Precedents for International Label Non-compliance

CONTROLLED//PROPIN//BASIC

Source Document: CVB-MAN-5100, *CVB Operations Manual*, Chapter 4.2.1

Table of Contents

1. **Purpose and Scope**
2. **Abbreviations, Barcode Concepts/Definitions, and References**
3. **Precedents: General Information**
4. **Precedents: Claims Language on Label**
5. **Precedents: Packaging and Labeling Final Rule and Other Codified**
6. **Precedents: Recommendation Statements on Label**
7. **Precedents: Product-Specific Statements on Label**
8. **Precedents: Species-Specific Statements on Label**
9. **Precedents: Foreign Registration and Regulatory Authorizations**
10. **Barcodes on Label**

Appendix I. Criteria/Wording for Labeling Precedents (Internal use only)

1. Purpose and Scope

This document provides precedents of regulatory flexibility in which non-compliance to 9 CFR 112.8, labels for export only, or 112.2(e), special labels for export, is granted for use on labels for export only. All labels must comply with 9 CFR 112.1 and Special Labels for Export must also comply with 9 CFR 112.2(e). Mounting sheets are marked "For Export Only".

9 CFR 112.1
Labels, stamps, marks, statements, stickers, or alterations to affixed labels shall not make the label false or misleading or illegible in any manner.

9 CFR 112.2(e)
Regulation for Special Labels for Export.

9 CFR 112.8 For export only.
"The applicable regulations for packaging and labeling a biological product produced in the United States shall apply to such biological product if exported from the United States except as otherwise provided in this section. Only labels approved as provided in § 112.5 shall be used."

The navigation pane may be helpful to review sections in this document.

2. Abbreviations, Barcode Concepts/Definitions, and References

2.1 Abbreviations used in this document:

1D	One (1)-dimensional barcode
2D	Two (2)-dimensional barcode
9 CFR	Title 9, *Code of Federal Regulations*
APHIS	Animal and Plant Health Inspection Service
ATN	Abbreviated True Name
BVDV	Bovine Viral Diarrhea Virus
CLI	Certificate of Licensing and Inspection
CVB	Center for Veterinary Biologics
DOI	Duration of immunity
EHV	Equine Herpes Virus
IC	Inspection and Compliance Unit of CVB
ICE	International Electrotechnical Commission
ISO	International Organization for Standardization
JMAFF	Japan Ministry of Agriculture, Forestry, and Fisheries that regulates veterinary biologics
NA	Not applicable
NCAH	National Centers for Animal Health
OOI	Onset of immunity
OP	Outline of Production
PCN	Product Code Number
PCS	Product Compilation Summary

QR Code	Quick Response Code
ST	Single Tier
U.S.	United States
USDA	United States Department of Agriculture
VLN	US Veterinary Biologics Establishment Number or Establishment Number
VSM	Veterinary Services Memorandum

2.2 Barcode Concepts/definitions used in this document:

1D Codes	Barcodes or graphical image (vertical lines and spaces) that allow data to be presented in one linear direction. Limited number of characters. Depends on a database. Scanned with a laser scanner to read.
2D Codes	Barcodes or graphical image (dots, shapes, and patterns) that allow data to be presented in two directions, both horizontal and vertical directions. Codes can work independently of a database. Requires software and a camera or other imaging device to read.
Data Matrix Code	Barcodes or graphical image that allow use of alphanumeric and binary data with defined capacity for characters/letters/numbers. Typically an "L" shape grid on a white background. A type of a two-dimensional barcode. Follows ISO/IEC 16022 for data matrix symbology.
QR Codes	Barcodes or graphical image that allow use of alphanumeric and binary data with defined capacity for characters/letters/numbers. Typically a square grid on a white background. A type of a two-dimensional barcode. Follows ISO/IEC 18004 for QR code symbology.

2.3 The following regulations and guidance documents pertain:

- 9 CFR Part 112
- 9 CFR 112 Revision: 2015 Packaging and Labeling Final Rule APHIS-2008-008
- 9 CFR 112 Revision: 2016 Single Tier Claim Final Rule APHIS-2011-0049
- VSM 800.54 Guidelines for the Preparation and Review of Labeling Materials
- VSM 800.206 General Licensing Considerations: Preparing Outlines of Production for Vaccines, Bacterins, Antigens, and Toxoids and Diagnostic Test Kits
- VSM 800.208 Special Labels for Product for Export
- VSM 800.213 Licensing Guidelines for Production Platform-Based, Non-Replicating, Nonviable Products
- VSM 800.214 Prescription Platform Product Biologics
- CVB Notices

- Reviewer Chapter(s) providing guidance on labeling on the APHIS website
- ICSOP0044 on the APHIS website IC document, "Export Certificates and Certificates of Licensing and Inspection"

3. Precedents: General Information

3.1 Regulatory flexibility

Sections 4-10 of this document provide regulatory flexibility extended to export only labels and Special Labels for Export.

The use of "NA" for Special Labels for Export may not exclude regulatory flexibility; the decision will be based upon documentation from the regulatory authority of the importing country. Consult the CVB for additional guidance.

3.2 Translations

3.2.1 Requirement for translation 9 CFR 112.5

"(f) Special requirements for foreign language labels:

(1) An accurate English translation must accompany each foreign language label submitted for approval. A statement affirming the accuracy of the translation must also be included.

(2) Foreign language portion of a bilingual label shall be a true translation of the English portion. Reference to additional information on the enclosure shall not be made unless that enclosure is also bilingual."

3.2.2 English translation

The English translation of non-English text must be accurate and correct. Certified translations are not required. Given the increasing accuracy of online translation tools, and the inherent cultural differences in translation that may lead to misunderstandings, firms are encouraged to translate as close to the approved English version as possible, and to avoid colloquialisms that may not lend themselves to adequate review.

3.2.3 Accuracy of translation

Firms are to affirm the accuracy of translations.

- NCAH Portal submission: Submission electronically through the NCAH Portal affirms the submission is accurate per the statement selected upon completion of the submission to CVB, "I agree that I've looked over this information and everything entered is true to my knowledge."
- Hardcopy submission: Include a statement such as "The accuracy of the translation is affirmed" or similar in the submission or on the mounting sheet(s).

3.3 Specify destination country

The country of destination (importing country) must be identified on the mounting sheet for Special Labels for Export. The declaration is optional for export only labels.

3.4 Regulatory authority documentation

- Special Labels for Export require written authorization from regulatory officials of the importing country or region per 9 CFR 112.2(e). English translations must be provided. Firms must include the documentation in the submission or provide the Mail Log number where the documentation and translation may be found on the mounting sheet.
- Export only labels typically do not require regulatory documentation unless when required to support use of regulatory flexibility.

3.5 License Restrictions

Include wording required by license restrictions.

4. Precedents: Claim Language on Label

4.1 Claim language

Regulatory flexibility for the following list of topics regarding claim language is found in Section 4.2 Table 1 below:

- Claims-4 tier claim
- Claims-4 tier and DOI statement
- Claims-4 tier and OOI statement
- Claims-Production claims
- Claims-productdata.aphis.usda.gov website statement (ST eligible products)
- Claims-ST claim (ST eligible products)
- Claims-ST claim and minimum age not required prior to licensure statement (ST eligible products)
- Claims-ST claim and DOI statement (ST eligible products)
- Claims-ST claim and OOI statement (ST eligible products)
- Claims-ST claim and 2nd paragraph (ST eligible products)
- Meets USDA requirements statement
- Minimum age
- Minimum age not assigned-4 tier claim
- Minimum age not assigned-ST claim
- Target species poultry wording

4.2 Table 1 Regulatory Flexibility for Topics by Claim Language on Label

Requirements/Reference 9 CFR or Veterinary Services Memorandum (VSM)	**Regulatory Flexibility for Export Only Label**	**Regulatory Flexibility for Special Label for Export**
Claims- 4-tier claim Allergenic and allergenic prescription products; antibody products per 9 CFR 113.450; autogenous products; diagnostic products; AND historical claim granted for other products if stated in OP.	Wording on label claim is not exactly as approved by the USDA in OP but meets the same intent without overt exaggeration. This includes the use of 4-tier language and substitutions of "prevention" for "control/reduction".	Claim not approved and not supported by data on file with CVB.
Claims- 4-tier claim and DOI statement Allergenic and allergenic prescription products; antibody products per 9 CFR 113.450; autogenous products; diagnostic products; AND historical claim granted for other products if stated in OP.	DOI wording on label claim is not exactly as approved by the USDA in OP but meets the same intent without overt exaggeration.	Claim not approved and not supported by data on file with CVB.
Claims- 4-tier claim and OOI statement Allergenic and allergenic prescription products; antibody products per 9 CFR 113.450; autogenous products; diagnostic products; AND historical claim granted for other products if stated in OP.	OOI wording on label claim is not exactly as approved by the USDA in OP but meets the same intent without overt exaggeration.	Claim not approved and not supported by data on file with CVB.
Claims-Production claims e.g., weight gain, weight loss	Not allowed.	Production claims allowed.
Claims- productdata.aphis.usda.gov website statement (ST eligible products) 112.2(a)(9)(v), 112.5(b)	Optional to have website statement with either 4-tier claim or ST claim when PCS present on APHIS website and website statement matches wording in OP or 9 CFR or VSM 800.54. Variation to website address itself is not allowed.	Not allowed.

Claims-ST claim 112.2(a)(12), 112.2 (a)(5), VSM 800.54 III.E. Bacterins; immunomodulators; cancer therapeutic products; platform and prescription platform products per VSM 800.213 and 214; toxoids; and vaccines.	Wording on label claim is not exactly as approved by the USDA in OP but meets the same intent without overt exaggeration. This includes the use of 4-tier language and substitutions of "prevention" for "control/reduction".	Claim not approved and not supported by data on file with CVB.
Claims-ST claim and minimum age not required prior to licensure statement 112.2(a)(12), 112.2 (a)(5), VSM 800.54 III.E Bacterins; immunomodulators; cancer therapeutic products; platform and prescription platform products per VSM 800.213 and 214; toxoids; and vaccines.	ST claim per OP or similar wording. • Optional to have minimum age not required prior to licensure statement.	Claim not approved and not supported by data on file with CVB.
Claims-ST claim and DOI statement 112.2(a)(12), 112.2 (a)(5), VSM 800.54 III.E Bacterins; immunomodulators; cancer therapeutic products; platform and prescription platform products per VSM 800.213 and 214; toxoids; and vaccines.	ST claim per OP or similar wording. • Optional to have DOI statement. • If DOI statement is present, must match OP.	Claim not approved and not supported by data on file with CVB.
Claims-ST claim and OOI statement 112.2(a)(12), 112.2 (a)(5), VSM 800.54 III.E Bacterins; immunomodulators; cancer therapeutic products; platform and prescription platform products per VSM 800.213 and 214; toxoids; and vaccines.	ST claim per OP or similar wording. • Optional to have OOI statement. • If OOI statement is present, must match OP.	Claim not approved and not supported by data on file with CVB.
Claims-ST claim and 2nd paragraph 112.2(a)(12), 112.2 (a)(5), VSM 800.54 III.E Bacterins; immunomodulators; cancer therapeutic products; platform and prescription platform products per VSM 800.213 and 214; toxoids; and vaccines.	ST claim per OP: • Optional to have 2nd paragraph statement of ST claim. • If 2nd paragraph statement present, must match OP.	Claim not approved and not supported by data on file with CVB.

Meets USDA requirements statement	Optional	Statement not allowed.
Minimum age	Age is stated per OP or older than stated in OP.	Recommended minimum age for use is less than what is approved by APHIS.
Minimum age not assigned-4 tier claim 112.2 (a)(5) Age was not required per 112 prior to regulation revision in 2015/2016 except as stated in 9 CFR 113.	If age is not stated in OP for 4-tier, then not required to appear on labeling; instead healthy <species> is stated.	Recommended minimum age for use is less than what is approved by APHIS.
Minimum age not assigned-ST claim 112.2 (a)(5) Age was not required per 112 prior to regulation revision in 2015/2016 except as stated in 9 CFR 113. No minimum age assigned during conversion from 4-tier to ST claim wording.	If age is not stated in OP for ST, then does not appear on labeling; instead healthy <species> is stated.	Recommended minimum age for use is less than what is approved by APHIS.
Target species poultry wording 112.2 (a)(5)	State specific species in claim then allow use of translation of "birds" elsewhere on label; chick=chicken, poults=turkey, breeding hen/layer acceptable.	Claim not approved and not supported by data on file with CVB.

5. Precedents: Packaging and Labeling Final Rule and Other Codified

5.1 Packaging and Labeling Requirements

Regulatory flexibility for the following list of topics regarding Packaging and Labeling Final Rule requirements is found in Section 5.2 Table 2 below:

- ATN-Firm generated
- Address
- Animal Use/Veterinary Use statement
- Do not mix statement
- Expiration date
- Full directions-see other label for full directions
- Human exposure statement
- Inactivation statement as disposal method

- Instructions for use
- Preservatives
- PCN
- Recoverable quantity
- Route of administration
- Safety in breeding animals
- Serial or lot number
- Storage temperature
- Telephone number (contact phone number)
- Trade Name
- True Name
- True Name same font and size Trade Name
- Use entire contents statement for multiple dose container
- VLN
- Withdrawal period

5.2 Table 2 Regulatory Flexibility for Topics by Packaging and Labeling Final Rule and Other Requirements on Label

Requirements/Reference 9 CFR or Veterinary Services Memorandum (VSM)	**Regulatory Flexibility for Export Only**	**Regulatory Flexibility for Special Label for Export**
ATN- **Firm generated**	Abbreviation is firm generated and represents the composition or adequate description of the product.	NA
Address Producer (manufacturer)/ subsidiary/division/ distributor	• Not required on very small container if present on other labeling. • Producer/subsidiary/ division: provide State & U.S. • Distributor: provide country.	NA

Animal Use/Veterinary Use statement 112.2 (d)(3), 112.7(d)(1-2) VSM 800.54 III.M.	• Optional animal use/veterinary use statement. Animal or veterinary use indicates use in animals (and not humans). This does not mean use by or under the supervision of a veterinarian for use or administration. • 112.7(d)(1-2) required wording for live Rabies Virus products is not optional. • Note-this wording is not the same as wording to match a license restriction for use by or under a veterinarian.	NA
Do not mix statement 112.2 (a)(7)(i), VSM 800.54 Section III.L	• Optional wording per 9 CFR. • States permissible to mix with another licensed product; need data on file with CVB to allow and/or stated in OP.	Mixing with another specific product without data on file by CVB.
Expiration date 112.2(a)(9)(i)	Must match OP.	Longer dating period than approved in OP.
Full directions-see other label for full directions	• No statement on small final container, container and/or box to see insert for complete instructions when insert is always included in packaging. • If insert not included in the submission for review, then firm should comment on the mounting sheet the insert Label number that applies to the insert to always be included in packaging.	NA

Human exposure statement 112.2 (a)(7)(ii) VSM 800.54 III.N.	Optional and if present may use alternative wording.	NA
Inactivation statement as disposal method e.g., burn, inactivate, local authority, etc. 112.2 (a)(7)(iii)	Optional and if present may use alternative wording to refer to burn or per local/federal/state authority or similar.	NA
Instructions for use 112.2(a)(5)	Must match OP.	Use not approved by APHIS.
Preservatives 112.2 (a)(10) Export only to Japan; New Zealand; Canada; Australia; South Africa; EU; European Economic Area (EEA) countries when included in EU registrations: Iceland, Liechtenstein, and Norway; UK; Switzerland when included in or recognizing an EU registration.	• Must match OP. • Not declared or partially declared when importing country documentation explicitly states preservatives are not allowed/required to be stated on labeling.	Not declared or partially declared.
Preservatives 112.2 (a)(10) Export only to countries that are **NOT** Japan; New Zealand; Canada; Australia; South Africa; EU; European Economic Area (EEA) countries when included in EU registrations: Iceland, Liechtenstein, and Norway; UK; Switzerland when included in or recognizing an EU registration.	• Must match OP. • Not declared or partially declared when importing country documentation explicitly states preservatives are not allowed to be stated on labeling. • If not present and lack of importing country documentation that wording is prohibited, grant 2-year temporary label approval to allow time to update registration.	Not declared and importing country documentation does not explicitly include wording to prohibit preservatives on label.

PCN 112.2 (a)(3), VSM 800.54 III.D.	• Optional • PCN number as assigned by CVB and on product license if present. • If present may use alternative format to define PCN per 112 and VSM 800.54. • Flexibility to not be near or adjacent to VLN/VPN.	Must not appear.
Recoverable quantity 112.2(a)(9)(iii)	Not specified on container and stated on box.	NA
Route of administration 112.2 (a)(5)	Must match OP.	Routes not approved by APHIS.
Safety in breeding animals 112.7(c) pregnancy statement	Optional unless antigen is known to be unsafe in pregnant animals/other classes of animals (breeding male) then must state or importing country provides documentation that a statement regarding safety in breeding animals statement is specifically not required.	NA
Serial or lot number 112.2 (a)(9)(iv)	Use of lot or similar except for diagnostic products.	NA
Storage temperature 112.2 (a)(4), VSM 800.54 III.J.	• 2-7°C/35-46°F or not over 45°F. • Other temp if in OP. • Must be present on box if not on container and container refers to box. • Not required on very small container for poultry products stored in liquid nitrogen.	• Temp not approved as written in OP. • Holding at room temp for a period of time is not approved by APHIS.
Telephone number (contact phone number) 112.2(a)(2), VSM 800.54	Optional	NA

Trade Name 112.5(d)(2)(ii), VSM 800.54	• Optional. • For IC to issue a Certificate of Licensure and Inspection, one label (domestic or export only or special label for export) must be active with the Trade Name; see IC manual ICSOP0044 on the APHIS website or contact IC for additional guidance	NA
True Name 112.2 (a)(1), VSM 800.54 III.A.	True Name not as stated on license though wording indicates composition or adequate description of the product either where the True Name would be expected or elsewhere on the label.	NA
True Name similar/same font and size True Name 112.2(c) and 800.54 to not overshadow	Similar/same font and size of Trade Name to True Name allowed; cannot overshadow.	NA
Use entire contents statement for multiple dose container 112.2(a)(6) multi-dose 112.2(a)(9)(ii) # doses	• Optional multi-dose statement to use entire contents when first opened. • Number of doses is required.	NA

VLN 112.2 (a)(3), VSM 800.54 III.D.	• VLN as assigned by CVB and on Est. license. • May use alternative format to define or write VLN per 112 and VSM 800.54. • Flexibility to not be near or adjacent to PCN. • Name of producer/subsidiary/ division/distributor must be clearly stated so as not to cause confusion to end user. • Importing countries provides regulatory documentation that prohibits per 9 CFR 112.2(e)(2) and label meets all other requirements for non-compliances that would NOT be grounds for a special label.	Must not appear.
Withdrawal period 112.2(a)(8) food producing animals and horses	Optional or state as zero (0) days.	NA

6. Precedents: Recommendation Statements on Label

6.1 Recommendation statements

Regulatory flexibility for the following list of topics regarding recommendation statements is found in Section 6.2 Table 3 below:

- Maternal antibody interference statement
- Revaccination statement outside of the initial series allowed under 4-tier
- Vaccination schedule-initial series
- Vaccination-revaccination outside of initial series ST claim

6.2 Table 3 Regulatory Flexibility for Recommendation Statements on Label

Requirements/Reference 9 CFR or Veterinary Services Memorandum (VSM)	**Regulatory Flexibility for Export Only**	**Regulatory Flexibility for Special Label for Export**
Maternal antibody interference statement VSM 800.54, III.K.	• Optional and if present may use alternative wording. • Historically under 4-tier claim language to revaccinate when maternal antibody waned for species was allowed; statement allowable without data	NA
Revaccination statement outside of the initial series allowed under 4-tier	• Optional. • Historically under the 4-tier claim language, a statement to revaccinate annually was allowed and not data driven by DOI study; inclusion of a statement for annual revaccination is allowable without data.	DOI not approved.
Vaccination schedule-initial series 112.2(a)(5)	• Importing country provides documentation specifically stating that initial series not required and meets other requirements for export only. • Drinking water / spray vaccine; label has statement that animals must be revaccinated; revaccination statement is not in OP.	Differs from approved in OP.

Vaccination-revaccination outside of initial series ST claim 112.7(f), 113 Allowed revaccination statement for products licensed under 4-tier language in conversion to ST claim wording for export only labels without data to support revaccination time period.	• Optional unless Rabies Virus product or 9 CFR 112/113 requirement. • Optional to state revaccinate at each pregnancy if passive immunity claim.	Differs from approved in OP or outside of annual revaccination.

7. Precedents: Product-Specific Statements on Label

7.1 Product-specific statements

Regulatory flexibility for the following list of topics regarding product-specific statements is found in Section 7.2 Table 4 below:

- Antigen content statement per Section IV.I. of the OP statement including maximum antigen content
- Antigen content below Section IV.I. of the OP statement
- Antigen content above Section IV.I. of the OP statement
- Composition statement and Strain/Type/Genotype of Master Seed
- ISO symbols
- License restriction for Export Only due to manufacturing ingredient
- Master Seed strain identity
- Titer/value for potency below required for release per Section V.C. of the OP
- Titer/value for potency above required for release per Section V.C. of the OP
- Trade Name and liquid fractions of combination package
- Warning and caution statements and any other vital information for product's use that is product specific (codified 9 CFR 112 and 113)
- Warning and caution statements and any other vital information for product's use that is product specific (not codified, APHIS approved)

7.2 Table 4 Regulatory Flexibility for Product-Specific Statements on Label

Requirements/Reference 9 CFR or Veterinary Services Memorandum (VSM)	**Regulatory Flexibility for Export Only**	**Regulatory Flexibility for Special Label for Export**
Antigen content statement per Section IV.I. of the OP statement including maximum antigen content ***This is not potency**	• Optional text stating "minimum" antigen content per OP Section IV.I. • Antigen content statement cannot exceed any maximum antigen content approved in OP.	NA

Antigen content stated on label is below approved in Section IV.I. of the OP statement ***This is not potency**	Sketch if antigen content on label below level in OP.	NA
Antigen content stated on label is above approved in Section IV.I. of the OP statement ***This is not potency**	Sketch if antigen content states above maximum level in OP.	• Label has statement for antigen content that is above stated in OP. • Above maximum if present in OP. • Both instances above require firm to add comment on mounting sheet that only serials meeting the criteria will have the label. Reviewers add statement if firm does not.
Composition statement 112.7, 113 VSM 800.54, VSM 800.54, III.H.	Required for the following: • EHV type 1, 4 • Required BVDV type 1, 2 • Infectious bronchitis • Influenza	NA
ISO symbols VSM 800.54 III.G.	Alternatives to wording in VSM 800.54 if meaning is understood in symbol or explanation provided; cannot be false or misleading.	NA
License restriction for Export Only due to manufacturing ingredient	Firm has a license restricted for export only because of a manufacturing ingredient that is not allowed in the US. All statements on label are in compliance with filed export-only OP.	NA
Master Seed strain identity	Seed strain not in OP: firm provides information to prove the strain identity of the Seed though not written into OP. Firm should add to OP at next revision if not present.	Seed strain not in OP and firm cannot credibly demonstrate the strain identity of the Seed.

Titer/value for potency stated on label is below required for release per Section V.C. of the OP	Label has statement for minimum titer/potency value that is below that required in OP. CVB will release according to the OP. Firm adds a statement in the comment section of the mounting sheet "For export to <country>. To be affixed only to serials having a release titer of at least <titer>". to indicate CVB recognizes the potency discrepancy and only releases serials according to the OP. If firm did not add the statement, then reviewer adds to mounting sheet.	NA
Titer/value for potency stated on label is above required for release per Section V.C. of the OP	Label has statement for titer/potency value that is above stated in OP. CVB will release according to the OP. Firm adds a statement in the comment section of the mounting sheet, "For export to <country>. To be affixed only to serials having a release titer of at least <titer>". If firm did not add the statement, then reviewer adds to mounting sheet. The higher titer must be in Section VI.A. of the OP per VSM 800.206 for IC to issue a Certificate for Licensure and Inspection Otherwise, following guidance in IC document ICSOP0044available on the APHIS website.	NA

Trade Name and liquid fractions of combination packages	Trade Names must not be false or misleading.	In a combination package, the Trade Name of the liquid fractions was changed to match the Trade Name of the freeze-dried fraction.
Warning and caution statements and other vital information for product's use that is product specific (codified 9 CFR 112 and 113)	Must be present as written in OP especially if impact purity, safety, potency, and/or efficacy of product use. Alternatively, importing country documentation explicitly stating not required.	NA
Warning and caution statements and other vital information for product's use that is product specific (not codified, APHIS approved)	Should be present as written in OP especially if impact purity, safety, potency, and/or efficacy of product use.	NA

8. Precedents: Species-Specific Statements on Label

8.1 Species-Specific Statements

Regulatory flexibility for the following list of topics regarding product-specific statements is found in Section 8.2 Table 5 below:

- Dose Volume in Limited Administrations to Poultry and Swine
- Equine Parvovirus-Hepatitis statement
- Species use not approved

8.2 Table 5 Regulatory Flexibility for Species-Specific Statements on Label

Requirements/Reference 9 CFR or Veterinary Services Memorandum (VSM)	Regulatory Flexibility for Export Only	Regulatory Flexibility for Special Label for Export
Dose Volume in Limited Administrations to Poultry and Swine	Allowable to not include a dose volume for administrations as listed: • Poultry: wing web, drinking water, Beak-O-Vac, aerosol/coarse spray • Swine: drinking water	NA

Equine Parvovirus-Hepatitis statement for antibody products per 9 CFR 113.450 when derived from horses	Statements needed: • Product administered to horses must have a caution statement regarding use of product is associated with Theiler's Disease • Products not administered to horses must have a caution statement to not use in horses. Lack of statements above allowed when importing country documentation provides wording that the statements may be omitted.	Not present and no documentation from importing regulatory authority that statement must be omitted.
Species not approved by APHIS	Must match OP.	Use in species not approved by APHIS.

9. Precedents: Foreign Registration and Regulatory Authorizations

9.1 Foreign Registration and Foreign Regulatory Authority Authorizations

List of topics regarding foreign registration and foreign regulatory authority authorizations is found in Section 9.2 Table 6 below:

- Foreign registration numbers
- Foreign regulatory authority identification
- Foreign regulatory authorization expiration dating

9.2 Table 6 Regulatory Flexibility for Foreign Registration and Foreign Regulatory Authority Authorizations

Requirements/Reference 9 CFR or Veterinary Services Memorandum (VSM)	Regulatory Flexibility for Export Only	Regulatory Flexibility for Special Label for Export
Foreign registration number	Foreign registration numbers present and otherwise meets requirement for export only.	NA
Foreign regulatory authority identification	Foreign regulatory authority ID present and otherwise meets requirement for export only.	NA

Foreign regulatory authorization expiration dating	When the regulatory authorization has an expiration date; grant temporary approval to label and add 2 years to the expiration date. Export only does not require regulatory authorization unless as needed in this document	When the regulatory authorization has an expiration date; grant temporary approval to label and add 2 years to the expiration date.

10. Barcodes on Label

10.1. Barcodes on Label

Regulatory flexibility for the following list of topics regarding barcodes is found in Section 10.2 Table 7 below:

- JMAFF
  Use of barcodes for export only labels, and special labels for export to Japan. The use is based on our understanding that JMAFF has control of the barcode.

10.2 Table 7 Regulatory Flexibility for Barcodes on Label

Requirements/Reference 9 CFR or Veterinary Services Memorandum (VSM)	**Regulatory Flexibility for Export Only**	**Regulatory Flexibility for Special Label for Export**
Labels for export only to Japan with barcodes linking to JMAFF website	JMAFF QR codes for website. Firm should ensure the label has an active QR code that can be scanned to direct to the JMAFF website or provide a document with the active link and/or website link. CVB understands that the Japanese regulatory authority reviews labels with 2D Codes before use in Japan.	JMAFF QR codes for website. Firm should ensure the label has an active QR code that can be scanned to direct to the JMAFF website or provide a document with the active link and/or website link. CVB understands that the Japanese regulatory authority reviews labels with 2D Codes before use in Japan.