Food Safety and Inspection Service

Protecting Public Health and Preventing Foodborne Illness
Generic Labeling Overview

Labeling and Program Delivery Staff, FSIS
September 25th 2019
Food Safety and Inspection Service:
Presentation Outline

- Prior label approval and generic labeling
- Label Submission and Approval System (LSAS)
- Streamlining the label submission process
- Resources
- Contacting FSIS for guidance
Prior Label Approval and Generic Labeling Regulations
Food Safety and Inspection Service:
Prior Label Approval Authority – FMIA-21 U.S.C. 607(d), PPIA 21 USC 458(b)

- Acts require food manufacturers to obtain prior approval for labels of meat and poultry products before products may be marketed
- “No article subject to this [Act] shall be sold or offered for sale .... But established trade names and other marking and labeling and containers which are not false or misleading and which are approved by the Secretary are permitted.”
- Prior label approval (coupled with continuous inspection) has broad ramifications in terms of public policy and regulatory enforcement
USDA has established requirements for the content and design of labels [9 CFR Part 317 (meat), 9 CFR 381 Subpart N and Y (poultry)]

Requirements are based on the statutory mandate to assure that labels are truthful, accurate, and not misleading, and that products are not misbranded

Required labeling features in regulations are linked to misbranding provisions of Acts

Policy Memos/Food Standards and Labeling Policy Book/Compliance Policy Guides = interpretations of the Acts and regulatory requirements
The Labeling and Program Delivery Staff (LPDS) within the Office of Policy and Program Development (OPPD) administers the FSIS prior approval process.

- Process of label evaluation provided in FSIS Notices/Policy Guidance/Website
- Meat/poultry/egg product manufacturers must examine and learn the statutory, regulatory, policy, and procedural requirements for labeling to be able to ship product in commerce that bears USDA mark of inspection.
Food Safety and Inspection Service:
Terms Defined: Generic Approval, Sketch Approval, Final Labeling, Temporary

- **Generic label approval** - approval of labeling or modifications to labeling prior approved by the Agency without submitting such labeling to FSIS for sketch approval. To be generically approved all mandatory labeling features must be in conformance with FSIS regulations.

- **Sketch approval** - approval provided by LPDS when labels, other than those submitted for temporary, are submitted for approval.

- **Final labels** - labels applied to product prior to distribution in commerce.

- **Temporary approval** - approval granted for up to 6 months to use labels that are not in compliance with FSIS regulations. May not misrepresent the product, create a health or safety situation, or provide an economic advantage.
NOW, only four categories of meat and poultry product labels require LPDS review.

ALL OTHER labels that do not fit into one of the four categories do not require sketch approval by LPDS.
**Food Safety and Inspection Service:**

**Prior Label Approval**

- Only certain types of labeling require submission for evaluation by LPDS
  - labels for temporary approval (9 CFR 412.1(c)(4))
  - labels for products produced under religious exemption (9 CFR 412.1(c)(1))
  - labels for products for export with labeling deviations (9 CFR 412.1(c)(2))
  - labels with special statements and claims (9 CFR 412.1(c)(3))

- FSIS will continue to require the submission of such labels because they are more likely to present significant policy issues that have health or economic significance
A temporary label approval may be granted for labels with a deficiency that does not pose any potential health, safety or dietary problems to the consumer or provide a company an economic advantage (9 CFR 412.1(f)(1)).

Temporary approvals typically do not exceed 180 days, may be less and extensions can be granted on a case-by-case basis.

Examples include:
- Incorrect legend on label (e.g., poultry legend on a meat label)
- Order of predominance of ingredients has changed
- Nutrition values not rounded in accordance with FSIS regulations
Religious-exempt product (poultry) does not receive the mark of inspection and, therefore, deviates from the general labeling requirements for meat and poultry products.

Poultry processed in accordance with:

- Buddhist religious beliefs (head and feet remain on eviscerated poultry)
- Confucian religious beliefs (poultry is not eviscerated, head and feet intact)
- Islamic (or Halal) religious beliefs (poultry is eviscerated, head-on, with or without the feet intact, in ready-to-cook form)
Exports of U.S. meat and poultry products occur under agreements between the U.S. government and foreign governments.

Includes ensuring that any changes made to labels on meat and poultry products are allowed per the importing country’s laws (9 CFR 317.7 and 381.128).

Most labels marked “for export only” bear labeling deviations that cannot be used domestically must be sketch approved by LPDS.

412.1(c)(2) allows for export only labels with only changes to the net weight in metric units and required features entirely in a foreign language to be approved generically.
Detailed list of special statements and claims requiring LPDS approval and examples of claims eligible for generic approval is available on FSIS website


List will be periodically updated to reflect commonly asked questions regarding special statements and claims
Food Safety and Inspection Service:
Special Statements and Claim Examples

- Natural claims, e.g. “All Natural”, “100% Natural”
- Negative Claims, e.g., “no milk,” “no preservatives”
- Statements that identify a product as “organic”
- Front of Pack (FOP) nutrition statements, e.g., “0 grams trans fat per serving”
- Claims of the use of non-genetically engineered ingredients
- Health claims defined in 21 CFR Subpart E, e.g. dietary saturated fat and cholesterol and risk of coronary heart disease (21 CFR 101.75)
- Claims regarding meat and poultry production practices (e.g., claims regarding the raising of animals such as “no antibiotics administered” or “vegetarian fed”)

NOTE: Additional information regarding special statements and claims is available in Appendix 1 in the FSIS Compliance Guidance for Label Approval found at: https://www.fsis.usda.gov/wps/wcm/connect/bf170761-33e3-4a2d-8f86-940c2698e2c5/Label-Approval-Guide.pdf?MOD=AJPERES
Some factual statements and claims do NOT require submitting for approval and are approved generically under 9 CFR 412.2(b)

Examples include:
- Allergen or contains statements, e.g., “contains (name of ingredient)”
- AMS Grading (USDA Prime, Choice, Select)
- Flavor profiles (teriyaki flavored)
- Foreign language on domestic products
- Geographic claims (refer to 9 CFR 317.8(b)(1))
- “Hand crafted,” “handmade” claims
- Kosher and Halal claims (excludes certified claims)
- “New,” “Now,” and “Improved” claims

NOTE: Additional information regarding factual statements and claims is available in Appendix 2 in the FSIS Compliance Guidance for Label Approval found at: https://www.fsis.usda.gov/wps/wcm/connect/bf170761-33e3-4a2d-8f86-940c2698e2c5/Label-Approval-Guide.pdf?MOD=AJPERES
Food Safety and Inspection Service:
Special Statements and Claims: Sketch Approval Required

Safe Handling Instructions
This product was prepared from inspected and passed meat and/or poultry. Some food products may contain bacteria that could cause illness if the product is mishandled or cooked improperly.

- Keep refrigerated or frozen.
- Thaw in refrigerator or microwave.
- Keep raw meat and poultry separate from other foods.
- Wash working surfaces (including cutting boards), utensils, and hands after touching raw meat or poultry.
- Cook thoroughly.
- Keep hot foods hot. Refrigerate leftovers immediately or discard.

*A Good Win! Farms®
est 2010

Without Added Antibiotics
- Barn Roaming, Never Confined to a Lot
- Grass Fed
- Organic

Special Statements and Claims

Beef Flat Iron Steak

*Minimally Processed, No Artificial Ingredients

Keep Refrigerated

Net Weight: 48 oz (3 lbs)

Distributed By:
20101 Beltsville Rd
Sunnyside, MD 12345
Certified Organic by LPDD Organic Certifying
Food Safety and Inspection Service:
Special Statements and Claims: Sketch Approval Required

![Image](image_url)

- **All Natural***
- **Fully Cooked**
- **Grilled White Chicken Chunks on a wooden skewer**
- **All of our chickens are raised without antibiotics!**
- **Serving suggestion**
- **Ingredients**: chicken breast, salt, pepper
- **Minimally Processed, no artificial ingredients**
- **CERTIFIED HALAL BY THE HOUSTON HALAL ALLIANCE**
- **Keep Refrigerated**
- **Net Wt. 32 oz. (2 lbs.)**

Packed for: House of Kabob, Houston, TX 77252
Food Safety and Inspection Service:
Statements and Claims: Generic Example

NEW!

Packed for: House of Kabob, Houston, TX 77252

Grilled White Chicken Chunks
on a wooden skewer

Fully Cooked

Made with only White Chicken!!!

Factual statements and claims

Ingredients: chicken breast, salt, pepper

Serving suggestion

Keep Refrigerated

Net Wt. 32 oz. (2 lbs.)
Food Safety and Inspection Service: Types of Label Approval

**Sketch**
- Label review process by LPDS
- Printer’s proof or equivalent that is sufficiently legible to clearly show all labeling features, size, and location
- May be hand drawn, computer generated or other reasonable facsimile
- Must clearly reflect and project the final version of the label
- Specific categories of labels require sketch approval
- Sketch approved labels reviewed by LPDS are either “approved” or “approved as modified”
- A “Sketch” label is the concept of a label while “Final” label is the label that is applied to product before distribution in commerce

**Generic**
- The approval of labeling or modifications to labeling prior approved by the Agency without submitting such labeling to FSIS for sketch approval
- Requires that all mandatory labeling features are in conformance with FSIS regulations
- Although not submitted to FSIS for approval, generically approved labels are approved by being in compliance with applicable regulations

**NOTE:** Establishments are responsible for ensuring final labels applied to product are in compliance with FSIS regulations, including making modifications noted by LPDS during sketch review.

**NOTE:** FSIS Inspectors do not generically approve labels. Establishments do not generically approve labels. FSIS approves labels through generic labeling regulations.
Establishments are required to keep records of all labeling.

Labeling record must include:
- Final label applied to product
- Product formulation
- Processing procedures
- Supporting documentation, including prior sketch approval from LPDS (if applicable)

Required records prescribed by 9 CFR 320.1(b)(10), 381.175(b)(6), and 412.1.

The final rule added the requirement establishments maintain as part of the labeling record, supporting documentation needed to show that the label is consistent with the Federal meat and poultry regulations and policies on labeling as described in 9 CFR 412.1.

Labeling record for any label generically approved must include a complete copy of the original LPDS approval (if the original required LPDS approval).
Food Safety and Inspection Service:
Points of Clarification

- FSIS Inspectors do not generically approve labels
- FSIS in-plant inspection personnel will continue to conduct in-plant label verification activities
- Labels will be generically approved if they meet the criteria listed in 9 CFR 412.2(b)
- Establishments do not generically approve labels. Generically approved labels are approved by FSIS and display all applicable mandatory features in compliance with federal regulations
Food Safety and Inspection Service: Points of Clarification

- Generic approval regulations do not apply to egg products
  - Proposed rule published expanding the generic labeling criteria for processed egg products

- Generic approval regulations also do not apply to exotic species under voluntary inspection
  - All labels for exotic species products must be approved by LPDS, including any changes to sketch approved labels (e.g. buffalo jerky)
  - Amenable products with exotic species used as an ingredient may be generically approved if they do not fall into any of the four categories of labels requiring LPDS approval (e.g. bison jerky, beef added)
Label Submission and Approval System (LSAS)
LSAS is the electronic submission system for label applications

To get an LSAS account, requires a USDA eAuthentication account with a verified identity

Integrates and implements a secure electronic label application process for establishments to submit label applications and appeals

Enrollment and use instructions at

Food Safety and Inspection Service:
Paper Label Applications

- Still accepted by LPDS
- Longer wait time because of additional processing steps
- Use FSIS Form 7234-1
- Instructions and tips for paper label submission found at:
  https://www.fsis.usda.gov/wps/wcm/connect/90be18ef-db69-4b51-81cf-1f1ec7e1014e/LSAS-Integration-Paper-Label-Applications.pdf?MOD=AJPERES
Food Safety and Inspection Service: Labeling Procedure

- All labels are evaluated within LSAS
- Entered 2 ways
  - Entered electronically by company or designee
  - Paper copies scanned by LPDS (slower)
- Labels returned due to errors or missing information are resubmitted for follow up evaluation
  - “Resubmittals” are automatically assigned to the top of the review queue in LSAS
Food Safety and Inspection Service:  
First and Second Priority Labels

**First Priority**
- Labels which require LPDS evaluation as per 9 CFR 412.1:
  - Temporary labels
  - Religious-Exempt product
  - Labels for Export bearing labeling deviations
  - Labels bearing special statements or claims
- Reviewed in the order in which they are received

**Second Priority (Voluntary Evaluation)**
- Labels which do not require LPDS evaluation as per 9 CFR 412.2
- Establishments may request voluntary evaluation by LPDS of generically approved labels
- Applications for voluntary evaluation will be placed in a second priority queue and will take longer to be reviewed
Food Safety and Inspection Service:  
Generic Label Advisor (GLA)

- LSAS tool to assist submitters in determining whether a label is eligible for generic approval
- Generic labeling regulations (9 CFR 412.2) incorporated into the GLA
- Submitter responds to a series of questions
  - Based on the responses, GLA determines if the label can be generically approved
  - LSAS will generate a certificate that can be included in the submitter’s labeling records
    - May be included as supporting documentation in the labeling record
    - Is not required for labels to be generically approved
    - Accuracy of the information generated by the GLA is based upon the answers provided by the submitter
Food Safety and Inspection Service:  
Extraordinary Circumstances continued

- FSIS will conduct expedited label evaluations under the following extraordinary circumstances:
  - when misbranded product has been retained ("tagged") by inspection program personnel in an official establishment or
  - when a temporary label approval is needed to remove an unforeseeable impediment to movement of meat, poultry or egg products

- Applications must be identified as an extraordinary circumstance and must explain why an expedited evaluation is needed
Food Safety and Inspection Service: 
Extraordinary Circumstances

- Special note on final product labels “Tagged” for labeling non-compliance
  - Final label must be brought in to compliance by correcting the non-compliance
  - Requests for the temporary use of final labels not in compliance with FSIS regulations and policies must be submitted to LPDS for review. (Emergency reviews may be requested in this instance.)

- Labels that may be generically approved and are voluntarily submitted for review do not qualify as an extraordinary circumstance

- Any label that may be generically approved does not require LPDS approval to enter commerce, therefore emergency review will not be granted
Food Safety and Inspection Service:

Streamlining Label Submission Process
Food Safety and Inspection Service:  
FSIS Response to Increase in Volume of Labels

- LPDS has allocated more resources towards label approval  
  - several staff in training  
  - dedicated hours every day for label review

- LPDS will plan another update to the label approval guideline to include more examples of the types of changes that can be made by generic approval

- “Tips for Faster Label Approval Process” published biweekly in the FSIS Constituent Update
Food Safety and Inspection Service: Industry Strategies for Streamlined Submissions

- Submit complete information, legible labels, and label images that are large enough to be reviewed.
- Orient pages in the same direction to minimize the need for LPDS to reorient pages in the application.
- Include only information required to support information on the label.
  - Missing documentation will likely result in a returned application.
  - Including excessive documentation results in unnecessary delays for LPDS reviewers.
- Submit applications via LSAS instead of paper applications.
- Use askFSIS to introduce new and novel claims and obtain LPDS feedback.
Food Safety and Inspection Service:  
“Blanket” Approval

- Blanket approval allows certain information to be added to other products without having to submit each individual label bearing the same type of information for approval.

- Refers to an approval that covers multiple labels or product lines—e.g. Front of Pack nutrition statements, Certified State programs.

- Application for a blanket approval includes:
  - completed application form 7234-1
  - copy of at least one of the product labels
  - attachment that indicates a list of products or line of products to which the same information will be applied, e.g. FOP nutrition.
An establishment produces 50 types of frozen meals. The establishment intends to add a Front of Pack (FOP) statement for all of the products that will identify the number of calories and grams of protein. Instead of submitting 50 label applications, the establishment can submit a complete label and label application for one of the products and indicate in an attachment that the FOP format/statement will be added to all products produced at the establishment.

A label is submitted for an organic chicken breast with no antibiotics added. Attached to the label application is a list of additional cuts i.e. chicken thigh and/or chicken wings. This is a blanket approval, since all of the cuts of the chicken will be approved through one label approval.

Labels for an entire line of beef products were approved with a “no MSG” claim. The establishment wants to add a “grass fed” claim to all the beef product labels in the line. Instead of submitting separate applications for each of the individual products, the establishment should submit a request for blanket approval for one of the products and indicate that the grass fed claim will be applied to all beef products.
In this example, if the establishment references in the application that the FOP statements will be applied to other products:

- Calories, saturated fat and sodium values may be removed or updated generically on other products to match the nutrition values for each individual product
- Any new FOP statements (e.g. protein, sugar) must be submitted to LPDS for approval
FULLY COOKED
Chicken Nuggets
BREADED STAR SHAPED CHICKEN BREAST WITH RIB MEAT

EXCELLENT SOURCE OF PROTEIN

KEEP FROZEN
NET WT. 5 LBS (2.26kg)

Nutrition Facts
About 25 servings per container
Serving size 5 pieces (88g)
Amount per serving
Calories 230
% Daily Value
Total Fat 13g 20%
Saturated Fat 3g 15%
Trans Fat 0g
Cholesterol 40mg 13%
Sodium 480mg 20%
Total Carbohydrate 14g 5%
Dietary Fiber 3g 16%
Total Sugars 0g
Includes 0g Added Sugars
Protein 12g 24%

* The % Daily Value (DV) tells you how much a nutrient in a serving of food contributes to a daily diet. 2,000 calories a day is used for general nutrition advice.

INGREDIENTS: Chicken breast with rib meat, water, whole wheat flour, contains 2% or less of the following: dried garlic, corn flour, salt, spices, natural flavoring.

Breading set in vegetable oil.

CONTAINS: Wheat.

Tolreck Inc.
2123 Orange Drive,
Almond Ave., GA 00612
Food Safety and Inspection Service:
Modifications to Sketch Approved Labels with Special Statements and Claims

- Once a label is approved with a special statement or claim, changes can be made generically that are unrelated to the special claim, e.g.:
  - brand name, net weight, updating nutrition facts values, serving sizes (must be based on RACCs or longstanding appetizer RACC) and in some cases formulation changes

- Changes are generically approved when they do not impact the special claim:
  - removing ingredients, changes in the order of predominance of ingredients;
  - changes to the form of the product (e.g. link and pattie form); and
  - changes to brand names, vignettes, logos, and design are examples of changes that are generically approved

- With LPDS sketch approval can add to other labeling at Est.
  - Front of Pack nutrition statements if same format as on the approval
  - May transfer label approval to another Est. Excludes organic products
Resources
Food Safety and Inspection Service:
Food Standards and Labeling Policy Book

- Available online at:
- Provides additional guidance regarding FSIS standards outside of the regulations
- Used in conjunction with the Meat and Poultry Inspection Regulations and FSIS Directives and Notices
- Composite of policy and day-to-day labeling decisions
- Claims found in the Policy Book may be approved generically except: natural claims, negative claims
Food Safety and Inspection Service:
Special Statements and Claims vs. Factual Statements and Claims

- Compliance Guidance for Label Approval was updated in August 2017

- Provides detailed list of “special” statements and claims requiring LPDS approval = 1st Priority

- Provides examples of common factual statements and claims eligible for generic approval = 2nd Priority

- List will be updated periodically to reflect commonly asked questions regarding special statements and claims
2007-FSIS launched askFSIS, designed to help answer technical and policy-related questions from IPP, industry, consumers, other stakeholders, and the public

Interactive application provides in-depth answers to technical questions

Contains a knowledge base of searchable questions and answers

Allows visitors to seek answers to questions about topics such as: exporting, importing, labeling, sampling, and other inspection-related policies, programs, and procedures

LPDS highly recommends industry use askFSIS to inquire about new and novel claims instead of LSAS
Food Safety and Inspection Service:
FSIS Guidelines for:

• Documentation Needed to Substantiate Animal Raising Claims, September 2016:
  https://www.fsis.usda.gov/wps/wcm/connect/6fe3cd56-6809-4239-b7a2-bcc82a30588/RaisingClaims.pdf?MOD=AIPERES will be revised soon based on comments

• Label Approval, August 2017

• Label Submission Checklist:

• LSAS User Guide:

• FSIS Constituent Update Archives:

• Information Required for Requesting a Temporary Approval:

• Ten Most Commonly Asked Labeling Questions:

• See the 10 Most Common Mistakes at the FSIS web site
  https://www.fsis.usda.gov/wps/portal/fsis/topics/regulatory-compliance/labeling/labeling-procedures/ten-most-common-mistakes-made-on-a-label
Food Safety and Inspection Service:
Questions? Contact LPDS

Submit a Question to askFSIS

- [http://askfsis.custhelp.com](http://askfsis.custhelp.com)
- Questions are sent to a main portal, triaged, and assigned to the correct expert based on subject matter.

Call:

- Main: 301.504.0878
- Distribution Unit: 301.504.0883

Labeling Procedures