Food Labeling Basics

Presented by
California Department of Public Health
Food and Drug Branch (FDB)

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Food Safety

Why?

Overview

Food Safety

Our Common Goal

Overview

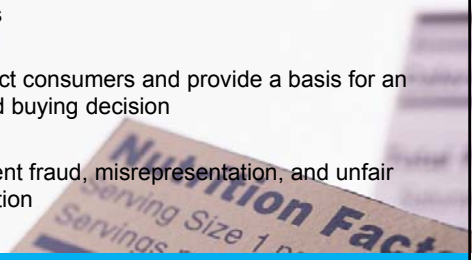
The California Department of Public Health – Food and Drug Branch (FDB) regulates food manufacturing, storage, distribution, and

LABELING

Overview

Purpose -

- To inform consumers about a product and its contents
- To protect consumers and provide a basis for an informed buying decision
- To prevent fraud, misrepresentation, and unfair competition



Overview

Misbranded Food –

- False or misleading in any particular
- Unregistered company
- Non-conformance with applicable laws/regulations (described in Health and Safety Code (H&SC) § 110660 et seq.)

Overview

What We Are Doing Today

* Label Parts
* Claims
* Warning Statements
* Additional Considerations
* Resources

Overview

Not Doing Today

* Copies of laws and regulations
* Dietary Supplements and DSHEA
* Acting as consultants

Overview

Food Labeling Laws and Regulations

* Sherman Food, Drug and Cosmetic Law (H&SC §109875 et seq.)
* Title 21, Code of Federal Regulations (CFR), Part 101
* Food, Drug and Cosmetic Act (FD&C)
* Fair Packaging and Labeling Act (FPLA)
* Nutrition Labeling and Education Act (NLEA)
* Food Allergen Labeling and Consumer Protection Act (FALCPA)
* Dietary Supplement Health and Education Act (DSHEA)
* Much more!

Overview

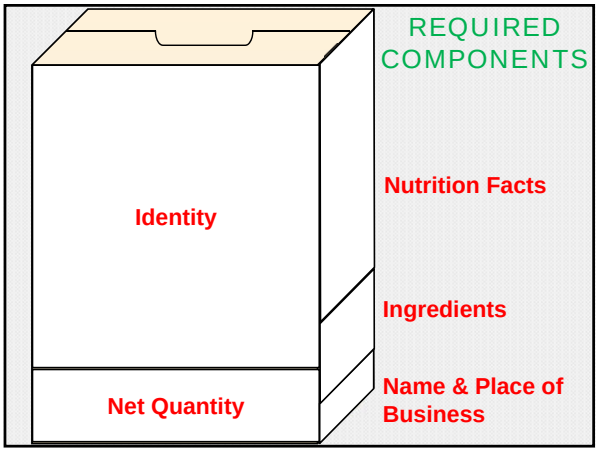
Five Required Components of Food Labels

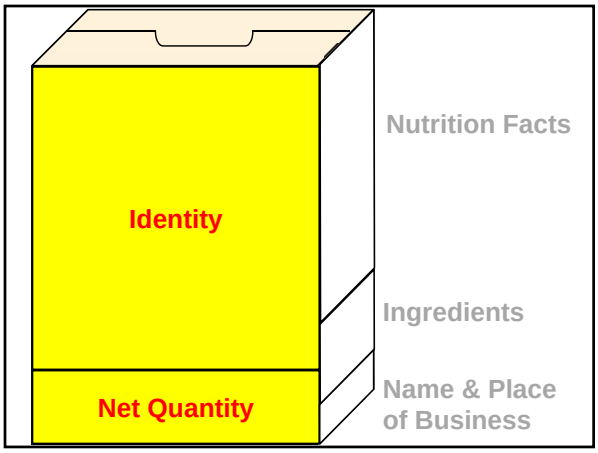
Principle Display Panel (PDP)

1. Identity
2. Net Quantity

Information Panel (IP)

3. Name and Place of Business
4. Ingredients
5. Nutrition Facts



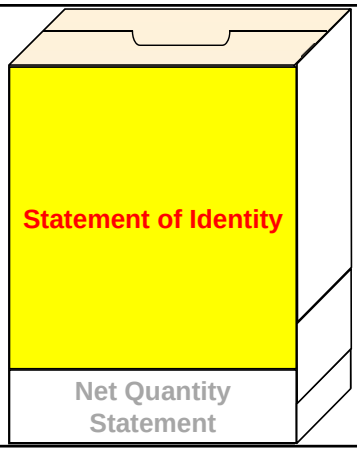


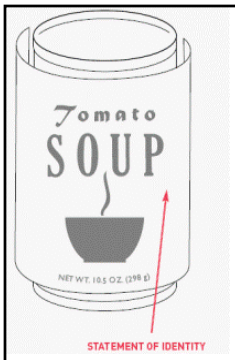
Principle Display Panel (PDP)

The part of a label that is most likely to be displayed under customary conditions of display for retail sale

21 CFR 101.1

PDP Definition





Must be one of the following:

* Name specified in any applicable federal law
* The common or usual name of the food
* An appropriately descriptive term, or when nature of the food is obvious, a commonly used fanciful name

21 CFR 101.3(a) & (b)

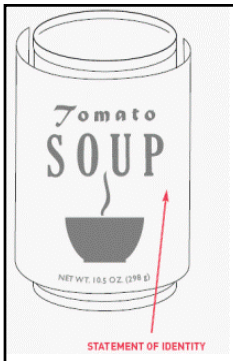
Statement of Identity

Standards of Identity

21 CFR, Parts 130-169 establish Standards of Identity for naming many foods. ***Some*** examples:

Milk and cream, yogurt 131, Cheese 133, Frozen desserts 135, Breads 136, Cereals and Flours 137, Noodles 139, Canned fruits 145, Canned fruit juices 146, Fruit butters, jellies, preserves 150, Fruit pies 152, Canned vegetables 155, Vegetable juices 156, Frozen vegetables 158, Eggs and egg products 160, Fish and shellfish 161, Cacao 163, Tree nuts and peanuts 164, Beverages 165, Margarine 166, Sweeteners and table syrups 168, Food dressings and flavorings 169

Statement of Identity



Must be one of the following:

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* An appropriately descriptive term, or when nature of the food is obvious, a commonly used fanciful name

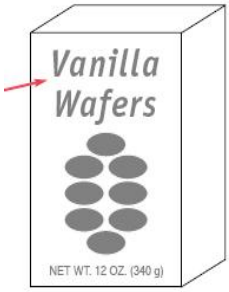
21 CFR 101.3(a) & (b)

Statement of Identity

Identify the fanciful names used with these descriptive phrases.

A. The Original Gourmet Jelly Bean
B. Peanut Butter Cup
C. Chocolate – Caramel – Cookie Bars
D. Milk Chocolate – Coconut & Almond
E. Chewy Caramel – Milk Chocolate – Crispy Crunchies
F. Bursting with Peanuts, Rich Caramel and Chewy Nougat
G. Sour then Sweet – Soft and Chewy Candy

Statement of Identity



The name shall be:

* In bold type
* Parallel to the base of the package
* In a size relative to the most prominent printed matter on the PDP

21 CFR 101.3(d)

Statement of Identity

Labels must declare the particular form (whole, slices, diced, etc.) as part of the statement of identity if the food is sold in different forms.

Exceptions:

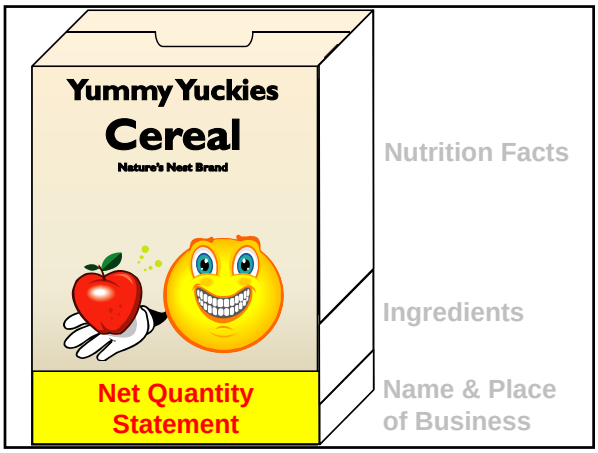
* If the form is visible through the container
* If the form is depicted by an appropriate vignette

Statement of Identity

A food is misbranded if it is an **imitation** of another food and not labeled as such and immediately followed by the name of the food imitated.

21 CFR 101.3(e)

Statement of Identity



State the amount of ***food*** in the container

21 CFR 101.7

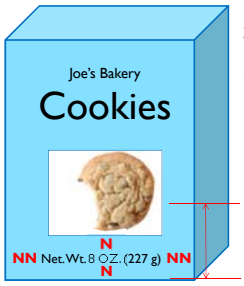
* Solid, semisolid or viscous: state the weight (pounds, ounces, grams, etc.)
* Liquids: state the fluid measure (gallons, fluid ounces, etc.)
* When liquid is usually discarded, a drained weight is the accurate measure, use "Dr. Wt." or "Net Dr. Wt."
* Sometimes a numeric count is acceptable

Net Quantity Statement

Must be in easily legible boldface print or type and in distinct contrast to other information on the package.

21 CFR 101.7 (h)

Net Quantity Statement



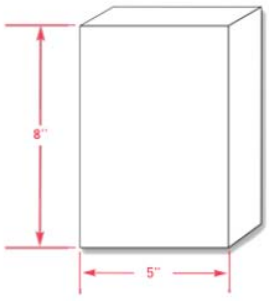
It must be located at the bottom 30% of PDP 21 CFR 101.7 (f)

Margins:

* Separated from information above and below by the height of a capital letter "N"
* Separated from information to the left and right by twice the width of a capital letter "N"

Net Quantity Statement

Net Quantity Statement



Area of Principle Display Panel (PDP)

Is the area of the side or surface that bears the principle display panel

21 CFR 101.1

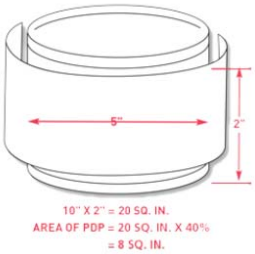
Net Quantity Statement

Area of Principle Display Panel

For cylindrical containers, or near cylinders, the formula is:

40% X Height X Circumference

21 CFR 101.1



Net Quantity Statement

Minimum Type Size

Based on area of PDP. 21 CFR 101.7 (h) and (i)

* If upper and lower case letters are used, the lower case "o" must meet the minimum type size
* If only capital letters are used, the upper case "O" must meet the minimum type size

Area of PDP	Minimum Type Size
5 sq. in. or less	1/16 in.
More than 5 sq. in. but not more than 25 sq. in.	1/8 in.
More than 25 sq. in. but not more than 100 sq. in.	3/16 in.
More than 100 sq. in. but not more than 400 sq. in.	1/4 in.
Over 400 sq. in.	1/2 in.

Net Quantity Statement

Dual Declaration of Net Contents

15 U.S.C. § 1453(a)(2)

Use the most appropriate units of <u>both</u> the customary (U. S.) system of measure and the metric system.

Net Quantity Statement

Dual Declaration of Net Contents

	Customary	Metric
Weight	Pounds (lbs) Ounces (oz)	Kilograms (kg) Grams (g)
Volume	Gallons (gal) Quarts (qt) Pints (pt) Fluid Ounces (fl oz)	Liters (L) Milliliters (mL)

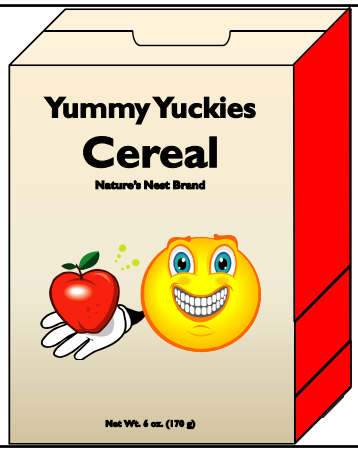
Net Quantity Statement

The Net Quantity Statement must not be deceptive 21 CFR 101.7 (o)

NO: Net Wt. = 2 LARGE oz. (56.8 g)
NO: Net Wt. = 2 BIG oz. (56.8 g)
NO: Net Wt. = 2 generous oz. (56.8 g)
YES: Net Wt. = 2 oz. (56.8 g)

Net Quantity Statement

Information Panel

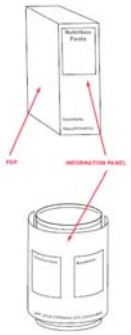


INFORMATION PANEL:

Nutrition Facts

Ingredients

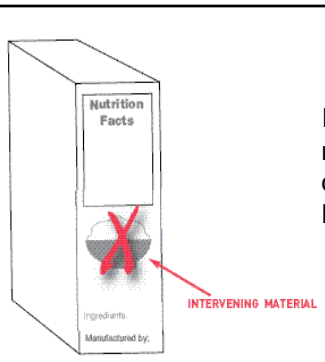
Name & Place of Business



Information Panel (IP) is the panel to the right of the PDP.
21 CFR 101.2(a)

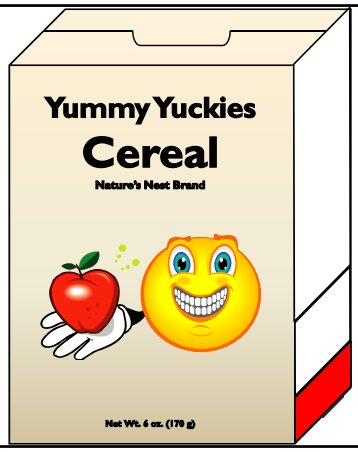
* If not usable, then the IP is the next panel to the right
  * If the package has an alternate PDP, the IP is to the right of any PDP
  * If the top of the container is the PDP, the IP is any panel adjacent to the PDP

Information Panel



No intervening material allowed on the Information Panel 21 CFR, 101.2(e)

Information Panel



Nutrition Facts

Ingredients

Name & Place of Business

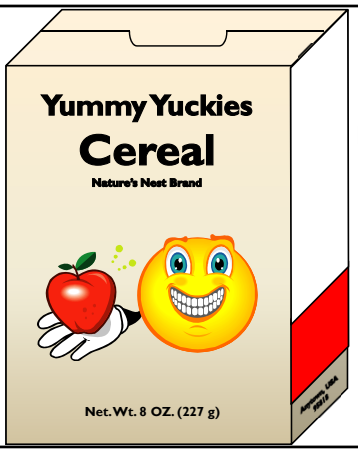
Responsibility Statement

21 CFR 101.5

Indicate the name of the responsible party, street address, city, state, and ZIP.

- May omit street address if in ***local*** directory.
- Qualifying language
  - "Manufactured for ___"
  - "Distributed by ___."

Name and Place of Business



Nutrition Facts

Ingredients

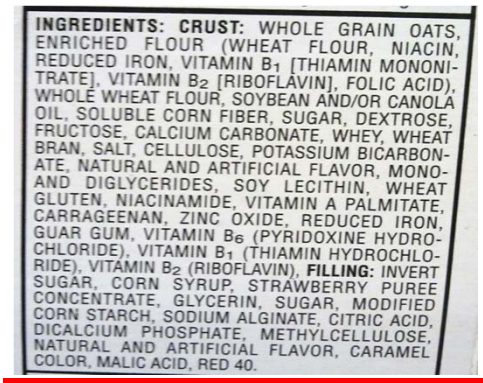
Name & Place of Business

Prominent and Easy to Read

21 CFR 101.4(a); 101.2 (c)

- List ingredients by common name
- Descending order of predominance
- Minimum 1/16 inch type size (based on lowercase "o")

Ingredients List



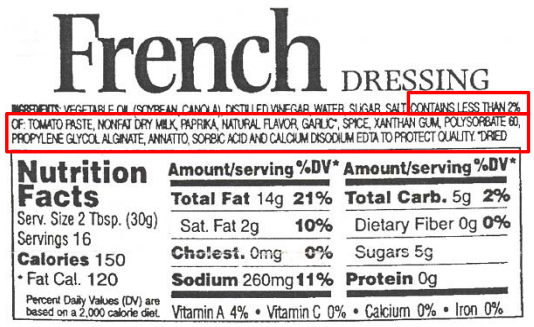
INGREDIENTS: CRUST: WHOLE GRAIN OATS, ENRICHED FLOUR (WHEAT FLOUR, NIACIN, REDUCED IRON, VITAMIN B_1 [THIAMIN MONONITRATE], VITAMIN B_2 [RIBOFLAVIN], FOLIC ACID), WHOLE WHEAT FLOUR, SOYBEAN AND/OR CANOLA OIL, SOLUBLE CORN FIBER, SUGAR, DEXTROSE, FRUCTOSE, CALCIUM CARBONATE, WHEY, WHEAT BRAN, SALT, CELLULOSE, POTASSIUM BICARBONATE, NATURAL AND ARTIFICIAL FLAVOR, MONO- AND DIGLYCERIDES, SOY LECITHIN, WHEAT GLUTEN, NIACINAMIDE, VITAMIN A PALMITATE, CARRAGEENAN, ZINC OXIDE, REDUCED IRON, GUAR GUM, VITAMIN B_6 (PYRIDOXINE HYDROCHLORIDE), VITAMIN B_1 (THIAMIN HYDROCHLORIDE), VITAMIN B_2 (RIBOFLAVIN), **FILLING:** INVERT SUGAR, CORN SYRUP, STRAWBERRY PUREE CONCENTRATE, GLYCERIN, SUGAR, MODIFIED CORN STARCH, SODIUM ALGINATE, CITRIC ACID, DICALCIUM PHOSPHATE, METHYLCELLULOSE, NATURAL AND ARTIFICIAL FLAVOR, CARAMEL COLOR, MALIC ACID, RED 40.

Ingredients List

"Contains 2% or less of _____"

21 CFR, 101.4(a)(2)

Ingredients List


French DRESSING

INGREDIENTS: VEGETABLE OIL (SOYBEAN, CANOLA), DISTILLED VINEGAR, WATER, SUGAR, SALT, CONTAINS LESS THAN 2% OF: TOMATO PASTE, NONFAT DRY MILK, PAPRIKA, NATURAL FLAVOR, GARLIC*, SPICE, XANTHAN GUM, POLYSORBATE 60, PROPYLENE GLYCOL ALGINATE, ANNATTO, SORBIC ACID AND CALCIUM DISODIUM EDTA TO PROTECT QUALITY. *DRIED

Nutrition Facts	Amount/serving	%DV*	Amount/serving	%DV*
Serv. Size 2 Tbsp. (30g)	**Total Fat** 14g	**21%**	**Total Carb.** 5g	**2%**
Servings 16	Sat. Fat 2g	**10%**	Dietary Fiber 0g	**0%**
Calories 150	**Cholest.** 0mg	**0%**	Sugars 5g	
* Fat Cal. 120	**Sodium** 260mg	**11%**	**Protein** 0g	

Percent Daily Values (DV) are based on a 2,000 calorie diet.

Vitamin A 4% • Vitamin C 0% • Calcium 0% • Iron 0%

Ingredients List

List Sub-Ingredients

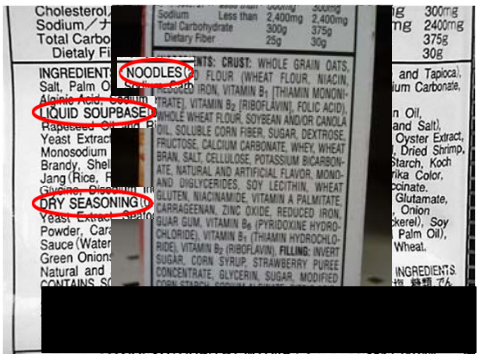
21 CFR 101.4(b)(2)

1. Main Ingredient (sub-ingredients)
   e.g., "Enriched Flour (Wheat Flour, Niacin, Reduced Iron, Thiamin Mononitrate, Riboflavin, Folic Acid),"
   or
2. Report sub-ingredients along with main ingredients by weight-predominance.

Ingredients List

If product has two major components (e.g., turnover and filling), you may list the ingredients for each component separately.

Ingredients List



Ingredients List

Incidental additives that are at *insignificant levels*, and serve no function or technical effect are exempt from labeling requirements. 21 CFR 101.100(a)(3)

* Sulfiting agents <10 ppm 21 CFR 101.100(a)(4)

> NOTE: Food allergens are **NOT** exempt

Ingredients List

Preservatives
21 CFR 101.22(j)

- Listed by common or usual name
- Listed with their function
  - "…to promote color retention"
  - "…to retard spoilage"
  - "…a mold inhibitor"
  - "…to help protect flavor"

Ingredients List

Spices

21 CFR 101.22

Declaration

1. "spice"
2. common or usual name

Exceptions

- "spice and coloring"
- onion, garlic, celery, etc.

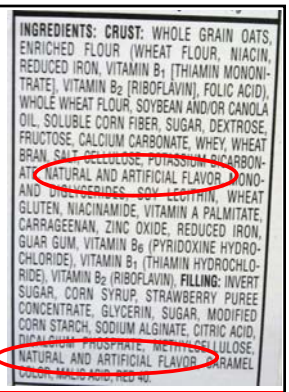
Ingredients List

Flavorings

21 CFR 101.22

May be declared as "natural flavor," "artificial flavor," "natural and artificial flavors."

* If singular natural flavor, say "strawberry flavor."
* If singular artificial flavor, say "artificial banana flavor."



Ingredients List

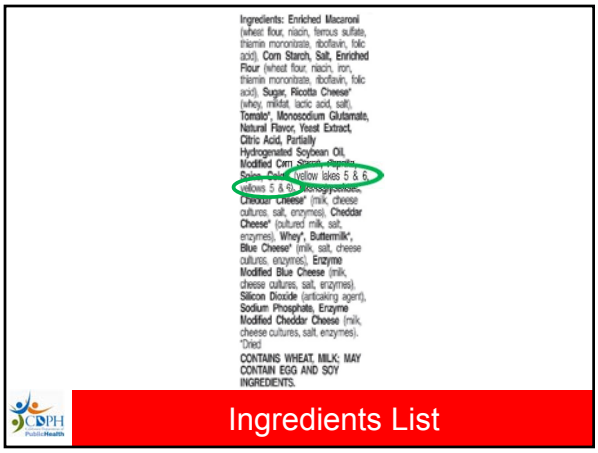
Colorings

Declare in two ways 21 CFR, ***PARTS*** 74 and 82
http://www.gpo.gov/fdsys/pkg/CFR-2001-title21-vol1/content-detail.html

1. Certified colors: list by specific or abbreviated color name and number (e.g., "FD&C Red No. 40" or "Red 40")

Certified color additives and their *lakes* are separate ingredients. They must be declared separately (e.g., **Blue 1 Lake**). 21 CFR 101.22(k)(1)

Ingredients List



Colorings

2. Non-Certified Colors: list by specific names (e.g., "caramel coloring," or collectively "artificial color," or "artificial coloring").

Example: Carmine or Cochineal Extract must be specifically listed.

Ingredients List

Fats, Oils, and Blends

21 CFR 101.4(b)(14)

* Declared by common or usual name (e.g., "cottonseed oil")

* Fat/oil blends: "Vegetable oil (Partially Hydrogenated Palm Kernel Oil, Canola Oil)"

* Hydrogenated oils must be declared accordingly
  - "Hydrogenated"
  - "Partially Hydrogenated"

Ingredients List

Hydrogenation

Common or usual name

INGREDIENTS: ENRICHED FLOUR (WHEAT FLOUR, NIACIN, REDUCED IRON, THIAMIN MONONITRATE [VITAMIN B1], RIBOFLAVIN [VITAMIN B2], FOLIC ACID), SUGAR, VEGETABLE OIL (PARTIALLY HYDROGENATED PALM KERNEL AND/OR COTTONSEED OIL, SOYBEAN AND PALM OIL), COCOA, CARAMEL COLOR, CONTAINS TWO PERCENT OR LESS OF COCOA PROCESSED WITH ALKALI, INVERT SUGAR, WHEY, LEAVENING (BAKING SODA, MONOCALCIUM PHOSPHATE), CORNSTARCH, SALT, SOY LECITHIN, NATURAL AND ARTIFICIAL FLAVOR, OIL OF PEPPERMINT.

CONTAINS WHEAT, MILK AND SOY INGREDIENTS.

Ingredients List

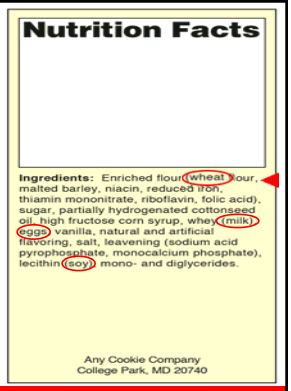
Eight Major Allergens

- Peanuts
- Fish
- Milk
- Eggs
- Wheat
- Soy
- Crustacean Shellfish
- Tree Nuts

Ingredients List

Two ways to declare Major Allergens:

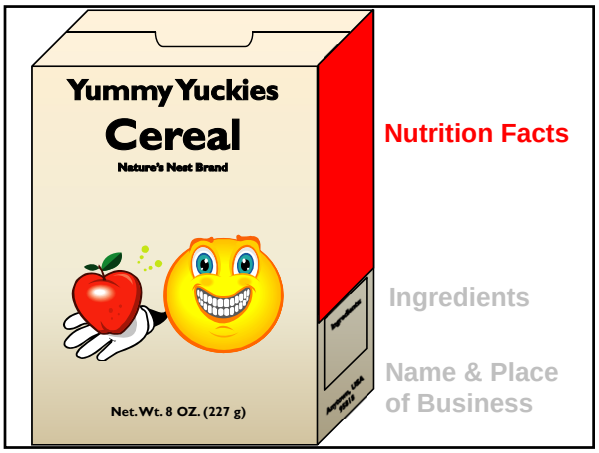
1. Within the Ingredients Statement:



Ingredients List

2. Immediately after Ingredients with a "**Contains**" Statement:

Ingredients List



Nutrition Facts shall be provided for all products intended for human consumption and offered for sale 21 CFR 101.9

* If *packaged*, use the specified label format

* If *not packaged*, make information available at the point of purchase
(e.g., use a sign or card on the counter)

* Even when exempted per 21 CFR 101.9(j), there could still be special labeling required

Nutrition Facts

Summary of Exemptions (21 CFR 101.9)

- Manufactured by small businesses
- Food served in restaurants for immediate consumption
- Bulk food shipped for further processing/packaging
- Foods that provide no significant nutrition such as instant coffee
- Dietary supplements
- Medical foods

Nutrition Facts

Point of Purchase Labeling 21 CFR 101.9(a)(2)

Nutrition Facts

GENERAL REQUIREMENTS:

- **Serving Size:** Based on reference amount customarily consumed (RACC). Use a common household measure 21 CFR 101.12
- **Servings per container**

Nutrition Facts

GENERAL REQUIREMENTS:

- **Total Calories**
- ~~**Calories from Fat**~~ Remove before 2018 (2019)
  - **<5 calories/serving – express as 0**
  - **5 - 50 calories/serving – 5 calorie increments**
  - **> 51 calories –10 calorie increments**

Nutrition Facts

REQUIRED

- Total Fat
- Saturated Fat
- Trans Fat

VOLUNTARY

- Polyunsaturated Fat
  - mandatory when monounsaturated fat is declared
- Monounsaturated Fat
  - mandatory when making a claim about fatty acids or cholesterol

Nutrition Facts

REQUIRED

- Cholesterol
- Sodium
  - Round to zero if <5 mg
  - To the nearest 5mg if 5mg to 140mg
  - To the nearest 10mg if more than 140mg

VOLUNTARY

- Potassium
  - Immediately following sodium
  - same rounding requirements as sodium

Nutrition Facts

REQUIRED

- Total Carbohydrate, Dietary Fiber, Sugars
  - If <1g/serving, may use "Contains less than 1 gram"
  - If <0.5 g/serving, may use 0

Nutrition Facts

Protein 21 CFR 101.9(c)(7)

- List to the nearest gram (g).
  - If less than 0.5g, may declare as 0.
  - If greater than 0.5 g and less than 1 g, may state "Contains less than 1 gram"

Nutrition Facts

REQUIRED 21 CFR 101.9(c)(8)

Vitamins and Minerals

- **Vitamin D**
- **Calcium**
- **Iron**
- **Potassium**
- **Others listed (24) if included as a nutrient supplement or if a claim is made about them.**

Nutrition Facts

REQUIRED 21 CFR 101.9(c)(8)

Vitamins and Minerals

- As a % of the Recommended Daily Intake (RDI) and expressed as a % of DV.
  - To nearest 2% if ≤10% of RDI
  - To nearest 5% if between 10% and 50%
  - To nearest 10% increment above 50%

Nutrition Facts

Consider hiring a 3rd party consultant or laboratory to verify results. There are also internet-based programs that will help you create a Nutrition Facts Label. Try these search terms:

- Free nutrition label generator
- Ingredients panel generator
- Create nutrition facts application
- Create nutrition facts panel
- Nutrition facts program

Nutrition Facts

Small Packages

- **<40 sq. inches total surface area**

Nutrition Facts

5 servings per container
Serving size 1/6 cup (28g)
Calories per serving 90

Amount/serving	% DV	Amount/serving	% DV
Total Fat 2g	3%	**Total Carb.** 15g	5%
Sat. Fat 1g	5%	Fiber 0g	0%
Trans Fat 0.5g		Total Sugars 14g	
Cholesterol 10mg	3%	Incl. 13g Added Sugars	26%
Sodium 200mg	9%	**Protein** 3g	

Vitamin D 0% • Calcium 6% • Iron 6% • Potassium 10%

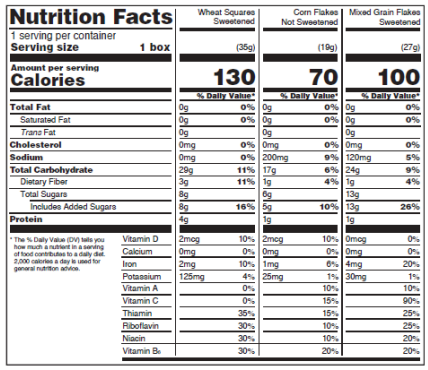
Alternate Formats

Small Packages

- **<40 sq. inches total surface area**

Nutrition Facts Servings: 12, **Serv. size: 1 mint (2g),**
Amount per serving: **Calories 5,** **Total Fat** 0g (0% DV), Sat. Fat 0g (0% DV), *Trans* Fat 0g, **Cholest.** 0mg (0% DV), **Sodium** 0mg (0% DV), **Total Carb.** 2g (1% DV), Fiber 0g (0% DV), Total Sugars 2g (Incl. 2g Added Sugars, 4% DV), **Protein** 0g, Vit. D (0% DV), Calcium (0% DV), Iron (0% DV), Potas. (5% DV).

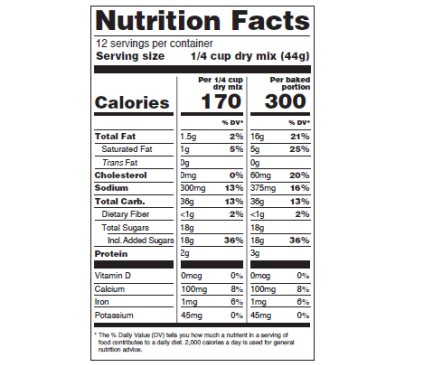
Alternate Formats



Nutrition Facts	Wheat Squares Sweetened	Corn Flakes Not Sweetened	Mixed Grain Flakes Sweetened
1 serving per container			
Serving size	1 box	(35g)	(19g)	(27g)
Amount per serving			
Calories	130	70	100
	% Daily Value*	% Daily Value*	% Daily Value*
Total Fat	0g 0%	0g 0%	0g 0%
Saturated Fat	0g 0%	0g 0%	0g 0%
Trans Fat	0g	0g	0g
Cholesterol	0mg 0%	0mg 0%	0mg 0%
Sodium	0mg 0%	200mg 9%	120mg 5%
Total Carbohydrate	29g 11%	17g 6%	24g 9%
Dietary Fiber	3g 11%	1g 4%	1g 4%
Total Sugars	8g	6g	13g
Includes Added Sugars	8g 16%	5g 10%	13g 26%
Protein	4g	1g	1g
Vitamin D	2mcg 10%	2mcg 10%	0mcg 0%
Calcium	0mg 0%	0mg 0%	0mg 0%
Iron	2mg 10%	1mg 6%	4mg 20%
Potassium	125mg 4%	25mg 1%	30mg 1%
Vitamin A	0%	10%	10%
Vitamin C	0%	15%	90%
Thiamin	35%	15%	25%
Riboflavin	30%	10%	25%
Niacin	30%	10%	20%
Vitamin B_6	30%	20%	20%

* 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.

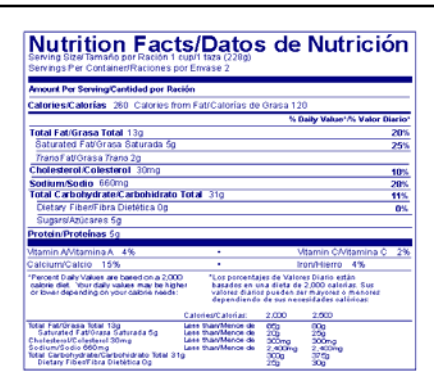
Variety Packs Consumed Individually



Nutrition Facts	Per 1/4 cup dry mix	Per baked portion
12 servings per container		
Serving size	1/4 cup dry mix (44g)	
Calories	170	300
	% DV*	% DV*
Total Fat	1.5g 2%	16g 21%
Saturated Fat	1g 5%	5g 25%
Trans Fat	0g	0g
Cholesterol	0mg 0%	60mg 20%
Sodium	300mg 13%	375mg 16%
Total Carb.	36g 13%	36g 13%
Dietary Fiber	<1g 2%	<1g 2%
Total Sugars	18g	18g
Incl. Added Sugars	18g 36%	18g 36%
Protein	2g	3g
Vitamin D	0mcg 0%	0mcg 0%
Calcium	100mg 8%	100mg 8%
Iron	1mg 6%	1mg 6%
Potassium	45mg 0%	45mg 0%

* 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.

As Packaged/ As Prepared Format



Nutrition Facts/Datos de Nutrición

Serving Size/Tamaño por Ración 1 cup/1 taza (228g)
Servings Per Container/Raciones por Envase 2

Amount Per Serving/Cantidad por Ración

Calories/Calorías 260 Calories from Fat/Calorías de Grasa 120

	% Daily Value*/% Valor Diario*
Total Fat/Grasa Total 13g	20%
Saturated Fat/Grasa Saturada 5g	25%
Trans Fat/Grasa *Trans* 2g	
Cholesterol/Colesterol 30mg	10%
Sodium/Sodio 660mg	28%
Total Carbohydrate/Carbohidrato Total 31g	11%
Dietary Fiber/Fibra Dietética 0g	0%
Sugars/Azúcares 5g	
Protein/Proteínas 5g	

Vitamin A/Vitamina A 4% • Vitamin C/Vitamina C 2%
Calcium/Calcio 15% • Iron/Hierro 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:

*Los porcentajes de Valores Diario están basados en una dieta de 2,000 calorías. Sus valores diarios pueden ser mayores o menores dependiendo de sus necesidades calóricas:

	Calories/Calorías:	2,000	2,500
Total Fat/Grasa Total 13g	Less than/Menos de	60g	80g
Saturated Fat/Grasa Saturada 5g	Less than/Menos de	20g	25g
Cholesterol/Colesterol 30mg	Less than/Menos de	300mg	300mg
Sodium/Sodio 660mg	Less than/Menos de	2,400mg	2,400mg
Total Carbohydrate/Carbohidrato Total 31g		300g	375g
Dietary Fiber/Fibra Dietética 0g		25g	30g

Bilingual Format

Changes to the Nutrition Facts Label

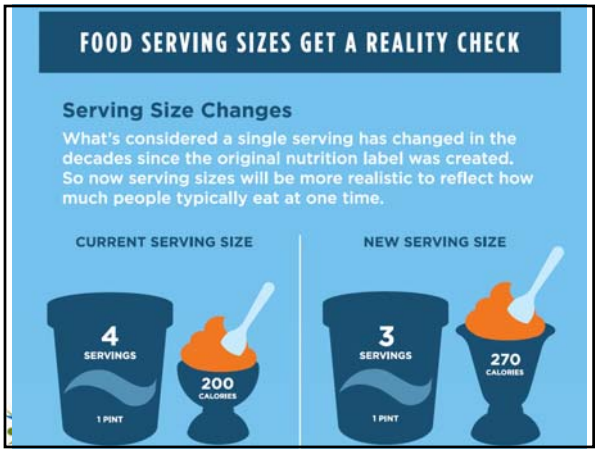
Compliance Dates

7/26/2018

7/26/2019

(for small businesses – those with less than $10 million dollars of annual food sales)

- Serving Size
- Calories
- Fats
- Added Sugars
- Micronutrients
- New Footnote



Nutrition Facts

2 servings per container

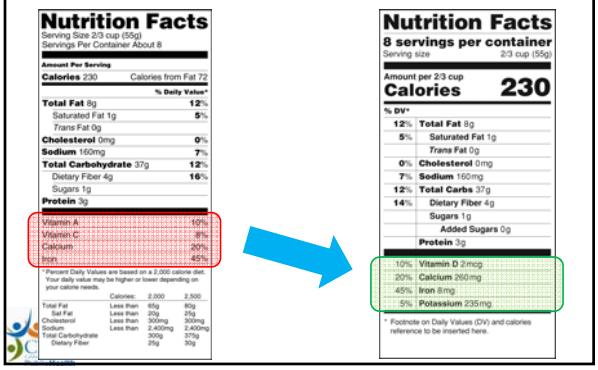
Serving size **1 cup (255g)**

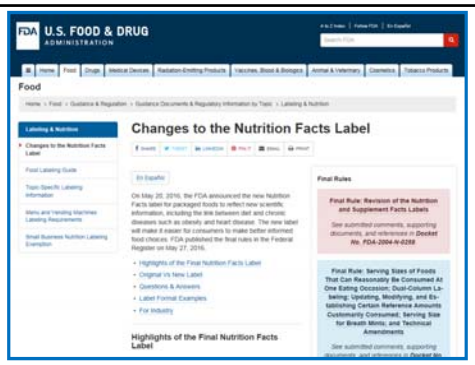
	Per serving		Per container	
Calories	**220**		**440**	
		% DV*		% DV*
Total Fat	5g	**6%**	10g	**13%**
Saturated Fat	2g	**10%**	4g	**20%**
Trans Fat	0g		0g	
Cholesterol	15mg	**5%**	30mg	**10%**
Sodium	240mg	**10%**	480mg	**21%**
Total Carb.	35g	**13%**	70g	**25%**
Dietary Fiber	6g	**21%**	12g	**43%**
Total Sugars	7g		14g	
Incl. Added Sugars	4g	**8%**	8g	**16%**
Protein	9g		18g	
Vitamin D	5mcg	25%	10mcg	50%
Calcium	200mg	15%	400mg	30%
Iron	1mg	6%	2mg	10%
Potassium	470mg	10%	940mg	20%

* 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.

Dual Column Display

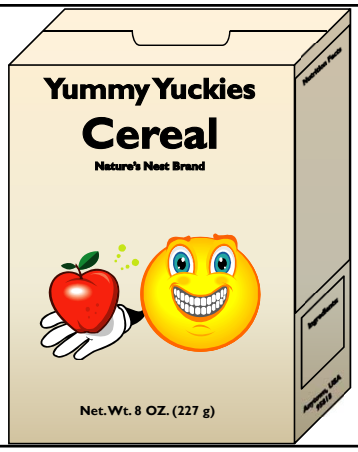
Micronutrients





www.FDA.gov

Search for "*Changes to the Nutrition Facts Label*"



2 ways to format the PDP:

21 CFR 101.2(b)

1. Combine **all** required statements, including the PDP and Information Panel statements, on the PDP

OR

2. Place only **statement of identity** + **net quantity statement** on the PDP, remainder on the Information Panel

Claims

A. Nutrient Content
B. Health
C. Structure/Function
D. Organic
E. Juice
F. Gluten Free

Nutrient Content Claims (NCC)

- Characterize the level of a food nutrient, directly or by implication

21 CFR 101.13(a) & (b)

* "Low Fat"
* "A Good Source of…"; " High in…"
* "Less"; "Fewer"; "More"
* "Light"
* "Contains…"; "Provides…"

A. Nutrient Content Claims

A claim must **not** be:

- More prominent than the Statement of Identity
- Larger than twice the size of the Statement of Identity

21 CFR 101.13(f)

A. Nutrient Content Claims

When a Nutrient Content Claim is made, nutrient levels must meet labeling requirements.

- Per *Reference Amount Customarily Consumed* (RACC) 21 CFR 101.12

OR

- Per the type of food:
  - Meal products 21 CFR 101.13(l)
  - Main dishes 21 CFR 101.13(m)

A. Nutrient Content Claims

RACC and Serving Size

- RACC 21 CFR 101.12
  - based on survey data (1987)
  - Table 1 (infants/toddlers up to 4 years old)
  - Table 2 (children 4 years old to adults)
  - used to derive a serving size
- Serving Size
  - Derived from RACC
  - Fractional amount of product in common household measure and grams to the RACC)

A. Nutrient Content Claims

Sample Calculation of Serving Size

Serving Size for a 454 gram, whole pizza.

1. RACC for Pizza from Table 2 in 21 CFR 101.12 (b) (140 grams)
2. Calculate the fraction of the pizza that is closest to the 140 gram RACC (1/3 X 454 = 151 g; 1/4 X 454 = 113 g). Note 151g is closer to 140g
3. The serving size is the pizza fraction closest to the RACC, with its corresponding gram weight (1/3 pizza or 151g)

While the RACC is 140g for all pizzas, the serving size for this pizza is 151g.

A. Nutrient Content Claims

Qualifying nutrient levels for making a claim are in:

Appendices A and B of the FDA's
A Food Labeling Guide

http://www.fda.gov/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/LabelingNutrition/ucm2006828.htm

A. Nutrient Content Claims

Low Fat Chicken Soup!

Requirement 21 CFR 101.62 (b)
- Individual Food
- 3g or less of total fat per RACC

Determination
- 245 g RACC
- Label A – 0 g fat
- Label B – 5 g fat

Label A

Nutrition Facts
Serving Size 1 cup (245g)
Servings Per Container

Amount Per Serving	
Calories 80	Calories from Fat 0
	% Daily Value*
Total Fat 0g	0%
Saturated 0g	0%
Trans Fat 0g	
Cholesterol 5mg	2%
Sodium 105mg	4%
Total Carbohydrate 12g	4%
Dietary Fiber 0g	0%
Sugars 12g	
Protein 8g	

Vitamin A 10% • Vitamin C 0%
Calcium 30% • Iron 0%

Label B

Nutrition Facts
Serving Size 1 cup (244g)
Servings Per Container

Amount Per Serving	
Calories 120	Calories from Fat 45
	% Daily Value*
Total Fat 5g	8%
Saturated 3g	15%
Trans Fat 0g	
Cholesterol 20mg	7%
Sodium 100mg	4%
Total Carbohydrate 11g	4%
Dietary Fiber 0g	0%
Sugars 11g	
Protein 8g	

Vitamin A 10% • Vitamin C 0%
Calcium 30% • Iron 0%

A. Nutrient Content Claims

Low Fat Pizza!

Requirement 21 CFR 101.62 (b)

- Meal/Main Dish
- 3g or less of total fat per 100 g
- <30% calories from fat

Determination

- Label A – meets both
- Label B
  - 3 g of fat
  - 37.5% calories from fat

A. Nutrient Content Claims

Relative Claims 21 CFR, 101.13(j)

For example, "Reduced…" ; "Lite…" etc.

Two ways to display relative claims:

1. The % or fraction relative to a reference food
   - Adjacent to most prominent claim
2. Comparison of amount of nutrient per serving to a reference food
   - Adjacent to claim or on IP

A. Nutrient Content Claims

"A Good Source of Calcium"

* Must contain 10-19% of the DV per RACC

A. Nutrient Content Claims

"Healthy" – Health, Healthful, Healthfully, Healthier… 21 CFR 101.65 (d)(2)

Total Fat
Saturated Fat
Sodium
Cholesterol
Beneficial Nutrients
Fortification 21CFR 104.20

A. Nutrient Content Claims

- Describes relationship between food component and a disease/condition
- Cannot claim to diagnose, cure, mitigate, treat
- Disqualifying nutrient levels

21 CFR 101.14

B. Health

- Typically used for dietary supplements only
- The effects must be derived from the nutritive value of the food.
- Supported by substantial scientific evidence.

21 CFR 101.93

C. Structure/Function (S/F)

- California Organic Products Act (COPA) H&SC 110810 – 110959
- USDA's National Organic Program (NOP) Title 7 CFR Part 205
- Products labeled "Organic" must be certified by accredited 3rd party
  - Certifier's name must be on IP

D. Organic Claims

- "100% Organic": all ingredients are Certified Organic ingredients (COI)
- "Organic": 95% COI
- "Made With Organic": 70-95% COI
- "Made with organic _____"
  - Three or fewer organic items listed in statement
  - May have more identified in ingredient list

D. Organic Claims

Prohibited Organic Claims

"Transitional Organic"
"Organic When Available"
Similar terminology

D. Organic Claims

Juice is the aqueous liquid expressed or extracted from a fruit or vegetable, the purees from the edible portion, or any concentrate of such liquid or puree.
21 CFR 120.1

E. Juices

Beverages that are 100% juice or purport to contain juice

Declare % on the IP, near the top
* "Contains 50 percent Apple Juice"
* "50% Apple Juice"

If less than 1% juice, total percentage shall be declared as
"Less than 1 percent _____ juice" or
"Less than 1 percent juice"

E. Juices

Standardized naming conventions for beverages that contain fruit or vegetable juice.
21 CFR 102.33

- Examples
  - "Cherry Juice **from concentrate**"
  - "**Diluted** grape juice **beverage**"
  - "grape juice **drink**"
- Details and exemptions 21 CFR 101.30

E. Juices

Gluten Free is defined as *either* food that:

* Is inherently gluten free, or
* Has a final gluten concentration <20 ppm

> It is a voluntary claim
> The threshold is required, but testing is not
> Compliance deadline was August 5, 2014

https://www.federalregister.gov/articles/2013/08/05/2013-18813/food-labeling-gluten-free-labeling-of-foods

F. "Gluten Free" Claims

Warning Statements and Required Declarations

A. Federal

1. Self Pressurized Containers 21 CFR 101.17(a), (b)
2. Chlorofluorocarbon 21 CFR 101.17(c), 40 CFR Part 82
3. Protein Products 21 CFR 101.17(d)
4. Dietary Supplement (Iron/Iron Salt) 21 CFR 101.17(e)
5. Psyllium Husk 21 CFR 101.17(f)
6. Juices 21 CFR 101.17(g)
7. Shell Eggs 21 CFR 101.17(h)

A. Federal

B. California

1. Potentially Hazardous Foods (H&SC 110700)
2. Stimulant Laxatives (17 CCR 10750)
3. Custard and Cream Fillings (17 CCR 12001)
4. Apricot Kernels (17 CCR 10786)
5. Raw Oysters (17 CCR 13675)

B. California

"Potentially hazardous food" means any food capable of supporting growth of infectious or toxigenic micro-organisms when held at temperatures above 45 degrees Fahrenheit." H&SC 110005

Potentially Hazardous Foods

Potentially hazardous processed foods that are preserved by refrigeration must be conspicuously labeled "Perishable Keep Refrigerated"
H&SC 110700

Potentially Hazardous Foods

Provide warning on label if food contains substance that has a laxative impact

17 CCR § 10750; Table A

"NOTICE: This product contains [name of substance(s) and common name(s) if different]. Read and follow directions carefully. Do not use if you have or develop diarrhea, loose stools, or abdominal pain because [insert common name] may worsen these conditions and be harmful to your health. Consult your physician if you have frequent diarrhea or if you are pregnant, nursing, taking medication, or have a medical condition."

Laxatives

B. California

1. Potentially Hazardous Foods (H&S 110700)
2. Stimulant Laxatives (17 CCR 10750)
3. Custard and Cream Fillings (17 CCR 12001)
4. Apricot Kernels (17 CCR 10786)
5. Raw Oysters (17 CCR 13675)

B. California

Lot Coding System

Best If Used By Date (BIUB)

Date of Production

"Natural"

Additional Considerations

Food Labeling Exercise

Resources

CDPH – Food and Drug Branch

Food Safety Program

- www.cdph.ca.gov/programs/Pages/FDB%20Food%20Safety%20Program.aspx

General Food Labeling

- www.cdph.ca.gov/programs/Documents/fdblabel.pdf

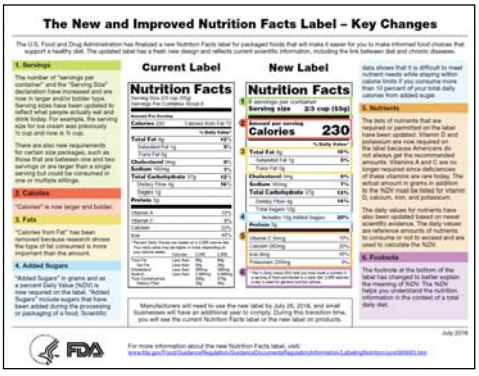
Gluten

- www.cdph.ca.gov/services/Documents/fdbRIgde45.pdf

Resources

Resources

Resources



Resources

Resources

1. **United States Food and Drug Administration (FDA)**
   - *A Food Labeling Guide* (Publication) http://www.fda.gov/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/LabelingNutrition/ucm2006828.htm
   - Proposed Nutrition Facts Label http://www.fda.gov/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/LabelingNutrition/ucm385663.htm
2. **United States Department of Agriculture (USDA)**
   - Nutrient Database for Standard Reference http://ndb.nal.usda.gov/
   - Country of Origin Labeling http://www.ams.usda.gov/AMSv1.0/COOL
3. **Federal Trade Commission – Bureau of Consumer Protection**
   - Complying with the Made In USA Standard http://www.business.ftc.gov/documents/bus03-complying-made-usa-standard

Questions?

Industry Education and Training Unit
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Phone: (916) 650 – 6500