

# FSIS Compliance Guideline for Label Approval

## August 2017



This guideline is designed to help establishments determine:

- The special statements or claims on labels which require submission to FSIS for approval.
- The factual statements and claims on labels that are eligible for generic approval.
- Changes that can be made to labels approved with special statements and claims without additional FSIS review.
- Changes to labels approved with special statements and claims that FSIS needs to approve.
- Labels for Product Line or Multiple Product Lines with identical claims.
- Special Statements and claims that can be generically approved after the first approval from LPDS.
- Additional information about label approval.

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## 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 LPDS 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 LPDS.

**Key Point:**

**LPDS 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 LPDS for approval. Included are specific examples of special statements and claims that must be submitted to LPDS for approval. This guideline also provides examples of statements and claims that do not need to be submitted to LPDS and may be generically approved. LPDS will update the lists periodically as it evaluates new statements and claims on meat and poultry product labels. 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.

FSIS has also updated the guideline to provide clarification on: 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, labels for entire product line or multiple product lines with identical claims (blanket approval) and information of special statements and claims that can be generically approved after receiving first approval from LPDS. Finally, FSIS has updated the guideline to include information on additional resources that may be utilized to obtain information on labeling requirements.

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 LPDS 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 November 2015. FSIS will update this guideline as necessary, when new information becomes available.

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

- FSIS updated Appendix 1 to include several new special statements and claims and rearranged some special statements and claims for readability.
- FSIS updated Appendix 2 to include several new factual statements and claims and rearranged some factual statements and claims for readability.
- FSIS added Appendix 3 to provide clarification on the types of changes that can be made with labels approved with special statements and claims without additional LPDS review.
- FSIS added Appendix 4 to provide clarification on the types of changes that cannot be made with labels approved with special statements and claims without additional LPDS review.
- FSIS added Appendix 5 to include clarification on submitting labels for an entire product line or multiple product labels bearing identical claims (e.g., request for blanket approvals).
- FSIS added Appendix 6 to provide clarification on the special statements and claims

that can be generically approved after this first approval from LPDS.

- FSIS moved information previously included in Appendix 3 on additional information for label approvals to Appendix 7.

### **How can I comment on this guideline?**

FSIS is seeking comments 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 and the Agency will update the document in response to the comments.

### **Comments may be submitted by any of the following methods:**

Federal eRulemaking portal online submission at [regulations.gov](http://www.regulations.gov): This website provides the ability to type short comments directly into the comment field on this webpage or attach a file for lengthier comments. Go to <http://www.regulations.gov> and follow the online instructions at that site for submitting comments.

Mail, including CD-ROM's, and hand-or-courier-delivered items: send to Docket Clerk, U.S. Department of Agriculture (USDA), FSIS, Patriots Plaza 3, 1400 Independence Avenue SW, Mailstop 3782, 8-163A Washington, DC 20250-3700.

All items submitted by mail or electronic mail must include the Agency name, FSIS, and document title: **FSIS Compliance Guideline for Label Approval July 2017**. Comments received will be made available for public inspection and posted without change, including any personal information to <http://www.regulations.gov>.

Although FSIS is requesting comments on this guideline and may update it in response to comments, FSIS encourages establishments that wish to submit requests for label approval to begin using this guideline. The guideline reflects FSIS's current position.

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

If the desired information cannot be found within the Compliance guideline, FSIS recommends that users search the publicly posted Questions & Answers (Q&As) in the askFSIS database or submit questions through [askFSIS](http://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 **Special Statements and Claims 2017 Compliance Guideline**

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**.

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## **FSIS Compliance Guideline for Label Approval:**

FSIS is publishing this compliance guideline to provide information about the types of 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.

The categories of labels that need to be submitted to LPDS 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 for temporary approval (9 CFR 412.1 (c) (4)); and
- 4) Labels with special statements and claims (9 CFR 412.1 (c) (3)).

Below is additional information about special statements and claims that require submission to LPDS for approval: factual statements and claims that are generically approved, changes that can be made to labels approved with special statements and claims without additional FSIS review, changes that cannot be made to labels approved with special statements and claims without additional FSIS review, labels for entire product lines or multiple product lines with identical claims (blanket approvals), special statements and claims that can be generically approved after first approval LPDS, and additional information about label approval. Additional information can be found in each of the appendices summarized below.

### **Appendix 1: 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 the Food Standards and Labeling Policy Book.

- 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 test for E-coli O157:H7”). See Appendix 1 for an expanded list of examples of special statements and claims.

### **Appendix 2: 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 LPDS 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.

**Appendix 3: Changes can be made to labels approved with special statements and claims without additional LPDS review:**

Once a label is approved by LPDS for compliance with 9 CFR 412.1, there are a number of changes that can be made to the label that do not require resubmission to the LPDS. For changes to be made to these labels without submission to LPDS, the change has to 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.

**Appendix 4: Changes that cannot be made to labels approved with special statements and claims without additional LPDS review:**

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



- A label with a negative claim (e.g., “No MSG”) was approved by LPDS, 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 LPDS 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 LPDS 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 LPDS.

**Appendix 5: Labels for Product Line or Multiple Products with Identical Claims (i.e., requests for blanket approval):**

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 LPDS 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 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 cuts packages. In order to get all the organic chicken cut packages 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 poultry cuts that will also use the new claims. This is a blanket approval because all of the cuts of the chicken listed in the application will be approved through one label submission.
- An establishment has an entire line of beef sausages were approved with a “no MSG” claim. The establishment wants to add a “grass fed” claim to all of 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 grass fed beef claim and a list of all the products in the line. The addition of a grass fed claim does not affect the previously approved “no MSG” claim because there is no change to the ingredients. The addition of the grass fed 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.

#### **Appendix 6: 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 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 LPDS approval, the label must be submitted to LPDS 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 LPDS 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 LPDS 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 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 LPDS requirements. See Appendix 6 for additional examples.

#### **Appendix 7: 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 LPDS staff prior to entering commerce and general information about label approval.

## Additional Resources:

- **General Labeling Information**
  - [Label Submission and Approval System \(LSAS\)](#)
  - [A Guide to Federal Food Labeling Requirements for Meat and Poultry Products](#)
  - [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](#)
  - [askFSIS](#)
  - [askFSIS-Reaction Flavors](#)
  - [Descriptive Designation for raw meat and poultry products containing added solutions](#)
  - [Descriptive Designation for needle-or blade-tenderized \(mechanically tenderized\) beef products](#)
  - [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](#)
- **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](#)
  - [Procedures-non-genetically-engineered- statement on organic meat and poultry products](#)
  - [Statements that Bioengineered or Genetically Modified Ingredients or Animal Feed were not used in meat, poultry or egg products](#)
- **Other Labeling Information**
  - [Salmonella Performance Standards](#)
  - [Food Safety and Inspection Service Directive 10,010.1 Revision 4](#)
  - [Compliance Guidelines for STEC Organisms Sampled and Tested Labeling Claims](#)

## Appendix 1: Special Statements and Claims

LPDS 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 LPDS 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 entries 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 references 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,” “we cannot prevent cross contamination,” 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 Parma Ham)+
- Certified State programs (e.g., certified product of Louisiana).
- Certified tender
- Environmentally Raised
- Egg Free\*
- Family Farmed Raised\*+
- Farm Raised+
- FDA nutrition panel: [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, \* baked not fried, heart smart, made with vegetable oil\*, made with olive oil\*, made without butter, no tropical oils\*, protein snack\*, protein snack box\*, rubbed with olive oil\*, reduced guilt, statements about specific types of oil)
- 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 non-amenable product produced under FSIS voluntary inspection (e.g., closed-face sandwiches and rabbit products)
- 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 with special statements and claims\*
- Lightly breaded
- 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 cows 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, no dairy\*, 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](#) \*)\*+

- Any label for non-amenable product produced under FSIS voluntary inspection (e.g., closed-face sandwiches and buffalo 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 [Salmonella Performance Standards](#)\*
- 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)/ Third party State Certification Programs (e.g. Arizona Grown or 100% Made in Puerto Rico)
- Sustainable, Sustainable farming, Sustainably Raised+
- 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\*
- 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 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 LPDS 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 entries 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.\*
- Amish
- AMS Grading for (e.g., prime, choice, select and grade A).
- Ancient grain, made with
- Awards
- Baby food and/or toddler food stages e.g. stage 1, step 1 and stage 2, step 1
- 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)
- Extra and more than statements (e.g., cheesier macaroni and cheese, more chicken less breading)\*
- 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 (for more information see [askFSIS-Reaction Flavors](#))
- Foreign language on domestic products or exported products\*
- Geographic claims that comply with 9 CFR 317.8 (b)(1)
- Geographic flag with corresponding statement, (e.g., Italian Flag 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.
- 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
- 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, women owned)\*
- Made in USA\*
- Multi grain, made with
- New, new and improved, New flavor
- 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
- 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
- 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 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
- Transglutaminase enzyme(TG) (products containing this ingredient)\*
- Wholesome from the beginning\*
- 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 that can be made 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 LPDS. Included in that group of labels, are those labels that have special statement and claims on the label that were previously approved by LPDS. Thus once a label is approved there is a number of changes that can be made to the label that do not impact the previously approved claims. The key to the changes are revisions that do not impact the previously approved special statement or claim. 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 include cooking instructions for the oven but now the establishment is adding instructions for the microwave.
- Addition of a bar code
- Addition of defined nutrition claim
- 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 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 with the exception of 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 with the exception of organic product. Changes to the establishment number for organic products must be evaluated by LPDS staff.
- Changes to exotic species labels (e.g., brand name, logo, signature line)
- 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 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 LPDS staff would need to be submitted for approval.
- Removal of previously approved claim

#### **Appendix 4: Changes that cannot be made with special statements and claims without additional 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 evaluation. 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 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 LPDS
- Changing the organic certifier on an approved label
- Removal of a claim or statement (e.g. Gluten Free) from an export label that would create an unapproved additional deviation. The label would require evaluation by LPDS

## **Appendix 5: Labels for Product Line or Multiple Products with identical claims (blanket approvals)**

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. 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 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
- 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

## **Appendix 6: 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 and after that initial approval, the label can be generically approved. 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 LPDS. If the special statement and claim is changed at all from the initial LPDS approval, the label must be submitted to LPDS for evaluation. For more in depth explanation see Label Approval Guideline on page 9.

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

- 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
- 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



## **Appendix 7: Additional Information for Label Approval**

This section provides additional information about the three other categories of labels that LPDS 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 may not bear the mark of inspection. Because of this, the labels deviate from labeling requirements and must be approved by LPDS.

### **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. In order 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 LPDS 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 the formula that does not impact the order of predominance. 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 LPDS.

### **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. Plant transfers are a special type of temporary approval which is granted approval 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 performs a General Labeling Task in the Public Health Inspection System (PHIS) as part of their regular label verification activities under FSIS 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 inspectors generically approve labels.

Although not submitted to FSIS, generically approved labels are approved by FSIS provided they are in compliance with applicable regulations in 9 CFR 412.2 (b).

For additional information, see FSIS Directive 7222.1 [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](#).



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