

History of the Single Tier Label Claim

All label claims for veterinary biologicals are based on statistical significance and clinical relevance of efficacy data provided by manufacturers. Historically, veterinary biologicals were assigned one of 4 tiers of effectiveness, depending on the magnitude of the observed protective effects:

- for the prevention of infection,
- for the prevention of disease,
- as an aid in the prevention of disease, or
- as an aid in the control/reduction of disease.

Distinctions between these levels were not well understood by many users of biological products, resulting in potential misinterpretation of label information.

In response to this concern, the USDA is now using a single statement (e.g., “This product has been shown to be effective for the vaccination of healthy animals X weeks of age or older against * * *”) to replace the previous 4 tiers of effectiveness. The rigor with which the USDA evaluates efficacy data for statistical and clinical meaningfulness has not changed.

In addition to a standardized claim statement, a standardized Product Compilation Summary of the efficacy and safety studies used to support licensure is available for review on this website.