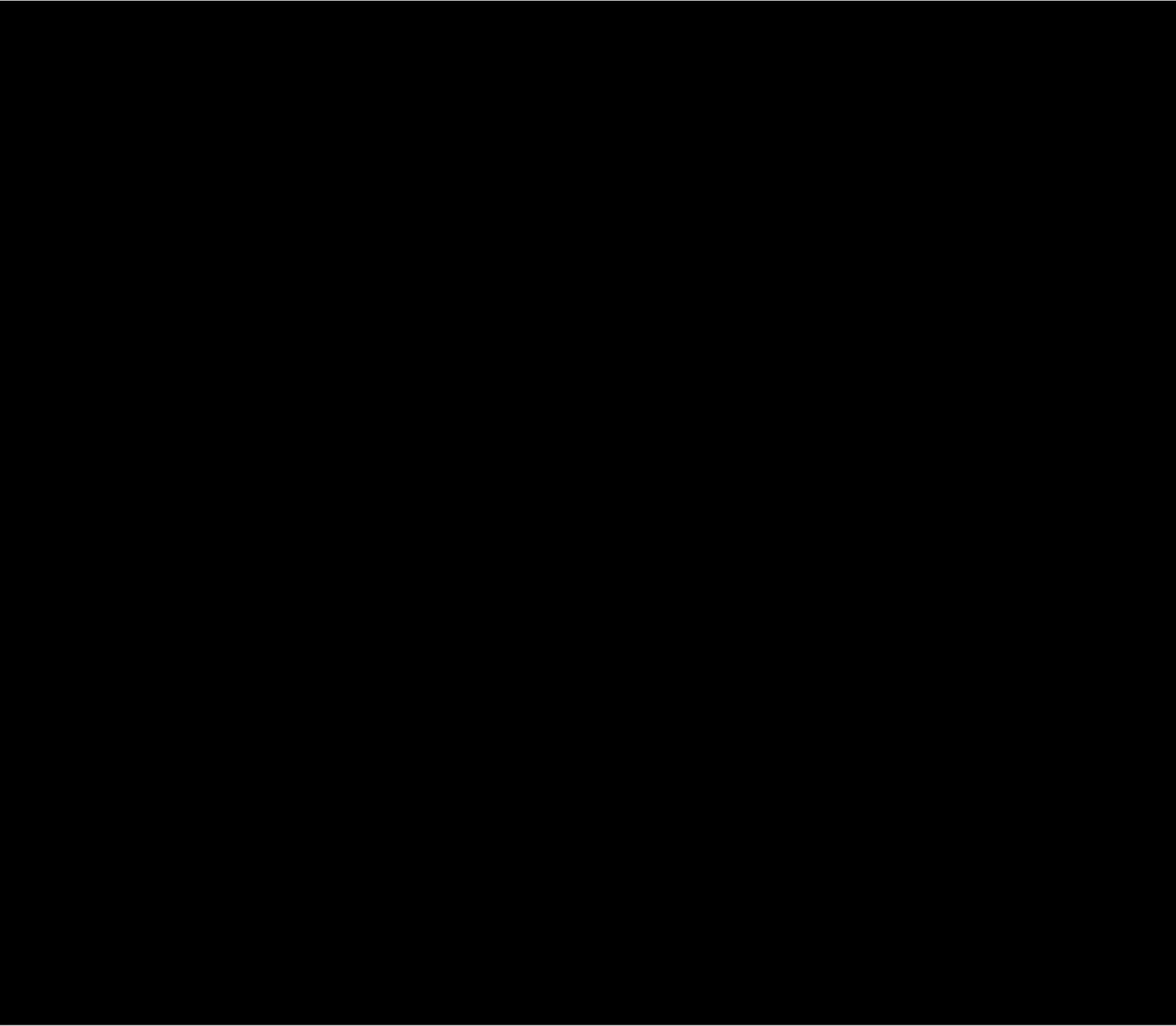
Applicable Studies

Complete a product study summary (informally referred to as an eFOIA summary) for all efficacy and reference qualification studies, not just pivotal licensing studies for new product license applications. Include “reasonable expectation of efficacy” studies for conditional licensure. Include studies that were not considered acceptable to support study objective (unsatisfactory studies), unless they were unsatisfactory due to infectious disease in the study animals that was unrelated to the challenge used in the study.

Procedure

1. Complete a product study summary using the template shown in Appendix I. Complete the fields according to the guidance shown in Appendix I. Write the summary so that it is understandable to somebody who does not have ready access to the entire study report. Avoid regulatory jargon; the report should be understandable to a field veterinarian or other knowledgeable product user.





2. Print a hard copy of the summary. Concurrently with printing a hard copy, upload an electronic copy of the product study summary to the electronic mail log, under the applicable mail log number.

3. The hard copy is routed with the draft CVB correspondence to the firm regarding the study. Correspondence reviewers are expected to look for the product study summary and to verify that an electronic copy was uploaded to the electronic mail log.. If a summary is not included, the submission should be returned to the reviewer with a request to write the summary. Once the

CVB correspondence is reviewed and mailed, the hard copy is added to the #1 file for the product along with a copy of the outgoing correspondence.

4.



Appendix I. Guidelines for Completing a CVB Efficacy Study Summary

Establishment	
Product Code	<ul style="list-style-type: none"> Enter only the “primary” code with which the study was actually conducted. If the results of the study will also be extrapolated to other related products, it is permissible to list those codes in the Other Pertinent Information section. Do not include the licensing status of the code.
True Name	Enter only the true name of the code listed above.
Mail Log Number	Enter the mail Log Number of the incoming efficacy study submission
Study Identifier (# or name)	
Submission Date	
Study Purpose	<ul style="list-style-type: none"> Keep it simple and understandable for field veterinarians; do not use regulatory slang. List only the primary purpose; do not attempt to include every tangential purpose to which the data might be extrapolated.
Product & Dosing	
Number of product doses & timing of administration	If nonvaccinated controls received a placebo, include a brief description of the placebo product.
Dose volume	
Route of administration	
Animals	
Number of animals/group	If animals were excluded during the course of the study, enter the number of animals that were actually used in the data analysis. (<i>If the excluded animals impacted the regulatory decision, note the circumstances of any exclusions in Other Pertinent Information.</i>)
Type of animals and age @ first vaccination/treatment	
Challenge	
Challenge organism & dose	If multiple replicate titrations were performed to determine the average challenge dose, include only the mean.

Method & timing of challenge	<ul style="list-style-type: none"> • If the timing of the challenge is expressed as Day X, ensure that you have defined the context of X. Example: If the animals were challenged 35 days after the first vaccination, don't say challenged on "Day 35" unless you have already defined the first vaccination as Day 0. •
Outcome/Results	
Description of outcome variable	<ul style="list-style-type: none"> • Include <u>only</u> the outcome variable(s) that formed the basis for your regulatory decision. Do not attempt to include every outcome variable the firm evaluated if they did not factor into your regulatory decision. • Indicate how the outcome variable was measured. If the outcome was based on clinical signs, list the actual signs evaluated; don't just say "clinical signs". • Ensure that results are included below for each listed outcome. • An outcome is a single observation that is made on each subject. Thus, do not define the outcome variable as "a reduction of ..." or "a difference in ..." which are comparisons of group summary measures.
Observation interval after challenge	<ul style="list-style-type: none"> • Include how many days after challenge the animals were observed, as well as the frequency of observations (for example daily clinical observations for 2 weeks, blood samples tested for viremia every 3 days for 2 weeks, etc). Include how/when frequently animals were monitored, as well as if/when they were necropsied
Results	<ul style="list-style-type: none"> • Enter the CVB's statistical analysis, not the firm's. (Statistics will provide electronic copies of their tables and graphics to paste into the e-FOIA form.) • List only the results for outcomes that formed the basis of your regulatory decision. • If a scoring system was used, do not list arbitrary numeric scores (e.g, nasal discharge=1); instead define what the score means (e.g., nasal discharge = mild serous). Remember that the summary must be understandable to someone who does not have access to the entire study report. • If results are expressed as mitigated fraction, ensure that a shift estimator and quartile values are also included. Statistics has a template table for this information.
Label claim	
Claim approved (Y/N)	
Other pertinent information	