

Revisions to Outlines of Production for Single Tier Label Claims

Section VI of Outlines of Production must be updated to contain approved single-tier language for products within the scope of the Single Tier Rule. Outlines may be updated *at any time* through the single tier implementation period (2017-2020), provided that it is no later than when labels bearing single tier language are approved. During the transition, both single tier and 4-tier language may be listed in Section VI. Because of the flexibility in when this update can be made, firms are encouraged whenever possible to combine this revision with other changes, instead of making a special submission solely for this change.

An example update is shown below. The original 4-tier claim is in black text. Additions are in red.

Outline Section VI.D

This product has been shown to be effective for the vaccination of healthy horses 4 months of age or older against Eastern, Western, and Venezuelan encephalomyelitis; tetanus; respiratory diseases caused by equine herpesvirus type 1 and equine influenza virus type A2; and West Nile virus. The duration of immunity against equine influenza is at least 6 months, and against West Nile virus is at least 12 months. For more information regarding efficacy and safety data, see productdata.aphis.usda.gov.

The following is the prior 4-tier claim, which may still appear on certain labels through the implementation period specified in the final rule for APHIS Docket 2011-0049. Labels solely for export may bear 4-tier claims indefinitely if allowed by the importing country.

For vaccination of healthy horses 4 months of age or older as an aid in the prevention of disease caused by Eastern, Western, and Venezuelan encephalomyelitis, and tetanus; as an aid in the prevention of viremia and mortality, and an aid in the reduction of severity of clinical disease caused by West Nile virus, and as an aid in the reduction of respiratory disease caused by equine herpesvirus type 1, and equine influenza virus type A2. The duration of immunity against equine influenza is at least 6 months and against West Nile virus is at least 12 months.

After the implementation period is over, the 4-tier language may be removed from the Outline during routine annual review (no special submission required), unless it still applies to active export-only labeling.