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Single Tier Label Claim (STLC) Industry Guidance

Last Modified:

As part of a movement in 2015 toward single-tier effectiveness statements, 9CFR 112.5(b) was amended to require publication of efficacy and safety study summaries on the APHIS website [Licensed Veterinary Biological Product Information](#). This web page provides details to licensees, permittees, and applicants on preparing and submitting information for those summaries.

A summary of a single study is known herein as an Individual Study Summary (ISS). It is prepared by the licensee and reviewed/edited/cleared by the Center for Veterinary Biologics (CVB) for standard content and appearance. All of the ISSs applicable to a single biological product are then compiled into a Product Compilation Summary (PCS), which is posted to [Licensed Veterinary Biological Product Information](#). The compilation is performed by the CVB.

Scope of Products Affected by Single-Tier

- Vaccines (including prescription platform products), bacterins, toxoids, and immunomodulators are included under the scope of the new rule.
- Products exempted include: antibody products, diagnostic test kits, autogenous, and allergenic extracts.

Scope of Studies Requiring Single-Tier Summaries

[Review this section to determine which of your firm's studies require an Individual Study Summary](#)

Individual Study Summary (ISS) Procedure

Use the ISS template provided by the CVB. Refer to the line-wise instructions provided in the following section for details on how to prepare the ISS. Submit the ISS to CVB as a Microsoft Word document to facilitate editing by CVB. Contact the CVB at CVB.Single.Tier@usda.gov if you do not have access to Microsoft Word software.

[ISS template](#) (24.29 KB)

[ISS template line-wise instructions](#) (203.41 KB)

[Data Requirements](#)

[Submission guidance and instructions](#)

[Examples of a variety of Individual Study Summaries](#) (685.66 KB) **Updated April 8, 2020*

[Implementation timeline](#) (96.42 KB) **Updated November 19, 2019*

Product Compilation Summaries (PCSs)

[Review this section for more information on Product Compilation Summaries](#)

Updating Product Codes Associated With Approved ISSs

Licensees and permittees may need to update the list of product codes associated with a cleared (approved) ISS. See [more instructions](#).

Revisions to Outlines of Production for Single Tier Label Claims

[Review this document for more information on Outline of Production Revisions for Single Tier Label Claim and see an example](#) (109 KB)

Do you want a printable version of all the STLC guidance?

[Click here for the printable version of the "Guidance to Industry Preparing Supporting Summaries for Single Tier \(Single Label Claim\) Effectiveness Statements" document](#) (436.3 KB)

Questions?

Questions may be directed to CVB.Single.Tier@usda.gov.

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