United States Department of Agriculture

Animal and Plant Health Inspection Service

Veterinary Services

Center for Veterinary Biologics

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CENTER FOR VETERINARY BIOLOGICS NOTICE NO. 11-10

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

FROM: Richard E. Hill, Jr. */s/ Richard E. Hill, Jr.*
Director
Center for Veterinary Biologics

SUBJECT: Paper Reduction Initiatives

I. PURPOSE

This notice informs veterinary biologics licensees, permittees, and applicants that the Center for Veterinary Biologics (CVB) will accept most submissions as double-sided copy. To reduce paper consumption further, certain supplemental information may be submitted solely in electronic format.

II. BACKGROUND

In compliance with biologics regulations (9 CFR 101-118), biologics licensees, permittees, and applicants must submit various types of documentation to the CVB. Official submissions to the CVB are currently provided as single-sided paper copy.

III. POLICY

A. Double-sided copy

Effective immediately, licensees, permittees, and applicants may submit documentation, except for Outlines of Production, Special Outlines, and APHIS Forms 2008, as unbound double-sided copy. Margins on the 11-inch sides of standard 8.5 x 11-inch paper should be no less than one inch.

B. Electronic files for supplemental information

There is no change to the requirement that official submissions to the CVB must be submitted in hard copy, with original signatures. Effective immediately, however, eligible supplemental information may be submitted solely in

electronic form on appropriately identified electronic storage media. The electronic files should be submitted with the required hard-copy portion in a single submission package.

1. Eligibility for electronic submission

Hard-copy submissions should contain sufficient detail to stand alone. Hard-copy study reports, for example, should describe the study conducted, present the results and data analysis, and justify the study conclusions. To facilitate regulatory review, however, submitters frequently append supplemental information including, but not necessarily limited to, copies of:

- Reporting sheets used by study personnel to capture raw data for individual animals enrolled in a study (submitted in addition to compiled data appearing in the hard-copy report)
- Data capture forms/bench records extracted from product manufacturing documentation (submitted in addition to a pertinent summary in the hard-copy report)
- Raw output from statistical analysis software (submitted in addition to a data analysis summary in the hard-copy report)
- Published articles from the scientific literature
- Published foreign regulations and guidance
- Documentation already on file at the CVB
- Prior CVB correspondence
- CVB regulations, policy documents, and supplemental assay methods

The above types of supplemental appendices may be submitted in electronic format.

2. Identification of electronic files

Affix a label to, or write directly on (as appropriate), the storage media and any packaging (protective sleeves or cases). Identify each component with the Establishment number, applicable Product Code(s), identifier(s) of report(s), and date of submission.

Ensure that individual files are named descriptively or include a key to the type of information found in each file.

Within the hard-copy report, refer the reader to each electronic file at the appropriate context point.