United States Department of Agriculture

Animal and Plant Health Inspection Service

Veterinary Services

Center for Veterinary Biologics

510 S. 17th Street,
Suite 104
Ames, IA 50010
(515) 232-5785
FAX (515) 232-7120

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CENTER FOR VETERINARY BIOLOGICS NOTICE NO. 07-04

Subject: Submission of Outsourced Studies

To: Biologics Licensees, Permittees, and Applicants
Veterinary Services Management Team
Directors, Center for Veterinary Biologics
Area Veterinarians in Charge, VS
State Veterinarians

I. PURPOSE

The purpose of this notice is to provide interested parties with guidance regarding the submission of materials to the Center for Veterinary Biologics (CVB) when outside service providers are involved.

II. BACKGROUND

Fee-for-service testing is a growing business utilized by the biologics industry. Although serial release testing must be performed by licensees on licensed premises, other studies and non-codified testing (especially that requiring specialized facilities and/or equipment) may be outsourced to competent service providers, provided that the licensee (or license applicant) maintains adequate oversight and the service provider agrees to inspection by the CVB at any time.

When both the licensee/applicant and the outside service provider are in contact with the CVB, there can be confusion regarding the routing and filing of submissions. The CVB may have document files associated with both the licensee/applicant and the service provider. Service providers may perform testing for more than one licensee/applicant. The following guidance is provided to clarify the delineation of responsibilities of the licensee/applicant and the service provider.

III. GUIDANCE

All correspondence (including study protocols and reports) regarding outsourced work should be submitted to the CVB by the licensee or license applicant, not the service provider. This does not preclude provider participation in the preparation of the submission, but it ensures that the licensee/applicant is aware of, and assumes legal responsibility for, all submissions that will be used to support product licensure.

Service providers requiring authorization to ship experimental product *from their facilities* should submit their own requests in accordance with Title 9, Code of Federal Regulations (9CFR), Section 103.3. If, however, the product being shipped is the property of another company, the identity of that company (including its CVB establishment code, if applicable) should be included in the request. The true name of the product (and product code, if applicable) also should be included. This will facilitate cross-referencing of these submissions to the applicable product files if the shipped product is, or eventually will be, in the licensing process.

Regulations require the submission of a summary report for any study authorized under 9CFR 103.3. These summaries should be provided by the entity shipping the product. Thus, when service providers request the authorization to ship, they should provide a brief summary when the work is completed, even if a more complete report is submitted by the licensee/applicant for the product. If the service provider is aware that a more complete report will be submitted by the licensee/applicant, this should be noted in the summary provided by the service provider.

/s/Richard E. Hill, Jr.

Richard E. Hill, Jr.
Director
Center for Veterinary Biologics