Current Implementation Timeline Single Label Claim and Labeling/Packaging Rules

- This timeline pertains to the following final rules:
 - o APHIS 2008-0008 Labeling and Packaging
 - o APHIS 2011-0049 Single Label Claim
- Products initially licensed in October 2016 may be labeled with single label claims voluntarily, provided that supporting study summaries are finalized prior to licensure.
- Products licensed after October 2016 must be in compliance with Single Label Claim and the Labeling & Packaging Rules at the time of licensure.
- Firms will have 4 years from October 2016 to bring legacy (currently licensed) products into compliance with the single label claim rule. An extension to the implementation period through October 31, 2021 was granted under the CVB Notice 19-14.
- Labeling/packaging updates for legacy products may be done simultaneously with single label claim updates if there is no other reason to update labels prior to adding single label claim language. If, however, a label is updated for miscellaneous reasons prior to adding single label claim language, then the CVB expects the provisions of the labeling/packaging rule to be incorporated when those other updates are made.
- Firms are expected to submit Individual Study Summaries (ISS) for 25% of their legacy products/year. The following general order is recommended for submitting summaries:
 - Feline products
 - o Equine
 - Canine
 - Swine
 - o Bovine
 - o Avian, Aquaculture, and Immunotherapeutics
- Species order is a general guideline, but summaries for other species may be submitted earlier if there is a practical reason to do so.
- Legacy products cannot be marketed with single label claims until supporting summary data are approved.
- Outlines may be updated at any time prior to using single label claims. Products initially licensed with 4-tier claims should list both 4-tier and single-tier language in Section VI until transition is complete.