

U.S. Food Labeling Regulations

Division of Food Labeling and Standards
Office of Nutrition and Food Labeling
Center for Food Safety and Applied
Nutrition (CFSAN)

Topics Covered

- FDA Food Responsibilities
- Mandatory Labeling
 - Statement of Identity
 - Net Quantity of Contents
 - Name and Place of Business
 - Ingredient Statement
 - Nutrition Labeling
 - Allergen labeling
- Voluntary Labeling
 - Nutrient Content Claims
 - Health Claims
 - Structure/Function Claims
 - Other Claims
- Miscellaneous Labeling Requirements
- What's on the Horizon?
- Resources
- Website
- Questions

FDA Food Responsibilities

- 20¢ of every consumer dollar in the US spent on FDA-regulated products
- FDA regulates safety & labeling of ~75% of all food consumed in the United States
 - Ensure that consumers are provided with accurate and useful information in food labeling
 - Encourage food product reformulation to create healthier products
- Close collaboration with CDC, NIH, USDA and other federal partners
- Most products containing red meat or poultry are regulated by USDA. Certain products with small amounts of red meat or poultry are regulated by FDA.
- Federal Trade Commission has primary responsibility for food advertising.



What Must be on a Food Label?



- Statement of identity (what the food is)
- Net Quantity of Contents (how much is in the package)
- Name and place of business (Manufacturer, Packer or Distributor)
- Ingredient statement (what is in the food)
- Nutrition Labeling (unless there is an exemption)
- Allergen Labeling (if applicable)

Principal Display Panel (PDP)

(21 CFR 101.1)

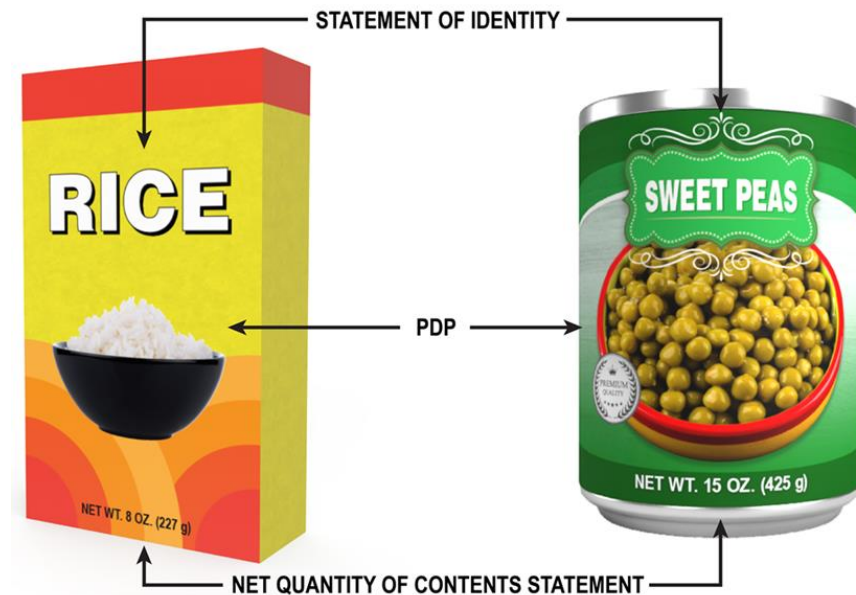
- Portion of label most likely to be seen by consumer at time of purchase
- Package can have alternate principal display panels



Principal Display Panel Must Contain



- Statement of identity (name of food)
- Net quantity of contents statement (amount of food in package)



Statement of Identity (21 CFR 101.3)



The name of the food

- Name required by law or regulation
 - Butter (law)
 - Cocoa, tomato juice, vanilla flavoring, etc.
 - Standards of Identity (21 CFR 131-169)
- Common or usual name of a food (21 CFR 102.5)
- Appropriately descriptive term

Statement of Identity with a Characterizing Flavor (21 CFR 101.22(i))



- If the product is promoted as having a characterizing flavor, the flavor may be included in the statement of identity (e.g., Strawberry, artificial strawberry)
 - Natural Flavor (21 CFR 101.22(i)(1))
 - Natural Apple Flavor
 - “Apple Flavored Drink” or “Natural Apple Flavored Drink”
 - Artificial Flavor (21 CFR 101.22(i)(2))
 - “Artificially Flavored Apple Drink”
 - With Other Natural Flavors (21 CFR 101.22(i)(1)(iii))
 - “Natural Apple Flavored Drink With Other Natural Flavors”



Net Quantity of Contents Statement



(21 CFR 101.7)

- Amount of food in package
 - Liquids-Volume— gallon/fl. oz./mL
- Must be placed on PDP, lower 30%, parallel to base, conspicuous
- Should state in metric and must state U. S. Customary measure
- Area of PDP determines type size



Information Panel

(21 CFR 101.2)

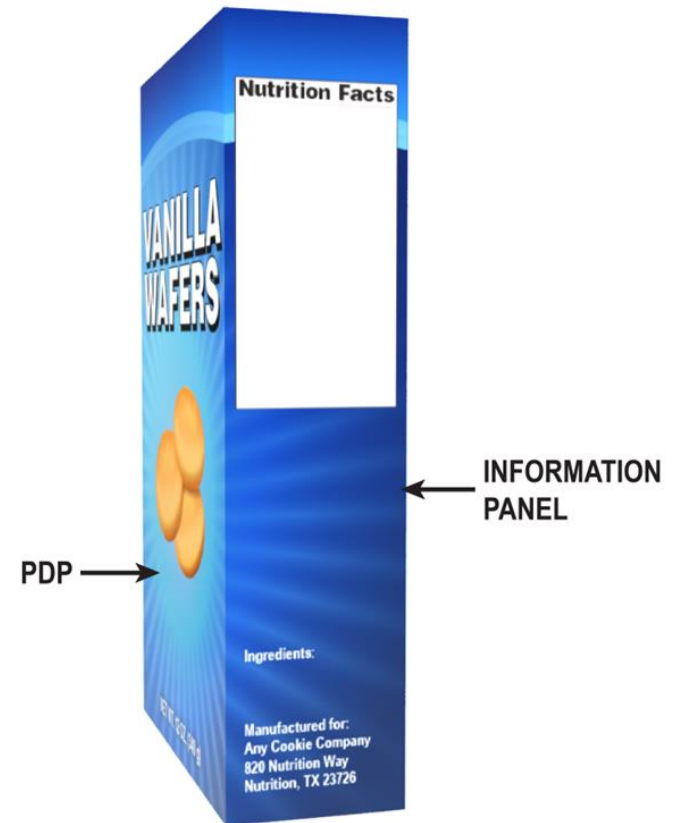
- Panel to the immediate right of PDP
- If this panel is unusable, then next panel to right



Information Panel Contains



- Name and address of firm
 - Example: manufacturer, packer, or distributor
- Ingredient list
- Nutrition Facts label (unless exempt)
- Allergen information (if applicable)



Name and Place of Business (21 CFR 101.5)



- Unless actual manufacturer – “distributed by”, “packed for”
- Address (city, state, country)
- Web address is not an acceptable substitute





Ingredient Statement (21 CFR 101.4)

- Each food ingredient listed in descending order of predominance by weight
- Use common or name of ingredients
- Spices, flavors and certain colors may be listed generically (21 CFR 101.22(h) and 101.22(k))
- Must declare the function of preservatives (21 CFR 101.22(j))



Ingredient Statement

(21 CFR 101.4)

- Declare sub ingredients of multicomponent ingredients (21 CFR 101.4(b)(2))

Ingredients: Water, Sake (Water, Brown Rice, Yeast), Natural Flavor, Rebaudioside A, Vegetable Juice for Color, Potassium Sorbate (preservative), Carbon Dioxide

OR

Ingredients: Water, Brown Rice, Natural Flavor, Rebaudioside A, Vegetable Juice for Color, Yeast, Potassium Sorbate (preservative), Carbon Dioxide

Nutrition Labeling (21 CFR 101.9)



- Required on most products offered for sale
- The serving size is based on Reference Amounts Customarily Consumed (RACC)
- Exemptions and special labeling provisions
 - Examples:
 - Small Business exemptions
 - Insignificant amount of nutrients in food (plain tea)
- Generally, if a food contains a claim then it must have a nutrition label
- FDA's method of determining compliance is found in 21 CFR 101.9(g).
 - Class I-For added nutrients in fortified or fabricated foods the nutrient content of the composite sample must be at least equal to the declared value
 - Class II-For naturally occurring (indigenous) nutrients the nutrient content of the composite sample must be at least equal to 80% the declared value
 - For calories, total sugars, added sugars (when the only source of sugars in the food is added sugars), total fat, saturated fat, *trans* fat, cholesterol, or sodium, the nutrient content of the composite sample must not be greater than 20% in excess of the declared value

Nutrition Facts Label

Serving Size → 8 servings per container
Serving size 2/3 cup (55g)

Amount of Calories → **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 240mg	6%

Nutrients →

Footnote → * 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.

← **Percent Daily Value**

(For educational purposes only. These labels do not meet the labeling requirements described in 21 CFR 101.9.)

Mandatory Nutrients

15 Mandatory Nutrients

Calories	Total Sugars
Total fat	Added Sugars
Saturated fat	Protein
Trans fat	Vitamin D
Cholesterol	Calcium
Sodium	Iron
Total carbohydrate	Potassium
Dietary fiber	

Voluntary Nutrients

Voluntary Nutrients*	
Calories from saturated fat	Insoluble fiber
Polyunsaturated fat	Sugar alcohol
Monounsaturated fat	Other vitamins & minerals that have established RDI's
Fluoride	Beta-carotene (as % Vitamin A)
Soluble fiber	Folic acid

*Required if claim is made

Added Sugars Definition

Includes sugars that are either added during processing of foods includes:

- Syrups
- Brown sugar
- High fructose corn syrup
- Invert sugar
- Maltose
- Trehalose
- Honey
- Molasses
- Sucrose
- Lactose
- Maltose sugar
- Concentrated fruit juice*

*Sugars from concentrated fruit or vegetable juices in excess of what would be expected from 100 percent fruit or vegetable juice. Excludes fruit or vegetable juice concentrated from 100 percent fruit juice that is sold to consumers (e.g., frozen concentrated orange juice).

For more information: [Guidance for Industry: Nutrition and Supplement Facts Labels Questions and Answers Related to the Compliance Date, Added Sugars, and Declaration of Quantitative Amounts of Vitamins and Minerals | FDA](#)

Exemptions & Special Labeling Provisions (Nutrition Labeling Only)



- Bulk foods for further manufacturing (21 CFR 101.9(j)(9))
 - Small packages that have less than 12 square inches of available label space (21 CFR 101.9(j)(13))
 - Food sold from bulk containers- the nutrition information must be on display (21 CFR 101.9(j)(16))
 - Small Business Nutrition Labeling Exemption (SBNLE) (21 CFR 101.9(j)(18))
 - No Filing Required [101.9(j)(18)(iv)]
 - < 10 full time equivalent employee AND
 - < 10,000 units
 - Filing Required [101.9(j)(18)]
 - < 100 full time equivalent employees AND
 - < 100,000 units sold annually in U.S.
- OR
- < 100,000 anticipated to be sold annually in U.S.
 - <https://www.fda.gov/food/labeling-nutrition-guidance-documents-regulatory-information/small-business-nutrition-labeling-exemption-guide>

Major Food Allergens

- Section 403(w) of the FD&C Act
- Label declaration is satisfied by the name of the food source of the allergen, e.g. “soy,” “wheat”
- For tree nuts, fish and Crustacean shellfish, the name of the specific type of tree nut, fish or Crustacean shellfish must be declared, e.g., “almonds,” “flounder,” or “crab”



When Food Allergen Labeling Is Required



- A food ingredient that contains protein derived from a major food allergen, except for:
 - Raw agricultural commodities (fresh fruits and vegetables)
 - Food ingredient exempt under a petition or notification process specified in the law
 - A highly refined oil derived from one of these foods or an ingredient derived from such oil
- A major food allergen's common or usual name does not already identify its food source, AND,
- When that major food allergen's food source is not already identified elsewhere in the statement of ingredients for another allergenic ingredient.

Two Ways to Label Products Containing Major Food Allergens

OPTION 1

Nutrition Facts

Ingredients: Enriched flour (wheat flour, malted barley, niacin, reduced iron, thiamin mononitrate, riboflavin, folic acid), sugar, cottonseed oil, high fructose corn syrup, whey (milk), eggs, vanilla, natural and artificial flavoring, salt, leavening (sodium acid pyrophosphate, monocalcium phosphate), lecithin (soy), mono- and diglycerides.

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Nutrition, TX 23726

OR

OPTION 2

Nutrition Facts

Ingredients: Enriched flour (wheat flour, malted barley, niacin, reduced iron, thiamin mononitrate, riboflavin, folic acid), sugar, cottonseed oil, high fructose corn syrup, whey, eggs, vanilla, natural and artificial flavoring, salt, leavening (sodium acid pyrophosphate, monocalcium phosphate), lecithin, mono- and diglycerides.

Contains: Wheat, Milk, Egg and Soy.

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Nutrition, TX 23726

1. Include the name of the food source in parenthesis following the common or usual name of the major food allergen in the list of ingredients in instances when the name of the food source of the major food allergen does not appear elsewhere in the ingredient statement for another allergenic ingredient.

2. Place the word "Contains," followed by the name(s) of all the food sources from which the major food allergen(s) are derived, immediately after or adjacent to the list of ingredients, in a type size that is no smaller than that used for the ingredient list.

Allergen Advisory Statements



- Advisory labels such as “May contain” or “Made in the same facility” may not be used as a substitute for good manufacturing practices (GMPs)
- Must be truthful and not misleading

Example: Enriched Wheat Flour (wheat flour, niacin, reduced iron, thiamin mononitrate, riboflavin, folic acid), sugar, soybean oil, salt, baking soda, natural and artificial flavor.

May Contain eggs or nuts

Nutrient Content Claims

- Voluntary, not required
- Defined in 21 CFR 101.13
- Claims about the level of a nutrient
- Types of claims:
 - Expressed (“cholesterol free,” “sugar free,” “no added sugar”) or Implied (“high in oat bran”)
 - Inherent Claims (“broccoli, a naturally cholesterol free food”)
 - Relative Claims (“Reduced Fat,” “Light,” “Less”)



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Nutrient Content Claims

- General Requirements, 21 CFR 101.13
- Specific Requirements, 21 CFR 101.54-101.69, (Subpart D)
 - Examples: “sugar free,” “no added sugar” (21 CFR 101.60), “cholesterol free” (21 CFR 101.62)
- Must be authorized
 - By regulation
 - 21 CFR 101.13
 - 21 CFR part 101 subpart D
 - Vitamins, minerals, protein, antioxidants, fiber, fat, sodium, calories, sugars, sat fat, cholesterol, “healthy,” “light,” etc.
 - By FDAMA notification

Nutrient Content Claims

- Must meet all requirements for claim including nutrient levels
- Generally based on Reference Amount Customarily Consumed (RACC) 21 CFR 101.12
- May be other required information
- May require disclosure statements (e.g., “See back panel for information about cholesterol and other nutrients”) 21 CFR 101.13(h)

What is a Health Claim?



- Voluntary, not required
- Health claim means any claim made on the label or in labeling of a food that expressly or by implication, including “third party” references, written statements (e.g., a brand name including a term such as “heart”), symbols (e.g., a heart symbol), or vignettes, characterizes the relationship of any substance to a disease or health-related condition.
- 3 methods of FDA oversight
 - FDA issues regulation
 - FDA reviews notification submitted under FDAMA
 - FDA reviews qualified HC petition



Health Claims Authorized by Regulation

- General requirements 21 CFR 101.14
- Specific Requirements 21 CFR 101.70-101.83, (Subpart E)
- “Adequate calcium and vitamin D, as part of a well-balanced diet, along with physical activity, may reduce the risk of osteoporosis.”

FDAMA Health Claim

- Notification is based on an authoritative statement from an appropriate scientific body of the United States Government or the National Academy of Sciences (NAS) or any of its subdivisions.
- Potassium Containing Foods
 - "Diets containing foods that are good sources of potassium and low in sodium may reduce the risk of high blood pressure and stroke."



Qualified Health Claim

- “Scientific evidence suggests but does not prove that eating 1.5 ounces per day of most nuts, such as [*name of specific nut*], as part of a diet low in saturated fat and cholesterol may reduce the risk of heart disease. [See nutrition information for fat content].”



Structure/Function Claims (21 CFR 101.93)



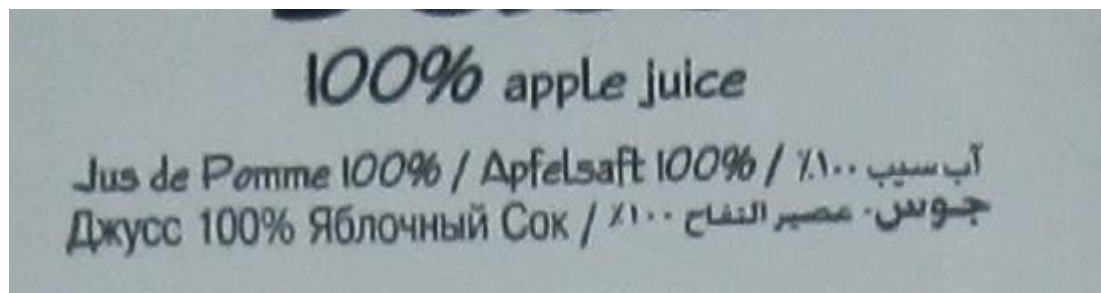
- Claims about the affect of a nutrient on the normal structure or function of the body or general well-being:
 - Calcium builds strong bones
- Manufacturers are responsible for determining the accuracy and truthfulness of the claim
- Must be truthful and not misleading
- Must derive from the nutritional value of the product
- May not explicitly or implicitly link the relationship to a disease or health-related condition

Other Claims

- If “free” is not defined, means complete absence of the named substance
- Examples: “Soy free,” “artificial color free,” and “caffeine free”
- FDA considers all color additives to be artificial color (21 CFR 70.3(f), 21 CFR 101.22(a)(4))
- Truthful not misleading

Multiple Languages

- All required label information must appear in English
- If the label has any representation in a second language, then all required label information must be in both English and the second language
- 21 CFR 101.15(c)



Online Labeling

- Purchase of product from website where product is promoted
- Product label refers consumer to website
- FDA Issued a Request for Information on Food Labeling in Online Grocery Shopping

Sticker Labels

- Mandatory labeling can be printed on a sticker and affixed to a package
- Sticker labels are often used to correct label deficiencies



What's on the Horizon?

See possible upcoming guidances here: [Foods Program Guidance Under Development | FDA](#)

- Questions and Answers Regarding Food Allergens, Including the Food Allergen Labeling Requirements of the Federal Food, Drug, and Cosmetic Act: Guidance for Industry (5th ed)
- Labeling of Plant-Based Alternatives to Animal-Derived Foods; Draft Guidance for Industry

What's on the Horizon?

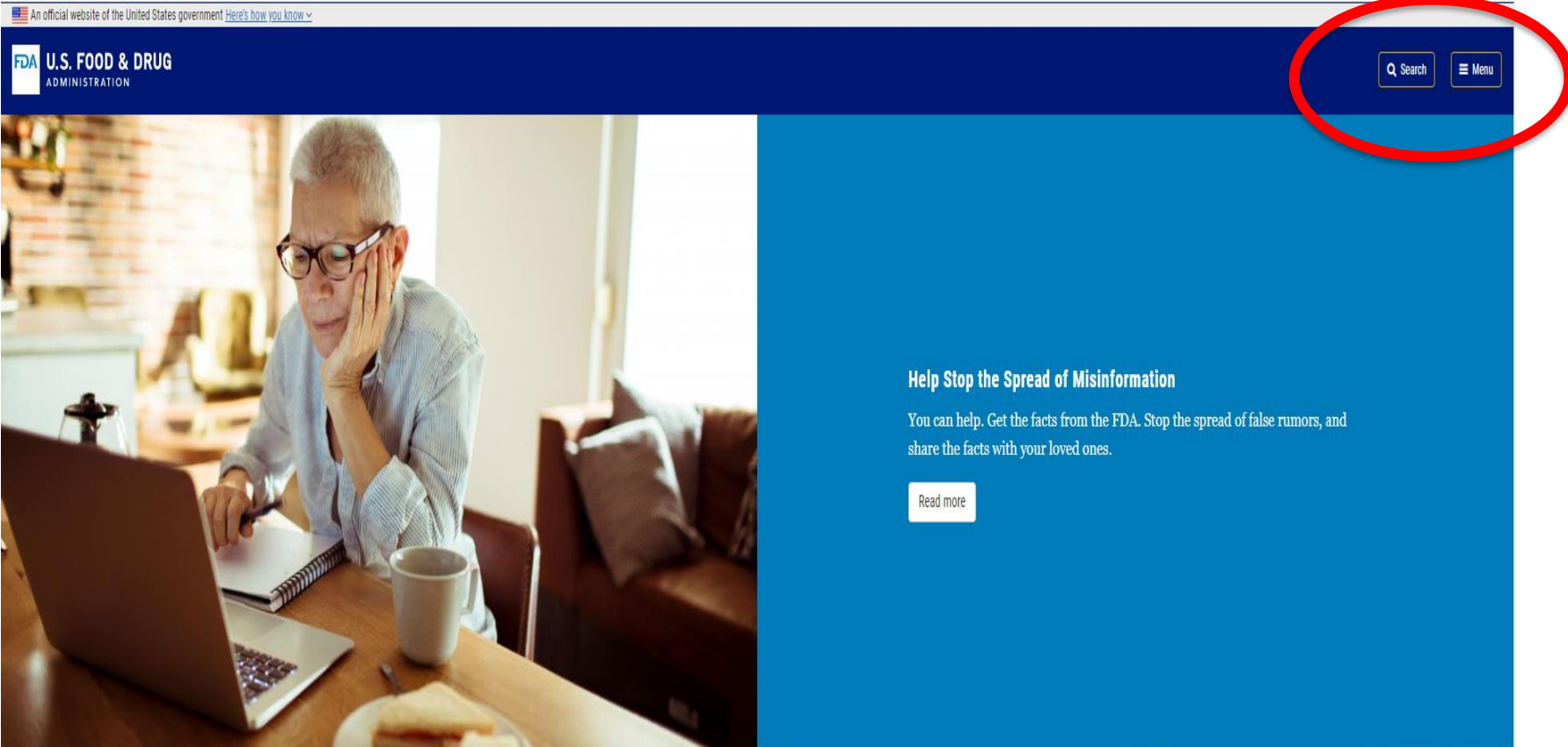
- CPG Sec 555.250 DRAFT: Major Food Allergen Labeling and Cross-contact: [CPG Sec 555.250 DRAFT: Major Food Allergen Labeling and Cross-contact | FDA](#)
- Draft Guidance for Industry: Hazard Analysis and Risk-Based Preventive Controls for Human Food (ch.11): [Draft Guidance for Industry: Hazard Analysis and Risk-Based Preventive Controls for Human Food | FDA](#)

Resources

- **A Food Labeling Guide** (<https://www.fda.gov/regulatory-information/search-fda-guidance-documents/guidance-industry-food-labeling-guide>)
 - (Chapter 7 about Nutrition Labeling is currently under revision and does not reflect all of the most up-to-date labeling requirements. Until the guide is updated, please refer the next link.)
- **Changes to the Nutrition Facts Label**
(<https://www.fda.gov/food/food-labeling-nutrition/industry-resources-changes-nutrition-facts-label>)
- **Label Claims**
(<https://www.fda.gov/food/food-labeling-nutrition/label-claims-conventional-foods-and-dietary-supplements>)
- **Allergen Labeling**
(<http://www.fda.gov/Food/IngredientsPackagingLabeling/FoodAllergens/default.htm>)
- **Code of Federal Regulations – Part 101**
(<https://www.ecfr.gov/current/title-21/chapter-I/subchapter-B/part-101?toc=1>)

Website

- www.fda.gov
- Use the search feature, “food labeling guide,” “food industry resources” or “nutrition” or,
- www.fda.gov/food/food-labeling-nutrition



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FDA U.S. FOOD & DRUG ADMINISTRATION

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You can help. Get the facts from the FDA. Stop the spread of false rumors, and share the facts with your loved ones.

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Questions

- Food and Cosmetics Information Center (FCIC) (<https://www.fda.gov/food/resources-you-food/industry-and-consumer-assistance-cfsan>)



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The Center for Food Safety and Applied Nutrition, known as CFSAN, provides services to consumers, domestic and foreign industry and other outside groups regarding field programs; agency administrative tasks; scientific analysis and support; and policy, planning and handling of critical issues related to food, dietary supplements, and cosmetics.

To reach us by telephone:
1-888-SAFEFOOD (1-888-723-3366)
10:00 AM - 4:00 PM EST
Closed Thursdays 12:30 PM – 1:30 PM EST

To write us by mail:
U.S. Food and Drug Administration
Center for Food Safety and Applied

Contacting Us About FSMA
The FDA Food Safety Modernization Act (FSMA), the most sweeping reform of our food safety laws in more than 70 years, was signed into law by President Obama on January 4, 2011.
It aims to ensure the U.S. food supply

Content current as of: 03/10/2023

Regulated Product(s)
Cosmetics
Dietary Supplements
Food & Beverages

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Questions?

