



Animal and Plant
Health Inspection
Service

Veterinary Services

Center for Veterinary
Biologics

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CENTER FOR VETERINARY BIOLOGICS NOTICE NO. 16-15

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

FROM: Byron E. Rippke
Director

SUBJECT: Implementation of Single Label Claim and Labeling/Packaging Rules

I. PURPOSE

The purpose of this notice is to announce procedures for implementation of the Single Label Claim and Labeling/Packaging Rules recently published as final rules in the *Federal Register*.

II. BACKGROUND

APHIS Rule 2011-0049 (Single Label Claim for Veterinary Biological Products) was published July 10, 2015, to provide a simpler labeling format that would better communicate product performance to the user. It also requires publication of a standardized summary of the efficacy and safety data submitted to the Animal and Plant Health Inspection Service in support of product licensure. The Center for Veterinary Biologics (CVB) elected to delay implementation of the Single Label Claim rule until companion docket APHIS 2008-0008, which would also require labeling updates, was finalized.

APHIS Rule 2008-008 (Labeling and Packaging), published August 29, 2016, updates numerous requirements for label content and packaging requirements. The implementation date for this rule is October 31, 2016. Because the two rules are now final, the CVB will begin coordinated implementation of both rules.

III. ACTION

Licensees, permittees, and applicants should refer to the [Single Tier Label Claim \(STLC\) Industry Guidance page](#) of the CVB website. This page contains detailed instructions on preparing standardized summaries of efficacy and safety data as well as numerous examples. Individuals wishing more assistance may send questions or a request for a teleconference to cvb.single.tier@aphis.usda.gov.

[Veterinary Services Memorandum No. 800.54](#), Guidelines for the Preparation and Review of Labeling Materials, will be updated and a [Draft for Comment posted to the CVB website](#) prior to October 31, 2016. The revised memorandum will provide guidance related to the Labeling and Packaging rule.

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IV. IMPLEMENTATION/APPLICABILITY

The Single Tier Label Claim rule applies to vaccines, bacterins, toxoids, and immunomodulators. Products exempted from this rule include antibody products, diagnostic test kits, autogenous or prescription products, and allergenic extracts.

The Labeling and Packaging rule applies to all products.

Licensees and permittees may voluntarily comply with the provisions of both rules for products initially licensed prior to October 31, 2016. Labeling for products initially licensed after that date must be in compliance with both rules.

Labeling for products licensed with 4-tier language, rather than a single tier claim, will be transitioned over a 4-year period, beginning October 31, 2016. Details of the timeline are found on the [STLC Industry Guidance page](#) of the CVB website.