



CENTER FOR VETERINARY BIOLOGICS NOTICE NO. 19-14

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: Byron E. Rippke
Director

SUBJECT: Extension of Implementation Period of Single Tier Label Claim

I. PURPOSE

The purpose of this notice is to announce procedures for extending the implementation period of the Single Tier Label Claim published as a final rule in the Federal Register. Submission of standardized summaries and labeling for products licensed with 4-tier language, rather than a single tier claim, will now be transitioned over a 5-year period, beginning October 31, 2016, and extending through October 31, 2021.

II. BACKGROUND

The Animal and Plant Health Inspection Service (APHIS) published APHIS Rule 2011-0049 (Single Label Claim for Veterinary Biological Products) 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 APHIS in support of product licensure. CVB Notice 16-15 announced the implementation period for licensees and permittees to conform labeling to the Single Tier Label Claim final rule. The implementation date for the final rule was October 31, 2016, and the original transition period was four years.

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 for 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@usda.gov.

[Veterinary Services Memorandum 800.54](#), Guidelines for the Preparation and Review of Labeling Materials, provides guidance related to the Single Tier Label Claim final rule.

IV. IMPLEMENTATION/APPLICABILITY

Submission of standardized summaries and labeling for products licensed with 4-tier language, rather than a single tier claim, will now be transitioned over a 5-year period, beginning October 31, 2016, and extending through October 31, 2021. Labeling temporarily approved through October 31, 2020, for the original 4-year implementation period will automatically be extended by one year to October 31, 2021.