



September 5, 2013

CENTER FOR VETERINARY BIOLOGICS NOTICE NO. 13-13

**United States
Department of
Agriculture**

Animal and Plant
Health Inspection
Service

Veterinary Services

Center for Veterinary
Biologics

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

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

SUBJECT: Electronic Submissions for Policy, Evaluation, and Licensing

I. PURPOSE

The purpose of this Notice is to inform licensees, permittees, and applicants that the Center for Veterinary Biologics (CVB) is now accepting licensing submissions via electronic format on disposable media. This Notice applies to submissions for Policy, Evaluation and Licensing (PEL), except those submissions that are accompanied by APHIS Form 2015 (e.g. labels and outlines).

II. BACKGROUND

In May 2013, as one of CVB's Business Process Improvement initiatives to streamline the licensing process, CVB-PEL began a pilot project with several firms for electronic submissions. As a result, we have established internal and external procedures and are now able to receive electronic submissions from all Veterinary Biologics firms.

III. ACTION

We invite all firms to submit applicable documents on disposable media, as described in the Guidance to the Industry. The Guidance is available on the CVB website at: http://www.aphis.usda.gov/animal_health/vet_biologics/vb_data_formats.shtml

IV. IMPLEMENTATION

This change will be effective immediately from the date of this Notice. We highly recommend that, prior to the first electronic submission, each firm schedule a teleconference so that we can familiarize you with the process and answer questions. Please send your request by email to CVB@aphis.usda.gov with "Schedule a Teleconference on Electronic Submissions" in the subject line.

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Hard copy submissions will continue to be accepted in order to accommodate firms that are not able to submit documents electronically. Note, however, that the CVB intends to process all applicable submissions electronically and will scan all paper submissions into electronic files. Be advised that scanned paper documents will gain fewer processing efficiencies compared to documents prepared directly from a digital source application.

The CVB prepared the Guidance to Industry based on the results of our recent pilot project. Although it has been posted to the web site before formally soliciting feedback from all firms, we wish to emphasize that the Guidance is a work in progress. Therefore, we invite all firms to utilize the new process and then comment on the Guidance. We will update it based on feedback received by November 1, 2013.