

Precedents for International Label Non-compliance (VSM No. 800.208)

*****Special Labels cannot have the USDA Establishment Number*****

*****Normal Labels must have the USDA Establishment Number*****

Element	Non-compliance	Disposition			
Claims	Label has production claims.	Special			
Claims	Wording on label claims is not exactly as approved by the USDA but meets the same intent without overt exaggeration. This includes the use of "one-level" claims, such as "for vaccination against Disease X" and substitutions of "prevention" for "control/reduction".	Normal			
Claims	Label has statement for minimum titer/potency that is below that required domestically, BUT the firm has no intention of distributing any serials that do not pass the higher potency required domestically.	Normal, with comment about the potency discrepancy.			
Claims	Label has statement for minimum titer/potency that is above that required for release domestically.	Normal, <i>provided that</i> the mounting sheet contains the proper restriction.			
Claims	Foreign label has text regarding "minimum" antigen content (Outline Section IV.I) for the product.	Normal, provided the values do not exceed the values in the Outline, Section IV.I; Sketch if the values do exceed.			
Claims	Recommended minimum age for use is less than what is approved by APHIS.	Special			
Claims	Label has claims for a particular strain of Seed. USDA does not have data proving the Seed is that strain.	Normal, if the firm can prove the strain identity of the Seed. Process as Special if the firm cannot credibly demonstrate the strain identity of the Seed.			
Dating period	The expiration date that will be put on the label will have a longer dating period than that allowed by USDA.	Special			
Disposal	No burn statement.	Normal			
Disposal	Recommendation for disposal other than burning (example: treat used vial with lye).	Normal			
Establishment Number	Label meets all other requirements for USDA, but has no USDA Est Number.	Sketch			
Establishment Number	Label has "cosmetic" non-compliances that would <u>not</u> be considered grounds for a Special label. All claims and instructions for use meet USDA approval. Label does NOT have a USDA Est. Number.	Sketch			

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Establishment Number	Label has claims or instructions for use that are not approved by USDA. The label bears the USDA establishment number.	Sketch		
Instructions for Use	Label has routes of administration not approved by USDA.	Special		
Instructions for Use	States it is permissible to mix product with another specific product, and data are on file with USDA (and have been reviewed) to show mixing does not cause a problem.	Normal		
Instructions for Use	No statement to use entire contents when first opened.	Normal		
Instructions for Use	No statement on container and/or box to see insert for complete instructions.	Normal		
Instructions for Use	Small container label does not include an instruction to see the insert for full instructions (but an insert is provided).	Normal		
Instructions for Use	Label does not include the recommendation to revaccinate.	Normal		
Instructions for Use	Drinking water / spray vaccine; foreign-approved label has statement that animals must be revaccinated; revaccination statement is not in OP.	Normal		
Instructions for Use	Outline has claim for one species, but label has claims for additional species. Foreign government had approved the claim statement.	Special		
Manufacturing	Firm has a license restricted for export only because of a manufacturing ingredient that is not allowed in the US. All labeling statements are in compliance with filed export-only Outline.	Normal		
Preservatives	Not declared	Normal		
Recoverable quantity	Not specified on container	Normal		
Registration numbers	Label has foreign registration numbers but otherwise meets USDA requirements.	Normal		
Registration numbers	Foreign Regulatory Authority ID is prominently displayed on the label	Normal		
Statement	Submitted as a special label without the Est. # and contains a route that was not approved by the USDA, but has a statement that the product meets US regulations.	Sketch		
Storage temperature	Not specified on container label.	Normal, provided there is a box label that specifies the storage temperature.		
Storage temperature	Range is 2-8 degrees C.	Normal		

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Storage temperature	Statement that product must be held at room temperature for 3 hours before using.	Special		
Terminology	Use of term "Lot Number" instead of "Serial Number".	Normal, but should not be used on diagnostic test kits.		
Trade Name	Overshadows True Name	Normal		
Trade Name	In combination package, the Trade Name of the liquid fractions was changed to match the Trade Name of the freeze-dried fraction.	Special		
True Name	Does not match product license exactly, but is an adequate description of the product.	Normal		
True Name	There is none. No other description of product contents.	Sketch		
True Name	No true name BUT there is text elsewhere on the label describing the composition of the product.	Normal		
Withdrawal period	Stated as 0 days.	Normal		
Withdrawal period	Not specified.	Normal		