



United States Department of Agriculture

One Team, One Purpose



Food Safety and Inspection Service

Protecting Public Health and Preventing Foodborne Illness



Food Safety and Inspection Service:

FSIS Labeling Overview and Generic Label Approval

Labeling and Program Delivery Staff (LPDS)
October 21, 2014

Food Safety and Inspection Service: Webinar Overview

- Background information
- Required labeling features
- New generic labeling regulations
- Sample labels
- Label submission
- Labeling record
- Useful resources



Food Safety and Inspection Service:

Background Information

Food Safety and Inspection Service:

Introduction

- U.S. Department of Agriculture (USDA) assures that meat and poultry products in interstate or foreign commerce are wholesome, not adulterated, and properly marked, labeled and packaged
- USDA's Food Safety and Inspection Service (FSIS) is responsible for the development and application of labeling requirements applicable to meat and poultry products
- FSIS is charged with developing the labeling policy by which it is determined if a meat or poultry product is misbranded or adulterated

Food Safety and Inspection Service: Labeling and Program Delivery Staff (LPDS)

- Staff within the Office of Policy and Program Development (OPPD) of FSIS
- LPDS Functions include
 - Administering the Agency’s prior label approval program
 - Responding to inquiries (e.g., askFSIS and phone calls) on FSIS labeling regulations and policies
 - Performing amenability determinations for FSIS and developing compliance policy guidance for special statements and claims (e.g., animal production raising claims)
 - Writing regulations, FSIS Directives, FSIS Notices, and other policy guidance documents for meat, poultry, and egg product labeling and standards issues
 - Providing labeling-related training for stakeholders, including FSIS personnel
 - Developing and managing Agency research to explore consumer use and understanding of labeling features (e.g., cooking instructions, safe food handling)

Food Safety and Inspection Service: Prior Label Approval

- *Federal Meat Inspection Act (FMIA) and Poultry Products Inspection Act (PPIA)* require food manufacturers to obtain prior approval for labels of meat and poultry products before products may be marketed
- Prior approval is granted one of two ways:
 - Sketch approval which is approved by the Labeling and Program Delivery Staff (LPDS)
 - Generic approval which is approved by being in compliance with applicable regulations

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

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

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: FSIS Inspectors do not generically approve labels. Establishments do not generically approve labels. FSIS approves labels through generic labeling regulations.

Food Safety and Inspection Service:

Required Labeling Features

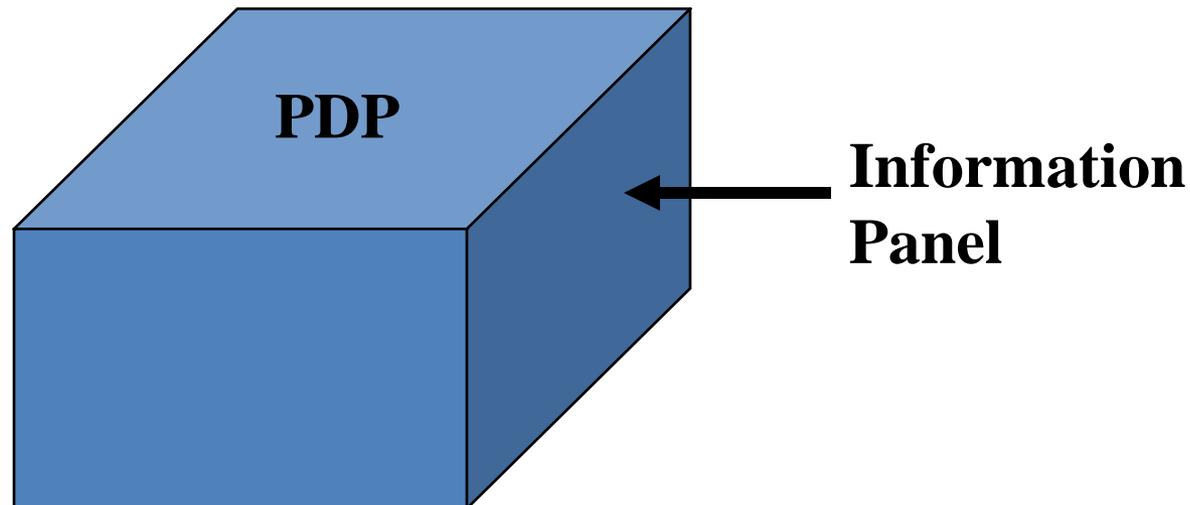
Food Safety and Inspection Service: Required Labeling Features

- Labels have up to eight (8) required features
- Regulations specify where on the label some of the features must be located
 - Principal Display Panel (PDP)
 - 9 CFR 317.2(c) and (d), 9 CFR 381.116
 - Information Panel (IP)
 - 9 CFR 317.2 (m), 9 CFR 381.116(c)

Food Safety and Inspection Service:

Principal Display Panel and Information Panel

- PDP is the part of the label most likely to be displayed, presented...when offered for sale under customary conditions
- IP is any portion of a label not on the PDP that is displaying certain mandatory features



Food Safety and Inspection Service:

Required Labeling Features

Four features are required on the principal display panel (PDP):

(1) Product name

9 CFR 317.2(e)/381.117(a)

(2) Handling Statement, if product is perishable

9 CFR 317.2(k)/381.125(a)

(3) Inspection Legend/Est. number

9 CFR 312.2(b)/381.96 & 381.123(b)(2)

(4) Net weight for product sold at retail (except variable net weight products)

9 CFR 317.2(h)/381.121

Food Safety and Inspection Service: Required Labeling Features

The remaining four features may be located on the PDP or on the information panel:

(5) Name and place of business of the manufacturer, packer or distributor
9 CFR 317.2(g)(2)/381.122

(6) Ingredients statement displaying all ingredients in descending order of predominance

9 CFR 317.2(c)(2)/381.118

(7) Nutrition labeling (unless an exemption applies)

9 CFR 317.300-400/381.400-500

(8) Safe Handling Instructions if the product is not ready-to-eat (may be located on any panel)

9 CFR 317.2(l)/381.125(b)

Food Safety and Inspection Service:

Required Labeling Features: Summary Table

Feature	Reference	Location	Applies to
Product Name	9 CFR 317.2(c)(1) or 381.117	Principal display panel	All products
Inspection Legend	9 CFR 317.2(c)(5) or 381.123	Principal display panel	All products
Handling Statement (e.g. "Keep Frozen")	9 CFR 317.2(k) or 381.125(a)	Principal display panel	Products requiring special handling to maintain wholesomeness
Net Weight Statement	9 CFR 317.2(h) or 381.121	Principal display panel	Product sold at retail, unless the net weight is applied at retail
Ingredients Statement*	9 CFR 317.2(f) or 381.118	Information panel or Principal display panel	Products with multiple ingredients
Address Line	9 CFR 317.2(g) or 381.112	Information panel or Principal display panel	All products
Nutrition Facts Panel	by 9 CFR 317.300 or 381.400	Information panel or Principal display panel	Products not exempted by 9 CFR 317.400 or 381.500
Safe Handling Instructions	9 CFR 317.2(l) or 381.125(b)	Information panel or Principal display panel	Products with a not-ready-to-eat meat or poultry component

Food Safety and Inspection Service: Sample Label

GROUND BEEF

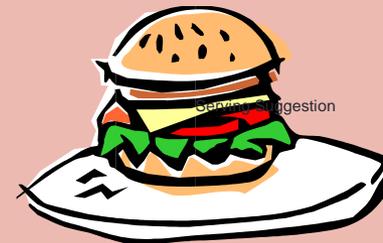
Ingredients: Beef, salt, pepper, garlic powder

Keep Frozen

Distributed by: Felix's Kitchen,
Frederick, MD 21701



Nutrition Facts	
Serving Size: 4 oz. (112g)	
Servings Per Container: 4	
Amount Per Serving	
Calories 170	Cal. from Fat 70
% Daily Value*	
Total Fat 8g	12%
Saturated Fat 3.5g	18%
Trans Fat 0.5g	
Cholesterol 70mg	23%
Sodium 75mg	3%
Total Carbohydrate 0g	0%
Protein 23g	
Iron 15%	
Not a significant source of dietary fiber, sugars, vitamin A, vitamin C and calcium.	
*Percent Daily Values are based on a 2,000 calorie diet.	



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. For your protection, follow these safe handling instructions.

-  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.

Net Wt. 16 oz. (1 lb.)

Food Safety and Inspection Service: Sample Label

PDP

Mindy's Meatloaf



Serving
Suggestion

Keep
Refrigerated

Net Weight: 26 oz (1.625 lbs.)



IP

Ingredients: Beef, Pork, Veal, Bread Crumbs (flour, wheat flour, salt, pepper and seasoning), flavorings, natural flavorings, spices, sugar, dextrose, water

Distributed by:
Mallon Industries, West Seneca, NY 14224

Heating Instructions:

Remove from package
Put in pan

Preheat oven to 350 degrees
Heat for 60 minutes or it reaches an internal temperature of 165 degrees as measured by a meat thermometer.

Nutrition Facts

Serving Size: 3 oz (84g)
Servings Per Container: About 13

Amount Per Serving	
Calories 150	Calories from Fat 80
% Daily Values*	
Total Fat 9g	14%
Saturated Fat 2.5g	12%
Trans Fat 0g	
Cholesterol 30mg	10%
Sodium 440mg	18%
Total Carbohydrate 6g	2%
Protein 10g	
Calcium 4%	• Iron 15%

Not a significant source of dietary fiber, sugars, vitamin A and vitamin C.
*Percent Daily Values are based on a 2,000 calorie diet.

Food Safety and Inspection Service:

New Generic Labeling Regulations

Food Safety and Inspection Service: New Generic Labeling Final Rule

- Effective January 6, 2014, the final rule amended FSIS regulations to combine the previous regulations that provided for labeling approval (9 CFR 317.4 and 381.132) and generically approved labeling (9 CFR 317.5 and 381.133) for meat and poultry products into one new section
- New label approval regulations for meat *and* poultry products now in 9 CFR 412.1; approval of generic labels now in 9 CFR 412.2
 - Current regulations found online at www.ecfr.gov

Food Safety and Inspection Service: Generic Approval

- Final rule amended the meat and poultry products inspection regulations to expand the circumstances under which the labels of meat and poultry products are generically approved by the Agency
- Prior to issuance of the Generic Final Rule
 - FSIS regulations specified when a generic approval could be undertaken by an establishment (9 CFR 317.5 and 381.133)
 - specific labels were eligible for generic approval AND
 - certain changes could be made generically to sketch approved labels
- NOW, four categories of 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: New Generic Labeling Final Rule

- 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

Food Safety and Inspection Service:

LPDS Approval Required: Temporary Label 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 approval not to exceed 180 days
 - Plant transfers are granted for up to 60 days
 - Additional 60-day extension may be granted
- Granted on a case-by-case basis
- Four conditions for temporary approval described in the regulations (9 CFR 412.1(f)(1)) must be met
- Approval process unchanged by the new generic labeling rule

Food Safety and Inspection Service: Temporary Label Approval Submission

- Address all four components of 9 CFR 412.1(f)(1)
- Clearly explain the specific labeling deviations that are present on the label
- Ingredients statement deficiencies must clearly list which ingredients are on the label but not in the product and which ingredients are in the product but not on the label
- Complete previously approved label information in Box 6b of Form 7234-1 or in the “Approval Information” section of LSAS
- If requesting extension of a temporary approval, explain in detail why the extension is necessary

Food Safety and Inspection Service: Temporary Label Approval: Examples

- Incorrect legend on label (e.g. poultry legend on a meat label)
- Order of predominance of ingredients has changed
- Specific multi-ingredient item has changed resulting in incorrect sublisting of some ingredient (e.g. spice mix)
- New ingredient has been added to formulation but is not on the label
- Address of the establishment has changed
- Incomplete product name (e.g. “smoke flavor added” qualifier missing)

Food Safety and Inspection Service:

LPDS Sketch Approval Required:

Religious Exemption Statements (9 CFR 412.1(c)(1))

- Religious-exempt product (poultry) does not receive the mark of inspection and, therefore, deviates from the general labeling requirements for meat and poultry products
- Labels for religious-exempt product must be submitted to LPDS for sketch approval
- Ritually-slaughtered meat and poultry products receive the mark of inspection (Kosher, Halal) and may be approved generically provided that they don't meet one of the other labeling categories requiring LPDS approval

Food Safety and Inspection Service: Religious Exemption: Examples

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)
- Kosher processed and handled, non-eviscerated, head and feet intact

*Ritually slaughtered meat and poultry products (Halal, Kosher) are produced under Federal inspection and are **not** included in this category*

Food Safety and Inspection Service:

LPDS Sketch Approval Required:

Export Labels Bearing Labeling Deviations (9 CFR 412.1(c)(2))

- Exports of U.S. meat and poultry products occur under agreements between the U.S. government and foreign governments
- Agreements require U.S. government approval of labels on exported meat and poultry products which bear labeling deviations
- 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" that bear labeling deviations 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

Food Safety and Inspection Service:

Common Deviations on Export Labels that require label submission

- No Safe Handling Instructions
- Nutrition Facts Panels in formats not permitted on domestic labels
- Different/alternate spelling of ingredient names
- Not sublisting of certain standardized foods, e.g., cheeses or enriched flour

Food Safety and Inspection Service:

Export Label Deviations which do not require LPDS sketch approval

- Net Weight in metric units
- Required features entirely in a foreign language
- 9 CFR 412.1(c)(2)

Food Safety and Inspection Service:

LPDS Sketch Approval Required:

Special Statements and Claims Defined in 9 CFR 412.1(e)

- Detailed list of special statements and claims requiring LPDS approval and examples of claims eligible for generic approval is available on FSIS website
<http://www.fsis.usda.gov/wps/wcm/connect/bf170761-33e3-4a2d-8f86-940c2698e2c5/Comp-Guide-Labeling-Evaluation-Approval.pdf?MOD=AJPERES>
- List includes commonly used special statements and claims
- List will be periodically updated to reflect commonly asked questions regarding special statements and claims

Food Safety and Inspection Service:

Special Statements and Claims: LPDS Approval Required

- 3rd party raising claims or programs (i.e. Global Animal partnership, AMS Process verified or certified programs, American Heart Association (AHA) claims)
- Claims regarding meat and poultry production practices (i.e. claims regarding the raising of animals such as “no antibiotics administered” or “vegetarian fed”)
- Breed claims (Berkshire, Angus, Hereford, etc)
- Certified claims, Certified Halal
- Gluten free: both certified and non certified
- 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)
Implied Nutrition Claims for example Heart Smart, Baked Not Fried, Made without Butter
- Instructional or disclaimer statements concerning pathogens, such as “for cooking only”; “not tested for E. coli O157:H7”; or “For high pressure pasteurization at establishment ABC”

Food Safety and Inspection Service:

Special Statements and Claims: Sketch Approval Required (continued)

- Natural claims, e.g. “All Natural”, “100% Natural”
- Negative claims or “free” claims (no MSG, no MSG added, no preservatives)
- Statements that identify a product as “organic” or containing organic ingredients
- Omega 3 factual statements
- “Whole Grain”, “Made with Whole Grains”, “Made with whole wheat” claims
- Nutritional Front of Pack statements, for example “0 grams trans fat per serving”, Nutrition facts Up Front
- Claims of the use of non-genetically engineered ingredients
- Claims that are undefined in FSIS regulations or the Food Standards and Labeling Policy Book (*Note: natural and negative claims are defined in the policy book but will continue to be required to be submitted for approval*).

Food Safety and Inspection Service:
Statements: Generic Approval Permitted

- Some statements and claims are not considered “special” under 9 CFR 412.1 (e), e.g. statements of fact
- Statements and claims of this type may be approved generically (9 CFR 412.2(b))
- The next two slides review examples of statements that are not considered special and may be approved generically

Food Safety and Inspection Service: Statements: Generic Approval Permitted

- All, 100%, pure
- Allergen or “Contains (name of ingredient)” statements (e.g., contains soy)
- AMS Grading (Prime, choice, grade A)
- Child Nutrition Boxes
- Flavor Profiles (e.g. made with fennel, teriyaki flavored, made with real cheese, only white meat)
- Foreign Language on domestic products
- Geographic claims (refer to 9 CFR 317.8(b)(1))

Food Safety and Inspection Service: Statements: Generic Approval Permitted

- Green Claims/Environmental Claims
- Halal, Kosher (not certified)
- Hand pulled style/hand pinched style
- Handcrafted, handmade, hand slaughtered, hand crafted style
- Home Style
- For HRI only, Institutional use only, etc
- Nutrition Claims (defined)
- Ready in/Cooks in (number of minutes or seconds)
- Oven roasted or similar statements

Food Safety and Inspection Service: Points of Clarification

- Generic Rule does not apply to egg products
 - Expanding the generic labeling criteria for processed egg products is being considered as a separate rule
- Generic Rule also does 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)

Food Safety and Inspection Service: Points of Clarification

- FSIS Inspectors do not generically approve labels
- FSIS in-plant inspection personnel will continue to verify labels as part of the General Labeling task
- 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

Label Examples

Food Safety and Inspection Service:

Special Statements and Claims: Sketch Approval Required

Special Statements and Claims

Beef Raised

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

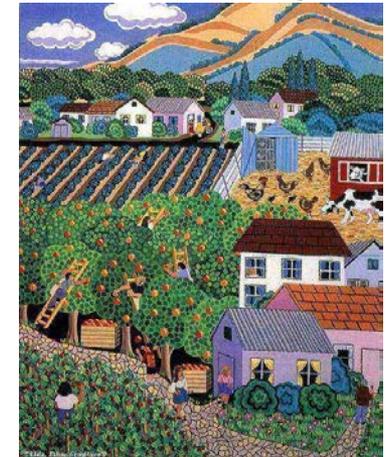
A Good Win! Farms®

est 2010



**All Natural*
Pasture
Raised**

**Beef Flat Iron
Steak**



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. For your protection, follow these safe handling instructions.

-  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.

***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: Statements and Claims: Generic Example

Generic
statements
and claims

Packed for: House of Kabob, Houston, TX 77252



NEW!

Fully Cooked

Chicken Kabobs

Grilled White Chicken Chunks
on a wooden skewer

HALAL

Made with only White Chicken!!!

Ingredients: chicken breast,
salt, pepper

Serving suggestion

Keep Refrigerated

Net Wt. 32 oz. (2 lbs.)

Food Safety and Inspection Service:

Special Statements and Claims: Sketch Approval Required

Packed for: House of Kabob, Houston, TX 77252



All Natural*

Fully Cooked

Chicken Kabobs

Grilled White Chicken Chunks
on a wooden skewer

All of our chickens are raised without antibiotics!

Ingredients: chicken breast,
salt, pepper

Serving suggestion

*Minimally Processed, no artificial ingredients

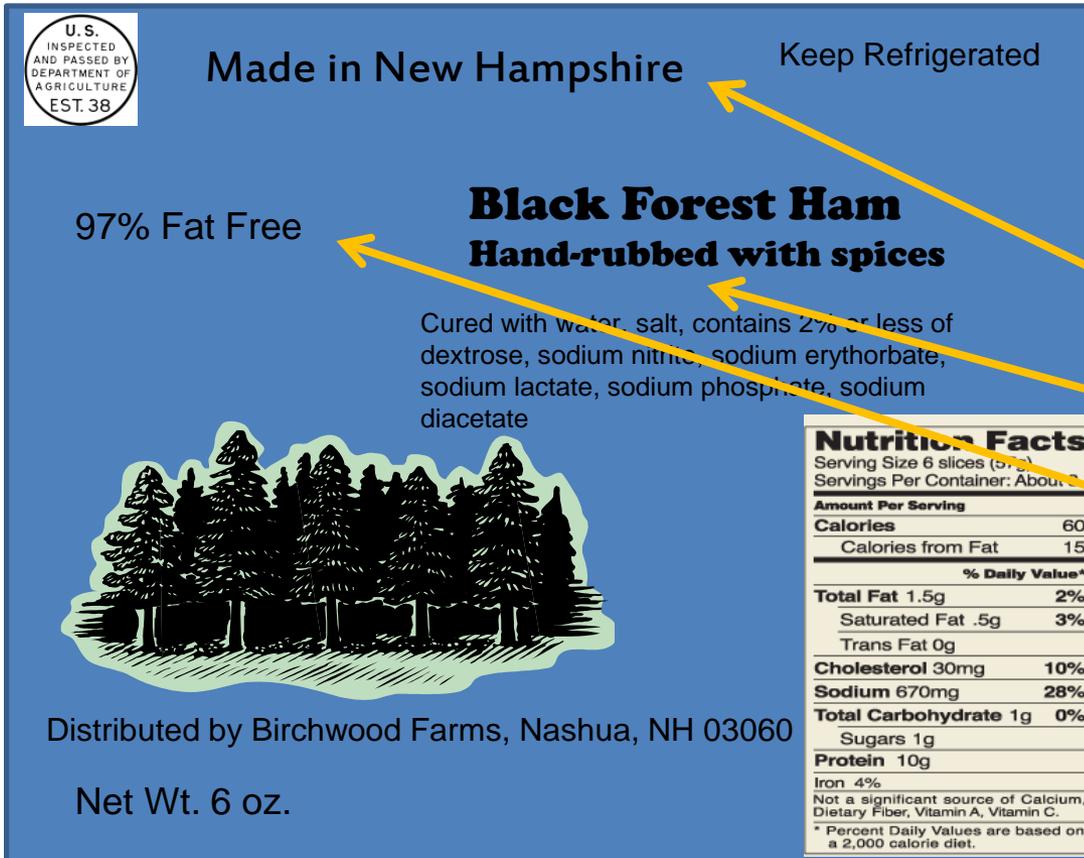
CERTIFIED HALAL BY THE HOUSTON HALAL ALLIANCE

Keep Refrigerated

Net Wt. 32 oz. (2 lbs.)

Special
Statements
and Claims

Food Safety and Inspection Service: Statements and Claims: Generic Example



U.S. INSPECTED AND PASSED BY DEPARTMENT OF AGRICULTURE EST. 38

Made in New Hampshire

Keep Refrigerated

97% Fat Free

Black Forest Ham

Hand-rubbed with spices

Cured with water, salt, contains 2% or less of dextrose, sodium nitrite, sodium erythorbate, sodium lactate, sodium phosphate, sodium diacetate



Distributed by Birchwood Farms, Nashua, NH 03060

Net Wt. 6 oz.

Nutrition Facts	
Serving Size 6 slices (57g)	
Servings Per Container: About 1	
Amount Per Serving	
Calories	60
Calories from Fat	15
% Daily Value*	
Total Fat 1.5g	2%
Saturated Fat .5g	3%
Trans Fat 0g	
Cholesterol 30mg	10%
Sodium 670mg	28%
Total Carbohydrate 1g	0%
Sugars 1g	
Protein 10g	
Iron 4%	

Not a significant source of Calcium, Dietary Fiber, Vitamin A, Vitamin C.
* Percent Daily Values are based on a 2,000 calorie diet.

Generic statements and claims

Food Safety and Inspection Service: Special Statements and Claims: Sketch Approval Required

Special
Statements
and Claims

U.S.
INSPECTED BY
AND PASSED BY
DEPARTMENT OF
AGRICULTURE
EST. 38

Keep Refrigerated



Sliced Black Forest Ham

Cured with water, salt, contains
2% or less of dextrose, sodium
nitrite, sodium erythorbate,
sodium lactate, sodium
phosphate, sodium diacetate

Gluten Free

Made in
New
Hampshire

0 g Trans fat per serving

Distributed by Birchwood Farms, Nashua, NH 03060

Net Wt. 6 oz.

Nutrition Facts
Serving Size 6 slices (57g)
Servings Per Container: About 3

Amount Per Serving	
Calories	60
Calories from Fat	15
% Daily Value*	
Total Fat 1.5g	2%
Saturated Fat .5g	3%
Trans Fat 0g	
Cholesterol 30mg	10%
Sodium 670mg	28%
Total Carbohydrate 1g	0%
Sugars 1g	
Protein 10g	
Iron 4%	

Not a significant source of Calcium, Dietary Fiber, Vitamin A, Vitamin C.
* Percent Daily Values are based on a 2,000 calorie diet.

Food Safety and Inspection Service:

Label Submission

Food Safety and Inspection Service: Label Review Process

- Labels that do not fit into one or more of the four categories of labels requiring LPDS approval are generically approved by their compliance with applicable regulations
- If an establishment elects to submit a generically approved label to LPDS for review, the label will be assigned a lower priority than those labels that **require** approval by LPDS
- Labels classified as “first priority” or “second priority” based on whether or not labels require LPDS review
- Generic Final Rule referenced a higher priority given to those labels **requiring** review
- Establishments note claims on label applications on paper labels and in LSAS
- LPDS staff also verify that labels are categorized correctly

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
- Wait time for review has decreased significantly since the generic changes took effect

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 may take longer to be reviewed

Food Safety and Inspection Service: Second Priority (Voluntary Evaluation): Paper

- Type “Generic” after “Other claims” in Block 10 of FSIS Form 7234-1
- Paper labels that may be generically approved which are not marked as “Generic” in Block 10 will be placed in the second priority queue

According to the Paperwork Reduction Act of 1995, an agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a valid OMB control number. The valid OMB control number for this information collection is 0550-0002. The time required to complete this information collection is estimated to average 75 minutes per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. This form has been approved by OMB for web distribution.

U.S. DEPARTMENT OF AGRICULTURE
FOOD SAFETY AND INSPECTION SERVICE

APPLICATION FOR APPROVAL OF LABELS, MARKING OR DEVICE

FSIS has determined that information provided in items 11, 15, and 16 is exempt from mandatory disclosure under the Freedom of Information Act 5 U.S.C. 552(b)(4).
APPLICANT: See Page 5 for instructions.

1. AGENT NAME, ADDRESS, TELEPHONE NO. (If acting as Agent, complete this block, otherwise leave blank.)

2. FOR USDA USE ONLY

3. FOR USDA USE ONLY

4. ESTABLISHMENT NO. / FOREIGN COUNTRY (if applicable)

PAGE _____ of _____

4a. TYPE OF PRODUCT
 Egg Meat
 Poultry Other

5a. NAME OF PRODUCT

5b. HACCP PROCESS CATEGORY (Select one)
 01: Slaughter - all species
 02: Raw Product - ground
 03: Raw Product - not ground
 04: Thermally processed - commercially sterile
 05: Not heat treated - shelf stable
 06: Heat treated - shelf stable
 07: Fully cooked - not shelf stable
 08: Heat treated but not fully cooked - not shelf stable
 09: Product with secondary inhibitors - not shelf stable

5c. TYPE OF APPROVAL REQUESTED
 SKETCH TEMPORARY
 EXTENSION OF TEMPORARY

5d. WAS THE LABEL PREVIOUSLY APPROVED?
 YES → Date of approval: _____
 Prior approval number: _____
 NO
 Number of labels on hand: _____
 Number of days requested: _____

7a. AREA OF PRINCIPAL DISPLAY PANEL (Square inches)

7b. TOTAL AVAILABLE LABELING SPACE FOR ENTIRE PACKAGE (Square inches)

8. Does this label include a USDA-AMS Child Nutrition Program CN-Logo? Yes No

9. (FOR USDA-AMS USE ONLY) CN Identification Number Assigned

10. Are there any special claims, guarantees, or foreign language on the label?
 YES NO (If yes, check all that apply)
 Allergen Statements
 Animal Production/Breed/Raising
 Certified/Verified
 Environmental/Green
 Export Only Labels/widevariations from Domestic Requirements
 Foreign Language
 Geographic/Undefined Style
 Grading Terms
 Guarantees
 Natural/Organic
 Nutrition/Health
 Religious Exemption
 Other Claims: Specify _____

11. NAME AND ADDRESS OF FIRM (Below and between dots)

12. SIGNATURE OF APPLICANT OR AGENT

13. DATE

14. (FOR USDA USE ONLY) CONDITIONS APPLYING TO USE OF LABELS OR DEVICE

FSIS FORM 7234-1 (1/16/2011) REPLACES FSIS FORM 7234-1 (09/01/2009), WHICH IS OBSOLETE.

Check the “Other Claims” box and type “generic”

Food Safety and Inspection Service: Second Priority (Voluntary Evaluation): LSAS

- ***New* question in Step 2:** Product Information: “Are you requesting a voluntary review of a submission which can be generically approved?”
 - Required field
 - Select “yes” or “no”
- In Step 3: Special Claims Information, check the “Other Claims” box and type “generic” in the box entitled “Other claim description”
- LSAS labels with requests for voluntary review will be added to the second priority queue
- Generic labels incorrectly marked with the “No” button selected will be moved by LPDS Staff Officer to the second priority queue

Food Safety and Inspection Service: LSAS Special Claims Information

Special Claims Information

According to the Paperwork Reduction Act of 1995, an agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a valid OMB control number. The valid OMB control number for this information collection is 0593-0092. The time required to complete this information collection is estimated to average 75 minutes per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information.

Please indicate any special claims, guarantees, or foreign languages that appear on the label. (check all that apply):

- Allergen Statements
- Animal Production/Breed/Raising
- Certified/Verified
- Environmental/Green
- Export only Labels w/deviations from Domestic Requirements
- Foreign Language
- Geographic/Undefined Style
- Grading Terms
- Guarantees
- Natural/Organic
- Nutrition/Health
- Religious Exemption
- Other Claims (Indicate specific claim(s) in the space provided below in the Other Claim Description box)

Other Claim Description:

To request a Voluntary Review of a Generic label, check the “Other Claims” box and type “Generic” in the “Other Claim Description” box

<< Previous

Save

Save and Continue >>

Exit Editor

Food Safety and Inspection Service: Generic Label Advisor

- Updated to reflect the new generic regulations
- The GLA is a tool, not a requirement for generic approval
 - GLA guides applicants through a series of questions to determine if a label requires submission
 - Use of the GLA is not required to submit a label through LSAS
 - Use of the GLA is not required to verify that a label is generically approved



Food Safety and Inspection Service:

Note on Second Priority (Voluntary) Review

- LPDS will assess all labels to determine if label review is required
- LPDS determination that a label may be generically approved is NOT a label approval
- The establishment is responsible for ensuring that the final label meets all applicable labeling regulations
- Generically approved labels awaiting voluntary review do not require approval by LPDS
 - may be used provided that the labels are in compliance with applicable regulations
 - labels placed in the second priority queue may take longer to be reviewed

Food Safety and Inspection Service: Label Review Process

First Priority Review

Paper and LSAS labels reviewed by LPDS will be marked as either:

- Sketch Approved
- Sketch Modified, with required changes noted
- Returned
 - Returned first priority labels must be resubmitted to LPDS for approval
 - Resubmitted first priority will be reviewed when they are received and will not be “re-queued”

Second Priority (Voluntary) Review

Paper and LSAS labels reviewed by LPDS will be marked as either:

- Sketch Approved
- Sketch Modified, with required changes noted
- Returned
 - Returned labels are NOT required to be resubmitted to LPDS for approval since they are approved generically once the noted changes are made
 - Returned labels resubmitted to LPDS will be placed at the bottom of the second priority queue on the day they are received
 - There is no resubmittal priority for labels that may be generically approved

Food Safety and Inspection Service: Extraordinary Circumstances

- 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
- 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.)

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

Food Safety and Inspection Service: Blanket Approval: Example

- 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

U.S. INSPECTED AND PASSED BY DEPARTMENT OF AGRICULTURE EST. 38

Per 1/5 pizza

450 CALORIES	5g SAT FAT 25% DV	360mg SODIUM 15% DV
------------------------	--------------------------------	----------------------------------

Pepperoni Pizza

Keep Refrigerated

Chloe's House of Pizza, Pittsburgh, PA 15232

Food Safety and Inspection Service:

Labeling Record

Food Safety and Inspection Service:

Labeling Record

- 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)(11), 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: Supporting Documentation: Examples

- AMS Schedule G for breed claims such as Angus
- Support for the use of State approved agricultural logos such as “Go Texan” or “Kentucky Proud”
- Description in the processing procedures that the product is “hand tossed” for a “hand tossed” claim
- Prior approved label with FOP keys to support FOP keys on a different product
- Third party verification for geographic style such as from a culinary institute supporting the use of “Mongolian Style”
- Organic certificate from the National Organic Program for both the slaughter facility and the animal grower
- Certificate from a specific regional Halal certifying entity to support a “Certified Halal” claim
- Documentation that ink used for printing the label is made from 100% soy ink

Food Safety and Inspection Service:

Resources

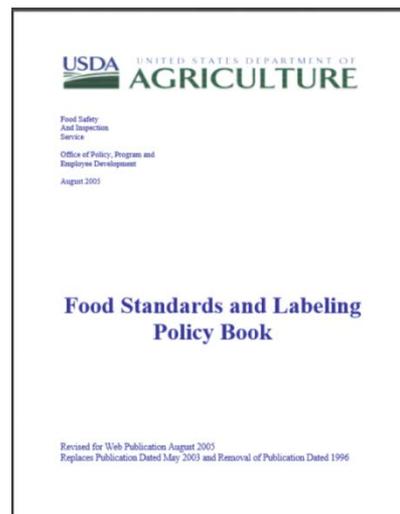
Food Safety and Inspection Service: Food Standards and Labeling Policy Book

- Available online at:
http://www.fsis.usda.gov/OPPDE/larc/Policies/Labeling_Policy_Book_082005.pdf
- 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: Food Standards and Labeling Policy Book

- FSIS has decided to stop adding policy guidance to the Food Standards and Labeling Policy Book
- FSIS will continue to amend or remove items in the book, as necessary, but it will no longer add new material to it

The Agency will convey new labeling policy by other means, such as compliance policy guides



Food Safety and Inspection Service:

<http://www.fsis.usda.gov>

► Topics → Regulatory Compliance → Labeling/Label Approval

The screenshot shows the USDA Food Safety and Inspection Service website. The breadcrumb trail is 'Topics / Regulatory Compliance / Labeling/Label Approval'. The left sidebar contains a list of navigation links, with 'Regulatory Compliance' highlighted. The main content area features a section titled 'Labeling/Label Approval' with a sub-link 'Generic Label Approval' that is circled in blue. A blue arrow points from a green callout box on the right to this link. The callout box contains the text: 'Home page for all generic labeling resources'. Below the main content, there are links for 'Label Submission and Approval System (LSAS)' and 'Safe and Suitable Ingredients used in the Production of Meat, Poultry, and Egg Products'.

Home page
for all generic
labeling
resources

Note: Other labeling resources may also be found on this page

Food Safety and Inspection Service: Generic Labeling Home Page

Labeling Policies - Mozilla Firefox

File Edit View History Bookmarks Tools Help

Labeling Policies

www.fsis.usda.gov/wps/portal/fgis/topics/regulatory-compliance/labeling/Labeling-Policies#Generic

Google

- Food Safety Education
- Data Collection and Reports
- Food Defense and Emergency Response
- Inspection
- International Affairs
- Recalls and Public Health Alerts
- Regulatory Compliance
- Regulations, Directives and Notices
- Rulemaking
- Science

FSIS guidance information, the Food Standards and Labeling Policy Book and Policy Memorandums, nutrition labeling information and other resource material regarding meat, poultry, and egg product labeling policies.

- Basics of Labeling
- Generic Label Approval
- Irradiation
- Natural or Regenerated Collagen Sausage Casing
- Net Weight Labeling of Meat and Poultry Products
- Nutrition Labeling Information
- Product Dating
- Standards of Identify

Basics of Labeling

The Food Standards and Labeling Policy Book, Policy Memorandums, A Guide to Federal Food Labeling Requirements for Meat and Poultry Products, directives and other resource material regarding labeling of meat, poultry, and egg products can be found here.

Generic Label Approval

- Slides: [Generic Label Approval | PDF](#)
PowerPoint presentation used during the January 14, 2014 webinar concerning the expanded circumstances in which labels may be considered "generically approved."
- Related Documents:
 - Labeling that Needs to be Submitted to the Labeling and Program Delivery Staff for Evaluation and Approval
 - Food Standards and Labeling Policy Book
 - Guide to Federal Food Labeling Requirements for Meat, Poultry and Egg Products:
 - Final Rule: [Prior Label Approval System: Generic Label Approval \(Nov 7, 2013\)](#)
 - Questions and Answers Concerning the Recently Published Generic Labeling Final Rule

Food Safety and Inspection Service: Available Resources

FSIS Main Labeling Website:

<http://www.fsis.usda.gov/wps/portal/fsis/topics/regulatory-compliance/labeling>

Generic Labeling Resources:

<http://www.fsis.usda.gov/wps/portal/fsis/topics/regulatory-compliance/labeling/Labeling-Policies>

Allergens - Voluntary Labeling Statements:

<http://www.fsis.usda.gov/wps/portal/fsis/topics/regulatory-compliance/labeling/ingredients-guidance/allergens-voluntary-labeling-statements>



Submit questions through askFSIS <http://askfsis.custhelp.com>

Call LPDS at (800) 233-3935

Food Safety and Inspection Service:

Questions?

