FSIS Guideline for Label Approval

March 2024

FSIS-GD-2024-0001

This guideline is designed to help establishments determine whether their labels must be submitted to FSIS' Labeling and Program Delivery Staff (LPDS) for approval.

Table of Contents

Preface

This is a revised version of the FSIS Guideline for Label Approval. It replaces the January 2023 version of the guideline. FSIS is updating the guidance to provide information about voluntary "Product of USA," "Made in the USA," or alternative claims that specify processing or preparation steps that occur in the United States based on the final rule, "Voluntary Labeling of FSIS-Regulated Products with U.S.-Origin Claims" https://www.fsis.usda.gov/policy/federal-register-rulemaking/federal-register-rules/voluntary-labeling-fsis-regulated. In addition, FSIS has made a few additional clarifications or corrections.

This guideline represents FSIS' current thinking on these topics and should be considered effective as of its issuance. Establishments that used previous versions of the FSIS Guideline for Label Approval should update their procedures as necessary based on this guideline. For purposes of this document, the term "establishment(s)" includes official meat and poultry establishments and egg products plants, unless otherwise indicated.

The information in this guideline is provided to assist establishments in meeting regulatory requirements. The contents of this document do not have the force and effect of law and are not meant to bind the public in any way. This document is intended only to provide clarity to industry regarding existing requirements under the regulations.

This guideline is focused on small and very small establishments, in support of the Small Business Administration's initiative to provide small businesses with compliance assistance under the Small Business Regulatory Enforcement Fairness Act. However, all establishments may apply the recommendations in this guideline. It is important that small and very small establishments have access to a full range of scientific and technical support, and the assistance needed to label products in compliance with FSIS regulations. Although large establishments can benefit from the information provided, focusing the guideline on the needs of small and very small establishments provides them with assistance that may be otherwise unavailable to them.

Purpose

This guideline provides information about the types of labels that must be submitted to LPDS for approval. Specifically, LPDS must review three categories of labels before they may be used in commerce: labels for religious exempt products (9 CFR 412.1(c)(1)), labels with special statements and claims (9 CFR 412.1(c)(3)), and labels for temporary approval 9 CFR 412.1(c)(4). All other categories of labels are considered "generically approved," meaning they may be used in commerce without prior review by LPDS provided that they meet all applicable labeling requirements. All labels, including generically approved labels, are, subject to routine

Key Point

LPDS only needs to evaluate three types of labels prior to use in commerce (9 CFR 412.1(c).

1) **Labels for religious exempt products 9 CFR 412.1(c)(1).**
2) **Labels with special statements and claims 9 CFR 412.1 (c)(3)**
3) **Labels for temporary approval 9 CFR 412.1 (c)(4).**

verification by FSIS field inspectors to ensure ongoing compliance with FSIS labeling requirements. All labels, whether submitted to LPDS for approval or generically approved, are required to comply with all FSIS labeling requirements.

To assist establishments with the design and modification of their product labels, this guideline includes specific examples of special statements and claims that must be submitted to LPDS for approval. This guideline also provides examples of: (1) factual statements and claims that are eligible for generic approval, (2) changes that can be made to labels approved with special statements and claims without additional LPDS review, (3) changes that cannot be made to labels approved with special statements and claims without additional LPDS review, (4) blanket label approvals (labels for product line or multiple product lines with identical claims), (5) information about negative claims, (6) information about export labels with deviations from domestic requirements, and (7) geographic claims on labels and (8) additional information about label approval.

Reason for Reissuing the Guideline

FSIS has reissued the guideline to add new requirements for voluntary U.S.-origin claims established by the final rule, "Voluntary Labeling of FSIS-Regulated Products with U.S.-Origin Claims" https://www.fsis.usda.gov/policy/federal-register-rulemaking/federal-register-rules/voluntary-labeling-fsis-regulated. Establishments choosing to include voluntary U.S.-origin claims on the labels of products under FSIS mandatory inspection or voluntary inspection services will need to comply with the new regulatory requirements under the final rule on the next uniform compliance date for new labeling regulations, January 1, 2026.

Changes from the Previous Version of the Guideline

This guideline, dated March 2024, is final and replaces the previous version dated January 2023. FSIS will update this guideline, as necessary, when new information becomes available.

This version incorporates the following changes:

- FSIS added the section "Product of USA," "Made in the USA," and Other Voluntary U.S.-Origin Claims" that explains the requirements for the voluntary U.S.-origin label claims, "Product of USA" and "Made in the USA." The section also explains the requirements for voluntary label claims other than "Product of USA" or "Made in the USA" to designate the U.S.-origin component of a FSIS-regulated (i.e., produced under FSIS mandatory or voluntary inspection services) product's preparation and processing.
- In the appendices, A bold red asterisk (*) marks new or updated entries to the appendix. Items previously on the list not marked by a bold **red** asterisk **(*)** may have been rearranged for ease of readability. A bold plus (**+**) marks claims that reference a guideline that is hyperlinked at the end of the appendix. A red bold hash (**#**) marks reference that there is additional information about this factual negative statement in Appendix 7.

- Appendix 1 now includes new examples of special statements and claims that require LPDS approval before they can be used on labels of product in commerce (e.g., “natural” and “no animal by-products” claims). Some other types of claims were moved from Appendix 1 to Appendix 2, given they are now eligible for generic approval (e.g., uncured and certain negative claims)).

- Appendix 2 now includes several new factual statements and claims that do not require LPDS approval before they can be used on labels of product in commerce (e.g., “Authentic,” “Double Smoked,” “gluten free,” “uncured,” and certain negative claims).

- Appendix 3 no longer references export labels that deviate from domestic requirements, as those labels are no longer required to be submitted to LPDS for approval.

- Appendix 4 no longer includes two examples of export labels, given they are now eligible for generic label approval.

- Appendix 5 includes new examples of labels that can be approved as a blanket approval.

- Appendix 6 includes new examples of special statements and claims that can be generically approved after receiving the first approval from LPDS.

- Appendix 7 has been added to provide information and examples about the types of negative claims that are generically approved.

- Appendix 8 has been added to provide information about the generic approval of export labels that deviate from domestic requirements and separate geographic claims into its own appendix.

- Appendix 9 has been updated to provide information about generic approval of geographic claims, which was previously included in Appendix 8.

- Appendix 10 has been added to provide information about “Additional Information for Label Approval,” which was the previous title of Appendix 7.

How to Effectively Use the Guideline

This guideline is organized to provide users with FSIS’s current thinking on its labeling regulations. To use this guideline, LPDS recommends that readers use the navigation headings to move efficiently through the document sections of interest. Hyperlinks, where provided, will quickly take you to the correct place in the document electronically

and are also provided for other complementary documents.

The Resources section of this guideline provides resource material used in the revision of this guidance.

How to Comment on the Guideline

FSIS is seeking public comment on this guideline as part of its efforts to continuously assess and improve the effectiveness of policy documents. All interested persons may submit comments regarding any aspect of this document, including but not limited to content, readability, applicability, and accessibility. The comment period will be **60** days from publication in the *Federal Register* of the final rule, "Voluntary Labeling of FSIS-Regulated Products with U.S.-Origin Claims" https://www.fsis.usda.gov/policy/federal-register-rulemaking/federal-register-rules/voluntary-labeling-fsis-regulated and, as appropriate, the Agency may update this guideline in response to comments. Although FSIS may make changes to future iterations of this guideline in response to comments, this document reflects current thinking. FSIS encourages establishments producing products discussed in this document to review it.

Comments may be submitted by either of the following methods:

Federal eRulemaking Portal Online submission at Regulations.gov. This website provides a way to type short comments directly into the comment field on the webpage or attach a file to submit lengthier comments. Follow the online instructions at that site to submit comments.

- Mail and hand- or courier-delivered items: Send to Docket Clerk, U.S. Department of Agriculture (USDA), FSIS, 1400 Independence Avenue SW, Washington, D.C. 20250-3700.

All items submitted by mail or electronic mail must include the Agency name, docket number FSIS-2022-0015, and document title: **FSIS GUIDELINE FOR LABEL APPROVAL**. Comments received will be made available for public inspection and posted without change, including any personal information, on https://www.regulations.gov.

Questions Regarding Topics in this Guideline

If after reading this guideline you still have questions, FSIS recommends searching the publicly posted Knowledge Articles ("Public Q&As") in the askFSIS database. If after searching the database, you still have questions, refer them to the Office of Policy and Program Development through askFSIS and select **Labeling** as the Inquiry type or by telephone at 1-800-233-3935.

Documenting these questions helps FSIS improve and refine present and future versions of the guideline and associated issuances.

FSIS Guideline for Label Approval

Background

FSIS is publishing this guideline to provide information about the types of labels that must be submitted to the Agency for approval, including specific examples of special statements and claims.

To prevent the introduction of adulterated or misbranded products into commerce, LPDS implements a prior label approval system for labels intended to be used on federally inspected meat, poultry, and egg products, including imported products (9 CFR 412). Without approved labels, meat, poultry, and egg products may not be sold, offered for sale, or otherwise distributed in commerce.

Under LPDS' prior label approval system, there are two types of label approval. First, certain categories of labels must receive "sketch approval" (9 CFR 412.1). To receive sketch approval, establishments must submit a rendering of their label (i.e., a "sketch label) to LPDS for evaluation prior to use in commerce. The sketch label must reasonably represent what the label will ultimately look like but need not be the actual final label applied to the product. Other categories of labels are "generically approved," meaning they are approved for use in commerce without LPDS evaluation so long as they are consistent with FSIS regulations (9 CFR 412.2). Establishments do not need to submit generically approved labels to LPDS for evaluation prior to use so long as they meet all applicable labeling requirements. However, all labels, including generically approved labels are subject to routine verification by FSIS field inspectors.

The categories of labels that require sketch approval and, therefore, need to be submitted to LPDS for evaluation are:

1) Labels for religious exempt products 9 CFR 412.1(c) (1);

2) Labels with special statements and claims 9 CFR 412.1 (c) (3); and

3) Labels for temporary approval 9 CFR 412.1(c) (4).

Below, there is further discussion about special statements and claims that require submission to LPDS for approval and additional information about generic approval, including:

- Voluntary labeling of FSIS-regulated products with U.S.-origin claims
- Special statements and claims that require submission to LPDS;
- Factual statements and claims that are generically approved;
- Changes that can be made to labels approved with special statements and claims without additional LPDS review;
- Changes that cannot be made to labels approved with special statements

and claims without additional LPDS review;

- Blanket label approvals (labels for product line or multiple product lines with identical claims);
- Special statements and claims that can be generically approved after first approval by LPDS;
- Information about negative claims;
- Information about export labels with deviations from domestic requirements;
- Information about geographic claims; and
- Additional information about label approval.

More information can also be found in each of the appendices summarized below.

Special Statements and Claims (9 CFR 412.1 (c) (3))

"Special statements and claims" are claims, logos, trademarks, and other symbols on labels that are generally not defined in FSIS regulations or in the Food Standards and Labeling Policy Book.

- An example of a logo or symbol is a graphic representation of a heart. Special statements and claims include "natural" claims, "certified gluten free" claims (e.g., Certified Gluten Free by XYZ entity), health claims, ingredient and processing method claims (e.g., high-pressure processing), claims regarding the raising of animals, organic claims, and instructional or disclaimer statements concerning pathogens (e.g., "for cooking only" or "not tested for *E-coli* O157:H7").

See Appendix 1 for an expanded list of examples of special statements and claims.

Factual Statements and Claims Generically Approved (9 CFR 412.2)

FSIS does not consider some factual statements applied to labels to be special statements or claims that require submission to LPDS for approval. Rather, they are statements of fact that must be supported in the labeling record. These factual statements are generically approved.

- Examples of factual statements in this category include defined geographic styles (e.g., "Italian Style"), "extra" or "more" statements (e.g., "10% more cheese"), geographic landmarks (e.g., Statue of Liberty, maps), organic ingredients listed in the ingredients statement (e.g., organic sugar or organic garlic), and allergen statements (e.g., "contains milk") consistent with the Food Allergen Labeling and Consumer Protection Act. Most negative claims (e.g., "No Pork") are also generically approved, including "gluten free" (without an accompanying certification statement) and "no monosodium glutamate (MSG)" or "no MSG added" with appropriate disclaimer statement. However, LPDS evaluation continues to be required for labels that bear negative claims relating to the raising of the animal from which the product is derived (e.g., "no antibiotics administered") or negative claims relating to the use of genetically modified ingredients. For more information about animal raising claims, see the Labeling Guideline on Documentation Needed to Substantiate Animal Raising Claims for Label Submissions (2019). For more information about negative claims related to the use of genetically modified ingredients, see the Labeling Guideline on

Statements that Bioengineered or Genetically-Modified Ingredients or Animal Feed were not used in Meat, Poultry of Egg Products.

See Appendix 2 for an expanded list of examples of factual statements that are generically approved.

Changes to Labels with Approved Special Statements and Claims That Do Not Require Additional LPDS Review

Once a label is approved by LPDS for compliance with 9 CFR 412.1, there are several changes that can be made to the label that do not require resubmission to LPDS. These changes are generically approved under 9 CFR 412.2. For such a change to be made, it must be unrelated to the special statement or claim. Some common examples include:

- The removal of an ingredient or change in order of predominance of an ingredient in a product formula for a label that was previously approved with a negative claim (e.g., "certified gluten free"). In this case, the removal of an ingredient or change in its order of predominance will not affect the special statement or claim.
- Changing the name of the cut of meat or poultry for a label previously approved with an animal-raising claim (e.g., raised without antibiotics). An example would include changing the name from chicken breast to chicken thigh. The change is generically approved provided the supporting documentation for the chicken is the same as documented in the previously approved label. In this case, changing the name of the cut of poultry will not affect the special statement or claim.
- Changing information such as the establishment number (except for products labeled as organic), signature line, preparation instructions, Hazard Analysis and Critical Control Points Category, or vignette for a label that was previously approved with a special statement or claim. These changes are generically approved as they will not affect the special statement or claim.

See Appendix 3 for a list of changes to labels with special statements and claims that can be generically approved.

Changes to Labels with Approved Special Statements and Claims that Require Additional LPDS Review

Sometimes, changes made to a previously approved label with special statements and claims require LPDS approval before the updated label may be used in commerce. Such changes include those that affect the special statement or claim and require LPDS to reevaluate the product formula or other relevant information. Examples include:

- A label with a negative claim (e.g., "certified gluten free") that was previously approved by LPDS. Now, the establishment wants to update its label to reflect the use of a new seasoning mix, which includes ingredients that were not in the product formula for the previously approved label. In this case, the establishment is required to resubmit the label to LPDS for approval, so the Agency can verify that the new ingredients do not contain any sources of gluten.
- If a company adds a grass-fed claim to a previously approved label with a "natural" and "certified gluten free" claim, the company must resubmit the label to LPDS for

approval because it contains a new special statement or claim not included as part of the previous approval.

See Appendix 4 for a list of examples of changes to labels with special statements and claims that need to be resubmitted to LPDS.

Blanket Label Approvals (Labels for product line or multiple products with identical claims)

In some cases, the addition of a special statement or claim to an entire line of products or multiple products will not require every single label to be submitted to LPDS for approval. Instead, establishments may submit a "blanket approval" application to LPDS along with a label for one of the products. The establishment should also include supporting documentation with its application indicating that the establishment is requesting approval for the use of the special statement or claim on multiple product labels. The label application should indicate that the special statement or claim will be added to an entire product line and should specify the product line, or, in the case of only certain labels, the application should list the product labels to which the approval would apply. Some examples include:

- An establishment produces 50 different frozen meals. The establishment intends to add a Front of Pack (FOP) statement for all 50 products that will identify the number of calories and grams of protein. In this case, the establishment should not submit 50 applications for different products in a product line for approval. Instead, the establishment should submit an application for blanket approval to LPDS, along with a label for one of the products. The label application should indicate that the FOP statement will be added to all frozen product meals produced at the establishment. The blanket approval will cover products to which the FOP statement is applied so there is no need for each individual label bearing the FOP information to be submitted for approval. The establishment should update the individual nutrient values within the FOP statement generically to match the nutrient values displayed in the nutrition facts panel for each of the meals. However, when a new nutrient is added to the FOP statement, the label can no longer be generically approved (e.g., adding sodium to the statement that already displays the calories and grams of protein). Adding a new nutrient to the FOP statement will require the revised label to be resubmitted to LPDS for evaluation and approval.

- An establishment produces X number of organic chicken parts. To obtain approval to label all organic chicken parts with a new claim, such as "no antibiotics," the establishment should submit one organic chicken breast package with the new "no antibiotic" claim to LPDS. The label application should also include a list of other chicken parts that will also use the new claim. This is a blanket approval because all the parts of the chicken listed in the application will be approved through one label submission.

- An establishment has an entire line of beef sausages that LPDS approved with a "certified gluten free" claim. The establishment wants to add a "made with grass fed beef" claim to all the other product labels in the beef sausage product line. Instead of submitting separate applications for each of the

individual products, the establishment should submit a request for blanket approval with the necessary supporting documentation for the "made with grass-fed beef" claim and a list of all the products in the line. The addition of a "made with grass-fed beef" claim does not affect the previously approved "certified gluten free" claim because there is no change to the ingredients. The addition of the "made with grass-fed beef" claim for products formulated with grass fed beef is a type of claim that can be approved through a request for blanket approval.

See Appendix 5 for additional types of special statements and claims that can be approved through a blanket approval.

Special Statements and Claims Generically Approved After the First Approval from LPDS

There are certain types of special statements and claims that LPDS only needs to see once to ensure compliance with the regulations. After this initial review, the special statements and claims are generically approved for use on any other product produced by the establishment on the condition that future labels using the special statements and claims follow all FSIS requirements and that the special statements and claims are not changed in any way from the initial LPDS approval. Some examples include:

- A label that displays a USDA Food Shield was approved for a Chicken Cordon Bleu product. The establishment wants to add the shield to a Chicken Parmesan product as well. Because the establishment has the prior approval from LPDS for the USDA Food shield and has the supporting documentation from the USDA Agricultural Marketing Service (AMS) on file, the Chicken Parmesan label can be generically approved. This label can be generically approved because the shield was previously approved by LPDS and the label application has the documentation from AMS to support the use of the claim on the label.

- A label for chicken hot dogs was approved with a "certified halal" claim. The establishment now wants to make a certified halal chicken sausage. The establishment has the prior approval from LPDS for the certified halal claim and the supporting documentation from the certified Halal organization. This label can be generically approved because the establishment has the certification from the Halal organization that supports the use of the claim on the label. The establishment would need to ensure that the documentation is kept current per FSIS requirements.

See Appendix 6 for additional examples.

Negative Claims

The "negative" claims section provides label examples of ingredient-based claims (e.g., "gluten free without the accompanying certification statement," "No MSG/No MSG Added [with the accompanying disclaimer statement]," and "no preservatives" that can be generically approved. "Negative" claims are claims made on product labels that identify the absence of certain ingredients or types of ingredients and are generically approved. Negative claims labeling is allowed to indicate the absence of an ingredient

when that ingredient is expected or permitted by regulation or policy. This could also apply to ingredients which are not expected or permitted by regulation or policy if the ingredients could find their way into the product through a component. For example, the use of "no preservatives" on the label of "spaghetti with meat and sauce" (where regulations do not permit the direct addition of preservatives) would be acceptable if the product contained an ingredient, such as cooking oil, which could contain preservatives but do not. The claims are truthful and not misleading because the ingredients statement provides support that the product does not contain the ingredient. Also in this section are definitions of certain claims such as "No Artificial Flavors," "No Artificial Colors," "No Artificial Colors and Flavors," and "No Artificial Preservatives." There are sample labels to provide further explanation as to what is allowed on the label with these claims. Labels with negative claims that have animal-raising claims and/or non-genetically modified organisms (non-GMO) claims are not eligible for generic approval. An example of a negative claim that can be generically approved includes:

- A label with a gluten free claim. Gluten free highlights the absence of gluten containing ingredients. A claim such as gluten free can be verified by examining the ingredients statement for any gluten-containing ingredients. If the product does contain any gluten containing ingredients, the claim would not be permitted on the label.

See *Appendix 7* for additional types of negative claims and label examples that can be generically approved.

Export Labels that Deviate from Domestic Requirements

The export labels with deviations from domestic requirements section provides information about the documentation and support needed for labels on products that are exported outside of the United States and have deviations from domestic requirements. Such labels must meet the requirements of the importing country, as indicated in the FSIS Export Library. An example of an export label that can be generically approved includes:

- A bratwurst label being exported that has a nutrition facts panel format that deviates from United States domestic requirements and the ingredients statement contains incomplete sublists of the ingredients. The label would be acceptable to generically approve as the label complies with the foreign country's labeling requirements. Documentation supporting the acceptability of the deviation should be kept in the establishment's labeling records to comply with 9 CFR 320.1(b)(10) and 381.175(b)(6). FSIS inspection program personnel (IPP) verify whether product for export meets requirements listed in the Export Library, including labeling, when certifying products for export. In addition to the information from the Export Library, additional documentation, such as a letter from the importer of record on letterhead, can be used to support that the label is in compliance with importing countries labeling requirements for verification purposes.

See *Appendix 8* for additional information about export labels that deviate from domestic requirements.

Geographic Claims on Labels

The geographic claims on labels section provides information about: labels that comply with 9 CFR 317.8 (b) (1) or 9 CFR 381.129 (b) (2); U.S. State endorsement programs that have a geographic emblematic design; U.S. State endorsement programs that do not have a geographic emblematic design; and geographic style documentation by third-party authority claims on labels. There is also a list of the geographic claims on labels that are found in the Food Standards and Labeling Policy Book. An example of a geographic claim that can be generically approved includes:

- A label with Tuscan Style in the product name can be generically approved. There would need to be support in the labeling record for the use of Tuscan style. The support would be documentation from an objective culinary authority (e.g., chef) who would give their definition of Tuscan style and explain how the product meets that definition. This documentation would need to be part of the labeling record each time the label is generically approved.

See *Appendix 9* for additional information about geographic claims that can be generically approved.

"Product of USA," "Made in the USA," and Other Voluntary U.S.-Origin Claims (9 CFR 412.3)

"Product of USA" and "Made in the USA" Claims

Voluntary U.S.-origin claims on labels of products under FSIS mandatory inspection or voluntary inspection services may be generically approved, provided that the labeling record is sufficient to support the claim. To make a "Product of USA" or "Made in the USA" claim, the product must be derived from an animal born, raised, slaughtered, and processed in the United States. For single ingredient items, the entire product must be derived from an animal born, raised, slaughtered, and processed in the United States (9 CFR 412.3(a)). For a multi-ingredient product, the product must be derived from animals born, raised, slaughtered, and processed in the United States; (2) all other ingredients in the product, other than spices and flavorings, must be of domestic origin; and (3) the preparation and processing steps for the multi-ingredient product must have occurred in the United States (9 CFR 412.3(b)).

Some examples of labels that can be generically approved under 9 CFR 412.3(a) and (b) are:

- A single ingredient pork product labeled with "Made in the USA," which is derived from an animal born, raised, slaughtered, and processed in the United States (9 CFR 412.3(a)), provided the labeling record includes sufficient information to support the claim. More information about the types of support that may maintained in the labeling record can be found below.

- A multi-ingredient pork sausage product labeled with "Product of USA," wherein all the FSIS-regulated ingredients are derived from animals born, raised, slaughtered, and processed in the United States; all other ingredients, other than spices and flavorings, are

of domestic origin; and the preparation and processing steps for the product occurred in the United States. The labeling record must include sufficient information to support the claim.

- A multi-ingredient meatloaf product label that has the statement "Made with U.S. Beef" can be generically approved, provided the labeling record includes sufficient support that the beef used in the product was derived from an animal born, raised, and slaughtered, and the meat then processed, in the United States.

- A single ingredient steak product label that has the statement "U.S. Beef" can be generically approved, provided the labeling record includes sufficient support that the beef product was derived from an animal born, raised, and slaughtered, and the meat then processed, in the United States.

Factual Claims Other than "Product of USA" and "Made in the USA"

Factual U.S.-origin claims other than "Product of USA" and "Made in the USA" may be made to designate the U.S.-origin component of a FSIS-regulated product's preparation and processing (9 CFR 412.3(c)). The claims must include a description of the preparation and processing steps that occurred in the United States upon which the claim is made. This claim description should provide meaningful consumer information about the specific type of preparation and processing steps that occurred in the United States. For example, the generalized claims "Processed in the United States" or "Manufactured in the United States" are so broad as to not provide the consumer meaningful information about what preparation and processing steps occurred in the United States.

Examples of labels that can be generically approved under 9 CFR 412.3(c), and that provide meaningful information about the product's preparation and processing, include:

- A label for single ingredient pork tenderloin that has the claim "sliced and packaged in the United States" can be generically approved, provided the labeling record includes sufficient support that the product has been sliced and packaged in the United States.

- A label for a beef empanada that has the statement "beef raised, slaughtered, and processed in the United States" can be generically approved, provided the labeling record includes sufficient support that the beef used in the product was derived from an animal raised and slaughtered, and the meat then processed, in the United States.

U.S. State, Territory, and Locality-Origin Claims

Under 9 CFR 412.3(d), labels that make a factual claim about a specific U.S. State, Territory, or locality can be generically approved, provided the claim meets the requirements for use of U.S.-origin claims under 9 CFR 412.3(a)-(c) with regards to the U.S. State, Territory, or locality origin. Some examples of a U.S. State, Territory, and locality-origin factual claim that can be generically approved include:

- A single ingredient beef label that has the factual claim “Product of Montana.” This claim must meet the requirements in 9 CFR 412.3(a) for the use of a voluntary “Product of...” claim on single ingredient products. That is, the product must be derived from an animal born, raised, slaughtered, and the meat then processed, in Montana. The label can be generically approved, provided there is sufficient support in the labeling record for the claim.

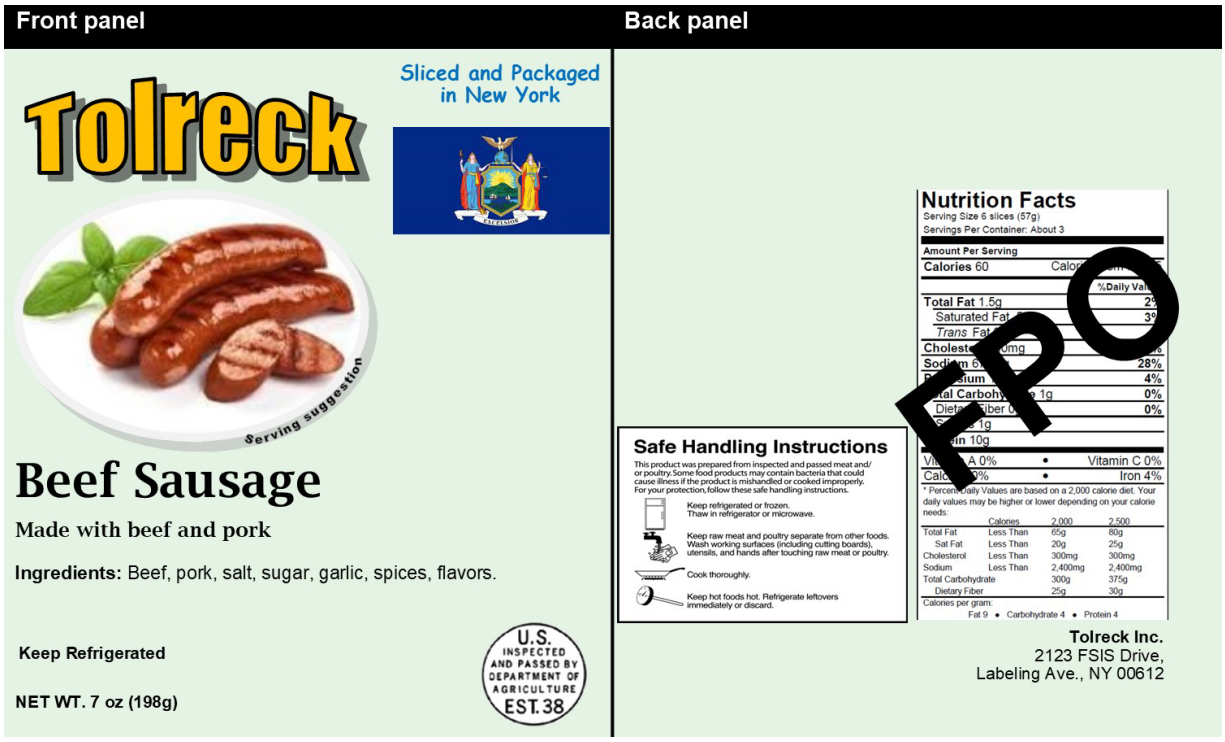
- A single ingredient beef product that is derived from an animal born, raised, and slaughtered in a foreign country, then brought to Oklahoma to be sliced and packaged, could have a voluntary factual claim “Sliced and Packaged in Oklahoma.” This claim would meet the requirements under 9 CFR 412.3(c) for the use of other voluntary U.S.-origin claims, provided there is sufficient support in the labeling record that the product was sliced and packaged in Oklahoma.

U.S. Flag Imagery

Displays of the U.S. flag, or a U.S. State or Territory flag, are permitted on labels of products under FSIS mandatory inspection or voluntary inspection services to designate the United States, U.S. State, or U.S. Territory origin of single and multi-ingredient products or components of a product’s preparation and processing (9 CFR 412.3(e)). The display of the flag must meet the requirements for use of voluntary U.S.-origin claims under 9 CFR 412.3(a)-(d). For the purposes of the display of a flag that meets the requirements for use of U.S.-origin claims other than “Product of USA” and “Made in the USA” under 9 CFR 412.3(c) or (d), the display must be accompanied by a description of the preparation and processing steps that occurred in the United States, or in the U.S. State, Territory, or locality. Examples of labels that can be generically approved under 9 CFR 412.3(e) include:

- A meat product labeled with a standalone display of the U.S. flag which is derived from an animal born, raised, slaughtered, and the meat then processed, in the United States, provided there is support in the labeling record for the claim.

- Display of the New York State flag on a pork product label with the claim “Sliced and Packaged in New York,” provided there is sufficient support in the labeling record that the product was sliced and packaged in New York. See the label example below for U.S. flag imagery that be generically approved.



Required Documentation to Support U.S.-Origin Claims

Official establishments and facilities under voluntary inspection choosing to use a voluntary U.S.-origin label claim will need to maintain, and provide FSIS access to, documentation sufficient to demonstrate that the product meets the regulatory criteria for use of the claim, and that the claim is not false or misleading, as the regulations require for the use of all generically approved labels. The recordkeeping requirements, including general examples of types of documentation that may be maintained to support a voluntary U.S.-origin claim, are in 9 CFR 412.3(f) and (g). Specific examples of the types of documentation that may be maintained include:

- For a “Product of USA” label claim on a single ingredient beef product, records from a ranch located in Wyoming demonstrating that the animal from which the product was derived was born, then raised until slaughter, on the ranch. (Note that this claim would require additional documentation to support that the product was also slaughtered and processed in the United States.)

- For a “Sliced and Packed in New Jersey” label claim on a pork sausage product, records from a processing facility located in New Jersey demonstrating that the product was sliced and packaged in the facility.

Additional Information for Label Approval

Appendix 10 provides general information about label approval and information about the other categories of labels (i.e., labels for temporary approval, including label transfers, and labels for product produced under religious exemption) that must be evaluated by LPDS prior to entering commerce.

Resources

General Labeling Information

- Label Submission and Approval System (LSAS)
- **Label Submission and Approval System (LSAS): User Guide for Industry Users**
- A Guide to Federal Food Labeling Requirements for Meat, Poultry, and Egg Products
- Allergens- Voluntary Labeling Statements
- askFSIS
- Check List for Mandatory Features on a Label
- Descriptive Designation for Needle-or Blade-tenderized Raw Beef Products as Required by 9 CFR 317.2(e)(3)
- Descriptive Designation for Raw Meat and Poultry Products Containing Added Solutions
- FSIS Directive 7000.2- Experimental and Sample Products Policy
- Extraordinary Circumstances- Procedures for Evaluating Labels
- FSIS Guideline on Kit Product Labeling
- Food Standards and Labeling Policy Book
- FSIS Directive 7221.1- Prior Labeling Approval
- FSIS Directive 7120.1- Safe and Suitable Ingredients Used in the Production of Meat, Poultry and Egg Products
- FSIS Form 7234-1- Application for Approval of Labels, Marking or Device
- Information Required for Requesting a Temporary Label Approval
- Labeling and Establishment Responsibilities
- Labeling and Consumer Protection: Proprietary Mixture Suppliers and Manufacturers Questions and Answers
- Labeling Policies
- Labeling Procedures
- Labeling Situations that Cannot Have a Temporary Approval
- Nutrition Facts Label Compliance: Voluntary use of FDA panel on USDA products prior to a FSIS final rule
- FSIS Directive 6030.1- Religious Exemption for the Slaughter and Processing of Poultry
- FSIS Directive 7000.4- Verifying Certain Transferred Labeling

Generic Labeling

- askFSIS Public Q&As: FSIS Labeling Records
- askFSIS Public Q&As: Generic Label Advisor 9 CFR Part 412.2
- askFSIS Public Q&As: Generic Label Advisor Certificate
- askFSIS Public Q&As: Generic Label Advisor Information
- Generic Label Approval Final Rule (January 18, 2023)

Claims Guidance

- Carbohydrate Labeling Statements Interim Policy Statement
- FSIS Guidance on the Labeling of Omega Fatty Acids Claims on Meat, Poultry and Egg Products

- FSIS Guideline on Whole Grain Statements on the Labeling of Meat and Poultry Products

Animal-Raising Claims and Non-GMO Claims

- Animal-Raising Claims Labeling Guidelines Updates
- FSIS Labeling Guideline on Documentation needed to substantiate Animal-Raising Claims for Label Submissions
- Statements that Bioengineered or Genetically Modified Ingredients or Animal Feed were not used in Meat, Poultry, or Egg products

Other Labeling Information

- Compliance Guidelines for Shiga Toxin Escherichia Coli (STEC) Organisms Sampled and Tested Labeling Claims for Boneless Beef Manufacturing Trimmings ("Beef Trim")
- Label Verification of Imported Raw Beef Products Labeled "For Cooking Only" or "For Full Lethality Treatment"

Appendix 1: Special Statements and Claims

LPDS **must preapprove** labels bearing the following special statements and claims prior to entering commerce. The label bearing a special statement or claim must be submitted to LPDS for sketch approval. Supporting documentation for the special statement or claim must be included as part of the labeling record.

A bold red asterisk (*) marks new or updated entries to the appendix. Items previously on the list not marked by a bold **red** asterisk (*) may have been rearranged for ease of readability.

- Allergen warning statement from processing in a meat and poultry plant (e.g., "made in a facility that also processes tree nuts and soy," and "may contain soy.")
- American Heart Association Logo
- AMS "certified compliance document" as related to Child Nutrition (CN) Labels
- AMS processing, AMS processing extra regulatory marking or verification programs*, AMS extra regulatory marking or verification programs
- Animal production claims (e.g., no animal byproducts*, no added antibiotics, no gestation crates*, no growth promotants including ractopamine*, no hormones added, no ractopamine a beta agonist growth promotant*, raised without antibiotics, vegetarian fed).
- Best Aqua Practice symbol
- Breed claims (e.g., Angus, Berkshire, Certified Angus, Hereford, British Quality Assured Pork*).
- Browned in Cottonseed oil (implied nutrition claim that must meet the regulatory definition for low in saturated fat)
- Cage Free
- Certified Claims (e.g., certified organic, certified gluten free, certified halal, certified select ingredients, CrossFit Certified, Certified Women's Business Enterprise, Employee Owned Certified) **+**
- Certified State programs (e.g., certified product of Louisiana).
- Certified tender
- Environmentally Raised
- Extra Trim
- Food and Drug Administration (FDA) nutrition panel, for more information see: Nutrition Facts Label Compliance: Voluntary use of FDA Panel on USDA Products Prior to an FSIS Final Rule
- Free from/ Certified free from (major food allergens and ingredients of public health concern) e.g., free of all major food allergens (milk, eggs, fish, Crustacean, shellfish, tree nuts, peanuts, wheat, soybeans, and—effective January 1, 2023—sesame.) *
- Free Range**+**
- Fruit Claims (e.g., made with real fruit, made with fruit, made with cranberries)
- Gluten free (certified)
- Great for You program
- Health claims defined in 21 CFR 101.14 and 101.70-83
- Hydroponically Grown*
- Humanely Raised**+**
- Implied nutrition claims (e.g., any version of a nutrition statement that does not

follow the regulations in 9 CFR 317.313 (b) (2) or 9 CFR 381.413 (b) (2), including, baked not fried, heart smart, made with vegetable oil, made with olive oil, made without butter, no butter (implied low saturated fat claim), no lard (implied low saturated fat claim), no tropical oils, non-fried, protein pals, protein snack, protein snack box, rubbed with olive oil, reduced guilt/guilt free*, statements about specific types of oil, thin battered, and breaded)

Instructional or disclaimer statements addressing pathogens on products going to another Federal establishment, (e.g., for cooking only, for full lethality treatment, for high pressure processing at establishment XXX)

- Labels for religious exempt poultry product not produced under Federal inspection (e.g., Buddhist, Confucius, Halal product not receiving the mark of inspection and Kosher product not receiving the mark of inspection)
- Labels for sample product (i.e., products not for sale that are for consumer testing within commerce facilities) with special statements and claims
- Local, Locally Raised, Grown Locally, Locally Sourced in geographic location (e.g., Locally Sourced in New York)+
- Made without genetically engineered ingredients claim (that do not have USDA organic certification on the label)
- Milk from cows not treated with rBST-no significant difference has been shown between milk derived from rBST treated and non rBST treated cow's statements on FDA products incorporated into USDA products
- MyPlate icon
- Natural claims (e.g., all natural, 100% natural, made with natural ingredients)
- Non-GMO or other statements from the guideline. For more information see:)
- Nutrition factual statements (e.g., 0 grams carbohydrates per serving, check marks associated with nutrition claim, nutritional facts up front (FOP), 0 grams trans-fat per serving)
- Omega 3 factual statements, (e.g., 200 mg omega 3 fatty acids per serving or any other use of the word omega 3, synonym for omega 3, or type of omega 3 fatty acid-alpha linoleic acid). For more information see: FSIS Guidance on the Labeling of Omega Fatty Acids Claims on Meat, Poultry and Egg Products
- Organic claims (e.g., organic, certified organic, made with organic ingredients)
- Paleo, Paleo Certified, Paleo Friendly
- Pasture Raised
- Pasteurized
- Quality Control, USDA Approved*
- Raised with care*
- Real Ingredients
- Regenerative claims*
- Sampled and tested claims for STEC organisms. For more information see: Compliance Guidelines for Shiga toxin Escherichia coli (STEC) Organisms Sampled and Tested Labeling Claims for Boneless Beef Manufacturing Trimmings ("Beef Trim")
- Safety claims (e.g., #1 Food Safety Priority, High pressure processing was used in the manufacturing of this product)
- Serving sizes in the nutrition facts panel that deviate from 9 CFR 317.309 (b) and 9 CFR 381.409 (b) or Guideline documents (e.g., "meal for 2" with the serving size of "½ package (300 g)." This is not in accordance with the RACC in 9 CFR 317.312 or 9 CFR 381.412 or the serving size rules in 9 CFR 317.309 (b) or 9 CFR 381.409 (b).

- State proposition statements (e.g., California Proposition 12* and Massachusetts Question 3 statements)
- Farming, Sustainably Raised
- Sustainable Forestry Initiative Certified Sourcing
- Super Trim
- Symbols on the label (e.g., arrows or check marks or hearts) in conjunction with nutrition claims
- Third-party raising claim programs (e.g., Audubon Certified*, AMS Processed Verified or Certified programs, American Grass-fed Association, Animal Welfare Association, and Global Animal Partnership)
- Trans fat in the nutrition facts panel for the first time
- USDA Contract Compliance (AMS program)*
- USDA Food shield (AMS program)*
- USDA Further Processed Certification Program (AMS program)*
- U.S. Farm Fresh
- Vegetable claims (e.g., made with premium vegetables, made with vegetables, 40% daily value of vegetables, made with Grade A Vegetables)
- Whole grain claims (e.g., made with whole grain, whole grain stamp, whole grain seal, whole grain in the product name, whole grain claims on CN labels, Whole wheat in the product name, whole grain). For more information see:
- WHOLE30

+ For more information see: Food Safety and Inspection Service Labeling Guideline on Documentation Needed to Substantiate Animal-Raising Claims for Label Submissions

Appendix 2: Factual Statements and Claims

The following statements and claims **do not require** LPDS approval prior to use in commerce. Labels with these factual statements and claims are generically approved if the label complies with all regulatory requirements and the statement or claim is truthful and not misleading. Supporting documentation for the statement or claim must be part of the labeling record. LPDS is ceasing evaluating voluntarily submitted generic labels. Generic labels that are submitted to LPDS for evaluation will be returned with a comment stating that the labels are generically approved and does not qualify for sketch approval.

A bold red asterisk (*) marks new or updated entries to the appendix. Items previously on the list not marked by a bold **red** asterisk (*) may have been rearranged for ease of readability.

- Any label for non-amenable product produced under FSIS voluntary inspection (e.g., closed-face sandwiches and exotic species products (e.g., buffalo, bison, venison))*
- 100% Steer/ Made with 100% steer*
- All, 100%, pure
- Aged/dry aged
- Air Chilled
- Allergen or "contains" statements at the end of ingredients statement.
- Allergen statements (e.g., "No: milk, eggs, shellfish, tree nuts, peanuts, wheat or soy," "Top allergen free: no milk, no eggs, no fish, no shellfish, no tree nuts, no wheat or gluten or no soy and—effective January 1, 2023—sesame." *)

  Allergen warning statements carried over from FDA products and listed at the end of the FDA component sublisting in the ingredients statement.
- Amish
- AMS Grading for (e.g., prime, choice, select and grade A).
- Ancient grain, made with
- Artisanal
- Authentic*
- Awards (e.g., Good Housekeeping Seal)
- Baby food and/or toddler food stages e.g., stage 1, step 1 and stage 2, step 1
- Big Agriculture, Factory Farming, Factory Agriculture*
- Beef is the main ingredient*
- Better is Possible
- Certified by SQF Quality Supplier
- Chicken is the main ingredient*
- CN box.
- Cold Smoked*
- Contains: a certain ingredient (states the presence of certain ingredients) e.g., contains: MSG, contains honey
- Containers of products sold under contract specifications to Federal government

agencies
- Country-of-origin labeling statements per 9 CFR 317.8 (b)
- Craft Sausage*
- Double Smoked*
- Egg labels that comply with 9 CFR 412.2
- Exotic Species/ products under voluntary FSIS inspection services
- Experimental Products
- Extra and more than statements (e.g., cheesier macaroni and cheese, more chicken less breading)
- Family Farmed Raised+
- Family-owned ranches*
- Farm Raised (livestock and poultry)+
- Farm raised on labels for Siluriformes
- Farm to Fork
- Farm to Table*
- Flexitarian*
- Free
- Fresh
- Fresh in conjunction with other descriptors (e.g., Deli Fresh, Valley Fresh, Fresh Slice, Premium Fresh, Premium Fresh Deli, Deli Fresh Meats, Farm Fresh, Farm Fresh Meats and Poultry Logo, Fresh Ideas, Fresh from the Heartland, Freshly Prepared and Fresh Selects)
- Flavor profiles (e.g., cheesy*, drizzled with olive oil, made with any type of cheese, BBQ flavored, chipotle flavored, made with fennel, made with fresh tomatoes, garlic flavored, made with Italian cheese, made with only white meat chicken, made with real cheese/made with 100%-real cheese, made with real chicken, made with real maple, made with real crème*, made with Spanish pimento, meaty*, teriyaki flavored, made with tomatoes)
- Flavors and reaction flavors
- Foreign language on domestic products or exported products that deviate from domestic requirements
- From the land for the land*
- Geographic claims on labels that comply with 9 CFR 317.8 (b)(1) and 9 CFR 381.129 (b) (2)
- Geographic logo (e.g., Eiffel tower, map, Mount Rushmore, outline of a specific region (State or Country))
- Geographic style defined in 9 CFR 317.8 (b) (1) and 9 CFR 381. 129 (b) (2) and the Food Standards and Labeling Policy Book (e.g., country style, Italian style, Mexican style)
- Geographic styles undefined (e.g., German Style and Tuscan style) Labels making this type of claim must have documentation of the approval of a third-party authority in their labeling record in support of the use of the undefined style.
- Goodness within
- Green claims or environmental claims (e.g., BPA Free (packaging), Made with recycled materials and made with soy ink)
- Guarantees
- Hand hung, hand pulled style, hand pinched style, and hand tossed style*
- Handcrafted, handmade, hand slaughtered, hand-crafted style
- Healthy Ideas logo
- Home style

- "Homegrown by Heroes" logo
- Juliane Date
- Ice glazed
- Inserts, tags, liners, pasters, and like devices
- International trade membership organization (e.g., USA Poultry and Egg Export Council)
- Irradiation, irradiation symbol
- Kosher claims on products
- Labels for amenable products containing exotic species
- Labels for containers of products sold under contract specifications to Federal Government agencies
- Labels for experimental product
- Labels for inedible product
- Labels for non-certified pet food
- Labels for Sample product without special statements and claims
- Lightly Seasoned
- Made by or made with statements (e.g., Made by Native Americans, made with rice from cooperatives in geographic area, veteran owned*, women owned)
- Made in USA
- Multi grain
- No additives (only permitted on single ingredient items)/No meat additives (must have meat component that is single ingredient item)*
- Negative or Free Claims (e.g. Casein Free, Egg Free, Free of Preservatives, Gluten Free, Lactose Free, Milk Free, Nut Free, Peanut Free, Preservative Free*, Tree Nut Free, No Alcohol, No artificial colors, no artificial flavors, no artificial preservatives with statement under claim "*see back panel for ingredients to preserve quality*", no binders or fillers *, no breading, no butter, no certified colors, certified synthetic colors, no corn syrup, no extenders*, no fillers or dyes, no gluten ingredients, no high fructose corn syrup, no imitation anything, no lard, no liquid smoke, no mechanically separated chicken, no mechanically separated pork, chicken or turkey, No MSG, No MSG added* with disclaimer statement * "*except for that naturally occurring in* [natural sources of MSG]", no nitrites, no nitrates, no nitrites and nitrates, no nitrites and nitrates added* with disclaimer statement* "*except for that naturally occurring in* [natural sources of nitrites and nitrates]", no pork/no pork added, no poultry/no poultry added, no preservatives, no preservatives added, not preserved, no sodium nitrite added* with disclaimer statement* "*except for that naturally occurring in* [natural sources of nitrites]"*, no sodium nitrate added * with disclaimer statement* "*except for the naturally occurring in* [natural sources of nitrate)]"*, no sodium phosphate *, no solutions added, no synthetic colors, no water added.
- New, new and improved, new flavor, new look*
- Noncertified religious exempt product (Halal guarantee, Halal on products receiving the mark of inspection, Halal Style, Halal symbol with trademark, Kosher)
- Not stunned*
- Number 1 brand (would need to have support in the labeling record for the claim)
- Nutrition claim defined in 9 CFR 317.313 - 317.380 and 9 CFR 381.413 - 381.480
- Organic ingredients in the ingredients statement* (e.g., organic tomatoes- would need to have support in the labeling record for the claim)
- Oven Roasted or similar statements
- Piece count
- Premium

- Product of USA
- Product received high pressure processing
- Products not intended for human consumption
- Products with standard of identity (e.g., meatloaf)
- Products without standard of identity (e.g., Wyngz- white chicken fritters)
- Promotions or other similar statements on the label (e.g., charity, holiday, kid tested, kid approved)
- Ready in/cooks in (number of seconds or minutes)
- Retained water statements
- Shipping containers
- Simple ingredients*
- Single ingredient products without claims (single cuts of meat and poultry)
- Small batch (would need to have support in the labeling record for the claim)*
- State endorsement programs that have a geographic emblematic design (e.g., "Go Texan- with map of Texas, Pride of New York- with map of New York, Made in Wisconsin- with map of Wisconsin, Nevada Grown-with map of Nevada)/ Third party State Certification Programs (e.g., 100% Made in Puerto Rico, Arizona Grown, Arkansas Grown, California Grown, Fresh from Florida, Missouri Grown, New York State Grown and Certified, Virginia's Finest- need to have certificate in the labeling record to support the use of the logo on the label current within the last year)*
- State endorsement programs that do not have a geographic emblematic design, (e.g., Kentucky Proud, made with Wisconsin Cheese- need to have certificate in the labeling record to support the use of the logo on the label current within the last year)
- Statements of limited use (e.g., for further processing, for HRI, institutional use only, for food service use only)
- Statements relating to free components (e.g., free packet of hot sauce included)
- Substitution of any unit of measurement with its abbreviation or any abbreviation with its unit of measurement
- Super marbling for rich taste and unbelievable juiciness*
- TG enzyme (transglutaminase enzyme) (products containing this ingredient)
- Trademark*
- Uncured in the product name/Uncured in the ingredients statement
- Value size*
- Wet aged*
- Wholesome from the beginning
- "Wild caught" on labels for Siluriformes
- Wrappers or other covers bearing pictorial designs, non-geographic emblematic designs or illustrations (e.g., floral arrangements, illustrations of animals, fireworks, etc.)
- X-rayed for bone detection
- Your journey begins here*

Appendix 3: Changes to labels approved with special statements and claims not requiring additional LPDS review

9 CFR 412.2 allows for labels to be generically approved provided they do not fall into any of the categories of the labels that must be evaluated by LPDS. Included in that group of labels are those labels that have a special statement or claim that were previously approved by LPDS. Thus, once a label is approved there are several changes that can be made to the label that do not impact the previously approved claims. **These revisions do not impact the previously approved special statement or claim. In addition, for the additional changes to be generically approved, there cannot be any formulation changes or addition of ingredients that were not part of the previously approved label.**

A bold red asterisk (*) marks new or updated entries to the appendix. Items previously on the list not marked by a bold **red** asterisk (*) may have been rearranged for ease of readability.

For more in-depth explanation see discussion on page 10. Examples of the types of label changes permitted are:

- Addition of additional cooking instructions, e.g., the label originally includes cooking instructions for a conventional oven but now the establishment is adding instructions for a microwave.
- Addition of a bar code
- Addition of a brand name or changes to a brand name that do not include a new claim
- Addition of defined nutrition claim
- Addition of Julian date
- Adding new establishments for certification claims that cover multiple establishments

  Addition of a map or geographic emblem without including emblem "brand made in"
- Addition of e-mail address or website information
- Addition of a logo or changes to a logo that does not include a new claim*
- Addition of a "non-GMO or "non-GE" claim to a certified organic label. For more information see Labeling Guideline on Statements that Bioengineered or Genetically Modified Ingredients or Animal Feed Were Not Used in Meat, Poultry or Egg Products.
- Addition of a nutrition facts panel
- Addition of a scan code app or QR (quick response) code
- Addition of geographic style to product names, e.g., Tuscan Style to a previously approved Italian Sausage label. When not an established style in the regulations or Food Standards and Labeling Policy Book, the third-party authority documentation must be included as part of the labeling record.
- Addition of a universal product code (UPC code)
- Additional meat or poultry cut not on the previous list of cuts approved except for organic claims
- Addition of trademark that does not impact previously approved special statement

or claim and does not add a new special statement or claim*

- Changes to the ad copy that does not include an additional claim that was not present on the previously approved label and does not conflict with the current claims on the label
- Changing an approved claim to a synonymous claim (e.g., changing from "no antibiotics used" to "raised without antibiotics")
- Changes to comply with Descriptive Designation for Raw Meat and Poultry Products Containing Added Solutions (9 CFR 317.2(e)(2) and 9 CFR 381.117(h))
- Changes to comply with Descriptive Designation for Needle-or Blade-tenderized Beef Products (9 CFR 317.2(e)(3))
- Changes to the cooking instructions provided it still complies with the requirements of the corresponding HACCP category
- Changes to the descriptive name
- Changes to the design of the label including layout. The establishment has the responsibility to ensure that all mandatory features are still in the required location.
- Changes to the design of the label including the layout to labels for export with deviations from domestic requirements. The establishment has the responsibility to ensure that all mandatory features are still in the required location and no new label deviations were created.
- Changes to an e-mail address or website that was on previously approved label
- Changes to the establishment number or legend except for organic product. (Changes to the establishment number for organic product must be evaluated by LPDS.)
- Changes to the form of the product (e.g., changing from link sausage to bulk sausage or changing from sausage patties to sausage links)*
- Changes to the HACCP category (e.g., change from raw product ground to fully cooked not shelf stable)
- Changes to the handling statement (e.g., keep refrigerated)
- Changes to the label for compliance with the added solutions regulations (9 CFR 317.2 (e) and 9 CFR 381.117).
- Changes to names of ingredients in the ingredients statement provided the addition complies with FDA or FSIS labeling policies
- Changes to the net weight, including the addition of net weight labels (e.g., a label was approved for 1 pound (lb.) and the new label is for 2 pounds (lbs.)
- Changes to the order of predominance or product formula without the addition of new ingredients
- Changes to the packaging (e.g., going from plastic container to plastic bag)
- Changes to the placement or location of the legend
- Changes to the product name (e.g., changing the product name from sausage to Italian sausage provided it meets the regulation and/or standards)
- Changes to the signature line (e.g., manufactured for or distributed by)
- Changes to values in the nutrition facts panel
- Changing from "GE to "GMO" on certified organic or other third-party certified labels. For more information see Labeling Guideline on Statements that Bioengineered or Genetically Modified Ingredients or Animal Feed Were Not Used in Meat, Poultry or Egg Products

- Removal of ingredients in product without the addition of new ingredients
- Removal of nutrition front of pack icon. The addition of an icon that was not previously evaluated by LPDS would need to be submitted for approval.
- Removal of previously approved claim.

Appendix 4: Changes to labels with special statements and claims that require LPDS review

9 CFR 412.1 states that certain changes to labels are not permitted to be made generically. The labels must be submitted to LPDS for approval.

A bold red asterisk (*) marks new or updated entries to the appendix. Items previously on the list not marked by a bold **red** asterisk (*) may have been rearranged for ease of readability.

For more in-depth explanation see discussion on page 10.

Examples on the types of label changes that cannot be made generically include:

- Addition of additional nutrients to the labels with nutrition front of pack (FOP) statement
- Addition of an animal-raising claim
- Addition of ingredients to labels with special statement and claims such as “Natural,” “Organic,” and “Certified Gluten Free”
- Change to the establishment number on labels with an organic claim
- Change to the ingredients without changing the label. That would require a temporary approval from LPDS
- Changing the organic certifier on an approved label

Appendix 5: Blanket Label Approvals (Product Line or Multiple Products with Identical Claims)

A Blanket Approval refers to an approval that would cover multiple products or product lines that is submitted to LPDS for approval because it falls under one or more of the four categories of labels described in 9 CFR 412.1.

A bold red asterisk (*) marks new or updated entries to the appendix. Items previously on the list not marked by a bold **red** asterisk (*) may have been rearranged for ease of readability.

For more in-depth explanation see discussion on page 11. Examples of labels that can be approved as a blanket approval:

- Addition of animal-production claim to line that also bears an ingredient-related claim
- Addition of FOP statements to multiple products in the same product line or company
- Addition of a new supplier for an approved animal- production claim
- AMS processing extra regulatory marking or verification programs*
- Changing the organic certifier on an approved label
- Changing the source of meat from a previously approved label when the claims and ingredients have not changed from the prior approval
- High pressure processed at establishment ABC
- Religious exempt products*
- USDA Contract Compliance (AMS program)*
- USDA Food Shield (AMS program)*
- USDA Further Processed Certification Program (AMS Program)*

Appendix 6: Special Statements and Claims Generically Approved After the First Approval from LPDS

There are certain types of special statements and claims for which LPDS only needs to see one label to ensure compliance with the regulations and after that initial approval, the label can be generically approved for additional products. This is provided that any future labels follow all FSIS rules, policies, and regulations. The establishment would also have to include a copy of the initial approval in their labeling record to provide assurance that the special statement or claim did initially receive approval from LPDS. If the special statement or claim has changed at all from the initial LPDS approval, the new label must be submitted to LPDS for evaluation.

For more in-depth explanation see discussion on page 12.

A bold red asterisk (*) marks new or updated entries to the appendix. Items previously on the list not marked by a bold **red** asterisk (*) may have been rearranged for ease of readability.

Examples of labels that can be generically approved after initial LPDS approval:

- AMS processing extra regulatory marking or verification programs*
- Nutrition FOP—provided the format, location and nutrients remain identical to the initial approval. If the establishment changes the format, location, or nutrients, then the new label must be evaluated by LPDS
- Certified Halal/Certified Zabihah Halal- must have documentation in the labeling record current within the last year to support the use of the claim
- Certified Kosher- must have documentation in the labeling record current within the last year to support the use of the claim
- Certified Women's Business Enterprise
- Employee Owned Certified
- FDA nutrition facts panel- one approval from LPDS per format (e.g., full format, simplified, linear, tabular, dual column, or aggregate format)
- For cooking only at establishment xyz- must have documentation in the labeling record to support that the product is being sent to another establishment for cooking
- High pressure processed at establishment ABC
- Sustainable Forestry Initiative Certified Sourcing
- USDA Contract Compliance (AMS program)*
- USDA Food Shield (AMS program)*
- USDA Further Processed Certification Program (AMS Program)*

Appendix 7: Negative Claims

Negative claims are claims that state a product does not contain a certain ingredient. Negative claims can be generically approved per 9 CFR 412.2 (b). Examples of negative claims include gluten free, no artificial colors, no artificial flavors, no artificial preservatives, no MSG, no MSG added, no nitrites and nitrates, no nitrites and nitrates added and no preservatives.

- **Gluten Free** is a negative claim that highlights the absence of certain gluten- containing ingredients in the ingredients statement. Certain gluten- containing ingredients such as wheat, rye, barley, or their crossbred hybrids like triticale. FSIS does not define gluten free in its regulations but applies FDA's requirements for the voluntary use of the claim in 21 CFR 101.91. A claim of "gluten free" is generically approved unless it is a **certified** claim, e.g., "Certified Gluten Free by (XYZ entity)." **Certified** gluten-free claims need to be submitted to LPDS for approval with support for the claim. See the sample label below for a gluten-free label claim that can be generically approved.

- **No Artificial Colors** is a negative claim that follows the entry in the Food Standards and Labeling Policy Book that the product doesn't contain any artificial colors as defined therein: Labels of products that are artificially colored either by artificial colors or natural colors must bear a statement to indicate the presence of the coloring, for example, "artificially colored" or "colored with annatto." See 9 CFR 317.2(j)(6) and 9 CFR 317.2(j)(7) Products whose true color is disguised by packing media, for example, colored pickling solutions, must also have labels that include a statement that indicates the presence of the color. The statement must

appear in a prominent and conspicuous manner contiguous to the product name. When a component within a product is artificially colored, for example, breading, sauce, and sausage, a qualifying statement is not necessary. However, in all cases, the presence of the coloring must appear in the ingredients statement. Common artificial colors are FD&C Yellow No. 5 or Yellow No. 5, Red Dye No. 40, FD&C Red No. 3, FD&C Green No. 3, and FD&C Blue No. 2. 21 CFR Part 73 lists color additives that are exempt from certification. Colors that are exempt from certification are not required to be declared by common or usual name on labels and may be declared as "colorings" or "color added." Examples of exempt colors include Annatto extract, Caramel, and Paprika oleoresin. In comparison, certified colors are listed in 21 CFR Part 74 and are required to be declared by common or usual name, e.g., FD&C Blue No. 1, FD&C Blue No 2, FD&C Green No. 3, FD&C Red No. 3, FD&C Red No. 40, FD&C Yellow No. 5, FD&C Yellow No. 6, Orange B, Citrus Red No. 2.

No Artificial Flavors is a negative claim that describes a product that contains no ingredients labeled as artificial flavors (e.g., Artificial Maple Flavor). Acceptable ingredients can include MSG, smoke flavor, flavors, natural flavors, disodium inosinate, disodium guanylate, hydrolyzed vegetable proteins, and yeast extracts. See the sample label below for a no artificial colors or flavors label that can be generically approved.

- **No artificial preservatives** mean the product would not contain any source of artificial preservative. LPDS has allowed the claim of no artificial preservatives under the following conditions so the consumer is not misled under 9 CFR

317.8 about whether the products is preserved or not.

The labeling claim would consist of:

1. A statement “See back panel for ingredients used to preserve quality” would appear on the front panel in immediate proximity to the “No Artificial Preservatives” claim. This will provide consumers with details about the claim-namely, the fact that the product has added ingredients that will help preserve product quality.

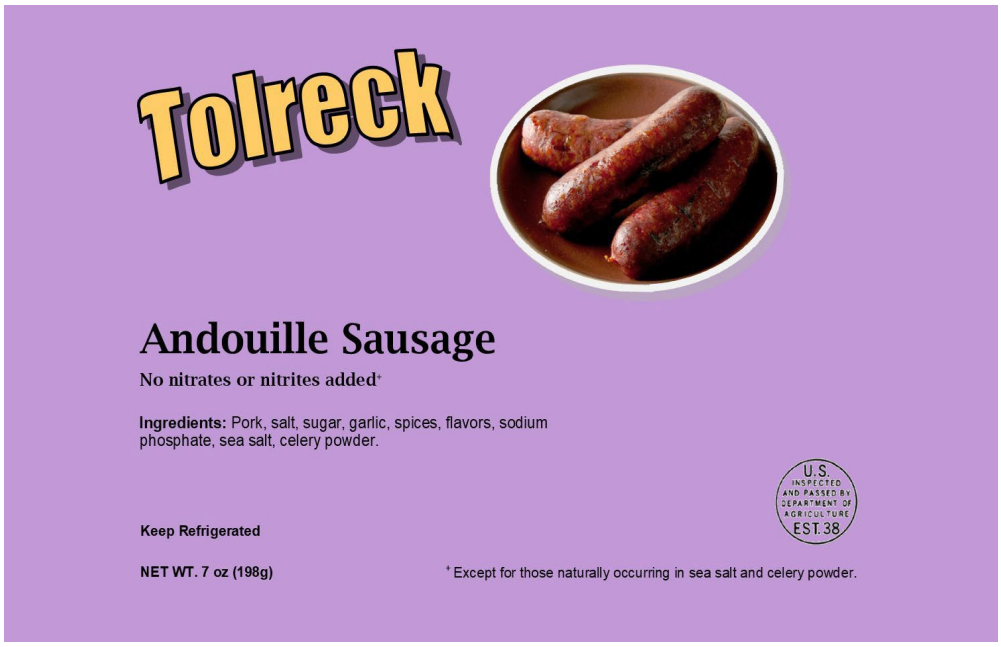
- Each ingredient added to preserve the product would be declared with an asterisk in the ingredient line. The asterisk would lead to the following explanatory statement below the ingredient line: “Ingredient to preserve quality” or perhaps a shortened form like “to preserve quality.” See sample label below for no artificial preservatives claim that can be generically approved.

- **No MSG** is a negative claim that means the product does not contain any sources of MSG. Common sources of MSG include any ingredient that is hydrolyzed or autolyzed such as autolyzed yeast extract. Other common sources of MSG are Worcestershire sauce and soy sauce. For a label that claims No MSG and does have a natural source of MSG, the claim would need to be changed to No MSG added with a disclaimer statement (see the next section for additional information). See sample label below for No MSG claim that can be generically approved.

- **No MSG Added** is a negative claim that means the product does not have any sources of MSG added but it does contain naturally occurring sources of MSG such as soy sauce or Worcestershire sauce. Other common ingredients include any ingredient that is hydrolyzed or autolyzed such as autolyzed yeast extract. For labels with this claim, it would need to state No MSG Added* and then have a corresponding asterisk on the same panel with the *except for that naturally occurring and identify the ingredients in the product that are the naturally occurring sources of MSG, e.g., “No MSG Added* *except for that naturally occurring in autolyzed yeast extract and Worcestershire sauce.” The disclaimer statement must be on the same panel as the claim. See sample label below for no MSG added claim that can be generically approved.

- **No Nitrites and Nitrates** is a negative claim that means that the product would have no natural sources of nitrites, nitrates, or nitrites and nitrates (e.g., sea salt, cultured celery powder, celery powder, cultured celery juice or celery juice). Products labeled as uncured would need to follow the 9 CFR 317.17 requirements. See sample label for no nitrites and nitrates claim that can be generically approved:

- **No Nitrites and Nitrates Added** is a negative claim that means that the product would have natural sources of nitrites, nitrates, or nitrites and nitrates (e.g., sea salt, cultured celery powder, celery powder, cultured celery juice or celery juice). For products with this claim, sea salt and salt cannot be combined into one ingredient, those ingredients must be declared separately. For products that declare those natural sources of cure, the label would need to have a disclaimer statement “No Nitrites or No Nitrates Added* *except for that naturally occurring in sea salt and celery powder” on the same panel as the claim For the ingredients cultured celery powder and cultured celery juice, they must be sublisted in the ingredients statement (e.g., cultured celery powder (celery powder, cultures and sea salt)). The disclaimer statement must be on the same panel as the claim. Products labeled as uncured would need to follow the 9 CFR 317.17 requirements. See sample label for no nitrites and nitrates added claim that can be generically approved.



- **No preservatives** is a negative claim that means the product would not contain any source of chemical preservatives in the product. Per 21 CFR 101.22 (a) (5) "Chemical Preservatives" means any chemical that, when added to food, tends to prevent or retard deterioration thereof, but does not include common salt, sugars, vinegars, spices, or oils extracted from spices, substances added to food by direct exposure thereof to wood smoke, or chemicals applied for their insecticidal or herbicidal properties. Some common chemical preservatives include ascorbic acid, BHA, BHT, calcium propionate, and sodium propionate. For more information about chemical preservatives, please see 9 CFR 424.21 and FSIS Directive 7120.1, *Safe and Suitable Ingredients Used in the Production of Meat, Poultry, and Egg Products*. See sample label below for no preservative label claims that can be generically approved.

Appendix 8: Export Labels with deviations from domestic requirements

Export Labels that Deviate from Domestic Requirements:

A labeling deviation is a feature on labeling that is not permitted on labeling domestically but is required or permitted by the importing country. FSIS regulations provide for deviations from domestic labeling requirements for products for export with deviations from domestic requirements under 9 CFR 317.7 and 9 CFR 381.128. Export labels that deviate from U.S. domestic requirements are approved generically provided the labeling deviations comply with the importing country's labeling requirements. Documentation supporting the acceptability of the deviation should be kept in the establishment's labeling records under 9 CFR 320.1(b)(11) and 381.175(b)(6).

FSIS maintains an Export Library that lists requirements for exported products that foreign authorities have officially communicated to FSIS, including labeling requirements. At times, foreign country labeling requirements conflict with domestic requirements. FSIS regulations (9 CFR 317.7 and 9 CFR 381.128) permit export product labels to deviate from FSIS' domestic labeling requirements to comply with foreign country requirements or to be marketed more easily in a foreign country.

Although there is no specific equivalent regulation for egg products, FSIS follows the same policy because such products, intended exclusively for export, must comply with foreign countries' requirements and are therefore not considered misbranded. FSIS IPP verify whether product for export meets requirements listed in the Export Library, including labeling, when certifying products for export.

The FSIS Export Library is a resource published by the agency for information on various countries importing requirements. In addition to the information in the Export Library, types of documentation typically used to support labeling deviations include a letter from the importer on its official letterhead, a letter from the government of the importing country, and excerpts from the importing country's regulations or laws, provided the source of the information can be verified by IPP e.g., a link to a government site listing official regulations. The information in the label record helps verify that the label complies with the importing country's requirements.

Appendix 9: Geographic Claims on Labels:

"Geographic claims" are claims displayed on a product label, such as a foreign country's flag, monument, or map. For example, the following claims displayed on a product label no longer require LPDS review prior to entering commerce: a Polish flag depicted on a Polish sausage product label, or an outline of the State of Nevada depicted on a product label for beef produced in Nevada. There are several types of geographic claims, including labels that comply with 9 CFR 317.8(b)(1) or 9 CFR 381.129(b), other options for geographic naming, state endorsement programs that have a geographic emblematic design, state endorsement programs that do not have a geographic emblematic design, and geographic style documentation by third-party authority.

Labels that comply with 9 CFR 317.8 (b) (1) or 9 CFR 381.129 (b) (2) requirements:

For a list of the established styles in the Food Standards and Labeling Policy Book, see the end of this appendix, if the style in question is not in this list, the label would need to comply with the requirements in 9 CFR 317.8 (b) (1), 9 CFR 381.129 (b) (2) or follow the third-party authority documentation requirement

State endorsement programs that have a geographic emblematic design (e.g., Wisconsin Cheese with a map of Wisconsin or use of flag):

State endorsement programs that have a geographic emblematic design (e.g., Go Texan with the map of Texas or Nevada Made with the map of Nevada) and a geographic logo or map are generically approved per 9 CFR 412.2 (b). The label must comply with 9 CFR 317.8 (b) (1), 9 CFR 381.129 (b) (2) or an established style in the Food Standards and Labeling Policy Book. In addition, there must be support in the labeling record for the claim. The support can be a certificate from the agency running the certification program or a letter stating the label complies with the requirements. The supporting documentation needs to be updated yearly. Note that, as discussed above (see **"Product of USA," "Made in the USA," and Other Voluntary U.S.-Origin Claims**), displays of the U.S. flag, or a U.S. State or Territory flag, on labels of products under FSIS mandatory inspection or voluntary inspection services must comply with 9 CFR 412.3(e) after the rule's compliance date (See "Voluntary Labeling of FSIS-Regulated Products with U.S.-Origin Claims" https://www.fsis.usda.gov/policy/federal-register-rulemaking/federal-register-rules/voluntary-labeling-fsis-regulated). U.S. State endorsement programs that do not have a geographic emblematic design:

For the U.S. State endorsement programs that do not have a geographic emblematic design (e.g., "Pride of New York," "Kentucky Proud"), there needs to be support in the labeling record for the claim. The support can be a certificate from the agency running the certification program or a letter stating the label complies with the requirements. The supporting documentation needs to be updated yearly.

Geographic Style Documentation by Third-Party Authority:

New geographic styles not listed in the Food Standards and Labeling Policy Book, for example, "Laos Style," must be supported by a third-party authority. The third-party authority could be a chef or other culinary authority providing a definition for the style

and stating how the product meets that definition. The geographic style documentation by a third-party authority must:

- Indicate the type of product as identified with and peculiar to the area represented by the geographical term.
- Indicate the characteristics of the X style in a manner that is quick and easy to understand. It may be a method of preparation and/or certain ingredients that are used.
- Have characteristics that are unique to the geographical style for which the documentation is being provided; and
- Provide the credentials of the person who is claiming to be the third-party authority.

Further, unless the new style is documented in the Food Standards and Labeling Policy Book, the company needs to include supporting information in every labeling record that is generically approved and with every label that is submitted for approval.

Documentation requirements for Geographic Claims:

The documentation for a geographic claim on a label must be updated once a year and be current for that year. The documentation to support the claim for a state endorsement program and state endorsement program with geographic emblematic design can be a certificate from a state agency. For the third-party authority, you need to have the supporting documentation and/or certificate updated once a year from the third-party authority to support the claim.

Some examples of styles defined in the Food Standards and Labeling Policy Book

- Asian Style
- Country Style
- Buffalo Style
- Cajun Style/Cajun Recipe
- Cantonese Style Spices
- Creole Style
- Italian Style (please note- Italian Style sausage must meet ~~9 CFR 319.145~~)
- Jamaican Style
- Jerk or Jerk Style
- Hawaiian Style
- Mediterranean Style
- Mexican Style
- Nacho Style, Nacho Flavor and Similar Terms
- New Orleans Style
- Oriental Style
- Santa Fe Style
- Southwestern Style
- Szechwan Style

- Thai Style

Appendix 10: Additional Information for Label Approval

This section provides additional information about the two other categories of labels that LPDS must evaluate. Also, the following provides some general information about label requirements.

Labels for religious exempt products (9 CFR 412.1 (c)(1)):

Poultry slaughtered under Buddhist, Confucian, Halal, or Kosher religious exemptions may not bear the mark of inspection. Because of this, the labels deviate from labeling requirements and must be approved by LPDS. For more information see FSIS Directive 6030.1, *Religious Exemption for the Slaughter and Processing of Poultry*

Labels for temporary approval (9 CFR 412.1 (c)(4)):

A temporary label approval may be granted for labels with a regulatory deviation that does not pose any potential health, safety, or dietary problems to the consumer.

Temporary approvals will be granted for up to 180 days, and establishments can apply for one extension of up to an additional 180 days. Label transfers are a special type of temporary approval which is granted for 60 days with one additional extension. Temporary label approval is granted on a case-by-case basis.

Example: A supplier changes ingredients and fails to inform the establishment, and the establishment needs to make a minor correction to the ingredients statement. The establishment can apply for a temporary approval to use the existing label, even though it does not have the correct ingredients statement.

Only LPDS can grant temporary approvals for labels with deficiencies. The submitter must address the four conditions for temporary approval listed in 9 CFR 412.1(f) and explain how they meet each condition. As part of their label application, they must also explain exactly what is wrong with their label. Example: A change in the ingredients statement from what was approved in the past. The submitter would submit both ingredients statements and highlight the differences between them.

FSIS Verification Activities at Establishments

FSIS IPP perform routine and directed General Labeling Tasks as assigned by the Public Health Inspection System as part of their regular label verification activities under FSIS Directive 7221.1, *Prior Labeling Approval*. FSIS IPP verify that final labels applied to final product follow applicable regulations by evaluating information in the establishment's labeling record and the label that is applied to the product (e.g., to verify that the ingredients statement on the label matches the product formula). Neither establishments, LPDS, nor FSIS inspectors generically approve labels. Rather, such labels are approved by the regulations provided they follow applicable requirements in 9 CFR 412.2 (b).

For additional information, see FSIS Directive 7221.1, *Prior Labeling Approval*.

Labeling and Establishment Responsibilities Concerning Label Approval

Establishments are required to keep records of all labeling, both generically approved, and sketch approved by LPDS, along with the product formulation and processing procedures, as prescribed in 9 CFR 320.1(b)(11), 9 CFR 381.175(b)(6), and 9 CFR 412.1. For labels that are sketch modified by LPDS, the establishment is responsible for making the changes on the label as noted by LPDS, prior to the final generic label approval and printing. For establishments that are making changes to labels previously approved by LPDS, they must update the labeling records and label to reflect the changes made. If the label has claims that are impacted by the ingredients, then the label would need to be resubmitted to LPDS for approval prior to use. 9 CFR 412.1(a) added the requirement that any additional documentation needed to support that the labels are consistent with the Federal meat and poultry regulations on labeling also be kept. For example, in a situation where an establishment is making an undefined geographic claim on a label ("Tuscan style"), documentation should be included to support that the style meets 9 CFR 317.8 (b). Companies must provide labeling records to FSIS personnel upon request as described in 9 CFR 412.1(a).

For additional information see: Labeling and Establishment Responsibilities.

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