



Food Safety and Inspection Service
U.S. DEPARTMENT OF AGRICULTURE

FSIS General Labeling Overview

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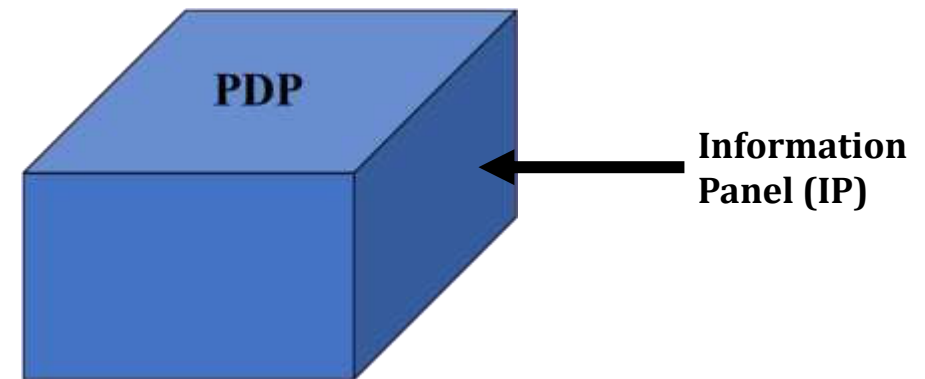
Outline

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- **Label Submission and Approval System**
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Required Labeling Features

Required Labeling Features

- Labels have up to eight (8) required labeling features
- Regulations specify where on the label some of the features must be located
 - Principal Display Panel (PDP)
 - PDP is the part of the label most likely to be displayed, presented... when offered for sale under customary conditions
 - 9 CFR 317.2(c) and (d), 9 CFR 381.116
 - Information Panel (IP)
 - 9 CFR 317.2 (m), 9 CFR 381.116(c)
 - IP is any portion of a label not on the PDP that is displaying certain mandatory features



Required Labeling Features - PDP

1. Product name
9 CFR 317.2(e)/381.117(a)
2. Handling Statement (on perishable products)
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

Required Labeling Features – IP

5. Name and place of business of the manufacturer, packer or distributor
9 CFR 317.2(g)(2)/381.122
6. Ingredient statement
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* (on not ready-to eat products)
9 CFR 317.2(l)/381.125(b)
* May appear on any panel (if applicable)

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)	Any panel	Products with a not-ready-to-eat meat or poultry component

Sample Label (Raw product)

GROUND BEEF

Ingredients: Beef, salt, pepper, garlic powder

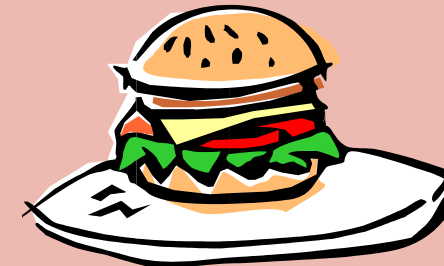
Keep Frozen

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.	

Net Wt. 16 oz. (1 lb.)



Serving Suggestion

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.

Sample Label (Fully cooked product)

PDP

Mindy's Meatloaf



Keep Refrigerated

Net Weight: 26 oz



IP

Ingredients: Beef, Pork, Veal, Breadcrumbs (flour, wheat flour, salt, pepper and seasoning [spices, sugar, garlic powder]), 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%
<small>Not a significant source of dietary fiber, sugars, vitamin A and vitamin C.</small>	
<small>*Percent Daily Values are based on a diet of 2,000 calories per day.</small>	

Prior Label Approval and Generic Labeling

Introduction

- Under the Federal Meat Inspection Act and Poultry Product Inspection Act, FSIS must approve the labels of meat and poultry products before the products can enter commerce.
- The sale and distribution of “misbranded” product is prohibited
- Generically approved labels do not need to be submitted to LPDS for approval before they enter commerce (9 CFR 412.2(a)(1)).

Modifications to Sketch Approved Labels with Special 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
- The FSIS Compliance Guideline for Label Approval contains guidance on what claims must be submitted for sketch approval, and which claims may be generically approved.

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

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!!!



Serving suggestion

Ingredients: chicken breast, salt, pepper

Keep Refrigerated

Net Wt. 32 oz. (2 lbs.)

The image shows a product label for 'Chicken Kabobs'. On the left, the text 'Generic statements and claims' has three green arrows pointing to the 'NEW!' star, the 'HALAL' text, and the 'Made with only White Chicken!!!' claim. The label itself is pink and contains various text elements: 'Packed for: House of Kabob, Houston, TX 77252' at the top; an 'INSPECTED U.S. DEPARTMENT OF AGRICULTURE P-42' seal in the top right; 'Fully Cooked' above the product name 'Chicken Kabobs'; 'Grilled White Chicken Chunks on a wooden skewer' below the product name; 'HALAL' in purple text; 'Made with only White Chicken!!!' in blue outlined text; a 'Serving suggestion' image of chicken kabobs; 'Ingredients: chicken breast, salt, pepper'; 'Keep Refrigerated' at the bottom left; and 'Net Wt. 32 oz. (2 lbs.)' at the bottom right.

Generic Label Approval Expansion

Generic Label Approval Expansion

- On January 18, 2023, FSIS published the Prior Label Approval System: Expansion of Generic Label Approval Final Rule, with a compliance date of March 20, 2023:
<https://www.federalregister.gov/documents/2023/01/18/2023-00693/prior-label-approval-system-expansion-of-generic-label-approval>
- Revisions to 9 CFR part 412.1 to expand those labels which may be generically approved include
 - export labels that deviate from FSIS requirements
 - labels listing “organic” ingredients in the ingredients statement
 - labels with geographic landmarks (e.g. foreign country's flag)
 - labels that make “negative” claims identifying the absence of certain ingredients or types of ingredients (e.g. No MSG Added)
 - labels of products that receive voluntary FSIS inspection (e.g., exotic species under 9 CFR part 352)
- LPDS will also cease evaluating labels submitted to FSIS that are eligible for generic approval

Animal Raising Claims

Animal Raising Claims

- FSIS has evaluated animal-raising claims on meat and poultry product labels for over 25 years
- Labels bearing these types claims refer to the way that the source animal for a meat or poultry product was raised, and need to be evaluated and approved.
- The Agency approves these claims if the animal raising information submitted with the label application supports the claim being made and the claim is truthful and not misleading.

Animal Raising Claims

Diet- 100% Grass Fed, Grass Finished, Vegetarian Fed

**Animal Welfare and Environmental Stewardship- “Humanely Raised,”
“Regenerative Farming” “Sustainably Sourced” “Raised with Care”**

**Negative Hormones Use- “No Added Hormones” “No Hormones
Administered Ever”**

**Negative Antibiotic Use- “Raised without Antibiotics” “No Added
Antibiotics” “No Antibiotics Ever” “No Sub-Therapeutic Antibiotics”
“No Antibiotics for Growth Promotion”**

Animal Raising Claims

Breeds: Beef- (Angus, Piedmontese, Wagyu), Poultry: (Silkie, Plymouth Rock, Slow Growth Heritage breed) Pork (Berkshire, Duroc) (Heritage Breeds)

Organic- Certified Organic by National Organic Program, Agricultural Marketing Service (AMS)

AMS, Process Verified Program (PVP) – 3rd Party Certification

Living/Raising/Raising Conditions (Free Range, Pasture Raised, Cage or Crate Free, Free to Roam)

Guideline on Documentation Needed to Substantiate Animal Raising Claims

For most animal raising claims, the documentation needed to support these claims are:

1. A detailed written description explaining the controls used for ensuring that the raising claim is valid from birth to harvest or the period of raising being referenced by the claim.

2. A signed and dated document describing how the animal are raised (e.g., vegetarian fed, raised without antibiotics, grass fed), to support that the specific claim made is truthful and not misleading;

3. A written description of the product tracing and segregation mechanism from time of slaughter or further processing through packaging and wholesale or retail distribution;

Guideline on Documentation Needed to Substantiate Animal Raising Claims

For most animal raising claims, the documentation needed to support these claims are:

4. A written description for the identification, control, and segregation of non-conforming animals/product; and

5. If a third-party certifies a claim, a current copy of the certificate.

Exceptions to Providing Documentation Previously Referenced

- Establishments may use purchased product in a secondary product or repack product bearing claims and may want to carry those claims over to a new label. Examples of claims that can be carried over include Breed Claims, Diet Claims, and Raising Claims.
- However, companies cannot carry over claims from purchased products that are certified by a third-party entity. For example, Organic, Process Verified Program, or Certified Humane cannot be carried forward without the company producing the final product having its own certification or verification.
- Some companies have chosen the USDA, Agricultural Marketing Service (AMS), Process Verified Program (PVP) as a 3rd party verification program for independently verification program by AMS auditors.

Exceptions to Providing Documentation Previously Referenced

Companies will need to provide the following:

1. A purchased product label that bears all claims being carried over.

2. A written description of the product tracing and segregation mechanism from receipt of purchased product through further processing, packaging, and wholesale or retail distribution;

Points of Clarification on the Guideline

- Products bearing certified claim must include:
 - name of the certifying entity
 - website address of the third-party certifier
- Certified organic products may be labeled with negative claims covered by the organic program without additional third-party certification or documentation when the negative claim is connected with an asterisk or other symbol to the explanatory statement “Produced in compliance with the USDA Organic Regulations”

Label Submission and Approval System

Label Submission and Approval System (LSAS)

- LSAS is the electronic submission system for label applications
- To get an LSAS account, you must first get an e-Authentication account
- Integrates and implements a secure electronic label application process for establishments to submit label applications and appeals
- Most labels are now submitted via LSAS; faster than paper.
- Enrollment instructions at: <https://www.fsis.usda.gov/guidelines/2005-0002>

Lamb Labeling

Lamb

For purposes of food labeling, FSIS's definition for lamb is a young sheep or lamb (ovine) carcass that meets the following criteria:

- Written documentation that the ovine is less than 14 months of age; and/or
- The presence of a break joint (epiphysis) of the distal metacarpal bone of either foreleg.

In the rare event that written age documentation is not available and there is no break joint on either foreleg, the non-eruption of the first pair of permanent incisors may also be considered adequate support for labeling sheep as "lamb." Note, however, if written documentation shows that the ovine is older than 14 months of age, the meat may not be labeled as "lamb" regardless of dentition.

9 CFR 317.8(b)(4): The term "spring lamb" or "genuine spring lamb" is applicable only to carcasses of new-crop lambs slaughtered during the period beginning in March and terminating not beyond the close of the week containing the first Monday in October.

Imported Lamb

- Imported lamb products are expected to comply with all US domestic labeling requirements.
- In addition, 9 CFR 327.14(a) and (b) require that imported product labels bear the words “Product of...” followed by the country of origin. On immediate containers, this statement must appear immediately under the product name or descriptive designation.
- Imported lamb labels frequently bear the special claims “grass fed” and/or “pasture raised”. These are considered Animal Raising special claims and require sketch approval.
- It is important to make sure that imported products receive any necessary sketch approval prior to importation, as they may be held at the border if they do not have the appropriate documentation for any special claims.

Resources

Resources

FSIS Compliance Guideline for Label Approval

- <https://www.fsis.usda.gov/guidelines/2017-0011>

Code of Federal Regulations

- <http://www.access.gpo.gov/nara/cfr/cfr-table-search.html>

FSIS Food Standards and Labeling Policy Book

- http://www.fsis.usda.gov/OPPDE/larc/Policies/Labeling_Policy_Book_082005.pdf

A Guide to Federal Food Labeling Requirements for Meat and Poultry Products

- http://www.fsis.usda.gov/pdf/labeling_requirements_guide.pdf

Labeling Guideline on Documentation Needed to Substantiate Animal Raising Claims for Label Submissions

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

Resources

Guideline on Allergen Statements

- <https://www.fsis.usda.gov/guidelines/2015-0019>

Guideline on Statements That Bioengineered or Genetically Modified (GM) Ingredients or Animal Feed Were Not Used in Meat, Poultry, or Egg Products

- https://www.fsis.usda.gov/sites/default/files/media_file/2020-08/labeling-guideline-bioengineered.pdf

Other guidance on ingredients, nutrition, claims, and other labeling policies and procedures:

- <https://www.fsis.usda.gov/inspection/compliance-guidance/labeling>

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- Questions are sent to a main portal, triaged, and assigned to the correct expert based on subject matter.

Call:

- Main: 301.504.0878

Labeling
Procedures

- <https://www.fsis.usda.gov/inspection/compliance-guidance/labeling>

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