



April 15, 2009

CENTER FOR VETERINARY BIOLOGICS NOTICE NO. 09-08

**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

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: APHIS Form 2015 Available Electronically

I. PURPOSE

The purpose of this notice is to inform interested parties of the availability of APHIS Form 2015 in an electronic format for submitting Outlines of Production and labels to the Center for Veterinary Biologics - Policy, Evaluation, and Licensing (CVB-PEL). The CVB-PEL is also reducing the required number of copies of Outlines of Production, Special Outlines, and revised pages submitted for review.

II. BACKGROUND

Title 9, Code of Federal Regulations (9 CFR), Parts 112.5(a) and 114.9(a)(7) require APHIS furnished transmittal forms be used when submitting sketches, labels, Outlines of Production, Special Outlines, and revised pages for review by the CVB-PEL. APHIS Form 2015 is currently supplied as a multi-carbon form. The CVB-PEL is providing APHIS Form 2015 in an Adobe[®] Acrobat .pdf format to replace the multi-carbon form. The electronic version of APHIS Form 2015 is available at our website:
http://www.aphis.usda.gov/animal_health/vet_biologics/vb_forms.shtml

III. POLICY

The multi-carbon APHIS Form 2015 will be available from the CVB-PEL until current supplies are depleted. After that time, the CVB-PEL will provide hard copies of the electronically available single-page forms.

In addition, 9 CFR 114.9(a) requires Biologics Licensees, Permittees, and Applicants to submit four copies of each Outline of Production, Special Outline, or revised pages for review. Due to changes in CVB-PEL filing procedures, the CVB-PEL will now require only two copies, both with original signatures, to be submitted for review.



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CENTER FOR VETERINARY BIOLOGICS NOTICE NO. 09-08

Page 2

Biologics Licensees, Permittees, and Applicants are encouraged to use the electronically available, fillable APHIS Form 2015 for submission to CVB-PEL. In Box 18, the CVB-PEL is requesting firms to include the name and title of the individual signing the form. The signed hard-copy APHIS Form 2015 along with two original signed copies of each Outline of Production, Special Outline, or revised pages, sketch or label must be submitted. APHIS Form 2015 and one copy of the Outline of Production, Special Outline, or revised pages, sketch or label will be returned to the firm after processing by the CVB-PEL.