



Animal and Plant  
Health Inspection  
Service

Veterinary Services

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## VETERINARY SERVICES MEMORANDUM NO. 800.54

**TO:** Veterinary Services Leadership Team  
Directors, Center for Veterinary Biologics  
Biologics Licensees, Permittees, and Applicants

**FROM:** Jack A. Shere  
Deputy Administrator

**SUBJECT:** Guidelines for the Preparation and Review of Labeling Materials

### I. PURPOSE

This memorandum provides guidance to licensees, permittees, and applicants regarding labeling materials for USDA-licensed products. Most labeling requirements are found in title 9, *Code of Federal Regulations*, part 112 (9 CFR 112). The Animal and Plant Health Inspection Service (APHIS) updated these requirements substantially in 2015 and 2016 by publishing Final Rule [2008-0008](#) (Labeling and Packaging) and Final Rule [2011-0049](#) (Single Label Claim). The guidance in this memorandum emphasizes or interprets aspects of labeling regulations that merit further detail.

### II. REPLACEMENT

This memorandum replaces Veterinary Services (VS) Memorandum No. 800.54 dated May 15, 2017.

### III. LABELING ELEMENTS

#### A. True Names

1. APHIS assigns True Names. Display the True Name on labeling with the exact wording printed on the product license or permit. Exception: Bovine parainfluenza may be presented as either Parainfluenza<sub>3</sub> or Parainfluenza 3.
2. In the case of very small container labels, firms may use an abbreviated version of the True Name if the full True Name is also provided on accompanying labeling materials. The abbreviated True Name appears on the product license or permit and must be reproduced exactly on labeling. Click here for a [list of standardized abbreviations](#).
3. Give equal emphasis (e.g., color, size, boldness, capital letters) to each term in the principal part of the True Name.

**B. Trade Names**

1. Except as otherwise provided, associate a Trade Name with a single product.
2. A manufacturer, distributor, or permittee must have the exclusive right – by ownership, assignment, exclusive-use license, or other means – to use a Trade Name on a product.
3. A distributor or permittee who owns an exclusive right to a Trade Name may transfer the Trade Name to a new manufacturer for use on the labeling of a substantially similar product for the distributor or permittee. APHIS will determine case by case whether a product is “substantially similar.” APHIS may require the new manufacturer to add a postscript to the Trade Name (Trade Name+x), where, in its opinion, the change of manufacturer creates a product that is substantially similar but not identical with respect to a factor posing a potential risk to users.
4. Configure the label so that the True Name is the most conspicuous feature. Place the Trade Name below the True Name, and do not allow the Trade Name to overshadow the True Name by size, color, or boldness.

**C. Functional Names**

Use Functional Names to identify individual diagnostic kit components. This contrasts to the True Name, assigned to the composite kit.

**D. Establishment and Product Codes**

The regulations at 9 CFR 112.2(a)(3) require labels to bear the U.S. Veterinary Biologics Establishment License Number (VLN) or the U.S. Veterinary Biological Product Permit Number (VPN), as well as the Product Code Number (PCN), except where specifically exempted. The current regulations state that ONLY the formats VLN, VPN, and PCN may be used.

In addition to the currently codified formats above, APHIS will continue to accept the following establishment abbreviations found in 9 CFR 112.2(a)(3) before implementing the Labeling and Packaging Rule:

- U.S. Veterinary License No.
- U.S. Vet. License No.
- U.S. Vet. Lic. No.
- U.S. Veterinary Permit No.
- U.S. Permit No.

Acceptable additional formats for PCN are:

- Product Code No.
- U.S. Vet. Prod. No.
- Prod. Code

Place an acceptable abbreviation next to the numbers; the numbers should not appear alone, without definition. The regulations also specify placing the establishment/permit number and product code number (VLN/PCN or VPN/PCN) adjacent to each other, in that order, on labeling. APHIS intends this to help the customer locate and recognize this information.

#### E. Indications Statements For Products Within the Scope of the Single Label Claim Rule

The Single Label Claim Rule applies to domestic labeling for vaccines, bacterins, toxoids, and immunomodulators, except for autogenous and prescription products and allergenic extracts. It does not apply to antibody products or diagnostic test kits.

##### 1. First paragraph

- a. Structure effectiveness claims according to the following formats:

Prophylactic products:

“This product has been shown to be effective for the vaccination of healthy (insert name of species) X weeks of age or older against (insert name of agent or disease). For more information regarding efficacy and safety data, see [productdata.aphis.usda.gov](http://productdata.aphis.usda.gov).”

Variation for therapeutic products:

“This product has been shown to be effective for the treatment of (insert name of species) X weeks of age or older against (insert name of agent or disease). For more information regarding efficacy and safety data, see [productdata.aphis.usda.gov](http://productdata.aphis.usda.gov).”

Variation for products providing passive protection:

“This product has been shown to be effective for the vaccination of healthy (insert name of species) to provide passive immunity against (insert name of agent or disease) in offspring.”

Synonyms for “offspring” (e.g., progeny, piglets, calves) may be used.

Minimum age is not required; see Section III.F.2 of this memorandum.

Variation for products with conditional licenses:

“For the vaccination of <insert animal species> against <insert agent or disease>. This product license is conditional; efficacy and potency have not been fully demonstrated. For more information regarding safety data, see [productdata.aphis.usda.gov](http://productdata.aphis.usda.gov).”

- b. If the agent can cause more than one distinct disease syndrome, include the syndrome in the claim. Examples include:

“...against respiratory disease due to BVD1 and 2”

“...against persistently infected calves due to BVD1 and 2.”

- c. For prophylactic products, specify the demonstrated duration of immunity for each fraction or indicate that the duration is unknown. Clarify that it is a minimum duration of immunity, as the actual duration may be considerably longer. Place this information before the instruction to see [productdata.aphis.usda.gov](http://productdata.aphis.usda.gov).

Example: “The duration of immunity against viruses A and B is at least 12 months. The duration for the remaining viruses in this product has not been determined.”

- d. If APHIS has approved onset of immunity claims, include these here also.
- e. Do not include any other text in the first paragraph.

## 2. Optional second paragraph

If the product has been proven effective against specific disease signs or sequelae (e.g., mortality, viremia, shedding), firms may state this in a second paragraph.

- a. Do not use language that could be construed as a four-tier claim. Example of permissible language: “The vaccine has been shown to be effective against viremia and virus shedding in the feces.”
- b. Include only those signs/sequelae APHIS has specifically approved as part of a label claim.

## F. Minimum Age

Labeling for biologics other than diagnostic kits must include the minimum age of animals recommended for product use. This is based on the age of the animals used in the pivotal efficacy and field safety studies. If the age is not consistent between the studies, cite the older age in the indication statement. In some cases, firms may refer also to the younger age study in a paragraph appearing below the indication statement.

Firms may specify minimum weight in lieu of age for aquaculture products or other products where weight is a more meaningful criterion than age. For certain live poultry vaccines that may be transmitted to eggs, APHIS may require a statement “not to be used within X weeks of lay”.

Minimum age applies to an entire product, not individual fractions. For multivalent products with multiple supporting efficacy and safety studies, the minimum age for product use is based on the oldest animals used in any of the supporting studies.

1. Products Licensed Before Requirement to Establish Minimum Age

In 2002, APHIS published policy regarding the use of minimum-aged animals in licensing studies. For products licensed before APHIS required a minimum age for use, manufacturers may use the following indication statement: “This product has been shown to be effective for the vaccination of healthy (insert name of species) against (insert name of agent or disease). This product was licensed prior to the requirement to establish a minimum age for use. For more information regarding efficacy and safety data, see [productdata.aphis.usda.gov](http://productdata.aphis.usda.gov).”

2. Products for Use Only in Mature Animals

A minimum numeric age is not required for products used exclusively in mature animals. Examples include products with recommendations to use prior to breeding/parturition or if indicated for use in “adult” animals.

3. Therapeutic Products

A minimum age is not required for certain therapeutic products, such as cancer or atopy products, unless there is a specific safety concern. Such products are typically evaluated for efficacy in naturally affected animals from a variety of sources and covering a wide variety of ages. For therapeutic products where efficacy studies may feasibly be conducted in age-matched animals under a more controlled study design, minimum age requirements may apply.

G. ISO Symbols

APHIS allows specified symbols on container labeling in situations where the use of text is not practical. Permissible symbols are in accordance with ANSI/AAMI/ISO 15223-1:2012 and ASTM D5445-11a (ISO 780).

1. Click here for a [list of permissible symbols](#).
2. When using these symbols, include an explanatory key on the carton or the product enclosure. For multi-language labels, the explanatory key must include all languages appearing in the labeling.

H. Antigen Type/Strain When Not Included in the True Name

1. Some agents have multiple generally recognized types or strains that impact vaccine effectiveness. The True Name frequently specifies only the agent in the vaccine. Examples include, but are not limited to, vaccines containing equine

rhinopneumonitis virus, bovine virus diarrhea virus, and porcine circovirus. In these cases, provide additional detail on the type/strain included in the product elsewhere on the labeling.

2. Disclose the subtypes and strains included in influenza products. For recombinant/reassortant/subunit products, provide the subtype and strain of the parent isolate. Designate the strains according to accepted standards of influenza virus nomenclature (e.g., “A/equine/Miami/63(H3N8)” or “A/swine/Wisconsin/458/98(H1N1)”). Further identify the strains with commonly used, scientifically justified terms such as “A2,” “European,” “American,” “atypical,” or “classical.” If the product does not contain the N subtype gene, disclose this information on the labeling.
3. For products included under the Single Label Claim rule, place strain information in the paragraph following the first codified indication statement unless the labeling has a specific “Composition” section where this information could be placed.

#### I. Minimum Potency

Labeling may include minimum potency specifications but, if included, provide the through-dating specification. If a foreign marketing authority requires release specifications, indicate that the stated specifications are those for serial release.

#### J. Storage Temperature

The regulations in 9 CFR 112.2(a)(4) state that the storage temperature recommendation for biological products will be stated as 2 to 8 °C or 35 to 46 °F, or both. Some products, however, have special storage conditions with differing temperature ranges. In such cases, the labeling must match the approved storage conditions as specified on the Outline of Production for the finished product.

#### K. Revaccination Statement

##### 1. Selective Enforcement

The regulations in 9 CFR 112.7(f) state that when no data support a revaccination interval, the following statement must be included on labeling: “The need for annual booster vaccinations has not been established for this product; consultation with a veterinarian is recommended.” APHIS will selectively enforce this regulation only for products intended for use in dogs, cats, and horses. Licensees and permittees may add similar information voluntarily to labeling for other animal species. Although the specific wording of this regulation discusses only annual revaccination, APHIS considers it applicable to any recommended revaccination interval, not just annual.

2. Need to Vaccinate vs. Minimum Duration of Immunity

APHIS considers a “need” to revaccinate to occur when immunity has waned sufficiently that it no longer provides meaningful protection against disease. This is distinct from recommending revaccination at the interval defined in a minimum duration of immunity study. Such studies demonstrate that immunity continues to provide meaningful protection at that time; immunity may not wane until much later.

3. Acceptable Approaches

Address revaccination recommendations in one of the following ways:

- a. Disclose the minimum duration of immunity in the indications statement and make no other comments about revaccination.
- b. Disclose the minimum duration of immunity in the indications statement and recommend contacting the veterinarian/manufacture for more information on revaccination frequency.
- c. For products licensed before November 2016, and which previously had labeling recommending a specific revaccination interval: In addition to the duration of immunity statement, add “Historically, annual (or other interval) revaccination has been recommended for this product. The need for this booster has not been established. Contact your veterinarian or manufacturer for more information on revaccination frequency.”

4. Passive Protection Products

Products intended for use in pregnant animals to provide passive immunity to offspring may bear an unqualified statement to revaccinate upon each successive gestation.

5. Maternal Antibody Interference

If a statement on potential maternal antibody interference is desired and appropriate, use the standardized statement below or equivalent. Do not specify absolute revaccination intervals to overcome maternal antibody.

“The presence of maternal antibody is known to interfere with the development of active immunity in <name of animal species> and additional boosters will be required in most young animals. For advice on revaccination frequency, consult your veterinarian.”

## 6. Revaccination During Stress or Disease Exposure

If a statement regarding booster vaccination during periods of stress or disease exposure is desired, use the standardized statement below or equivalent. Do not specify absolute revaccination intervals to overcome stress factors.

“For more information on revaccination in the face of stress or an exposure, contact your veterinarian.”

## 7. Who to Contact

When specifying who to contact for additional information, you may recommend 1) the veterinarian or 2) the veterinarian OR the manufacturer. It is not permissible to recommend only the manufacturer unless the product license has a restriction limiting sales only to veterinarians.

Widely accepted vaccination guidelines, such as the American Animal Hospital Association Canine Vaccination Guidelines and the American Association of Feline Practitioners Feline Vaccination Advisory Panel Report, may be cited if using the formal name of the guideline instead of slang terms.

## 8. Combination of Statements

The standardized revaccination statements in Section IV.K of this memorandum may be combined and edited into a more concise format when multiple statements apply to a single product.

Acceptable example: “For more information on revaccination frequency, in general or in the face of maternal antibody, stress, or a disease exposure, consult your veterinarian.”

## L. Mixing Statement

The regulation at 9 CFR 112.2(a)(7)(i) states that products other than diagnostic kits must bear the following statement: “Do not mix with other products, except as specified on this label.” The phrase “except as specified on this label” may be omitted when there is no other instruction recommending mixing.

## M. Animal Use Statement

The regulation at 9 CFR 112.2(d)(3) states, “The statement ‘For use in animals only’ may appear on the labeling as appropriate for a product to indicate that the product is recommended specifically for animals and not for humans.” Before 2016, the codified term was “for veterinary use only.” APHIS changed it to prevent confusion with use by

veterinarians only. APHIS will allow either phrase, “For use in animals only” or “For veterinary use only,” in most situations, where there is negligible risk for confusion.

#### N. Contact Physician Upon Exposure Statement

The regulation at 9 CFR 112.2(7)(ii) states that labeling for injectable products and other products containing hazardous components must include the statement, “In case of human exposure, contact a physician.” All injectable products, regardless of composition, must bear this statement. Additionally, it may be required for non-injectable products containing potentially hazardous components (chemical additives or live organisms).

### IV. LABEL TYPES

#### A. Container Labels

1. Current regulations (9 CFR 112.2) specify the information that must appear on final container labels. APHIS makes certain allowances for small labels with limited space, provided that omitted information appears elsewhere on carton labels or enclosures.
  - a. For biologics other than diagnostic test kit components, include the following elements, at a minimum, on small container labels:
    - i. Complete or abbreviated True Name.
    - ii. Serial number.
    - iii. Expiration date.
    - iv. Location of full labeling information.
    - v. Storage temperature.
    - vi. Establishment or permittee and product code identification.
    - vii. Statement to inactivate unused contents if the product contains viable agents.
  - b. For small final containers of diagnostic test kit components, include the following minimum information on small container labels:
    - i. Complete or abbreviated True Name of the kit\*.
    - ii. Functional and/or chemical name and lot number of the component.
    - iii. Establishment number or permittee.
    - iv. Product code of kit\*.
    - v. Storage temperature.

\*The True Name and product code are not required on small containers of interchangeable kit components, which may be packaged with multiple products.

2. The product code of the individually licensed component is not required on labeling used for component containers of a combination package. On the container label, refer the user to the carton for the product code. Separate container labels are not required for products marketed both as an individual product and as a component in a combination package.
3. Beyond the indications statement described in section III.E above, do not include supporting studies or other promotional statements about product effectiveness on the container label of products subject to the Single Label Claim rule. The following statements, however, are permissible on the container:
  - a. Product-specific warnings (e.g., may cause transient swelling) or other restrictions on use (e.g., only for use in seropositive herds).
  - b. Whether it can be used in breeding and/or pregnant animals (or other special animal category).
  - c. A general disclaimer that the product may not work as intended in ill, malnourished, or immunosuppressed animals.
  - d. A general description of disease an agent causes.

#### B. Carton Labels

The term “carton” in this section applies to boxes or other outer packaging in which product containers are marketed and also to “tray covers” that display underneath the surface of clear “clamshell” boxes.

1. Current regulations (9 CFR 112.2) specify the information that must appear on a carton, particularly if it is not included on the container. Place required elements on the outside of the carton, to view them without opening the carton.
2. Cartons also may bear non-required information if APHIS determines it is not false or misleading. Place non-required information on the outside or the inner surface of the carton, except as specified in section IV.B.3.
3. For products subject to the Single Label Claim Rule, place optional study data, or other information regarding product use, only on the inner surface of the carton. In such situations, the inner surface of the carton is analogous to an enclosure and is subject to the guidance for enclosures in section IV.C.

#### C. Enclosures

Label enclosures (aka circulars, inserts, or leaflets) are used to disseminate a wide variety of information about a product.

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1. Study summaries appearing on [productdata.aphis.usda.gov](http://productdata.aphis.usda.gov) may be reprinted on enclosures (or the inner surface of a carton), if desired. Ensure the reproduction is exact and without embellishment. Do not make any other remarks about these studies.
2. Additional data, not used in direct support of product licensure, may be printed on enclosures with APHIS approval.
  - a. APHIS does not intend this policy to provide a forum for product comparisons or to generate a marketing advantage. The following is an acceptable example of additional information: Data showing no loss in vaccine titer X hours after reconstitution.
  - b. Submit full study reports for any additional data to be included on regulated labeling. Before approving labels bearing the information, APHIS evaluates the labels and the supporting studies for potentially false or misleading implications but does not make a full regulatory determination regarding the study.
  - c. When such additional data appear on an enclosure, insert the following statement prominently at the top of the enclosure:
  - d. “See [productdata.aphis.usda.gov](http://productdata.aphis.usda.gov) for a summary of the studies approved by the USDA for licensing this product. This package insert also contains additional information developed by the licensee.”
3. When describing additional information on labeling, use plain language:
  - a. Do not use subjective descriptors, such as the data “clearly” demonstrate a “robust” effect.
  - b. Do not use terminology that could be construed as promoting [historical four-tier label claims](#).
  - c. Do not include complex statistical analyses, such as p-values, prevented fractions, or confidence intervals.
  - d. Do not summarize data to the point where conclusions could be misleading.
  - e. Do not state that the data are “on file” with APHIS, as this implies full regulatory review and endorsement.

### D. Shipping Labels

Shipping labels are labels on bulk outer packaging solely for means of identifying a product during shipment. Shipping labels for product shipped in bulk or unlabeled final

containers must contain, at a minimum, the following elements: True Name; serial number; name, address, and establishment number of the licensee or permittee; Product Code; volume or mass of contents; storage conditions; and, if applicable, a “For Export Only” statement. The terms “batch ID,” “lot number”, or similar term, may be used in lieu of serial numbers on For Further Manufacture products.

The regulations at 9 CFR 112.2(f)(1) state that manufacturers do not need to submit shipping labels for domestic use to APHIS for approval. The regulations at 9 CFR 112.8, however, require manufacturers to submit export shipping labels (9 CFR 112.8(c)). APHIS no longer enforces the regulation to submit export shipping labels for approval, but these labels continue to be subject to regulatory action.

#### E. Stickers

Occasionally, APHIS receives requests to use auxiliary stickers with approved labeling. Examples include, but are not limited to, informing the customer of a change in product formulation or instructions for use, or adding country-specific codes on labels otherwise suitable for many countries.

Submit stickers to APHIS in the following manner:

1. Place the sticker on a mounting sheet, either separately or in combination with the label with which it will be used.
2. If the sticker appears on a separate mounting sheet from the companion label, include information on the sticker mounting sheet regarding the manner in which it will be used. Examples: 1) “For use on the neck of the container with all approved container labels for export to Country X” 2) “For use with carton label 12345, affixed in the empty space to the left of the True Name, for 6 months after product launch.”
3. If the sticker is only intended for temporary use, provide a suggested expiration date on your submission. In this manner, APHIS will not require a separate action to inactivate/archive the label once its use is discontinued.
4. Make the label type for the sticker the same as the label with which the sticker will be used. For example, if placing the sticker on a carton, submit the sticker as a carton label.

#### F. Experimental Labels

Experimental labels are required for product shipped under 9 CFR 103.3. See VS Memorandum No. 800.67 for additional information on experimental labels.

### G. Distributor Labels

1. Arrange the names and addresses of the manufacturer and distributor on distributor labels in a manner that gives equal or greater emphasis to the manufacturer compared to the distributor.
  - a. Position the complete names and addresses of the manufacturer and distributor side by side with the manufacturer on the left. Alternatively, stack the information with the manufacturer on top of the distributor.
  - b. If only one name and address can fit on the front label panel, place the manufacturer on the front panel and the distributor on the back panel.
  - c. Give equal or greater emphasis to the manufacturer in all other aspects of the label. Examples include, but are not limited to, logo, size, shape, coloring, shading, font, print boldness, text arrangement, and print quality.
2. If using a distributor logo, ensure that the label, when considered in its entirety, does not create the impression that the distributor is the manufacturer.
3. Use the licensee's (producer's) telephone number, not the distributor's number, as the consumer contact telephone number. Alternatively, list telephone numbers for both the manufacturer and distributor.

### H. Export-Only Labels

Many countries accept labeling that does not meet all current APHIS regulations. APHIS extends considerable regulatory flexibility for differences that do not impact the claimed use or administration of the product and do not make false or misleading statements. Licensees may continue to use APHIS-approved non-expired export-only labeling as long as the importing authority accepts the labeling. There is no requirement to convert such labeling to meet the Single Label Claim or Labeling and Packaging rules.

New labeling proposed for export-only use, if it does not meet all APHIS regulations, will be considered for APHIS approval based on documentation of approval by the importing country's registration authority. APHIS will consider exceptions to current labeling regulations if the foreign approval allows such differences. Export-only labeling must, however, bear the U.S. Establishment Number unless the labeling qualifies as a Special Label for Export, per VS Memorandum No. 800.208, or the importing country specifically prohibits the inclusion of the U.S. Establishment Number.

Special Labels for Export are limited solely for use on product destined for the approving country or countries having reciprocal agreements with the approving country. Specify the destination country or countries on the label submission, either as part of the label text or as a comment in the body of the mounting sheet.

## I. Import Labels

If a foreign manufacturer affixes labels approved by APHIS for use on individual serials imported into the United States, the manufacturer cannot use those labels for serials distributed elsewhere. APHIS evaluates and releases for marketing only those serials imported into the United States. Other product cannot bear labeling with a U.S. Establishment Number.

## V. PRODUCT-SPECIFIC LABELING

### A. Autogenous Labels

By their nature, autogenous products may not bear any claims for efficacy or safety. Structure the indication statement to read:

“For vaccination against the organisms listed.”

Alternatively, the indication statement may be omitted from autogenous labeling. Labels for autogenous products are also exempt from the following requirements:

- Minimum animal age for use.
- Revaccination recommendation (beyond initial two-dose series).
- Statement regarding safety in pregnant animals.
- Reference to [productdata.aphis.usda.gov](http://productdata.aphis.usda.gov).
- Statement to use entire contents when first opened.

### B. Prescription Labels

By their nature, prescription platform products licensed in accordance with VS Memorandum 800.214 may not bear any claims for efficacy. Structure the indication statement to read:

“For vaccination against the organisms and strains listed. This product is a prescription platform veterinary biologic to be used under the supervision of a licensed veterinarian. Efficacy and potency have not been demonstrated. For more information regarding safety data, see [productdata.aphis.usda.gov](http://productdata.aphis.usda.gov).”

Prescription labels should direct the user to the prescribing veterinarian for more information on vaccination frequency.

### C. Rabies Vaccine

The regulations at 9 CFR 112.7(c) and (d) contain specific labeling language for rabies virus vaccines. Each section specifies that product is to be administered at 3 months of

age or older, with a repeat dose 1 year later. Subsequent vaccination is determined from the results of duration of immunity studies.

Consistent with all other products, APHIS expects the minimum age to agree with the age of animals used in the efficacy and safety studies, which may be more than 3 months. APHIS will not consider rabies label claims for animals less than 3 months.

Because of these regulations, APHIS bases the revaccination interval for Rabies Vaccine on the interval between vaccination and challenge used in the minimum duration of immunity study. This contrasts to all other products where the minimum duration of immunity is not considered to represent a need to immunize (see section III.K.2 of this memorandum). The subsequent revaccination interval may be rounded down to the nearest year.

For example, the following label text is acceptable where efficacy was demonstrated in 4-month-old dogs, challenged 39 months after vaccination:

“This product has been shown to be effective for the vaccination of healthy dogs, 4 months of age or older, against rabies. For more information regarding efficacy and safety data, see [productdata.aphis.usda.gov](http://productdata.aphis.usda.gov).

Vaccinate animals with a single dose, followed by a dose 1 year later. Vaccinate every 3 years subsequently.”

#### D. Feline Panleukopenia Vaccine

The regulations at 9 CFR 112.7(i) provide codified labeling language for Feline Panleukopenia Vaccine:

“Vaccinate healthy cats with one dose, except that if the animal is less than 12 weeks of age, a second dose should be given no earlier than 16 weeks of age.”

The label and packaging rule was intended to update this regulation to agree with currently accepted scientific thought that the final dose against panleukopenia in a kitten vaccination series should not occur younger than 16 weeks of age. The current regulation suggests, however, that a kitten needs, at most, two doses of vaccine, regardless of when the first dose was given. This may not be sufficient in kittens with a high level of maternal antibody. In this regard, the regulation should instead read: “Vaccinate healthy cats, except that if the animal is less than 16 weeks of age, the final dose should be given no earlier than 16 weeks of age.”

APHIS also recognizes that feline panleukopenia vaccine virus is most frequently found in multi-valent combinations with other common feline pathogens. It is cumbersome to combine the language of 9 CFR 112.7(i) with the preferred language in section III.K.5 of this memorandum. Therefore, labeling for multi-valent products containing feline

panleukopenia vaccine may contain the standardized maternal antibody statement in section III.K.5 without any specific mention of 9 CFR 112.7(i). Alternatively, products containing feline panleukopenia vaccine may contain the standardized maternal antibody statement in section III.K.5, and a final sentence stating the final dose should be given at no less than 16 weeks of age.

**E. Marek's Disease Vaccine**

For all Marek's disease products licensed before publication of 9 CFR 113.330 and for products solely containing Marek's virus serotype 3 (regardless of license date), the appropriate claim is against Marek's disease. Products containing Marek's virus serotype 1 or 2 and licensed with efficacy studies structured according to 9 CFR 113.330 may bear a claim against very virulent Marek's disease.

**F. Porcine Reproductive and Respiratory Syndrome Virus (PRRSV) Vaccine**

Labeling for live PRRSV vaccines requires the following warning statement or equivalent:

“Not for use in pregnant swine or boars. Vaccine virus may be shed and transmitted to other populations of swine in contact with vaccinated swine. The duration of potential vaccine virus transmission may vary. Use of the vaccine in herds intended to remain PRRS virus seronegative is contraindicated. Introduction of vaccinated pigs into herds intended to remain PRRS virus seronegative is contraindicated.”

**G. Foreign Animal Disease Products**

APHIS issues licenses for domestic production of products against foreign animal diseases (FADs) when the risk of introducing exotic agents into the United States is negligible (e.g., products containing synthetic peptides or antigens produced in recombinant systems). These products bear a license restriction, “For Export Only.” If a foreign disease incursion occurs, these licenses may be reissued quickly without the restriction, for domestic use. To this end, labeling which is fully compliant with domestic regulations and policy should be on file with APHIS for these products. Include the following statement on the label mounting sheet: “For domestic use as directed by APHIS in the event of a foreign animal disease outbreak.”

## VI. IMPLEMENTATION/APPLICABILITY

### A. Applicability

The Single Label Claim rule applies to USDA-licensed vaccines, bacterins, toxoids, and immunomodulators. The Labeling and Packaging rule applies to all USDA-licensed products. Exceptions to both rules may be made for Export-Only labeling (see section IV.H).

### B. Implementation

The Single Label Claim rule was effective September 8, 2015, with a 4-year implementation period. The Labeling and Packaging rule became effective October 31, 2016, with immediate implementation. APHIS delayed implementing the Single Label Claim rule until publication of the Labeling and Packaging rule, to minimize the number of individual label revisions. Thus, implementation of the Single Label Claim rule extends through October 31, 2020. Approximately 25 percent of labeling should be updated each year, 2017 through 2020.

1. If labels approved before November 2016 do not need to be replaced, or if they only require codified “minor” changes (9 CFR 112.5(d)), changes related to the Labeling and Packaging rule may be delayed until the product is scheduled for conversion to single-label claim language, according to the 4-year schedule. This prevents doing two major revisions to labeling when two would not otherwise be needed. Single-label claim language may not be added to labels until supporting efficacy and safety study summaries have been filed with APHIS to be posted on [productdata.aphis.usda.gov](http://productdata.aphis.usda.gov).

Licensees and permittees will be allowed a similar 4-year schedule to convert labeling for products outside the scope of the Single Label Claim rule if existing labeling does not require change (or only codified minor change) before the scheduled conversion date.

2. If labels approved before November 2016 require replacement for reasons other than codified minor changes, APHIS expects replacement labels to comply with the Labeling and Packaging rule, even if labeling for the product is not yet scheduled for conversion to comply with the Single Label Claim rule. In this case, the labeling will require at least two revisions anyway, so there is no reason to delay making changes due to the Labeling and Packaging rule.

APHIS expects labeling for products not within the scope of the Single Label Claim rule to comply with the Labeling and Packaging rule when submitting replacement labels for reasons other than codified minor changes, provided that all labeling is converted within the 4-year implementation period.

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3. Labeling for products licensed before November 2016 not in full compliance with both rules will be processed with temporary approval, with a default expiration date of October 31, 2020. APHIS reserves the right to reduce the dating for special circumstances or for licensees or permittees who are not making acceptable progress toward yearly conversion goals.
4. Update corresponding label text in Outlines of Production no later than when revised labels are submitted.