



Animal and Plant
Health Inspection
Service

Veterinary Services

Center for Veterinary
Biologics

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CENTER FOR VETERINARY BIOLOGICS NOTICE NO. 13-17

TO: Biologics Licensees, Permittees, and Applicants
Directors, Center for Veterinary Biologics
Veterinary Services Leadership Team

FROM: Byron E. Rippke /s/ *Byron E. Rippke*
Acting Director
Center for Veterinary Biologics

SUBJECT: Summary of Changes for Related Study Protocols

I. PURPOSE

This Notice pertains to all licensees, permittees, and applicants submitting study protocols for review by the Center for Veterinary Biologics, Policy, Evaluation, and Licensing (CVB-PEL) staff, per Veterinary Services Memorandum (VSM) 800.200, Appendix Section 2. The Notice serves to inform submitters on how they can help CVB-PEL staff expedite review of study protocols that are similar to previously reviewed protocols, by including a list of changes among such protocols. In some circumstances, the same approach may apply to similar protocols that are submitted concurrently.

II. BACKGROUND

CVB-PEL strives to provide priority review of study protocols. It is common for firms to submit a protocol that is similar to a previously reviewed protocol. For example, a firm may conduct a duration of immunity (DOI) study that is nearly identical in most respects to a short-term efficacy study except for the interval between vaccination and challenge. It would be to the firm's advantage for the DOI protocol to include a list of changes in the study design from the short-term efficacy protocol, so that CVB-PEL can expedite its review. Often, however, such a list of changes or differences is not provided, resulting in increased time for CVB-PEL review. Other examples include vaccination-challenge studies for reference qualification or non-interference that resemble an earlier short-term efficacy protocol.

VSM 800.200, Appendix Section 2.3.2, recommends that protocols include "background information justifying the proposed study, placing it in the context of the product's development, and supporting an understanding of its objective. Include a summary of all similar studies previously initiated with the current product or related products and a description of other relevant information." A list of changes from a previously reviewed protocol fits within such a summary.

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III. ACTION

Protocols may include a summary of changes from another previously reviewed protocol, if the two protocols are very similar. Doing so is likely to expedite CVB-PEL review of the protocol. The referenced protocol should be clearly identified, preferably with the CVB Mail Log number, the firm's protocol number or identifier (if any), and the date of the CVB response letter. In some circumstances, the same approach may apply to similar protocols that are submitted concurrently.

IV. IMPLEMENTATION/ APPLICABILITY

This Notice pertains to all study protocols submitted per VSM 800.200, Appendix Section 2. This policy will be effective immediately from the date of this Notice.