



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:

Labeling Seminar for Trading Partners, Foreign Establishments, and Importers

Labeling and Program Delivery Staff, FSIS
February 20th 2018

Food Safety and Inspection Service

Mission in Action



We are **the public** health agency in the USDA responsible for ensuring that meat, poultry, and processed egg products are safe, wholesome, and accurately labeled.

Our Authority

Through a series of Acts, Congress empowers FSIS to inspect all meat, poultry, and processed egg products in interstate commerce.

- Federal Meat Inspection Act (FMIA), 1906
- Agricultural Marketing Act (AMA), 1946
- Poultry Products Inspection Act (PPIA), 1957
- Humane Methods of Slaughter Act (HMSA), 1958
- Egg Products Inspection Act (EPIA), 1970

Food Safety and Inspection Service

One Team, One Purpose

**We work
together**
to accomplish
our mission of
protecting
public health.



Food Safety and Inspection Service

Foodborne Illness Prevention



Perform food safety inspection at more than 6,000 establishments nationwide



Maximize domestic and international compliance with food safety policies



Public education and outreach to increase safe food-handling practices



Collaborate with internal and external stakeholders

How FSIS prevents foodborne illness

Food Safety and Inspection Service: Office of Policy and Program Development

Policy and Program Development employees:

- Develop regulations as well as instructions for inspectors to implement these regulations
- modernize the agency's approach to counter emerging risks to meat, poultry, and processed egg products.



**This work yields constant
improvements as our inspection
evolves through time.**

Food Safety and Inspection Service: Presentation Outline

- FSIS jurisdiction
- Introduction to FSIS labeling requirements
- Prior label approval and generic labeling
- Special claims overview including animal raising claims
- Nutrition labeling update and overview
- Common labeling problems and areas of special emphasis
- Label Submission and Approval System (LSAS) and contacting FSIS for guidance



Food Safety and Inspection Service:

Jurisdiction

Food Safety and Inspection Service: Jurisdiction

- General “Amenability” Rule: Products under USDA are formulated with at least 3% raw or 2% or more cooked meat/poultry and/or meat/poultry byproducts; more than 10% poultry fat
- Exemptions from definition of a poultry product listed in 9 CFR 381.15, general policy found in Food Standards and Labeling Policy Book
- USDA jurisdiction over broad range of foods, e.g., reaction/process flavors; seasonings with meat/poultry; dinners/meals; soups; stews; sausages; cuts of meat/poultry



Food Safety and Inspection Service: Jurisdiction

- Determinations of whether a food product is “amenable” to the FSIS jurisdiction under the FMIA and PPIA are made by the Labeling and Program Delivery Staff (LPDS)
- Determinations are usually made in situations involving:
 - New product development/marketing
 - Exploration by a processor/importer
 - Compliance investigations

THE FAR SIDE GARY LARSON



"Sandwiches!"

Food Safety and Inspection Service: Joint FDA and FSIS Ingredient Approval Process

- Final rule published on December 23, 1999, “Food Ingredients and Sources of Radiation Listed or Approved for Use in the Production of Meat and Poultry Products”
- Consolidated 9 CFR 318.7 and 381.147 into new table of approved substances in 9 CFR 424.21 (c). Lists substance, general classification, permitted use levels, types of products
- MOU signed in 2000 that outlined the procedures for how FSIS and FDA will work together to implement the ingredient approval process
- For meat and poultry, FDA authorizes safety and FSIS determines suitability/efficacy of use
- All ingredients approved since 2000 are listed in FSIS Directive 7120.1
- Risk, Innovations, and Management Division (RIMS) evaluates ingredients for FSIS, updates directive, and coordinates efforts with FDA

Food Safety and Inspection Service: Suitability in Meat and Poultry Products

- Substance must be approved, “listed,” or otherwise “no objection” by FDA
- Proposed use must have a specific, technical purpose in the product/product category
- Use must be limited to specific amounts or ranges, lowest level for intended effect
- Use must not promote deception or mask spoilage indicators
- Must be properly declared on the label unless determined to be a processing aid or incidental additive (21 CFR 101.100 (a)(3))
- FSIS has the authority to make an independent evaluation of an additive with respect to use in meat, poultry, or egg products and restricts its use

Food Safety and Inspection Service: FDA and FSIS Regulatory Distinctions

- FDA accepts self determinations of GRAS, however, FSIS can not
- FDA's authority over products with self determined GRAS ingredients begins when products enter commerce
- FSIS must be able to find product not adulterated before it will apply mark of inspection to enter commerce, all ingredients must be determined to be safe and suitable prior to use in Federal establishment

Food Safety and Inspection Service:

Introduction to FSIS Labeling Requirements

Food Safety and Inspection Service: Required Labeling Features

- Up to 8 required labeling features
- Certain features must be in particular locations
 - Locations indicated in Title 9 Code of Federal Regulations, Section 317.2 and 381 Subpart N



Food Safety and Inspection Service:

Principal Display Panel (PDP) - 9 CFR 317.2(d)/381.116(b)

- Principal display panel (PDP)- the part of the label that is most likely to displayed, presented, shown or examined under customary conditions of display for sale.
- Depending on the label format can contain all mandatory features but certain mandatory features required to be on the pdp:
 - Product name
 - Inspection legend
 - Handling statement if required
 - Net weight statement if required
- Manufacture determines what panel is the pdp.

Food Safety and Inspection Service:
Principal Display Panel



Food Safety and Inspection Service:

Product Name - 9 CFR 317.2(e)/381.117(a)

- Standardized Name:
 - Frankfurter
 - Chicken burrito
 - Standards found in the regulations or the Food Standards and Labeling Policy Book
- Common or usual name:
 - Beef rib eye steak
 - Quesadilla
- Descriptive name:
 - Beef, water and binder product
 - Chicken, vegetables and cheese in pastry
- Nonspecific name:
 - Red meat products only
 - Product name must be immediately followed by the ingredients statement
 - Luncheon Loaf
 - Chuckwagon patty

Food Safety and Inspection Service:

Product Name



Food Safety and Inspection Service:

Handling Statement - 9 CFR 317.2(k)/381.125(a)

- Handling statements required for perishable products:
 - Keep refrigerated
 - Keep frozen
 - Previously handled frozen for your protection. Refreeze or keep refrigerated.

Food Safety and Inspection Service: Handling Statement



Food Safety and Inspection Service:

Net Weight Statement - 9 CFR 317.2(h)/381.121

- The statement of net quantity of contents shall appear on the PDP of all containers to be sold at retail intact.
- Exceptions:
 - Random weight consumer size immediate containers can be shipped to retail without a net weight statement
 - Product destined for HRI
- Net weight statements voluntary for all product not going to retail.

Food Safety and Inspection Service:
Net Weight



Food Safety and Inspection Service:

Inspection Legend and Establishment Number - 9 CFR 312.2(b)(1)/381.96 & 381.123(b)(2))

- It may be any size but it must be legible
- The number can be located:
 - Inside or outside of the legend
 - Anywhere on the exterior or a container
 - Off of the exterior when a statement identifies the location of the number e.g., “Est. No. on clip.”



Food Safety and Inspection Service:
Inspection Legend



Food Safety and Inspection Service:

Information Panel - 9 CFR 317.2(m)(1)/381.116(c)

- Information panel (IP) a particular location on the package other than the PDP. Certain mandatory features may be placed together to form the information panel:
 - Ingredients statement
 - Nutrition facts panel (if required)
 - Signature Line
- Mandatory features must be contiguous to each other.

Food Safety and Inspection Service:

Information Panel

IP

Nutrition Facts			
Serving Size 5 pieces (88g)			
Servings Per Container: About 25			
Amount Per Serving			
Calories 230		Calories from Fat 120	
		%Daily Value*	
Total Fat	13g		20%
Saturated Fat	3g		15%
Trans Fat	0g		
Cholesterol	40mg		13%
Sodium	480mg		20%
Potassium	0mg		0%
Total Carbohydrate	14g		5%
Dietary Fiber	3g		16%
Sugars	0g		
Protein	12g		24%
Vitamin A 0%	•	Vitamin C 0%	
Calcium 0%	•	Iron 4%	
* Percent Daily Values are based on a 2,000 calorie diet. Your daily values may be higher or lower depending on your calorie needs:			
	Calories	2,000	2,500
Total Fat	Less Than	65g	80g
Sat Fat	Less Than	20g	25g
Cholesterol	Less Than	300mg	300mg
Sodium	Less Than	2,400mg	2,400mg
Total Carbohydrate		300g	375g
Dietary Fiber		25g	30g
Calories per gram:			
Fat 9 • Carbohydrate 4 • Protein 4			

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.

Distributed by:
Tolreck Inc.
2123 Orange Drive,
Almond Ave., GA 00612

Food Safety and Inspection Service:

Ingredients Statement - 9 CFR 317.2(c)(2)/381.118

- Required when a product is fabricated from two or more ingredients
- Ingredients must be listed in descending order of predominance
 - Exception is when there are ingredients are present at levels of 2% or less, the ingredients can be in any order when preceded by the statement “contains 2% or less”
 - The increments are at 2%, 1.5%, 1%
- For certain types of products, different types of ingredients statements are permitted:
 - Ham and Bacon can have cure statements instead of ingredients statements e.g. Cured with water, salt sugar
 - Beef and Chicken products with just a solution can just have a solution statement e.g. Solution contains: water, salt, sugar

Food Safety and Inspection Service: Ingredients Statement

- Ingredients identified by source, e.g.,
 - Hydrolyzed (source) proteins
 - corn, casein, wheat gluten, wheat protein, milk protein, etc.
 - Hydrolyzed gelatin
 - Hydrolyzed (species and tissue of origin)
 - Autolyzed yeast
 - Autolyzed yeast extract

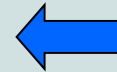
Food Safety and Inspection Service:

Ingredients Statement

IP

Nutrition Facts			
Serving Size 5 pieces (88g)			
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Amount Per Serving			
Calories 230		Calories from Fat 120	
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Cholesterol	40mg		13%
Sodium	480mg		20%
Potassium	0mg		0%
Total Carbohydrate	14g		5%
Dietary Fiber	3g		16%
Sugars	0g		
Protein	12g		24%
Vitamin A 0%	•	Vitamin C 0%	
Calcium 0%	•	Iron 4%	
* Percent Daily Values are based on a 2,000 calorie diet. Your daily values may be higher or lower depending on your calorie needs:			
	Calories	2,000	2,500
Total Fat	Less Than	65g	80g
Sat Fat	Less Than	20g	25g
Cholesterol	Less Than	300mg	300mg
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Calories per gram:			
Fat 9 • Carbohydrate 4 • Protein 4			

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.

Distributed by:
Tolreck Inc.
2123 Orange Drive,
Almond Ave., GA 00612

Food Safety and Inspection Service: Allergens

- Food Allergen Labeling and Consumer Protection Act (FALCPA) did not amend the FMIA, PPIA, and EPIA
- FSIS supports voluntary use of allergen statements, e.g., “contains: soy”
http://www.fsis.usda.gov/Regulations_&_Policies/Labeling_Allergens/index.asp
- LPDS evaluates “may contain” type statements on a case by case basis.

Food Safety and Inspection Service:

“May Contain” Statements: Federal Establishments

- May be submitted for evaluation and approval in very limited situations where good manufacturing practices, and effective sanitation standard operating procedures (SSOPs) cannot reasonably eliminate the unintended presence of certain ingredients
 - Chopped peanuts are used in making a dry Thai-style meat sauce mix, the necessity exists for a dry processing environment and, thus, the production equipment cannot be washed with water or other fluids. Peanut dust may become airborne and unavoidably contaminate other meat or poultry products manufactured in the same production area. In this situation, a statement about the manufacturing environment, as described above, or the use of a "may contain (name of allergenic ingredient)" statement may be used on meat and poultry product labeling.
- Not acceptable where it is used as a replacement for poor SSOPs, i.e., failure to prevent cross-contact between production runs

Food Safety and Inspection Service:

“May Contain” Statements: Purchased Products

- “May contain” and “produced in a facility” statements on purchased products need to be carried through to the labeling of meat or poultry product except where the establishment:
 - Contacts the supplier and confirms in writing that the statement is a cautionary statement, and no such ingredient is in the product; and
 - Includes a written statement in its hazard analysis to support why the “may contain” or “produced in a facility” statement is not carried forward to the finished meat or poultry product label
- Note: Carrying through statements of this type to the labeling of meat and poultry products in which the purchased components are used as ingredients is generically approved

Food Safety and Inspection Service:

Signature Line - 9 CFR 317.2(g)(2)/381.122

- Name and place of business of manufacturer, packer or distributor
- When listed in telephone or city directory:
 - Show by city, state or zip code
- When not listed in such directory:
 - Show full address

Food Safety and Inspection Service: Signature Line

IP

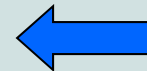
Nutrition Facts			
Serving Size 5 pieces (88g)			
Servings Per Container: About 25			
Amount Per Serving			
Calories 230		Calories from Fat 120	
		%Daily Value*	
Total Fat 13g		20%	
Saturated Fat 3g		15%	
Trans Fat 0g			
Cholesterol 40mg		13%	
Sodium 480mg		20%	
Potassium 0mg		0%	
Total Carbohydrate 14g		5%	
Dietary Fiber 3g		16%	
Sugars 0g			
Protein 12g		24%	
Vitamin A 0%		•	Vitamin C 0%
Calcium 0%		•	Iron 4%
* Percent Daily Values are based on a 2,000 calorie diet. Your daily values may be higher or lower depending on your calorie needs:			
	Calories	2,000	2,500
Total Fat	Less Than	65g	80g
Sat Fat	Less Than	20g	25g
Cholesterol	Less Than	300mg	300mg
Sodium	Less Than	2,400mg	2,400mg
Total Carbohydrate		300g	375g
Dietary Fiber		25g	30g
Calories per gram:			
Fat 9 • Carbohydrate 4 • Protein 4			

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.

Distributed by:
Tolreck Inc.
2123 Orange Drive,
Almond Ave., GA 00612



Food Safety and Inspection Service:

Nutrition Facts - 9 CFR 317.300-400/381.400-500

- Mandatory labeling for most products
- Top 40 cuts can have the nutrition facts information on the label itself or at retail
- Exemptions:
 - Small business
 - Product for HRI
 - Product for further processing
 - Product in very small packages

Nutrition Facts			
Serving Size 1/2 package (44g, about 1/4 cup dry mix)			
Servings Per Container 12			
Amount Per Serving	Mix	Baked	
Calories	190	280	
Calories from Fat	45	140	
% Daily Value**			
Total Fat 5g*	8%	24%	
Saturated Fat 2g	10%	13%	
Cholesterol 0mg	0%	23%	
Sodium 300mg	13%	13%	
Total Carbohydrate 34g	11%	11%	
Dietary Fiber 0g	0%	0%	
Sugars 18g			
Protein 2g			
Vitamin A	0%	0%	
Vitamin C	0%	0%	
Calcium	6%	6%	
Iron	2%	4%	
* Amount in Mix			
** Percent Daily Values are based on a 2,000 calorie diet. Your daily values may be higher or lower depending on your calorie needs:			
	Calories:	2,000	2,500
Total Fat	Less than	65g	80g
Sat Fat	Less than	20g	25g
Cholesterol	Less than	300mg	300mg
Sodium	Less than	2,400mg	2,400mg
Total Carbohydrate		300g	375g
Dietary Fiber		25g	30g
Calories per gram:			
Fat 9 • Carbohydrate 4 • Protein 4			

Food Safety and Inspection Service:

Nutrition Facts

IP



Nutrition Facts			
Serving Size 5 pieces (88g)			
Servings Per Container: About 25			
Amount Per Serving			
Calories 230		Calories from Fat 120	
		%Daily Value*	
Total Fat	13g		20%
Saturated Fat	3g		15%
<i>Trans</i> Fat	0g		
Cholesterol	40mg		13%
Sodium	480mg		20%
Potassium	0mg		0%
Total Carbohydrate	14g		5%
Dietary Fiber	3g		16%
Sugars	0g		
Protein	12g		24%
Vitamin A 0%	•	Vitamin C 0%	
Calcium 0%	•	Iron 4%	
* Percent Daily Values are based on a 2,000 calorie diet. Your daily values may be higher or lower depending on your calorie needs:			
	Calories	2,000	2,500
Total Fat	Less Than	65g	80g
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Cholesterol	Less Than	300mg	300mg
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Dietary Fiber		25g	30g
Calories per gram:			
Fat 9 • Carbohydrate 4 • Protein 4			

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.

Distributed by:
Tolreck Inc.
2123 Orange Drive,
Almond Ave., GA 00612

Food Safety and Inspection Service:

Safe Handling Instructions - 9 CFR 317.2(l)/381.125(b)

- Can appear anywhere on the label
- Must be on any product that is not ready to eat
- Must appear in one color with single color background
- Exemptions:
 - Products going for further processing at an official establishment
 - The product is not ready to eat but the meat/poultry component is ready to eat
 - Fried chicken dinner with raw vegetables

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.



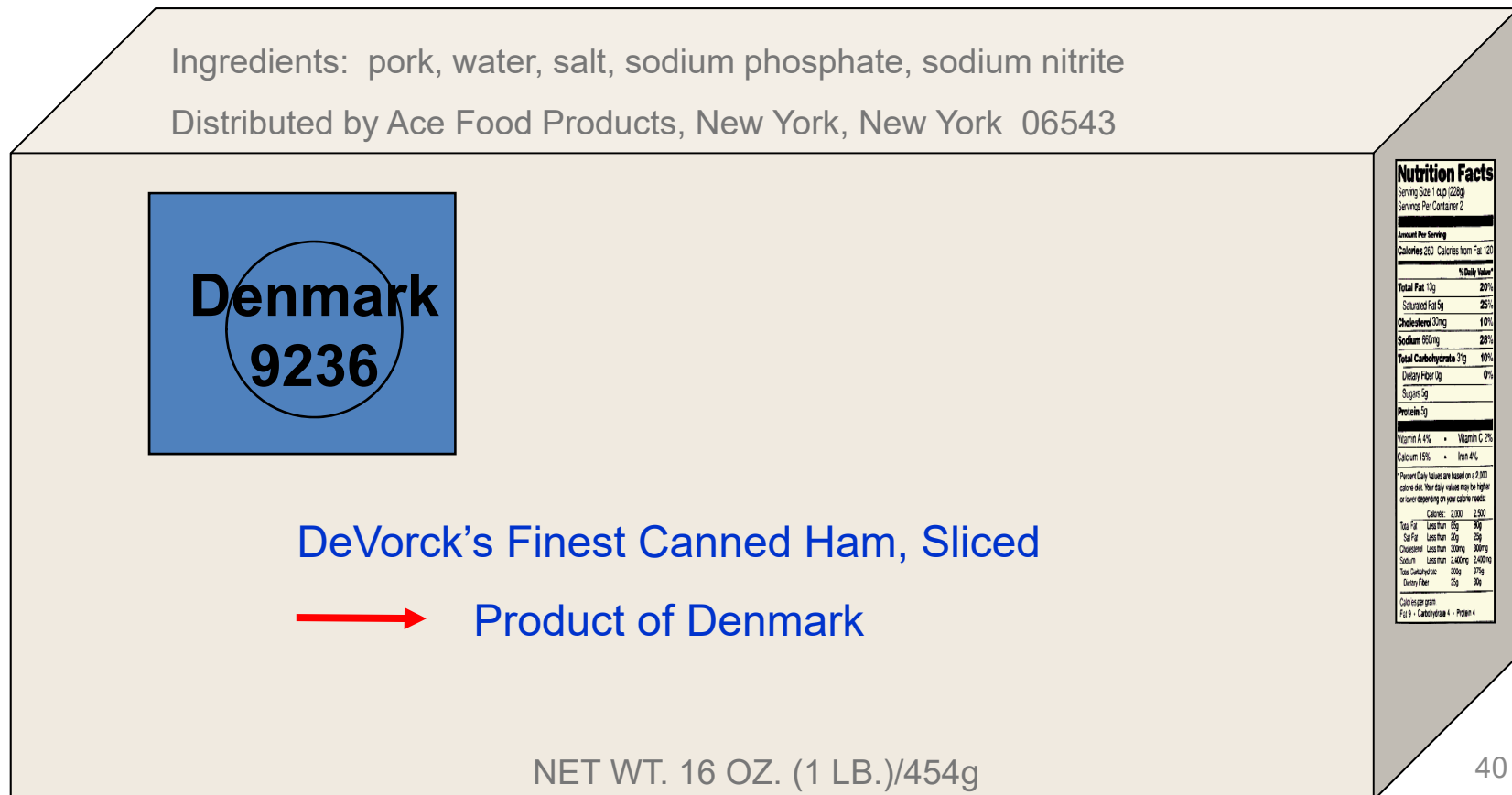
Cook thoroughly.



Keep hot foods hot. Refrigerate leftovers immediately or discard.

Food Safety and Inspection Service: Country of Origin

- Required on Principal Display Panel for Imports



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

Food Safety and Inspection Service: Sample Label

GROUND BEEF

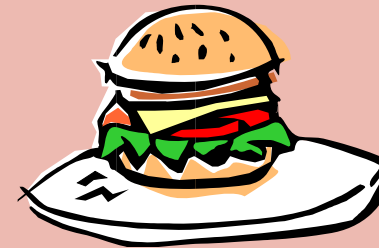
Ingredients: Beef, salt, pepper, garlic powder

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.	



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.



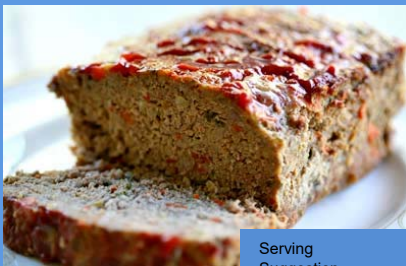
- Keep refrigerated or frozen. Thaw in refrigerator or microwave.
- Keep raw meat and poultry separate from other foods. Wash working surfaces (including cutting boards), utensils, and hands after touching raw meat or poultry.
- Cook thoroughly.
- Keep hot foods hot. Refrigerate leftovers immediately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

Net Wt. 16 oz. (1 lb.)

Food Safety and Inspection Service: Sample Label

PDP

Mindy's Meatloaf



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:

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.”
- USDA interprets statutory language as mandating pre-approval of all food labels before products may be offered for sale
- Prior label approval (coupled with continuous inspection) has broad ramifications in terms of public policy and regulatory enforcement

Food Safety and Inspection Service:

Responsibility for USDA's Label Approval Process -9 CFR 412.1 and 412.2

- 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

Food Safety and Inspection Service:

Responsibility for USDA's Label Approval Process

9 CFR 412.1, 412.2, and 590.411

- Procedures for label evaluation and approval of meat and poultry products not codified in 9 CFR
- Label approval regulations for egg products in 9 CFR 590.411
- 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 labeling approval**- approval of labeling or modifications to labeling prior approved by the Agency without submitting such labeling to FSIS for sketch approval. All mandatory labeling features are in conformance with FSIS regulations
- **Sketch approval**- approval provided by LPDS when labels, other than those submitted for temporary, are submitted to LPDS 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

Food Safety and Inspection Service: Generic Label Approval

- Generic approval of certain labels since 1983
- 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

Food Safety and Inspection Service: Prior Label 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
- 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

Food Safety and Inspection Service:

Temporary Label Approval (9 CFR 412.1(c)(4))

- 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 to 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

Food Safety and Inspection Service: Religious Exempt (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

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)

Food Safety and Inspection Service: 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
- 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

Food Safety and Inspection Service:
Special Statements and Claims (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 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”)

Food Safety and Inspection Service: Statements: Generic Approval Permitted

- Some statements and claims are not considered “special” under 9 CFR 412.1 (e)
- Statements and claims of this type may be approved generically (9 CFR 412.2(b))
- Examples include:
 - Allergen or contains statements “contains: (name of ingredient)”
 - AMS Grading (Prime, Choice, Select)
 - Flavor profiles (teriyaki flavored)
 - Foreign language on domestic products
 - Geographic claims (refer to 9 CFR 317.8(b)(1))

Food Safety and Inspection Service: Points of Clarification

- **Are previously approved labels containing special statements or claims eligible for generic approval when the only modification involves changes unrelated to the special statement or claim?**
- Yes. Previously approved labels containing special statements or claims may be generically approved if the modifications to the label are unrelated to the special statement or

<http://www.fsis.usda.gov/wps/wcm/connect/1364c48d-214b-41bf-bab8-6289f951cb31/Generic-Final-Rule-Overview-Industry.pdf?MOD=AJPERES>

Food Safety and Inspection Service: Points of Clarification

- **May the establishment number be changed generically from one establishment number to another in the case of a label bearing a special statement or claim? For example, may Plant B use an approved label from Plant A by simply changing the Establishment number from A to B?**
- Yes, this may be permitted under certain circumstances. If Plant B obtains a complete copy of the original label application and all associated supporting documentation necessary to support any special statements or claims on the original application approved for Plant A, then Plant B would have a complete label record on file and would be permitted to change the Est. number from A to B. In this case the information contained within the labeling application would be expected to remain the same (e.g. HACCP category, product formulation, processing procedures).

Note: exception is meat and poultry products labeled as “organic”

Food Safety and Inspection Service: Points of Clarification

- Generic approval regulations do not apply to egg products
 - Expanding the generic labeling criteria for processed egg products is being considered as a separate rule
- 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)

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:

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: Special Statements and Claims: Sketch Approval Required



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

HALAL

hicken abobs
Grilled White Chicken Chunks
on a wooden skewer

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

INSPECTED
U.S.
DEPARTMENT OF
AGRICULTURE
P-42

All Natural*

Fully Cooked

hicken abobs
Grilled White Chicken Chunks
on a wooden skewer

All of our chickens are raised without antibiotics!

Ingredients: chicken breast,
salt, pepper

CERTIFIED HALAL BY THE HOUSTON HALAL ALLIANCE

Keep Refrigerated

Net Wt. 32 oz. (2 lbs.)

Serving suggestion

*Minimally Processed, no artificial ingredients

Special
Statements
and Claims

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

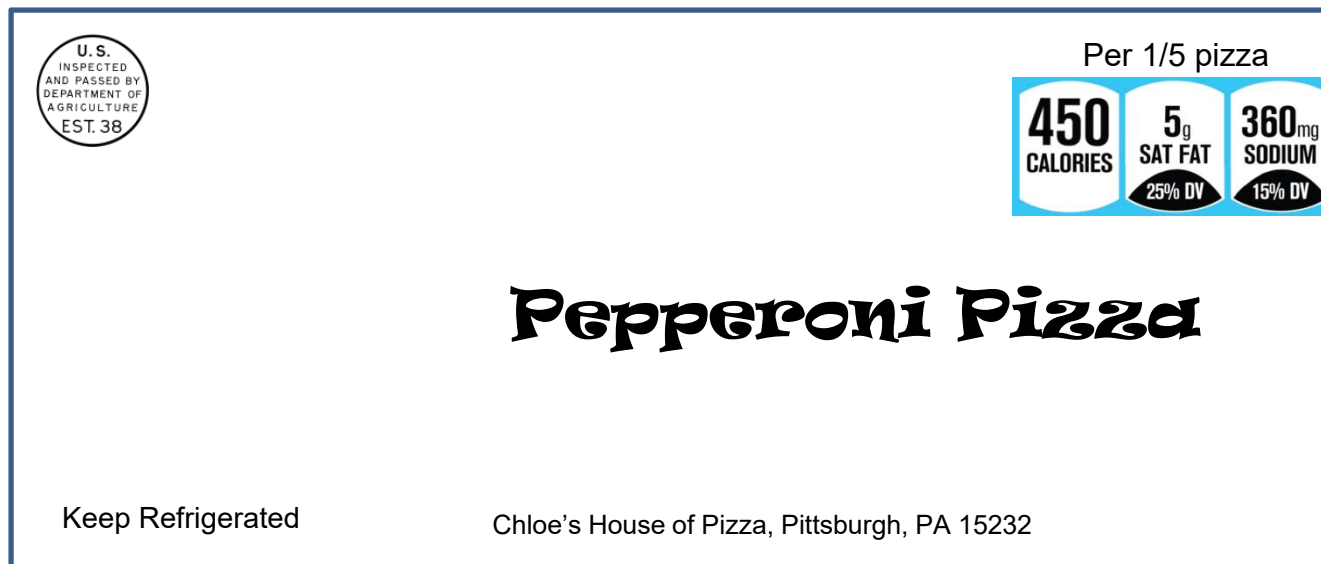
- Blanket approval allows certain information to be added to other products without having to submit each individual label bearing the same type of information for approval
- Refers to an approval that covers multiple labels or product lines
 - e.g. Front of Pack nutrition statements, Certified State 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 Examples

- 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.

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



Food Safety and Inspection Service: Labeling Records

- 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:

Special Claims Overview

Food Safety and Inspection Service:

Special Claims Policy Development with other Government Agencies

- In some cases, FSIS can establish new labeling policies without rulemaking
- FSIS consults with FDA, AMS, and CNPP to develop new policies (e.g., use of grade terms, identification of cuts of meat, factual statements on whole grains)
- FSIS has developed policies on trans fat, carbohydrates, and Omega 3 Fatty Acids
- Consistency with food labeling policies across all food categories an important consideration

Food Safety and Inspection Service:

Special Claims Policy Development with other Government Agencies

- MyPyramid and Whole Grain Statements
 - “Pepperoni Pizza with Whole Grain Crust” and “X g Whole Grain Per Serving”
- Omega 3 Fatty Acids
 - “X mg Omega 3 Fatty Acids per serving” from meat or poultry fed special diets
 - If a particular ingredient is being added, source must be identified, e.g., “X mg Omega 3 Fatty Acids from Fish Oil in Breeding”

Food Safety and Inspection Service:

Special Claims Policy Development with other Government Agencies

- In some cases, undefined claims may be approved provided they are not false or misleading under 9 CFR 317.8 and 381.129
- FSIS does not distinguish between “natural” and “artificial” preservative.
- “No Artificial Preservatives” permitted under certain conditions to ensure consumers were not misled:
 1. A statement “See back panel for ingredients used to preserve quality” would appear on the front panel in immediate proximity to the “No Artificial Preservatives” claim. This will provide consumers with details about the claim—namely, the fact that the product has added ingredients that will help preserve product quality.
 2. Each antimicrobial ingredient would be declared with an asterisk in the ingredient line. The asterisk would lead to the following explanatory statement below the ingredient line: “Ingredient to preserve quality” or perhaps a shortened form like “to preserve quality.”

Food Safety and Inspection Service: Non-Genetically Engineered Claims

- Historically, FSIS has allowed the use of the terms “genetically modified organism” or “GMO” on product labels or labeling only if the name of the third-party certifying organization contains these terms (e.g. “Non-GMO Project”)
- Recent legislation was enacted (Pub. L. 114-216) requiring the Secretary of Agriculture to develop and implement a mandatory national bioengineered food disclosure standard within 2 years
- FSIS has reconsidered its position and will allow the use of the terms “genetically modified organism” or “GMO” in negative claims provided that the label or labeling is otherwise truthful and not misleading
- Examples include:
 - “Chicken raised on a diet containing no genetically engineered ingredients,” or “Derived from beef fed no GMO feed.”
 - “No GMO ingredients,” “No genetically modified ingredients,” “Ingredients used are not bioengineered,” or “No genetically engineered ingredients through the use of modern biotechnology

Food Safety and Inspection Service: Non-Genetically Engineered Claims

- FSIS has approved labels that state the products meet the standards of a third-party certifier regarding the use of feed containing ingredients that are not genetically engineered, e.g. *“This pasture raised beef is fed a vegetarian diet that was produced in compliance with the Non GMO Project standard for avoidance of genetically engineered ingredients.”*
- The National Organic Program within the Agriculture Marketing Service in USDA is one example of a third-party certifying organization
- FSIS has determined that certain statements of this type are truthful and not misleading, and that they are claims that are verifiable
- FSIS published a compliance policy guide titled, *“Statements That Bioengineered or Genetically Modified (GM) Ingredients or Animal Feed Were Not Used in Meat, Poultry, or Egg Products”*
<http://www.fsis.usda.gov/wps/portal/fsis/topics/regulatory-compliance/labeling/claims-guidance/procedures-nongenetically-engineered-statement>

Food Safety and Inspection Service: Non-Genetically Engineered Claims

- For meat, poultry or egg products with previously approved GE negative claims, establishments are allowed to change the terms “non-genetically engineered” or “non-GE” to “non-GMO” or “no genetically modified organisms” without approval from FSIS; such changes are generically approved under 9 CFR 412.2
- If FSIS has approved an organic claim on the product label, establishments may add an applicable negative claim of the kind discussed in guidance document
- FSIS sought comments on this guidance as part of its efforts to continuously assess and improve the effectiveness of policy documents. 60 day comment period closed on 10/24/16. LPDS is in the process of evaluating the 200 comments received

Food Safety and Inspection Service:
Non-Genetically Engineered Claim Example



Food Safety and Inspection Service: Non-Genetically Engineered Claim Example

A Good Win! Farms® est 2010

All Natural**
Raised without
Added Antibiotics
No Added Hormones†

Fed a vegetarian diet
with No GMO
feed ingredients*

Organic Premium Fresh
Young Chicken



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.

KEEP REFRIGERATED

NET WT.
48 OZ (3 LB)

Distributed by A Good Win! Farms®
1224 Unique Dr.
Orlando, VE 00122
Certified Organic by ABC Green.

INSPECTED U.S. DEPARTMENT OF AGRICULTURE P-42

USDA ORGANIC

*This pasture raised chicken is fed an organic vegetarian diet with no GMO feed ingredients in compliance with the National Organic Program regulation.

**Minimally Processed, No Artificial Ingredients

†Federal Regulations do not permit the use of hormones in poultry.

Food Safety and Inspection Service:

Voluntary Statements about Use of Genetically Engineered Ingredients

- FSIS will evaluate voluntary statements on the presence of GE ingredients on a case by case basis
- Voluntary statements may be:
 - specific to a particular ingredient (e.g., “this product contains cornmeal from corn that was produced using modern biotechnology”) or
 - more general in cases where a meat or poultry product contains one or more genetically engineered ingredient (e.g., “made with genetically engineered ingredients”) or
 - Describe the purpose of use (e.g., “made with genetically engineered ingredients to reduce the impact of pesticide use on the environment”)
- The Agency will consider statements of this type special statements or claims that require review and approval by FSIS for compliance under 9 CFR 412.1(e)
- Establishments will need to submit documentation with their request for label approval to support that the statements are truthful and not misleading

Food Safety and Inspection Service: Animal Production Raising Claims

- For over 30 years FSIS has evaluated animal production claims by considering information on animal production practices submitted by companies as part of their label approval requests
- The Agency approved these claims if the animal production information submitted with the label application supported the claim being made and the claim was truthful and not misleading

Food Safety and Inspection Service: Examples of Claims

Examples of claims include, but are not limited to:

Grass Fed

Organic – certified Organic by a NOP certifying entity

No Added Antibiotics

No Added Hormones –Note: Hormones are only approved for use in beef cattle and sheep production. Therefore, the claim on other species of meat cannot be approved unless it is further qualified, e.g., linked to the statement on the same panel as the claim “Federal regulations prohibit the use of hormones in poultry (or pork, veal, or exotic, non-amenable meat products)”

Food Safety and Inspection Service: Animal Production Raising Claims

- For most animal production claims, the documentation needed to support these claims are:
 1. A detailed written protocol explaining controls for assuring the production claim from birth to harvest. If purchased, include protocol information from the supplier
 2. A signed affidavit declaring the specifics of the animal production claim(s) and that the claims are not false or misleading
 3. Product tracing and segregation mechanism from time of slaughter and/or further processing through packaging
 4. A protocol for the identification, control, and segregation of non-conforming animals/product
 5. A complete, current feed formulation using common and usual language or copies of the feed tags
 6. If a third-party certifies/verifies a claim, a current copy of the certification/verification should be provided

Food Safety and Inspection Service: New Animal Production Raising Claims Guideline

- FSIS published new guideline in September 2016 titled, *“Documentation Needed to Substantiate Animal Raising Claims for Label Submissions”*
- Provided clarification on the types of documentation needed to support specific raising claims (e.g., diet and breed)
- Comment period closed on December 15, 2016. Over 4,000 comments received
- FSIS is addressing the comments through a Federal Register Notice and updating the Compliance Policy Guideline

Food Safety and Inspection Service:

Nutrition Labeling

Food Safety and Inspection Service:

Nutrition Labeling

- FSIS is currently in the rule making process to update the nutrition regulations
- Proposed rule published in the FR January 19, 2017 (Docket No. FSIS_FRDOC_0001-0515). Proposal very similar to FDA final, followed same process for RACC analysis
- In the Fall Regulatory Agenda, the rule was listed as “Long Term Action”
<https://www.reginfo.gov/public/do/eAgendaViewRule?pubId=201710&RIN=0583-AD56>
- Long-Term Actions are items under development but for which the agency does not expect to have a regulatory action within the 12 months after publication of this edition of the Unified Agenda

Food Safety and Inspection Service: Nutrition Labeling

- Some proposed changes to the nutrition facts panel format:
 - Switched order and placement of servings per container
 - Bolded serving size and Calories
 - Increased font size for Calories
 - Updated Daily Reference Values (DRV's) which the %DV is based
 - Includes Xg Added Sugars with %DV
 - *Trans* Fat is mandatory
 - Vitamin D and Potassium are mandatory
 - Vitamin A and Vitamin C are voluntary
 - New footnote
 - Some packages will require 2 columns

Nutrition Facts	
8 servings per container	
Serving size	2/3 cup (55g)
Amount per serving	
Calories	230
% Daily Value*	
Total Fat 8g	10%
Saturated Fat 1g	5%
<i>Trans</i> Fat 0g	
Cholesterol 0mg	0%
Sodium 160mg	7%
Total Carbohydrate 37g	13%
Dietary Fiber 4g	14%
Total Sugars 12g	
Includes 10g Added Sugars	20%
Protein 3g	
Vitamin D 2mcg	10%
Calcium 260mg	20%
Iron 8mg	45%
Potassium 235mg	6%
* 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.	

Food Safety and Inspection Service: Nutrition Labeling

- Until a final rule for FSIS is published, FSIS amenable product labels may continue to use the current/original nutrition regulations in 9 CFR
- In the interim, FSIS labeling may Voluntarily use the new FDA format
- Companies should obtain one LPDS sketch for each specific format then same panel may be added to other labeling with generic approval per 9 CFR 412.2
- Once FSIS nutrition rule is final, amenable meat and poultry product labels will need to comply with the FSIS requirements within the applicable effective date
- FSIS Federal Register Notice (11/16/2016): Nutrition Facts Label Compliance <https://www.fsis.usda.gov/wps/wcm/connect/815c1ec3-0779-42e5-b5ec-b85494392efb/2016-0030.html?MOD=AJPERES>

Food Safety and Inspection Service:

Nutrition Labeling

- FDA Final (5/27/2016): Food Labeling: Revision of the Nutrition and Supplement Facts Labels
- <https://www.federalregister.gov/documents/2016/05/27/2016-11867/food-labeling-revision-of-the-nutrition-and-supplement-facts-labels#h-188>
- FDA Final (5/27/2016): Food Labeling: Serving Sizes of Foods That Can Reasonably Be Consumed At One Eating Occasion; Dual-Column Labeling; Updating, Modifying, and Establishing Certain Reference Amounts Customarily Consumed; Serving Size for Breath Mints; and Technical Amendments
- <https://www.federalregister.gov/documents/2016/05/27/2016-11865/food-labeling-serving-sizes-of-foods-that-can-reasonably-be-consumed-at-one-eating-occasion>
- FSIS Proposed (1/19/2017): Revision of the Nutrition Facts Labels for Meat and Poultry Products and Updating Certain Reference Amounts Customarily Consumed
- https://www.regulations.gov/document?D=FSIS_FRDOC_0001-0515

Nutrition Facts	
8 servings per container	
Serving size	2/3 cup (55g)
Amount per serving	
Calories	230
% Daily Value*	
Total Fat 8g	10%
Saturated Fat 1g	5%
Trans Fat 0g	
Cholesterol 0mg	0%
Sodium 160mg	7%
Total Carbohydrate 37g	13%
Dietary Fiber 4g	14%
Total Sugars 12g	
Includes 10g Added Sugars	20%
Protein 3g	
Vitamin D 2mcg	10%
Calcium 260mg	20%
Iron 8mg	45%
Potassium 235mg	6%
* 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.	

Food Safety and Inspection Service:

Areas of Special Emphasis

Food Safety and Inspection Service:

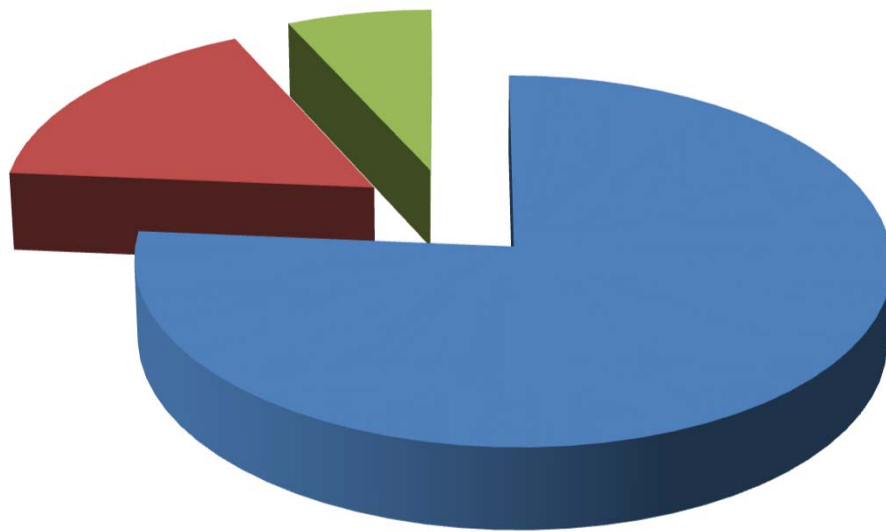
Allergen Labeling: Area of Continued Special Emphasis

- “Big 8” allergens (wheat, crustacean shellfish, eggs, fish, peanuts, milk, tree nuts, and soybeans) of greatest public health concern
- Situations involving non-declaration of “Big 8” allergens can result in Class 1 or Class 2 recall. Often the result of:
 - New ingredient and/or new supplier, product reformulation
 - Misprinted label or product placed in wrong package
- FSIS recommends control measures in establishments HACCP system to prevent the potential of undeclared allergens based on three basic principles:
 - Identify: Cross-referencing labels and product formulations with incoming ingredients; separation of allergenic materials in designated areas
 - Prevent and Control: Dedicated equipment; documented cleaning procedures with checklists; maintain methods for tracking product
 - Declare: Systems and checklists for determining labeling compliance (e.g., declaration of all ingredients) on final product and procedures for handling labeling discrepancies

Food Safety and Inspection Service:

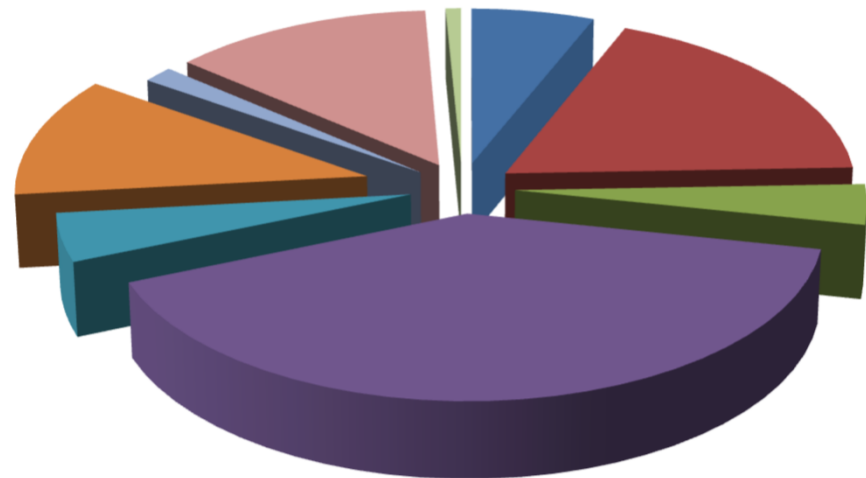
2017 Recall Summary by Classification and Reasons for Recall

Calendar Year 2017 - Recall
Classification (N = 131 Recalls)



■ Class I (100) ■ Class II (22) ■ Class III (9)

Calendar Year 2017 - Reasons for
Recall (N = 131 recalls)



■ STECs (8) ■ Extraneous / Foreign Material (24)
■ Processing Deviation (5) ■ Undeclared Allergen (53)
■ Undeclared Substance (6) ■ Listeria monocytogenes (15)
■ Residue (2) ■ Other (17)
■ Salmonella (1)

Food Safety and Inspection Service

FSIS Directive 7230.1: Ongoing Formulation Verification Task

IPP verify that all ingredients

- being used in the production of the product are present on the product formulation record

IPP verify that all ingredients

- from the product formulation are declared in the ingredients statement on the product label by common and usual name

IPP verify the label approval is on file

- and the applied labels are consistent with the establishment's label approval on file

Food Safety and Inspection Service

FSIS Directive 7230.1: Ongoing Formulation Verification Task

- Less establishments reporting no allergens
- Soy, wheat, milk most common allergens
 - Fish, tree nuts, shellfish, peanuts uncommon
- Increasing number of establishments incorporate multi-ingredient component
- Increasing number of establishments had an allergen control plan/program (typically prerequisite program)

Food Safety and Inspection Service

Updated 2015 Compliance Guidelines



- “FSIS Compliance Guidelines: Allergens and Ingredients of Public Health Concern: Identification, Prevention and Control, and Declaration through Labeling”
- Republished in November 2015, announced in *Federal Register*
- Includes Scenarios, diagrams, checklists
- <http://www.fsis.usda.gov/wps/wcm/connect/f9cbb0e9-6b4d-4132-ae27-53e0b52e840e/Allergens-Ingredients.pdf?MOD=AJPERES>

Food Safety and Inspection Service:
Descriptive Designation for Raw Meat and Poultry Products
Containing Added Solutions

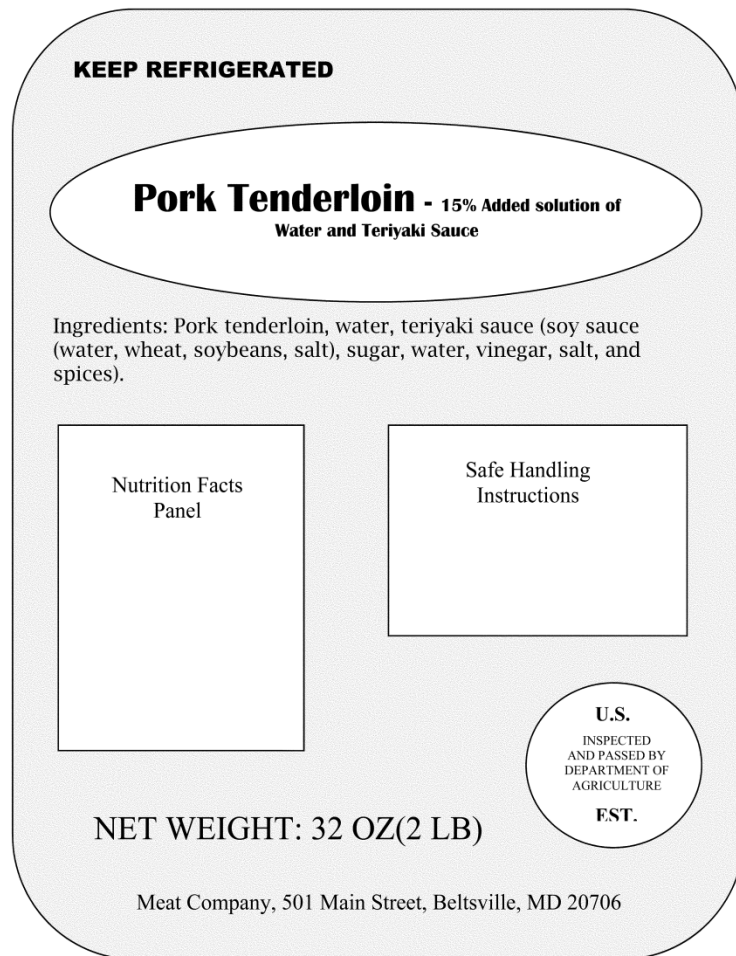
- Final rule titled, “Descriptive Designation for Raw Meat and Poultry Products Containing Added Solutions” published in *Federal Register* on December 31, 2014 (79 FR 79044)
<http://www.fsis.usda.gov/wps/wcm/connect/942b0716-42a9-4d0e-8e5f-3ba4d2dfc70d/2010-0012.pdf?MOD=AJPERES>
- In response to petitions, comments, and consideration of existing labeling policies that needed to be updated and consolidated to make the labeling of these products with added solution more meaningful to consumers
- Became effective January 1, 2016 for poultry and meat other than beef; May 17, 2016 for beef
- FSIS Notice Number 28-16 issued 5/3/2016

Food Safety and Inspection Service: Descriptive Designation for Raw Meat and Poultry Products Containing Added Solutions

- Applies to all raw meat and poultry products that:
 - Do not meet a standard of identity;
 - Are sold for retail sale, institutional use, or further processing;
 - Are produced in retail facilities, such as grocery stores
- Affects the following entities:
 - Domestic establishments;
 - Foreign establishments that export to the US;
 - Retailers that produce and label product

Food Safety and Inspection Service

Final Rule: Descriptive Designation for Raw Meat and Poultry Products Containing Added Solutions - the particulars



- Product name and descriptive designation must be in the same type font, the same color, and on a the same single-color background
- Percent solution must be a number with the percent sign
- Effective January 1, 2018: the smallest letter in the product name and descriptive designation may be no less than $\frac{1}{3}$ the size of the largest letter (currently the requirement is $\frac{1}{4}$ the size)

Food Safety and Inspection Service:
Descriptive Designation for Needle- or Blade-Tenderized
(Mechanically Tenderized) Beef Products

- FSIS published final rule titled, “Descriptive Designation for Needle- or Blade-Tenderized (Mechanically Tenderized) Beef Products” in *Federal Register* on May 18, 2015 (80 FR 28153)
- Effective May 17, 2016; FSIS Notice Number 29-16 issued on 5/12/16
- Products covered under rule:
 - Raw or partially cooked needle- or blade-tenderized beef products
 - Beef products injected with marinade or solution

Food Safety and Inspection Service: Descriptive Designation for Needle- or Blade-Tenderized (Mechanically Tenderized) Beef Products

Products not covered under rule:

- Any beef product that has been fully cooked, or is destined to be fully cooked at an official establishment
- Non-intact beef products that are clearly non-intact, e.g., ground beef patties, hamburger patties, beef patties
- Beef products that are tenderized by other than needle and blade, such as pounding or cubing, which visibly changes the appearance of the product, e.g., cubed beef steak
- Raw or partially cooked products labeled as “Corned Beef” that have been mechanically tenderized (including through injection of a solution)
- Raw mechanically tenderized beef products that are less than 1/8” thick, such as, beef bacon or carne asada, or raw mechanically tenderized beef products that are diced, such as stew meat.

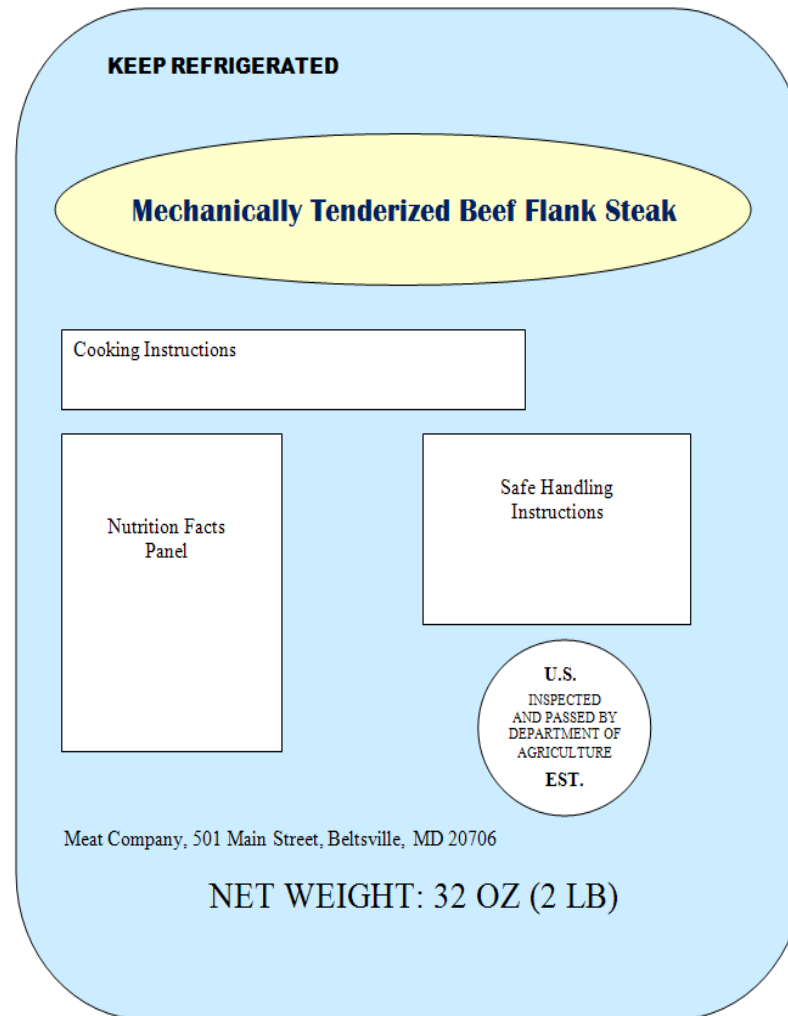
Food Safety and Inspection Service: Mechanically Tenderized Beef Products

Labels must bear:

- The descriptive designation “needle tenderized,” “blade tenderized,” or “mechanically tenderized” and an accurate description of the beef component in the product name; and
- The print in all words of the product name and descriptive designation must appear in a single type style and color on a single contrasting color background; and
- The smallest letter in the product name and descriptive designation may be no less than $\frac{1}{3}$ the size of the largest letter
- Validated cooking instructions for subject products destined for household consumers, hotels, restaurants, or similar institutions. Instructions need to include:
 - cooking method (baking, frying, etc.)
 - that these products need to be cooked to a specified minimum internal temperature,
 - whether these products need to be held at that minimum temperature or higher for a specified time before consumption, i.e., dwell time or rest time, to ensure that potential pathogens are destroyed,
 - and that the internal temperature should be measured by a thermometer.

Food Safety and Inspection Service:

Sample Label for Mechanically Tenderized Beef Flank Steak



Food Safety and Inspection Service:

Label Submission and Approval System (LSAS) and Contacting FSIS for Guidance

Food Safety and Inspection Service: Label Submission and Approval System

- LSAS is the electronic submission system for label applications
- To get an LSAS account, you must first get a Level 2 e-Authentication account
- Integrates and implements a secure electronic label application process for establishments to submit label applications and appeals
- Application processing via LSAS is faster than paper
- Interactive tutorials will be available online soon
- The Generic Label Advisor (GLA) can assist you in determining if your label requires sketch approval
- Enrollment and use instructions at
<http://www.fsis.usda.gov/wps/portal/fsis/topics/regulatory-compliance/labeling/labeling-procedures/label-submission-and-approval-system/lsas>

Food Safety and Inspection Service: Label Backlog

- LPDS has allocated more resources towards label approval
- LPDS is updating label approval guideline to include significantly more information, and a number of specific examples, on the types of changes that can be made generically to address industry concerns and help reduce the backlog
- Utilize generic! Many changes can be made to labels previously approved with special statements and claims (Key: changes have to be unrelated to claim)
- Don't add special statements and claims to labels just so labels will be evaluated as a 1st priority label; unnecessarily increases backlog
- Submit questions through askFSIS. Responses may be used as supporting documentation in labeling records (e.g., processing aid determination) and when submitting labels for approval

Food Safety and Inspection Service: Reducing Label Turnaround Time

- Constituent update posted June 10, 2016 on label backlog; industry has raised questions about types of changes that are generically approved
- Changes are generically approved when they do not have any impact on 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
- LPDS recognizes that multiple applications have been submitted which could be approved through a single application. LPDS will approve only one of the applications and will return the remainder of the applications and communicate that they are eligible for generic approval

Food Safety and Inspection Service: Contacting FSIS for Guidance

- 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

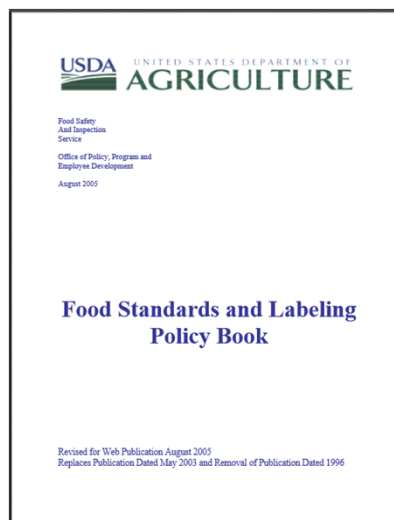
Food Safety and Inspection Service: Food Standards and Labeling Policy Book

- 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: Questions? Contact LPDS

