



Animal and Plant
Health Inspection
Service

Veterinary Services

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

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Notes:

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	Additional Review Instructions	ML#	notes
Claims	Label has production claims.	Special	[REDACTED]	[REDACTED]	[REDACTED]
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	[REDACTED]	[REDACTED]	[REDACTED]
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.	[REDACTED]	[REDACTED]	[REDACTED]
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.	[REDACTED]	[REDACTED]	[REDACTED]
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.	[REDACTED]	[REDACTED]	[REDACTED]
Claims	Recommended minimum age for use is less than what is approved by APHIS.	Special	[REDACTED]	[REDACTED]	[REDACTED]
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.	[REDACTED]	[REDACTED]	[REDACTED]
Claims	Currently approved export labels do not comply with new Labeling & Packaging Rules	Normal	[REDACTED]	[REDACTED]	[REDACTED]

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Normal labels must have the USDA Establishment Number					
Element	Non-compliance	Disposition	Additional Review Instructions	ML#	notes
Claims	Currently approved export labels do not comply with new Single Tier Rules	Normal			[REDACTED]
Claims	Claims do not agree with filed Outline of Production	Special			[REDACTED]
Claims	Claims on currently approved labels are not supported by data	Special			[REDACTED]
Dating period	The expiration date that will be put on the label will have a longer dating period than that allowed by USDA.	Special			[REDACTED]
Disposal	No burn statement.	Normal			[REDACTED]
Disposal	Recommendation for disposal other than burning (example: treat used vial with lye).	Normal			[REDACTED]
Equine Antibody Product	No statement that donors have tested negative for Equine Parvovirus, EIA, dourine, piroplasmiasis, brucellosis, and glanders. Also applies to omission of caution statement that use of equine serum/plasma has been associated with Theiler's Disease	Normal, provided that foreign regulatory authorities have provided formal documentation that they are aware of the omitted statement(s) and have approved the labeling with the omitted statement(s). Sketch if this documentation is not supplied.	[REDACTED]		[REDACTED]
Establishment Number	Label meets all other requirements for USDA, but has no USDA Est Number.	Sketch			[REDACTED]
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			[REDACTED]
Establishment Number	Label has claims or instructions for use that are not approved by USDA. The label bears the USDA establishment number.	Sketch	[REDACTED]		[REDACTED]
Instructions for Use	Label has routes of administration not approved by USDA.	Special			[REDACTED]
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			[REDACTED]

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Element	Non-compliance	Disposition	Additional Review Instructions	ML#	notes
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			[REDACTED]
Instructions for Use	Drinking water / spray vaccine; foreign-approved label has statement that animals must be revaccinated; revaccination statement is not in OP.	Normal			[REDACTED]
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			[REDACTED]
Preservatives	Not declared or partially declared on labels for Export Only to VICH countries (those with competent regulatory authority: Japan, New Zealand, Canada, Australia, South Africa, Central EMA).	Special			[REDACTED]
Preservatives	Not declared or partially declared on labels for Export Only to non-VICH countries.	Temporary Label not to exceed 2 years		[REDACTED]	[REDACTED]
Product Code	No Product Code on labeling materials	Normal			[REDACTED]

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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.			[REDACTED]
Storage temperature	Range is 2-7 degrees C.	Normal			[REDACTED]
Storage temperature	Statement that product must be held at room temperature for 3 hours before using.	Special			[REDACTED]
Terminology	Use of term "Lot Number" instead of "Serial Number".	Normal, but should not be used on diagnostic test kits.			[REDACTED]
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			[REDACTED]
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			