



United States  
Department of  
Agriculture



U.S. FOOD & DRUG  
ADMINISTRATION

# USDA/FDA Joint Public Meeting

## The Use of Cell Culture Technology to Develop Products Derived from Livestock and Poultry



## USDA/FDA Joint Public Meeting:

# The Use of Cell Culture Technology to Develop Products Derived from Livestock and Poultry

## **Wednesday, October 24 - Day 2 Housekeeping and Logistics**

- This public meeting is webcast live and open to the press
  - Film crews and print media are present
- Building Amenities and Rules
- Public Comment

USDA/FDA Joint Public Meeting:

The Use of Cell Culture Technology to Develop Products Derived from  
Livestock and Poultry

# **Welcome and Opening Remarks:**

Paul Kiecker

Acting Administrator, FSIS, USDA

USDA/FDA Joint Public Meeting:

The Use of Cell Culture Technology to Develop Products Derived from  
Livestock and Poultry

## **Opening Remarks:**

**Susan Mayne, Ph.D.,**

**Director, CFSAN, FDA**

## Session 5



# Regulatory Framework for Food Labeling

**Douglas Balentine, Director  
Office of Nutrition and Food Labeling**

**Food and Drug Administration**

**October 24, 2018**

# FD&C Act

- Federal Food, Drug, and Cosmetic Act
  - Food Additives Amendment, 1958
  - Nutrition Labeling and Education Act, 1990
  - FDA Modernization Act (FDAMA), 1997
  - Food Allergen Labeling and Consumer Protection Act of 2004 (FALCPA)

# Other Laws, Regulations, and Guidance

- Fair Packaging and Labeling Act
- Public Health Service Act
- Title 21, Code of Federal Regulations (21 CFR)
- Food Labeling Guide
- Compliance Policy Guides

# Labeling

All labels and other written, printed, or graphic matter (1) upon any article or any of its containers or wrappers, or (2) accompanying such article.

# FDA Regulates

- Food and drink
- Foods containing less than 2-3 percent meat or poultry in a formulated product
- Seafood (except catfish) and game meats

# Our Role in Food Labeling

- Ensuring labels are truthful and not misleading
- Issuing regulations and guidance
- Ensuring compliance with the regulations
- Informing consumers and industry about the regulations
- Working with domestic and international stakeholders

# Required Label Elements

- Statement of identity
- Net quantity of contents
- Ingredient statement
- Name and place of business of the manufacturer, packer, or distributor
- Nutrition labeling, unless exempt
- Allergen labeling
- Material facts about the food

# Voluntary Label Elements

- Nutrient content claims
- Health claims
- Other claims
- Other truthful and non-misleading information

# Statement of Identity (21 CFR 101.3)

- Common or usual name of food product
- Standard of identity name
- Descriptive name, not misleading

# Net Quantity of Contents

## (21 CFR 101.7)

- U.S. customary inch-pound system declaration required and metric
- Amount of food in a package exclusive of wrappers and packing material
- Qualifying phrases or terms not permitted, e.g., “large”, “jumbo”



# Ingredient Labeling

## (21 CFR 101.4)

List all ingredients by their common or usual name in products with 2 or more ingredients unless covered by a statutory or regulatory exemption

# Name and Place of Business (21 CFR 101.5)

- May list principal place of business if the food is manufactured at another place
- May use these terms if the company named on the label did not manufacture the food
  - “Manufactured for”
  - “Distributed by”
  - “Imported by”

# Nutrition Facts Label

## (21 CFR 101.9)

- Required on all foods offered for sale unless exempt
- Certain mandatory information must be included
- Format requirements

# Current Label

# New Label

<b>Nutrition Facts</b>			
Serving Size 2/3 cup (55g)			
Servings Per Container About 8			
Amount Per Serving			
<b>Calories</b> 230	Calories from Fat 72		
	% Daily Value*		
<b>Total Fat</b> 8g			<b>12%</b>
Saturated Fat 1g			<b>5%</b>
Trans Fat 0g			
<b>Cholesterol</b> 0mg			<b>0%</b>
<b>Sodium</b> 160mg			<b>7%</b>
<b>Total Carbohydrate</b> 37g			<b>12%</b>
Dietary Fiber 4g			<b>16%</b>
Sugars 12g			
<b>Protein</b> 3g			
<hr/>			
Vitamin A			10%
Vitamin C			8%
Calcium			20%
Iron			45%
* Percent Daily Values are based on a 2,000 calorie diet. Your daily value 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

<b>Nutrition Facts</b>			
1 8 servings per container			
<b>Serving size 2/3 cup (55g)</b>			
Amount per serving			
<b>Calories</b>			<b>230</b>
	% Daily Value*		
3 <b>Total Fat</b> 8g			<b>10%</b>
Saturated Fat 1g			<b>5%</b>
Trans Fat 0g			
<b>Cholesterol</b> 0mg			<b>0%</b>
<b>Sodium</b> 160mg			<b>7%</b>
<b>Total Carbohydrate</b> 37g			<b>13%</b>
Dietary Fiber 4g			<b>14%</b>
Total Sugars 12g			
4 Includes 10g Added Sugars			<b>20%</b>
<b>Protein</b> 3g			
5 Vitamin D 2mcg			10%
Calcium 200mg			15%
Iron 8mg			45%
Potassium 235mg			6%
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 Allergens

(FD&C Act Sections 201(qq), 403(w))

The source of major food allergens is required to be declared on food labeling in the ingredient statement or in a separate contains statement.

- Milk
- Egg
- Fish
- Crustacean shellfish
- Tree nuts
- Wheat
- Peanuts
- Soybeans

# Material Facts

(FD&C Act Sections 201(n) and 403(a))

A food is misbranded

- If the label does not reveal information about consequence of use
  - Products containing psyllium husks
  - Eggs (21 CFR 101.17)
- If the label fails to disclose facts that are material in light of representations on the label
  - Reduced fat margarine is not suitable for frying (21 CFR 101.13(d)(1))

# Statement of Identity

## (21 CFR 101.3)

1. Name established by law or regulation (21 CFR parts 130-169, 172, 184)
2. Common or usual name (21 CFR part 102)
3. Appropriately descriptive name or fanciful term

# Statement of Identity

Name specified by law

- Butter
- Nonfat Dry Milk  
(also defined in 21 CFR 131.125)

# Statement of Identity

Name established by regulation

- Standards of identity
  - Bottled water (21 CFR 165.110)
  - Macaroni product(21 CFR 139.110)
- Food additive regulations
  - Vitamin D2 bakers yeast (21 CFR 172.381)
- GRAS regulations
  - Canola oil (21 CFR 184.155)

# Common or Usual Name

## (21 CFR part 102)

- FDA provides general principles for establishing a common or usual name (21 CFR 102.5)
- FDA has established common or usual names for nonstandardized foods such as peanut spreads (21 CFR 102.23)

# **General Principles for Common or Usual Names (21 CFR 102.5)**

Describe basic nature of food

The common or usual name of a food, which may be a coined term, shall accurately identify or describe, in as simple and direct terms as possible, the basic nature of the food or its characterizing properties or ingredients.

# General Principles for Common or Usual Names (21 CFR 102.5)



% of characterizing ingredients

The common or usual name of a food shall include the percentage(s) of any characterizing ingredient(s) or component(s) when the proportion of such ingredient(s) or component(s) in the food has a material bearing on price or consumer acceptance or when the labeling or the appearance of the food may otherwise create an erroneous impression that such ingredient(s) or component(s) is present in an amount greater than is actually the case.



# **General Principles for Common or Usual Names (21 CFR 102.5)**

The need for a user of a food to add any characterizing ingredients or components shall be declared by an appropriate informative statement.

# General Principles for Common or Usual Names (21 CFR 102.5)

## Common usage

The common or usual name of a food can be established by common usage. For example, pretzels.

# Consideration of Material Facts

## Examples

- If a new food were significantly different from its counterpart such that the common or usual name no longer adequately described the new food, the name would have to be changed to a term that adequately and sufficiently described the new food. See 21 CFR 101.3 and 102.5.
- If a food differed from its counterpart in terms of how the food is used or with respect to the consequences of its use, a statement would have to be made in the labeling to describe the difference(s) in use or the consequences of its use.
- If a food had a significantly different nutritional property compared to its counterpart, the labeling of that food would have to describe such difference.

# For More Information

- [General labeling](http://www.fda.gov/food/labelingnutrition/default.htm):  
http://www.fda.gov/food/labelingnutrition/default.htm
- [Food Labeling Guide](http://www.fda.gov/foodlabelingguide): http://www.fda.gov/foodlabelingguide
- [Changes to NFL](http://go.usa.gov/xkHru): http://go.usa.gov/xkHru
- [Allergen labeling](http://www.fda.gov/food/ingredientspackaginglabeling/foodallergens/ucm2006768.htm):  
http://www.fda.gov/food/ingredientspackaginglabeling/foodallergens/ucm2006768.htm
- Call 888-723-3366 (Mon-Fri, 10 a.m.-4 p.m., eastern time; closed Thursday 12:30-1:30)
- [Submit inquiry form](http://cfsan.force.com/InquiryPage): http://cfsan.force.com/InquiryPage





United States  
Department of  
Agriculture

# Food Safety and Inspection Service

Protecting Public Health and Preventing Foodborne Illness



## Overview of Regulatory Frameworks for Mandatory Food Labeling Elements

**Jeff Canavan**

*Deputy Director, Office of Policy and Program Development, Labeling and Program Delivery Staff, FSIS, USDA*

## Food Safety and Inspection Service:

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

- **Principal display panel (PDP)**- the part of the label that is most likely to be displayed, presented, shown or examined under customary conditions of display for sale
- May contain all mandatory features but certain mandatory features are *required* to be on the PDP:
  - Product name
  - Inspection legend
  - Handling statement
  - Net weight statement



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
- Beef Stew
- Bacon

- **Common or usual name:**

- Beef Rib Eye Steak
- Quesadilla
- Pepperoni Pizza

- **Descriptive name:**

- Beef, Water and Modified Food Starch Product
- Chicken, Vegetables and Cheese in Pastry

- **Nonspecific name:**

- Product name must be immediately followed by the ingredients statement
  - Chuckwagon Patty



# Food Safety and Inspection Service:

## Product Name

**PDP**

# Tolreack



FULLY COOKED

**Chicken Nuggets**

WHOLE GRAIN BREADED STAR SHAPED  
CHICKEN BREAST WITH RIB MEAT



KEEP FROZEN

NET WT. 5 LBS (2.26kg)

## 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

**PDP**

# Tolreack



**FULLY COOKED**  
**Chicken Nuggets**  
WHOLE GRAIN BREADED STAR SHAPED  
CHICKEN BREAST WITH RIB MEAT



 **KEEP FROZEN**  
NET WT. 5 LBS (2.26kg)

## 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
  - 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

**PDP**

# Tolreack



FULLY COOKED  
**Chicken Nuggets**  
WHOLE GRAIN BREADED STAR SHAPED  
CHICKEN BREAST WITH RIB MEAT



KEEP FROZEN  
NET WT. 5 LBS (2.26kg)

## 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			
<b>Calories</b> 230	Calories from Fat 120		
%Daily Value*			
<b>Total Fat</b> 13g	<b>20%</b>		
Saturated Fat 3g	<b>15%</b>		
<i>Trans</i> Fat 0g			
<b>Cholesterol</b> 40mg	<b>13%</b>		
<b>Sodium</b> 480mg	<b>20%</b>		
<b>Potassium</b> 0mg	<b>0%</b>		
<b>Total Carbohydrate</b> 14g	<b>5%</b>		
Dietary Fiber 3g	<b>16%</b>		
Sugars 0g			
<b>Protein</b> 12g	<b>24%</b>		
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

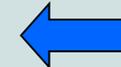
- Required when a product is fabricated from two or more ingredients
- Ingredients must be listed in descending order of predominance
  - Exception is when there are ingredients are present at levels of 2% or less, the ingredients can be in any order when preceded by the statement “contains 2% or less” (increments are at 2%, 1.5%, 1%)

# Food Safety and Inspection Service: Ingredients Statement

IP

Nutrition Facts			
Serving Size 5 pieces (88g)			
Servings Per Container: About 25			
Amount Per Serving			
<b>Calories</b> 230	Calories from Fat 120		
%Daily Value*			
<b>Total Fat</b> 13g	<b>20%</b>		
Saturated Fat 3g	<b>15%</b>		
<i>Trans</i> Fat 0g			
<b>Cholesterol</b> 40mg	<b>13%</b>		
<b>Sodium</b> 480mg	<b>20%</b>		
<b>Potassium</b> 0mg	<b>0%</b>		
<b>Total Carbohydrate</b> 14g	<b>5%</b>		
Dietary Fiber 3g	<b>16%</b>		
Sugars 0g			
<b>Protein</b> 12g	<b>24%</b>		
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:

### Name and Address of Manufacturer or Packer - 9 CFR 317.2(g)/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: Name and Address of Manufacturer or Packer

IP

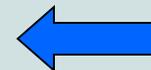
Nutrition Facts	
Serving Size 5 pieces (88g)	
Servings Per Container: About 25	
Amount Per Serving	
<b>Calories 230</b>	Calories from Fat 120
%Daily Value*	
<b>Total Fat 13g</b>	<b>20%</b>
Saturated Fat 3g	<b>15%</b>
<i>Trans</i> Fat 0g	
<b>Cholesterol 40mg</b>	<b>13%</b>
<b>Sodium 480mg</b>	<b>20%</b>
<b>Potassium 0mg</b>	<b>0%</b>
<b>Total Carbohydrate 14g</b>	<b>5%</b>
Dietary Fiber 3g	<b>16%</b>
Sugars 0g	
<b>Protein 12g</b>	<b>24%</b>
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
- 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
<b>Calories</b>	190	280
Calories from Fat	45	140
% Daily Value**		
<b>Total Fat</b> 5g*	8%	24%
Saturated Fat 2g	10%	13%
<b>Cholesterol</b> 0mg	0%	23%
<b>Sodium</b> 300mg	13%	13%
<b>Total Carbohydrate</b> 34g	11%	11%
Dietary Fiber 0g	0%	0%
Sugars 18g		
<b>Protein</b> 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			
<b>Calories</b> 230	Calories from Fat 120		
%Daily Value*			
<b>Total Fat</b> 13g	<b>20%</b>		
Saturated Fat 3g	<b>15%</b>		
<i>Trans</i> Fat 0g			
<b>Cholesterol</b> 40mg	<b>13%</b>		
<b>Sodium</b> 480mg	<b>20%</b>		
<b>Potassium</b> 0mg	<b>0%</b>		
<b>Total Carbohydrate</b> 14g	<b>5%</b>		
Dietary Fiber 3g	<b>16%</b>		
Sugars 0g			
<b>Protein</b> 12g	<b>24%</b>		
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:

### Safe Handling Instructions - 9 CFR 317.2(1)/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

## 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: Sample Label

## GROUND BEEF

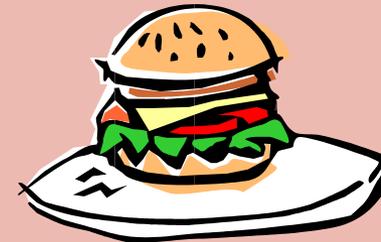
Ingredients: Beef, salt, pepper, garlic powder

Keep Frozen

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



Nutrition Facts	
Serving Size: 4 oz. (112g)	
Servings Per Container: 4	
Amount Per Serving	
<b>Calories</b> 170	Cal. from Fat 70
<b>% Daily Value*</b>	
<b>Total Fat</b> 8g	<b>12%</b>
Saturated Fat 3.5g	<b>18%</b>
Trans Fat 0.5g	
<b>Cholesterol</b> 70mg	<b>23%</b>
<b>Sodium</b> 75mg	<b>3%</b>
<b>Total Carbohydrate</b> 0g	<b>0%</b>
<b>Protein</b> 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



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	
<b>Calories</b> 150	Calories from Fat 80
% Daily Values*	
<b>Total Fat</b> 9g	<b>14%</b>
Saturated Fat 2.5g	<b>12%</b>
Trans Fat 0g	
<b>Cholesterol</b> 30mg	<b>10%</b>
<b>Sodium</b> 440mg	<b>18%</b>
<b>Total Carbohydrate</b> 6g	<b>2%</b>
<b>Protein</b> 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 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

## Food Safety and Inspection Service:

### USDA's Labeling Requirements

- 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

# Food Safety and Inspection Service: Types of Labels and Label Approval

- **Generic labeling**
- **Sketch approval**
- **Final labels**
- **Temporary**



## Food Safety and Inspection Service: Prior Label Approval

- Certain types of labeling require submission for evaluation by LPDS (9 CFR 412.1)
  - labels for temporary approval
  - labels for products produced under religious exemption
  - labels for products for export with labeling deviations
  - labels with special statements and claims
- FSIS requires 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:

### Labeling Records -9 CFR 320.1(b)(11), 381.175(b)(6)

- Labeling record must include:
  - Final label applied to product
  - Product formulation
  - Processing procedures
  - Supporting documentation, including prior sketch approval from LPDS (if applicable)
  
- Include supporting documentation to show that the label is consistent with the Federal meat and poultry regulations and policies on labeling

# 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 7221.1: General Labeling Verification Activities

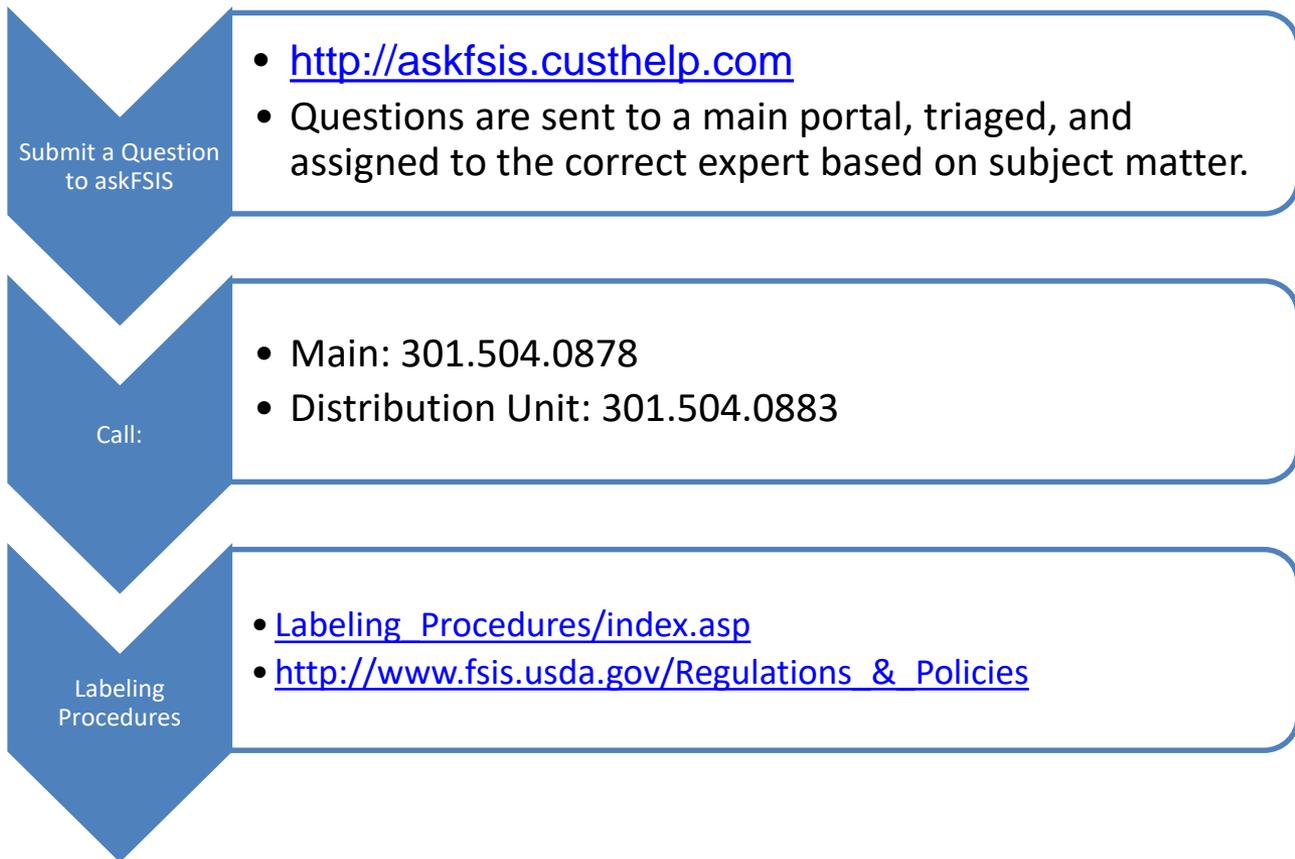
- Provides permanent instructions on how to conduct and document a label verification activity
- Verification focused on “final” label that is applied to product; consistent with Agency’s public health focus
- When labeling is non-compliant, establishments may take corrective actions by submitting for temporary approval or correcting label (e.g., with pressure sensitive stickers)

## Food Safety and Inspection Service:

### Procedures for Rescinding or Refusing Approval - 9 CFR 500.8

- Labels submitted to FSIS that are not in compliance with FSIS labeling regulations and policies may be approved as modified or rejected
- FSIS may rescind non-compliant labels to prevent future use
- Labeling and Program Delivery Staff in FSIS provides guidance to Inspection Program Personnel on labeling requirements during labeling verification activities

# Food Safety and Inspection Service: Questions? Contact LPDS





United States  
Department of  
Agriculture

# Food Safety and Inspection Service

Protecting Public Health and Preventing Foodborne Illness



## Current Landscape for Food Labeling

**Matthew Michael**

*Director, Issuances Staff, Office of Policy and Program Development, FSIS, USDA*

Food Safety and Inspection Service:  
Issuances Staff, Office of Policy and Program Development

- *Federal Register* Publications (Notices, Proposed Rules, and Final Rules)
- Guidance to Industry
- Instructions to Inspectors (FSIS Directives and Notices)
- Agency Responses to Petitions

# Food Safety and Inspection Service: Petitions Management

CODE OF FEDERAL REGULATIONS



CFR

OFFICE OF THE FEDERAL REGISTER

- Anyone may file a petition to FSIS to issue, amend, or repeal a regulation or policy
- FSIS regulations governing the petition process are in the 9 CFR 392
- FSIS makes petitions, comments, and responses available to the public at its headquarters and online

# Food Safety and Inspection Service: Regulations.gov

The screenshot shows the Regulations.gov website. At the top left is the logo "regulations.gov" with the tagline "Your Voice in Federal Decision-Making". To the right are navigation links: Home, Help, Resources, and Contact Us. Below these are three buttons: Search, Browse, and Learn. A central banner reads "Make a difference. Submit your comments and let your voice be heard." Below the banner is a search box with the text "SEARCH for: Rules, Comments, Adjudications or Supporting Documents:" and a "Search" button. To the left of the search box is a "What's Trending" section with four items, each with a closing date. To the right of the search box is a "Comments Due Soon" section with a list of time periods and counts. Below that is a "Newly Posted" section with a list of time periods and counts. On the far right is a box titled "Unable to submit a comment?" featuring an image of a drone and text about FAA Section 333. Below this box are links for "APIs for Developers", "Browse by Category", and "DOS Regulations Twitter Page". At the bottom of the page is a footer with five columns of links: Home, About Us, Resources, Help, and Connect With.

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SEARCH for: Rules, Comments, Adjudications or Supporting Documents:

Search

Advanced Search

### What's Trending

- Inadmissibility on Public Charge Grounds  
Closing on Dec 10, 2018
- Apprehension, Processing, Care, and Custody of Alien Minors and Unaccompanied Alien Children  
Closing on Nov 06, 2018
- International Drug Scheduling; Convention on Psychotropic Substances; Single Convention on Narcotic Drugs; ADB -FUBINACA...  
Closing on Oct 31, 2018
- Fisheries of the United States; Regulations for Striped Bass Fishing in the Block Island Transit Zone  
Closing on Nov 19, 2018
- National Primate Research Centers (Letter of Support for NABR)

### Comments Due Soon

- Today (20)
- Next 3 Days (47)
- Next 7 Days (147)
- Next 15 Days (323)
- Next 30 Days (622)
- Next 90 Days (935)

### Newly Posted

- Today (178)
- Last 3 Days (294)
- Last 7 Days (572)
- Last 15 Days (987)
- Last 30 Days (2,001)
- Last 90 Days (5,907)

### Unable to submit a comment?

#### FAA Section 333



The FAA has recently issued part 107, which addresses the majority of 333 petitions. Please visit [www.faa.gov/uas/](http://www.faa.gov/uas/)

#### APIs for Developers

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# Food Safety and Inspection Service: Petition from U.S. Cattlemen's Association (USCA)

FSIS Case No. 2018-  
Total No. of Pages: 124

BEFORE THE  
UNITED STATES DEPARTMENT OF  
AGRICULTURE, FOOD SAFETY AND INSPECTION  
SERVICE (FSIS)

In the matter of

BEEF AND MEAT LABELING  
REQUIREMENTS: TO EXCLUDE  
PRODUCTS NOT DERIVED DIRECTLY  
FROM ANIMALS RAISED AND  
SLAUGHTERED FROM THE DEFINITION  
OF "BEEF" AND "MEAT"

PETITION FOR THE IMPOSITION OF BEEF AND MEAT  
LABELING REQUIREMENTS: TO EXCLUDE PRODUCTS NOT  
DERIVED DIRECTLY FROM ANIMALS RAISED AND  
SLAUGHTERED FROM THE DEFINITION OF "BEEF" AND  
"MEAT"

Petitioner:

U.S. CATTLEMEN'S  
ASSOCIATION (USCA)

Counsel for Petitioner:

Terence P. Stewart, Esq.  
Lane S. Hurewitz, Esq.  
STEWART AND STEWART  
2100 M Street, Suite 200  
Washington, DC 20037  
Tel.: (202) 785-4185  
E-mail: tstewart@stewartlaw.com

Date: February 9, 2018

- Received on February 9, 2018
- Over 6,000 comments submitted to FSIS and posted on [www.regulations.gov](http://www.regulations.gov)
- Still under consideration by FSIS

## Food Safety and Inspection Service: USCA Petition: What Does it Request?

- Limit the definition of “beef” to product from cattle born, raised, and harvested in the traditional manner
- Limit the definition of "meat" to the tissue or flesh of animals that have been harvested in the traditional manner
- Add these definitions to the FSIS Food Standards and Labeling Policy Book

# Food Safety and Inspection Service: Labeling for New and Novel Processes and Products



- Irradiation
- Advanced Meat Recovery
- High Pressure Processing
- Modified Atmosphere Packaging



# **Current Landscape for Food Labeling**

**Dr. Douglas Balentine, Director  
Office of Nutrition and Food Labeling**

**Food and Drug Administration**

**October 24, 2018**

USDA/FDA Joint Public Meeting:

The Use of Cell Culture Technology to Develop Products Derived from  
Livestock and Poultry

**BREAK**

Public meeting will  
resume at 9:55 a.m. ET



United States  
Department of  
Agriculture



U.S. FOOD & DRUG  
ADMINISTRATION

# USDA/FDA Joint Public Meeting

## The Use of Cell Culture Technology to Develop Products Derived from Livestock and Poultry



USDA/FDA Joint Public Meeting:

The Use of Cell Culture Technology to Develop Products Derived from Livestock and Poultry

## **Session 5: Open Public Comment on Mandatory Labeling Elements**

- Should standards of identity or criteria for statements of identity be established for these products to ensure that product names are truthful, not misleading, and sufficiently differentiate cell cultured products from traditional products?
- Should the methods by which animal cell cultured products are produced (i.e., the culturing process) be considered required information for purposes of labeling? If so, what factors should be considered in accurately describing the production methods?

USDA/FDA Joint Public Meeting:

The Use of Cell Culture Technology to Develop Products Derived from Livestock and Poultry

## **Session 5: Open Public Comment on Mandatory Labeling Elements**

- Should the source of the animal cells (i.e., the species from which the cell line was initiated) be considered required information for the purposes of labeling?
- How should products containing both animal cell cultured products and traditional meat and poultry products be labeled?



United States  
Department of  
Agriculture

# Food Safety and Inspection Service

Protecting Public Health and Preventing Foodborne Illness



## Overview of Regulatory Frameworks for Claims

**Jeff Canavan**

*Deputy Director, Office of Policy and Program Development, Labeling and Program Delivery Staff, FSIS, USDA*

## Food Safety and Inspection Service: Types of Labeling Claims

- Some claims are defined in FSIS regulations
- Defined nutrient content claims (9 CFR 317.313 and 9 CFR 381.413)
  - Good source, high, and more claims
  - Light, low fat, low cholesterol, lower sodium
  - Low calorie, no sugar added, healthy
- Claims must be truthful and not misleading (9 CFR 317.8 and 381.129)
- Interested parties may petition the Agency for rulemaking to define new claims; not limited to nutrition

## Food Safety and Inspection Service:

### Special Statements and Claims not Defined in FSIS Regulations

- FSIS may publish labeling guidelines and will announce availability for public comment
- FSIS consults with Food and Drug Administration (FDA), Agriculture Marketing Service (AMS), Center for Nutrition Policy and Promotion (CNPP) and other government agencies as needed
- Consistency with food labeling policies across all food categories is an important consideration

# Food Safety and Inspection Service: Labeling Guideline Examples

**Marco's Nation**

**250 milligrams of Omega-3 Fatty Acids per serving from canola oil.**

FULLY COOKED

**Beef Patty**

Ingredients: Beef, water, canola oil, contains 2% or less of salt, sugar, beef stock, corn syrup, flavoring, sodium phosphate, yeast extract, modified food starch.

Keep Frozen

Net Wt. 18 oz (1 lb 2 oz)

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

Distributed by Marco's Nation, Inc.  
1224 Some Dr.  
Somewhere, VE 00122

Serving Size 1 patty (84g)	
Servings Per Container: 6	
Amount Per Serving	
<b>Calories 230</b>	Calories from Fat 170
<b>%Daily Value*</b>	
<b>Total Fat 19g</b>	<b>29%</b>
Saturated Fat 6g	<b>30%</b>
Trans Fat 0.5g	
<b>Cholesterol 60mg</b>	<b>20%</b>
<b>Sodium 450mg</b>	<b>19%</b>
<b>Potassium 0mg</b>	<b>0%</b>
<b>Total Carbohydrate 0g</b>	<b>0%</b>
Dietary Fiber 0g	<b>0%</b>
Sugars 0g	
<b>Protein 15g</b>	
Vitamin A 0%	• Vitamin C 0%
Calcium 0%	• Iron 8%
* 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	

## ■ 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 Breading”

<https://www.fsis.usda.gov/wps/wcm/connect/aff1ec68-a0be-431f-b3de-1ddb53079534/omega-fatty-acids.pdf?MOD=AJPERES>

# Food Safety and Inspection Service: Labeling Guideline Examples



- Whole Grain Statements
    - “Pepperoni Pizza with Whole Grain Crust” and “X g Whole Grain Per Serving”
- [https://www.fsis.usda.gov/wps/wcm/connect/6ea06856-e04d-46d7-befd-5b9287c55640/Food\\_Guide\\_MYPyramid\\_Policy.pdf?MOD=AJPERES](https://www.fsis.usda.gov/wps/wcm/connect/6ea06856-e04d-46d7-befd-5b9287c55640/Food_Guide_MYPyramid_Policy.pdf?MOD=AJPERES)

## Food Safety and Inspection Service: Special Statement and Claim Examples

- Negative Claims- Refer to absence of an ingredient or source of an ingredient (e.g., “ No MSG,” “No Soy”)
- May also be used to highlight the absence of a class of ingredients (e.g., “No Preservatives,” “Preservative Free Crust”)

## Food Safety and Inspection Service: Non-Genetically Engineered Claims

- FSIS has approved labels for products meet the standards of a third-party certifier, e.g. *“Fed a Vegetarian Diet with no GMO feed ingredients in compliance with the National Organic Program regulations.”*
- 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 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)**

**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.

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

## Food Safety and Inspection Service: Voluntary Statements about Use of Genetically Engineered (GE) 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”)

# Food Safety and Inspection Service: Animal Raising Claim Examples

Breeds (Angus, Piedmontese, Wagyu)

Raised Without Antibiotics

AMS Process Verified Program – 3<sup>rd</sup>  
Party Certification

MISSING

## 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

## Food Safety and Inspection Service: Animal Production Raising Claims

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

A Good Win! Farms®  
est. 2010

All Natural\*  
Pasture Raised

USDA  
ORGANIC

Premium Fresh Young Chicken

Chicken Have Been Raised:

- > Without Added Antibiotics
- > No Added Hormones†
- > This pasture raised chicken is fed a vegetarian diet that was produced in compliance with The National Organic Program's standards for avoidance of genetically engineered feed ingredients





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 raw meat or 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 Weight: 48 oz (3 lbs)

\*Minimally Processed, No Artificial Ingredients

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

Distributed By:  
2011 Beltsville Rd  
Sunnyside, MD 12345  
Certified Organic by LPDD  
Organic Certifying

- 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

<https://www.fsis.usda.gov/wps/wcm/connect/6fe3cd56-6809-4239-b7a2-bccb82a30588/RaisingClaims.pdf?MOD=AJPERES>

# Food Safety and Inspection Service: New Labeling Focus on Claims Verification



- December 2010 Final Rule, “Nutrition Labeling of Single-Ingredient Products and Ground or Chopped Meat and Poultry Products” (75 FR 82148) (Effective March 2012)
  - FSIS to collect samples of raw ground beef products for nutrient analysis in order to verify compliance with nutrition labeling requirements
  - **Project goal:** Surveillance sampling to identify if certain nutrient content information on labels is accurate or if further testing and enforcement by FSIS is warranted
- Criteria for sample selection:
  - Must be in consumer ready packaging with nutrition facts panel

## Food Safety and Inspection Service:

### New Labeling Focus on Claims Verification

- On-going concern about the truthfulness of labeling information, e.g., evidence of significant variation from the stated value of nutrient content associated with fat in raw ground beef
- Expanded the raw ground beef surveillance sampling program to double the number of samples analyzed in the laboratory
- FSIS has observed through its label approval system an increase in the number of applications for labels bearing negative claims highlighting the absence of various substances from or products, e.g., “no soy added.”

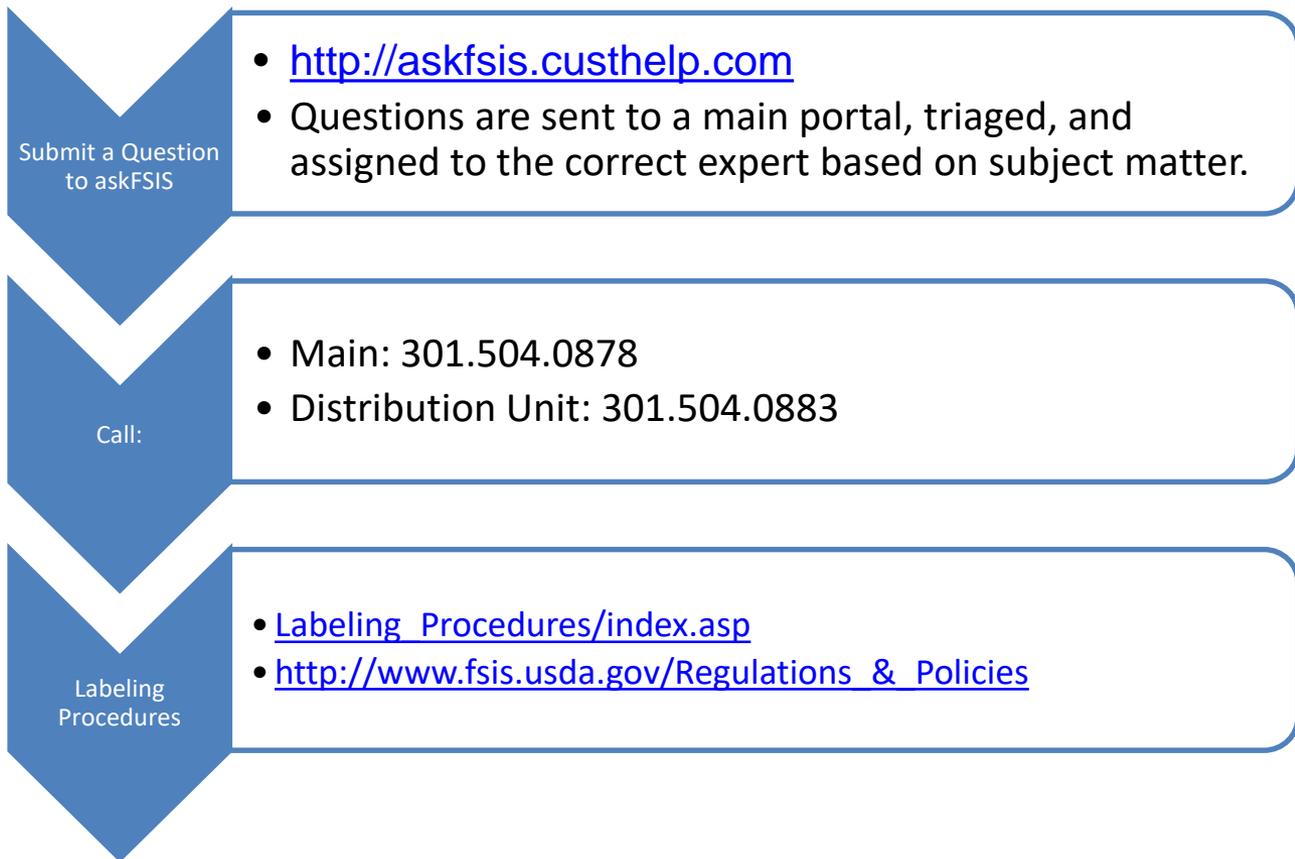
## Food Safety and Inspection Service:

### New Labeling Focus on Claims Verification

- In FY2018, FSIS expanded its exploratory sampling program to include verification of labeling claims for:
  - Raw, ground beef products with negative/no hormone claims
  - Raw chicken parts with negative/no antibiotics claims
  - Ready-to-eat products with negative/no soy claims

<https://www.fsis.usda.gov/wps/wcm/connect/4d0238e7-5238-4d77-acf1-db8e59c8e8b1/26-18.pdf?MOD=AJPERES>
- **Purpose of the sampling:** To verify industry's compliance with the Agency's labeling regulations and policies to ensure such claims are truthful and not misleading and to protect consumers from misbranded and economically adulterated meat and poultry products.

# Food Safety and Inspection Service: Questions? Contact LPDS



# **Regulatory Framework for Food Labeling Claims**

**Dr. Douglas Balentine, Director  
Office of Nutrition and Food Labeling**

**Food and Drug Administration**

**October 24, 2018**

# Claims

- 1990 Nutrition Labeling and Education Act establishes FDA's authority for
  - Nutrient content claims
  - Health claims
- Other truthful and non-misleading claims

# Nutrient Content Claims

- Describe the level of a nutrient or a dietary substance
- May be expressed (“low fat”) or implied (“high in oat bran”)
- Terms include “free,” “high,” “low”
- Comparative claims such as “more,” “reduced,” “lite”
- “Healthy”
- Simple amount or percent claims

Information on Nutrient Content Claims: <https://www.fda.gov/foodlabelingguide>

# Nutrient Content Claims

## General Requirements

- Must be authorized
  - By regulation
    - 21 CFR 101.13
    - 21 CFR part 101 subpart D
    - 21 CFR part 105
    - 21 CFR part 107
  - By FDAMA notification
- Products making a claim must bear nutrition labeling

# Nutrient Content Claims

## General Requirements

- Must meet all requirements for claim including nutrient levels
- Generally based on reference amount customarily consumed (RACC) 21 CFR 101.12
- May have other required information
- May require disclosure statements (e.g., “See back panel for information about cholesterol and other nutrients”)

# Nutrient Content Claim

## "Healthy"

- 1994 final rule defines healthy nutrient content claim
- Claim highlights foods that meet certain nutrient criteria
- FDA revisiting the definition of “healthy”

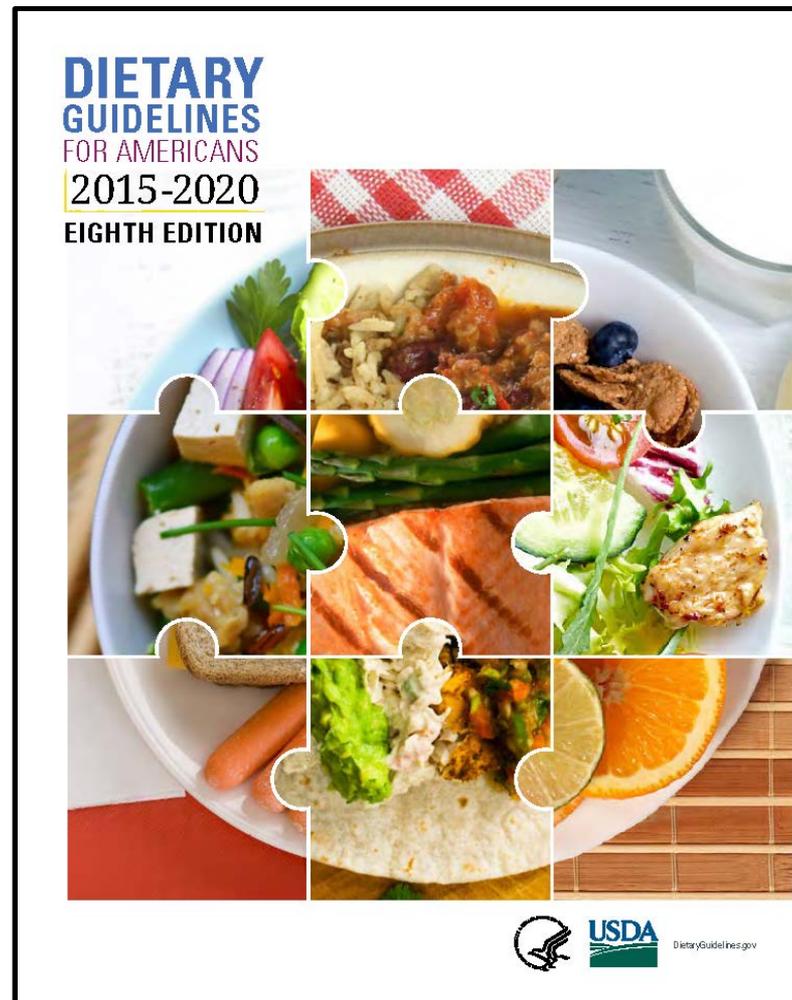
# "Healthy" on Food Labels

- *Federal Register* request for comments (9/28/16); over 1,000 comments received
- *Federal Register* notice of availability of guidance for industry, “Use of the Term ‘Healthy’ in the Labeling of Human Food Products” (9/28/16)
- Public meeting – March 9, 2017

# Dietary Guidelines

Healthy dietary patterns now

- Focus on food groups
- Focus on the type of fat rather than the total amount of fat consumed
- Address added sugars in the diet



# Health Claims

- Make an expressed or implied statement about relationship of a food substance to a disease or health-related condition for general U.S. population or subpopulation (e.g., women, elderly)
- Ability to reduce the risk of disease not treat, prevent, cure, or mitigate (drug)
- Require FDA review and evaluation before use

# Health Claims

- General requirements 21 CFR 101.14
- Must meet certain requirements
- Products with claim must bear nutrition labeling
- Generally based on reference amount customarily consumed (RACC)

# Types of Health Claims

- NLEA Authorized (Significant Scientific Agreement – SSA) - Codified in the CFR
- FDAMA – Authoritative statement
- Qualified – Enforcement discretion letter

# Elements of a Health Claim

1. Substance,
2. Disease or health-related condition, and
3. Relationship

A label “health message” that does not have all three elements is not a health claim covered by section 403(r) of the FD&C Act.

# Disqualifying Nutrient Levels

*Statutory basis –*

FDA shall not authorize a health claim for a food that contains any nutrient in an amount that increases the risk of a diet-related disease or health-related condition (but lets FDA make exceptions)

Section 403(r)(3)(A) FD&C Act

# SSA Health Claims

- Requirements in 21 CFR part 101 subpart E
- Currently 12 SSA health claims authorized in the regulations
  - May include different nutrients within a class, e.g., different soluble fibers
- Each health claim regulation lays out requirements for stated claim, substance, and food
- Model health claims provided
  - "Low fat diets rich in fiber-containing grain products, fruits, and vegetables may reduce the risk of some types of cancer, a disease associated with many factors." (101.76)
- <https://www.fda.gov/Food/LabelingNutrition/ucm2006876.htm>

# FDAMA Health Claims

- Based on authoritative statement from an appropriate scientific body of the U.S. Government or the National Academy of Sciences or its subdivisions
- May only use claim exactly as stated in notification
  - "Diets containing foods that are good sources of potassium and low in sodium may reduce the risk of high blood pressure and stroke."
- <https://www.fda.gov/Food/LabelingNutrition/ucm2006874.htm>

# Qualified Health Claims

- Supported by scientific evidence, but do not meet the more rigorous SSA standard required for an authorized health claim
- Enforcement discretion letter includes specific claim language that reflects the level of supporting scientific evidence and details of all enforcement discretion factors under which the FDA will not object to the use of the QHC
- "Supportive but not conclusive research shows that eating 1.5 ounces per day of walnuts, as part of a low saturated fat and low cholesterol diet and not resulting in increased caloric intake, may reduce the risk of coronary heart disease. See nutrition information for fat [and calorie] content."
- <http://www.fda.gov/Food/LabelingNutrition/ucm073992.htm>

# Other Claims and Statements

- Other types of claims such as how the product is made are voluntary
- If made, they must be truthful and not misleading under section 403(a)(1) of the FD&C Act
- Examples:
  - Gluten-free
  - Grown on a family-owned farm

# Food Labeling Guide

- For further information
    - See section 8 and applicable appendixes of the Food Labeling Guide
- <http://www.fda.gov/FoodLabelingGuide>



USDA/FDA Joint Public Meeting:

The Use of Cell Culture Technology to Develop Products Derived from  
Livestock and Poultry

# LUNCH

Public meeting will  
resume at 12:30 p.m. ET