

FSIS Compliance Guideline for Label Approval

July 2020



This guideline is designed to help establishments determine:

- The special statements or claims on labels that require submission to FSIS for approval
- The factual statements and claims on labels that are eligible for generic approval.
- Changes to labels approved with special statements and claims without additional FSIS review
- Changes to labels approved with special statements and claims that require FSIS 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 receiving the first approval from FSIS.
- Additional information about label approval.

USDA-FSIS

Preface

What is the purpose of this Compliance Guideline?

On November 7, 2013, the Food Safety and Inspection Service (FSIS) amended its prior label approval regulations to expand the circumstances in which certain types of labels are generically approved. The Labeling and Program Delivery Staff (LPDS) evaluates four categories of labels 9 CFR 412.1 (c): labels for religious exempt products 9 CFR 412.1 (c)(1), labels for export with deviations from domestic requirements 9 CFR 412.1 (c)(2), labels with special statements and claims 9 CFR 412.1 (c)(3), and labels for temporary approval 9 CFR 412.1 (c)(4). The FSIS staff also evaluates labels for egg products and for exotic species under voluntary USDA inspection. All other label applications may be generically approved without evaluation by FSIS.

Key Point:

**FSIS only needs to evaluate four types of labels
9 CFR 412.1 ((c)):**

- 1) Labels for religious exempt products 9 CFR 412.1 (c) (1).
- 2) Labels for export with deviations from domestic requirements 9 CFR 412.1 (c) (2).
- 3) Labels with special statements and claims 9 CFR 412.1 (c) (3).
- 4) Labels for temporary approval 9 CFR 412.1 ((c) (4)).

The compliance guideline provides information about the types of labels that must be submitted to FSIS for approval. Included are specific examples of special statements and claims that must be submitted to FSIS for approval. This guideline also provides examples of statements and claims that do not need to be submitted to FSIS and may be generically approved. FSIS will update the lists periodically as it evaluates new statements and claims on meat and poultry product labels. FSIS will announce new additions to the appendices via the constituent update. New and updated claims in the appendices of this revision are marked with a bold asterisk. Items previously on the list are not marked but may have been rearranged for ease of readability.

This version of the guideline replaces the version that published in August 2017. FSIS has updated the guideline to remove an incorrect reference (e.g. certified Parma ham) in Appendix 1 in response to a comment received on the previous version. FSIS has also updated the guideline with additional examples of special statements and claims (e.g. additional certification programs such as certified select ingredients) that must be submitted to FSIS for approval and with additional information about label approval for products for export with labeling deviations.

This document provides guidance to assist establishments in meeting FSIS regulations. It is important to note that this guideline represents FSIS's current position on the topic. FSIS encourages establishments to use the guideline.

Who is this guideline designed for?

This guideline is for establishments that are designing or modifying meat or poultry product labels with special statements and claims. The establishment must determine whether its labels require FSIS sketch approval, or whether they have been generically approved by FSIS. This guideline will assist the establishment in making this determination. This guideline is not for establishments who produce products that do not fall under 9 CFR Part 412; e.g., establishments that produce egg products and establishments that slaughter or process exotic species under voluntary inspection.

How will FSIS verify requirements related to this guideline?

9 CFR Part 412 addresses label approval requirements. FSIS In-plant personnel verify compliance with the regulations, when performing the General Labeling task in the Public Health Information System (PHIS.)

Is this version of the guideline final?

Yes. This version of the guideline is final and replaces the previous version dated August 2017. FSIS will update this guideline, as necessary, when new information becomes available.

What specific changes have been made to the guideline from the last version?

- Appendix 1 has been updated to remove the certified Parma Ham example.
- Appendix 1 has been updated to include several new special statements and claims (e.g. additional certification programs) that require FSIS approval before they can be used on labels of product in commerce.
- Appendix 2 has been updated to include several new factual statements and claims (e.g. Artisanal and Better is Possible) that do not require FSIS approval before they can be used on labels of product in commerce.
- Appendix 3 has been updated to include several examples of changes to labels with special statements and claims that can be made without additional FSIS review (e.g. addition of brand name that does not include a new claim and changes to the packaging.)
- Appendix 4 has been updated with two new export examples (e.g. changes to an export label that create new labeling deviations not previously approved by FSIS and

changes to an export label that impact previously approved special statements and claims.)

- Appendix 5 has been updated to include a new example (e.g. high pressure processed at establishment ABC) of blanket approvals (labels for product line or multiple products with identical claims.)

Appendix 6 has been updated to include several new examples (e.g. employee owned certified and sustainable forestry initiative certified sourcing) of special statements and claims that can be generically approved after receiving the first approval from FSIS.

What if I still have questions after I read this guideline?

If the desired information cannot be found within this Compliance guideline, FSIS recommends that users search the publicly posted Questions & Answers (Q&As) in the askFSIS database or submit questions through [askFSIS](#). Documenting the questions helps FSIS improve and refine present and future versions of the Compliance Guideline and associated issuances.

When submitting a question, use the **Submit a Question** tab, and enter the following information in the fields provided:

Subject Field: Enter **FSIS Compliance Guide for Label Approval 2020**

Question Field: Enter question with as much detail as possible

Product Field: Select **Labeling** from the drop-down menu

Category Field: Select **Labeling Regulations, Policies and Claims** from the drop-down menu

Policy Arena: Select **Domestic (U.S.) only** from the drop-down menu

When all fields are complete, press **Continue**.

Table of Contents

Preface	2
FSIS Compliance Guide for Label Approval	7
Additional Resources	12
Appendix 1: Special Statements and Claims	13
Appendix 2: Factual Statements and Claims Generically Approved	17
Appendix 3: Changes to labels approved with special statements and claims without additional FSIS review	20
Appendix 4: Changes to labels approved with special statements and claims that require FSIS review	23
Appendix 5: Blanket Label approvals (product lines or multiple products with identical claims)	24
Appendix 6: Special statements and claims generically approved after receiving the first approval from FSIS	25
Appendix 7: Additional Information for Label Approval	26

FSIS Compliance Guideline for Label Approval:

FSIS is publishing this compliance guideline to provide information about the types of meat and poultry product labels that need to be submitted to the Agency for approval, including specific examples of certain special statements and claims that are not generically approved. This guideline is not for establishments who produce products that do not fall under 9 CFR Part 412; e.g., establishments that produce egg products and establishments that slaughter or process exotic species under voluntary inspection

The categories of labels that need to be submitted to FSIS staff for evaluation are:

- 1) Labels for religious exempt products 9 CFR 412.1 ((c) (1)).
- 2) Labels for export with deviations from domestic labeling requirements 9 CFR 412.1 ((c) (2)).
- 3) Labels with special statements and claims 9 CFR 412 ((c) (3)); and
- 4) Labels for temporary approval 9 CFR 412.1 ((c) (4)).

Below is additional information about:

- Special statements and claims 9 CFR 412.1 ((c) (3))
- Factual Statements and Claims Generically Approved
- Changes to labels with approved special statements and claims without additional FSIS review
- Changes approved to labels with special statements and claims that require FSIS review
- Blanket Approvals (labels for product line or multiple products with identical claims)
- Special statements and claims generically approved after the first approval from FSIS
- Additional information for label approval

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

Special statements and claims including logos, trademarks, and other symbols on labels that are generally not defined in FSIS regulations or the Food Standards and Labeling Policy Book must be submitted to FSIS for approval.

- Examples of logos and symbols include graphic representations of hearts and geographic landmarks. Special statements and claims include “natural” and negative claims (e.g. “gluten free”), 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:

FSIS does not consider some factual statements applied to labels to be special statements or claims that require submission to FSIS for approval. These factual statements are generically approved.

- Examples of factual statements in this category include “extra” or “more” statements (e.g., 10% more cheese), defined geographic styles and allergen statements. Also, the addition of an allergen statement (e.g., “contains milk”) consistent with the Food Allergen and Consumer Protection Act is a statement that is generically approved. *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 without additional FSIS review:

Once a label is approved by FSIS for compliance with 9 CFR 412.1, there are several changes that can be made to the label that do not require resubmission to FSIS. For changes to be made to these labels without submission to FSIS, the change 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., 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, so the change is generically approved under 9 CFR 412.2.
- 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 source of 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, HACCP 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 approved to labels with special statements and claims that require FSIS review:

Sometimes changes made to a previously approved label with special statements and claims will require resubmitting the label to FSIS for approval. Changes that could affect the special statement or claim will require FSIS to reevaluate the product formula or other relevant information. Examples include:

- A label with a negative claim (e.g., “No MSG”) was approved by FSIS, and the establishment wants to use a new seasoning mix that includes ingredients that were not included in the product formula for the previously approved label. In this case, the establishment is required to resubmit the label to FSIS for approval, so the Agency can verify that the new ingredients do not contain naturally occurring sources of monosodium glutamate.
- If a company decides to add a new negative claim (e.g., no preservatives) to a previously approved label with a “natural” and “No MSG” claim, the establishment is required to resubmit the label to FSIS for approval because it contains a new special 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 FSIS.*

Blanket Label Approvals (Labels for Product Line or Multiple Products with Identical Claims):

In some cases, the addition of a special claim to an entire line of products or multiple products will not require every single label to be submitted to FSIS for approval. In certain situations, establishments may submit what is referred to as a request for “blanket approval.” An establishment may submit a request for a blanket approval by submitting a complete application and label for one of the products. The establishment should also attach to the request supporting documentation indicating that the establishment is requesting approval for the use of the special statement or statement on multiple product labels. The label application should indicate that the special 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 a request for blanket approval by submitting a complete label submission, including the label application, and mocked up label, for one of the products. The label application should indicate that the Front of Pack (FOP)

statement will be added to all frozen product meals produced at the establishment. The blanket approval will cover products to which the Front of Pack (FOP) statement is applied so there is no need for each individual label bearing the Front of Pack (FOP) information to be submitted for approval. The establishment should update the individual nutrient values within the Front of Pack (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 Front of Pack (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 Front of Pack (FOP) statement will require the revised label to be resubmitted to FSIS for evaluation and approval.

- An establishment produces X number of organic chicken parts. To get all the organic chicken parts labels with a new claim, such as no antibiotics, the establishment should submit one organic chicken breast package with the new no antibiotic claim. The label application should also include a list of other chicken parts that will also use the new claims. 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 were approved with a “no MSG” 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 “no MSG” 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 FSIS:

There are certain types of special statements and claims that FSIS only needs to see once to ensure compliance with the regulations and after the initial approval can be generically approved. These situations are on the condition that any future labels using the special statement and claim are in compliance with all FSIS rules, policies and regulations. If the special statement and claim is changed in any way from the initial FSIS approval, the label must be submitted to FSIS for evaluation. Some examples include:

- A label with a “Go Texan” logo was approved for a Chicken Cordon Bleu product. The establishment wants to add the logo to a Chicken Parmesan product as well. Because the establishment has the prior approval from FSIS for the “Go Texan” logo

and the supporting documentation from the State on file, the Chicken Parmesan label can be generically approved. This label can be generically approved because the logo was previously approved by FSIS and the label application has the documentation from the State to support the use of the claim on the label.

- A label for chicken hot dogs was approved with the certified halal claim. The establishment now wants to make a certified halal chicken sausage. The establishment has the prior approval from FSIS 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.*

Additional information for Label Approval:

This section provides information about the other categories of labels (labels for temporary approval, labels for export with deviations from domestic requirements, and labels for product produced under religious exemption) that must be evaluated by FSIS staff prior to entering commerce and general information about label approval. See *Appendix 7 for additional examples.*

Additional Resources:

- **General Labeling Information**

- [Label Submission and Approval System \(LSAS\)](#)
- [A Guide to Federal Food Labeling Requirements for Meat and Poultry Products](#)
- [Allergens- Voluntary Labeling Statements](#)
- [Food Safety and Inspection Service \(FSIS\) Guideline on Kit Product Labeling](#)
- [Food Standards and Labeling Policy Book](#)
- [Labeling Policies](#)
- [Labeling Procedures](#)
- [Labeling and Establishment Responsibilities](#)
- [Information for Requesting a Temporary Label Approval](#)
- [FSIS Directive 7221.1 Prior Label Approval](#)
- [FSIS Form 7234-1- Application for the Approval of Labels, Marking or Device](#)
- [askFSIS](#)
- [Descriptive Designation for raw meat and poultry products containing added solutions](#)
- [Descriptive Designation for needle-or blade-tenderized \(mechanically tenderized\) beef products](#)
- [FSIS Directive 7120.1- Safe and Suitable Ingredients used in the production of Meat, Poultry and Egg Products](#)
- [Proprietary Mixture Suppliers and Manufacturers Questions and Answers](#)
- [Voluntary use of FDA panel on USDA products prior to an FSIS final rule](#)

- **Generic Labeling**

- [Generic Label Approval Final Rule \(November 2013\)](#)
- [Generic Label Approval](#)
- [Questions and answers regarding the Generic Label Approval Final Rule](#)

- **Claims Guidance**

- [Food Safety and Inspection Service Guidance on the Labeling of Omega Fatty Acids Claims on Meat, Poultry and Egg Products](#)
- [Food Safety and Inspection Service Guideline on Whole Grain Statements on the Labeling of Meat and Poultry Products](#)

- **Animal Raising Claims and Non-GMO Claims**

- [Food Safety and Inspection Service 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 STEC Organisms Sampled and Tested Labeling Claims](#)
- [FSIS Directive 7000.4- Verifying Certain Transferred Labeling](#)
- [Label Verification of Imported Raw Beef Products Labeled "For Cooking Only" or "For Full Lethality Treatment"](#)

Appendix 1: Special Statements and Claims

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

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

A bold plus (+) marks claims that reference a compliance guide that is hyperlinked at the end of the appendix.

- 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 (AHA)
- AMS “certified compliance document” as related to Child Nutrition (CN) Labels
- AMS processing, AMS extra regulatory marking or verification programs +
- Animal production claims (e.g., no added antibiotics, no hormones added, raised without antibiotics, vegetarian fed). +
- Best Aquatic Practice (BPA) symbol
- Breed claims (e.g., Angus, Berkshire, Certified Angus, Hereford). +
- 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
- Egg Free
- Extra Trim*
- Family Farmed Raised+
- Farm Raised+
- FDA nutrition panel, for more information see: [Voluntary use of FDA panel on USDA products prior to an FSIS final rule](#)
- Free from allergen program (big 8 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)
- Free Range+
 - Fruit Claims (e.g., made with real fruit, made with fruit, made with cranberries)
 - Geographic logo or Flag (e.g., Eiffel tower, flag, map, Mount Rushmore, outline of a specific region (State or Country)).
 - Gluten free (certified or non-certified)
 - Great for You program
 - Health claims defined in 21 CFR 101.14 and 101.70-83
 - Humanely Raised+
 - Implied nutrition claims (e.g., any version of a nutrition statement that does not follow the regulations in 9 CFR 317.309- 9 CFR 317.380 or 9 CFR 381.409-9 CFR 381.480, including, baked not fried, heart smart, made with vegetable oil, made with olive oil, made without butter, no tropical oils, non-fried*, protein pals*, protein snack, protein snack box, rubbed with olive oil, reduced guilt, 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, for use in Type 1 course ground beef)
 - Labels for certified pet food
 - 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 in 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+
 - Minimally Processed
 - MyPlate icon
 - Natural claims (e.g., all natural, 100% natural, made with natural ingredients)
 - Negative or "Free" claims (e.g., no additives, no alcohol, not all natural, no animal by-products, no artificial colors, no artificial ingredients, no artificial preservatives, no breeding, no butter, casein free, no certified colors, no certified synthetic colors, egg free, no gestation crates, gluten free, no gluten ingredients, not gluten free, no growth promotants including ractopamine, no high fructose corn syrup, no imitation anything, lactose free, no lard, no liquid smoke, no mechanically separated chicken, no mechanically separated pork, chicken or turkey, no MSG, no MSG added, no

nitrites or nitrates, nut free, no oil, peanut free, no pork added, no poultry added, no preservatives, not preserved, no ractopamine a beta agonist growth promotant, no solutions added, not stunned, no synthetic colors, tree nut free, no water added, Non GMO or other statements from the guideline: [Statements that Bioengineered or Genetically Modified Ingredients or Animal Feed were not used in meat, poultry or egg products](#))+

- Nutrition factual statements (e.g., 0 grams carbohydrates per serving, check marks associated with nutrition claim, nutritional facts up front, 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: [Food Safety and Inspection Service Guidance on the Labeling of Omega Fatty Acids Claims on Meat, Poultry and Egg products](#)
- Organic Claims (e.g., organic, made with organic ingredients)+
- Organic ingredients in the ingredients statement (e.g., organic wheat flour, organic soy sauce) +
- Paleo, Paleo Certified, Paleo Friendly
- Pasture Raised+
- Pasteurized- see Pathogen Reduction – Salmonella and Campylobacter Performance Standards Verification Testing
- Real Ingredients*
- Sampled and tested claims for STEC organisms [Compliance Guidelines for STEC Organisms Sampled and Tested Labeling Claims](#)
- 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](#) and [9 CFR 381.409](#) 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 [381.412](#) or the serving size rules in [9 CFR 317.309 \(b\)](#) or [9 CFR 381.409 \(b\)](#).
- 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) *)
- Sustainable, Sustainable farming Sustainably Raised+
- Sustainable Forestry Initiative Certified Sourcing*
- Super Trim*
- Symbols on the label (e.g., arrows or check marks)
- Third-party raising claim programs (e.g., Agriculture Marketing Service (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*
- Tree nut free*
- U.S. Farm Fresh†
- Uncured in the product name/Uncured in the ingredients statement†
- 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 Child Nutrition (CN) labels, Whole wheat in the product name, whole grain). For more information see: [Food Safety and Inspection Service Guideline on Whole Grain Statements on the Labeling of Meat and Poultry Products](#).
- 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 that are Generically Approved

The following statements and claims do not require FSIS approval prior to use in commerce. Labels with these factual statements and claims may be 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.

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

- 100% American Farmed
- All, 100%, pure
- Aged/dry aged
- Air Chilled
- Allergen or “contains” statements at the end of ingredients statement.
- Allergen warning statements carried over from FDA products and listed at the end of the FDA component sublisting in the ingredients statement.
- Amenable products containing exotic species
- Amish
- AMS Grading for (e.g., prime, choice, select and grade A).
- Ancient grain, made with
- Artisanal*
- Awards (e.g., Good Housekeeping Seal) *
- Baby food and/or toddler food stages e.g. stage 1, step 1 and stage 2, step 1
- Better is Possible*
- Certified by SQF Quality Supplier
- Child Nutrition (CN) box.
- 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 statements (COOL) per [9 CFR 317.8 \(b\)](#)
- Experimental Products*
- Extra and more than statements (e.g., cheesier macaroni and cheese, more chicken less breading) *
- Farm raised on labels for Siluriformes*
- Farm to Fork*
- 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., 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 Spanish pimento, teriyaki flavored, made with tomatoes)
- Flavors and reaction flavors
- Foreign language on domestic products or exported products
- Geographic claims that comply with [9 CFR 317.8 \(b\)\(1\)](#)
- Geographic flag (e.g., Foreign Country Flag) with corresponding statement, accompanied by statement Made in USA) *
- Geographic style defined in [9 CFR 317.8 \(b\) \(1\)](#) 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, and hand pinched style
- Handcrafted, handmade, hand slaughtered, hand crafted style
- Healthy Ideas logo
- Home style
- Juliane Date*
- Inedible product
- 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
- Lightly Seasoned
- Made by or Made with statements (e.g. Made by Native Americans, made with rice from cooperatives in geographic area, women owned)
- Made in USA
- Multi grain, made with
- New, new and improved, New flavor
- Non-certified pet food
- Non-certified religious exempt product (Halal guarantee, Halal on products receiving the mark of inspection, Halal Style, Halal symbol with trademark, Kosher) *

- Number 1 brand
- Nutrition claim defined in 9 CFR 317.313-317.380 and 9 CFR 381.417-381.480
- Nutrition facts panel
- Oven Roasted or similar statements
- Piece count
- Premium*
- Processed in the USA 100%
- 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
- Sample product without special statements and claims
- Shipping containers
- Single ingredient products without claims (single cuts of meat and poultry)
- State endorsement programs that do not have a geographic emblematic design, (e.g., Kentucky Proud, Made with Wisconsin Cheese)
- Statements of limited use (e.g., for further processing, for Hotel Restaurant and Institution (HRI), for 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
- Transglutaminase enzyme (TG) (products containing this ingredient)
- 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

Appendix 3: Changes to labels approved with special statements and claims without additional FSIS 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 FSIS. Included in that group of labels, are those labels that have special statement and claims on the label that were previously approved by FSIS. Thus, once a label is approved there are a number of changes that can be made to the label that do not impact the previously approved claims. **The key to the changes is revisions that 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 prior approval.**

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

For more in-depth explanation see Label Approval Guideline on page 7.

Examples of the types of label changes permitted are:

- Addition of additional cooking instructions e.g., the label originally includes cooking instructions for the oven but now the establishment is adding instructions for the microwave.
- Addition of a bar code
- Addition of a brand name or changes to a brand name that does 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 flag that would have to be associated “made in USA,” “product of USA”. This would need to follow the requirements of 9 CFR 317.8 (b) (2).
- Addition of e-mail address or website information
- Addition of logo or changes to a logo that does not include a new claim*
- Addition of a “non-GMO or “non-GE” claim to certified organic label. For more information see [Statements that Bioengineered or Genetically Modified Ingredients or Animal Feed were not used in meat, poultry or egg products](#)
- Addition of nutrition facts panel
- Addition of a scan code app or Quick Response (QR) 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 UPC code
- Additional meat or poultry cut not on the previous list of cuts approved except for organic claims
- 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 mechanically 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. 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 e-mail address or website that was on previously approved label
- Changes to the establishment number or legend including on export labels with deviations except for organic product. Changes to the establishment number for organic products must be evaluated by FSIS staff.
- Changes to the HACCP category (e.g. change from raw product ground to fully cooked not shelf stable)
- Changes to the handling statement
- Changes to the label for compliance with the added solutions regulations (9 CFR 317.2 (e) and 9 CFR 381.117).
- Changes to name 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
- Changes to the signature line including on export labels with deviations
- 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 [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 FSIS staff would need to be submitted for approval.
- Removal of previously approved claim

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

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

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

For more in-depth explanation see Label Approval Guideline on page 7.

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

- Addition of additional nutrients to the labels with Front of Pack (FOP) statement
- Addition of an animal raising claim
- Addition of a flag, map, or geographic emblem without including the wording “brand made in”
- Addition of ingredients to labels with special statement and claims such as Natural, Organic, No MSG, No MSG added, Gluten Free, No Preservatives, Uncured, No Nitrites or Nitrates added, No Artificial Ingredients
- Change to the establishment number of labels with an organic claim
- Change to the ingredients without changing the label. That would require a temporary approval from FSIS
- Changing the organic certifier on an approved label
- Changes to an export label that create new labeling deviations not previously approved by FSIS (e.g., addition of a nutrition facts panel that was not included in the prior approval) *
- Changes to an export label that impact previously approved special statements and claims (e.g., including an ingredient that is not acceptable for natural) *

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 FSIS for approval because it falls under one or more of the four categories of labels described in 9 CFR 412.1.

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

For more in-depth explanation see Label Approval Guideline on page 8.

Examples of labels that can be approved as a blanket approval:

- Addition of animal raising claim to line that also bears an ingredient related claim
- Addition of Front of Pack (FOP) statements to multi products in the same product line or company
- Addition of a new supplier for an approved animal raising claim
- Addition of state endorsement programs that have a geographic emblematic design (e.g., Go Texan)*
- 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*

Appendix 6: Special Statements and Claims that FSIS needs to review for only one label

There are certain types of special statements and claims for which FSIS 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 are in compliance with 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 claim did initially receive approval from FSIS. If the special statement and claim is changed at all from the initial FSIS approval, the label must be submitted to FSIS for evaluation. For more in-depth explanation see Label Approval Guideline on page 9.

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

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

- Nutrition Front of Pack (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 FSIS
- 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 FSIS 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
- Geographic emblematic design- e.g. state map, flag, country map flag
- “Homegrown by Heroes” logo
- High pressure processed at establishment ABC*
- Sustainable Forestry Initiative Certified Sourcing*

Appendix 7: Additional Information for Label Approval where FSIS approval is required

This section provides additional information about the three other categories of labels that FSIS staff must evaluate. Also, there is information about label requirements in general.

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

Poultry slaughtered under Buddhist, Confucian, Halal, or Kosher religious exemptions do not bear the mark of inspection. Generically approved labeling is not appropriate for the labeling of religious-exempt product because such product does not receive the mark of inspection and, therefore, deviates from the general labeling requirements for meat and poultry products.

2. Export labels with deviations from domestic labeling requirements 9 CFR 412.1 ((c) (2)).

A labeling deviation is something that is not permitted on labeling domestically but is acceptable to the importing country. Export labels that do not comply with U.S. requirements (with the exception of printing labels in foreign language or printing labels that bear a statement of the quantity of contents in accordance with the usage of the country to which exported) can be approved for export only if the labeling deviations comply with the importing country's requirements and there is documentation supporting the acceptability of the deviation. The regulations that cover the need for documentation supporting labeling deviations are 9 CFR 317.7 and 9 CFR 381.128. For FSIS to ensure the labels are in compliance with the laws of the importing country, FSIS needs documentation to support the deviations are allowed. Documentation may be a letter from the importer on its official letterhead or from the government of the importing country. FSIS will also accept excerpts from the importing country's regulations or laws provided the source in the information can be verified e.g., a link to a government site listing official regulations.

The only deviations that do not require such documentation are labels that are completely in a foreign language (excluding the inspection legend), the net weight statement, the nutrition information format, and the need for safe handling instructions on raw or not ready to eat products. Each of these deviations is accounted for in the regulations. In this case, approval from FSIS is still required for the deviations in nutrition information format and safe handling instructions.

Additionally, changes that can be made to export labels generically include a change in the establishment number in the legend, change in the signature line and a change in order of predominance that does not impact previously approved claims.

The key to making changes to export labels generically is to ensure that the changes do not create another labeling deviation that was not listed on the prior label approval. If this does occur, then the label must be evaluated by FSIS.

3. 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 plants can apply for one extension of up to an additional 180 days. For 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 \(\(f\) \(1\)\)](#) and below:

- (i) The proposed label would not misrepresent the product.
- (ii) The use of the label would not present any potential health, safety, or dietary problems to the consumer.
- (iii) Denial of the request would create undue economic hardship; and
- (iv) An unfair competitive advantage would not result from the granting of the temporary approval.

The label application needs to explain how each condition is met. As part of their label application, they must also explain how label deviates from the original approval. For 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.

Plant transfers are a special type of temporary approval which is granted approval for 60 days with one additional extension. FSIS regulations (9 CFR 317.13 and 381.138(b)) allow an official establishment to transfer labels, wrappers, or containers bearing official marks with its establishment number to any other official establishment for temporary use. This transfer can only occur, however, in limited, special circumstances. For example, after a fire, an establishment may need to move its production to another facility. Likewise, to fill an unexpected large order, an establishment may need to arrange for temporary production at another facility. In these special circumstances, an establishment may transfer labels that bear its mark of inspection and establishment number to another establishment for use. LPDS, which grants temporary approvals, looks for information supporting the request that explains why a transfer of labeling is needed, the transferring

establishment's label approval, the date of labeling shipment, the quantity of labeling, the type of labeling material, and the prominent code that will be applied to labeling in order to track the product. FSIS has required for many years that receiving establishments using transferred labeling bearing a pre-printed establishment number (i.e., the transferring establishment's number) be code marked to identify the producing (receiving) establishment. Temporary label approval is granted on a case-by-case basis.

FSIS Verification Activities at Establishments

FSIS field personnel perform a General Labeling Task in the Public Health Inspection System (PHIS) as part of their regular label verification activities under FSIS Directive 7222.1. FSIS IPP verify that final labels applied to product are in compliance with 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 nor FSIS field personnel inspectors generically approve labels.

Although not submitted to FSIS, generically approved labels are approved by LPDS provided they are in compliance with applicable regulations 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 FSIS, along with the product formulation and processing procedures, as prescribed in 9 CFR 320.1(b)(11), 381.175(b)(6), and 412.1. 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 (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](#).



[askFSIS](#)

FSIS/USDA
www.fsis.usda.gov
2020