



Animal and Plant  
Health Inspection  
Service

Veterinary Services

Center for Veterinary  
Biologics

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## CENTER FOR VETERINARY BIOLOGICS NOTICE NO. 17-13

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

**FROM:** Byron Rippke  
Director

**SUBJECT:** Revised Scope of Eligibility for Studies Requiring Single-Tier Summaries

### I. PURPOSE

The purpose of this notice is to announce a change in the scope of eligibility for licensing studies requiring an Individual Study Summary (ISS) under APHIS Rule 2011-0049 (Single Label Claim for Veterinary Biological Products) and 9CFR 112.5(b).

### II. BACKGROUND

CVB Notice 16-15 announced the implementation of APHIS Rule 2011-0049 and referred readers to the [Single Tier Label Claim \(STLC\) Industry Guidance](#) page of the CVB website for detailed guidance on preparing and submitting standardized summaries of efficacy and safety data. The website includes a page focusing on the [scope of studies](#) requiring a single tier summary. The scope focused on the types of studies requiring a summary, regardless when the studies were conducted.

Concerns have arisen regarding the regulatory burden to licensees and permittees associated with locating old studies and formatting data to current standards. The scope of studies requiring a single tier summary is being amended to lessen the burden.

### III. POLICY

The [scope of studies](#) has been amended to state that only those eligible studies submitted on, or after, January 1, 2007, are required to have a full single tier summary. This submission date applies regardless of the actual license date of the product(s) to which the study applies. The types of studies (e.g., pivotal efficacy, safety) requiring a summary, and the types of products included under the single tier rule, have not changed.

Studies submitted prior to 2007 are exempt from the requirement for a full single tier summary. Instead, a placeholder statement will be posted to [productdata.aphis.usda.gov](http://productdata.aphis.usda.gov) to clarify that the licensing study was conducted prior to 2007. Licensees and permittees are welcome to submit full single tier summaries voluntarily for studies submitted prior to 2007. If full summaries are submitted, however, they must meet all requirements for format and content of single tier summaries.

**IV. IMPLEMENTATION/ APPLICABILITY**

This revised policy is effective immediately. Licensees and permittees are strongly encouraged to review updated detailed instructions on the [Single Tier Label Claim \(STLC\) Industry Guidance](#) page of the CVB website, particularly the [scope of studies](#) page and the example of a placeholder statement for studies pre-dating 2007 ([Example 17](#) in the list of example study summaries).