U.S. FOOD & DRUG ADMINISTRATION

Food Labeling

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

FDA/TTB primary labeling jurisdiction

- TTB: Federal Alcohol Administration Act (FAA Act) defines wine, distilled spirits, and malt beverages
- FDA: other beverages containing alcohol, including wines and ciders containing less than 7% alcohol and beer not made with both hops and malted barley

FDA U.S. FOOD & DRUG ADMINISTRATION

Topics Covered

Mandatory

- Statement of Identity
- Net Quantity of Contents
- Name and Place of Business
- Ingredient List
- Nutrition Labeling
- Allergen labeling
- Percentage Juice

Voluntary

- Nutrient Content Claims
- Health Claims
- Fortification Policy
- Alcohol Content Statements
- Geographic Origin
- Gluten-Free

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)
- Total % of juice (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))

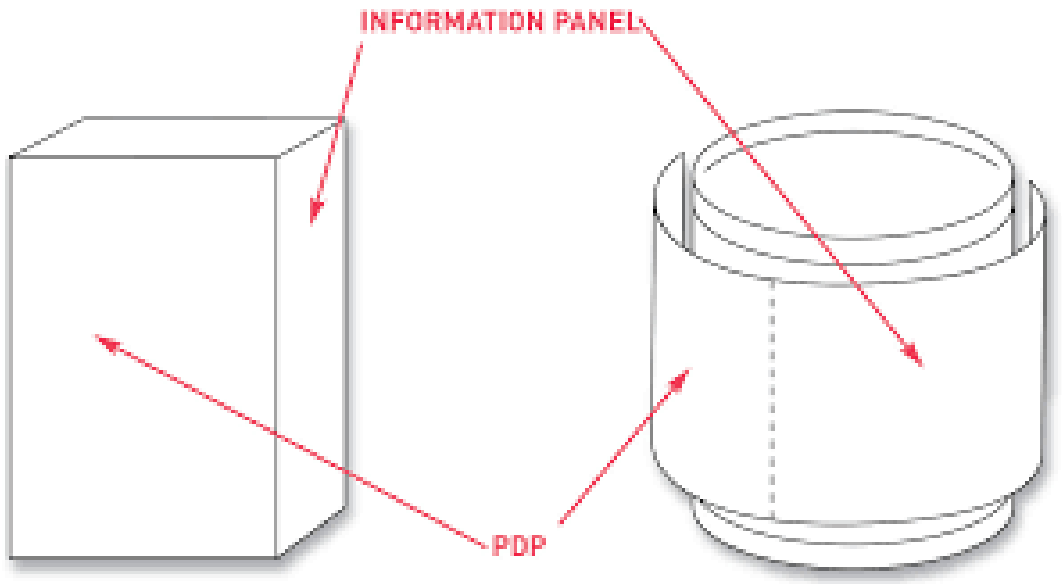
- If the product is promoted as having a characterizing flavor, the flavor should be included in the statement of identity (e.g., Strawberry, artificial strawberry)
  - Natural Flavor (21 CFR 101.22(i)(1))
    - Natural Mango Flavor
    - "Mango Flavored Hard Seltzer" or "Natural Mango Flavored Hard Seltzer"
  - Artificial Flavor (21 CFR 101.22(i)(2))
    - "Artificially Flavored Mango Hard Seltzer"
  - With Other Natural Flavors (21 CFR 101.22(i)(1)(iii))
    - "Natural Mango Flavored Hard Seltzer 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
- Multiunit retail packages- “6-16 oz. bottles-(96 fl oz)”

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)
- % juice (if applicable)

Name and place of Business (21 CFR 101.5)

- Unless actual manufacturer ("distributed by," "manufactured for")
- Address (city, state, zip code)
- Web address is not an acceptable substitute
- Country of Origin Labeling (COOL) required by U.S. Customs and Border Protection

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))
- Minimum type size (1/16 of an inch)

Ingredient Statement (21 CFR 101.4)

- Declare subingredients 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

Declaration of Sulfites

- Added sulfiting agents include sulfur dioxide, sodium sulfite, sodium bisulfite, potassium bisulfite, sodium metabisulfite and potassium metabisulfite (21 CFR 101.100(a)(4))
- Labeling is needed to alert sensitive individuals to the presence of added sulfiting agents
- Sulfites/sulfiting agents are not major food allergens under the Federal Food, Drug, and Cosmetic Act (the Act) and should not be listed in the "Contains" statement.
- If the sulfiting agents are functioning as preservatives, they must also be declared with their function (section 403(k) of the Act and 21 CFR 101.22(j))
- Please as refer to Import Alert 99-21 “Detention Without Physical Examination of Food Products Containing Undeclared Added Sulfiting Agents” accessible at https://www.accessdata.fda.gov/cms_ia/importalert_265.html

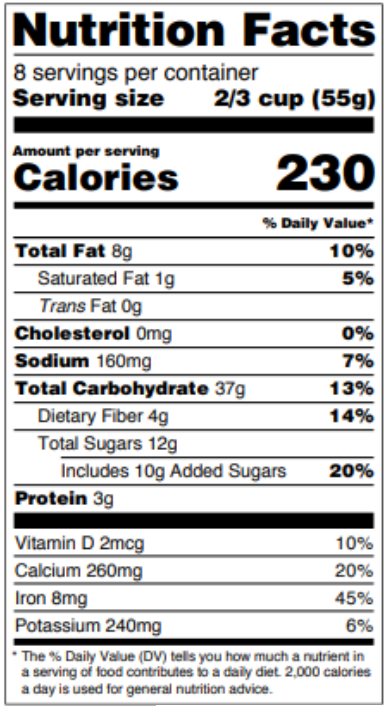
Declaration of Sulfites (cont'd.)

Source (added or natural) of sulfites	Provides a technical or functional effect	Level of Sulfites in Food	Ingredient Declaration
Added sulfiting agent	Provides a technical or functional effect in the food	Any level	Declare the sulfiting agent by the common or usual name of the ingredient, e.g., "sodium sulfite (preservative)"
Added sulfiting agent	Does not provide a technical or functional effect in the food	≥ 10 ppm	Declare the sulfiting agent by the common or usual name of the ingredient, e.g., "sodium sulfite" but, FDA will not object to "sulfiting agents" if the specific ingredient(s) is not known
Added sulfiting agent	Does not provide a technical or functional effect in the food	≤ 10 ppm	Not required
Naturally Occurring	N/A	N/A	Not required

Nutrition Labeling-2016 Key Changes

Nutrition Labeling (21 CFR 101.9)

- Required on most products offered for sale
- Exemptions and special labeling provisions (21 CFR 101.9(j)), e.g., small business, insignificant amount of nutrients (plain tea)
- Claims generally negate exemptions
- Nutrition information is based on Serving Size
- There are several formats that may be used, many beverages qualify for the simplified format if the food is not a significant source of certain nutrients (21 CFR 101.9(f))



Nutrition Facts

8 servings per container

Serving size **2/3 cup (55g)**

Amount per serving

Calories **230**

	% Daily Value*
Total Fat 8g	**10%**
Saturated Fat 1g	**5%**
Trans Fat 0g	
Cholesterol 0mg	**0%**
Sodium 160mg	**7%**
Total Carbohydrate 37g	**13%**
Dietary Fiber 4g	**14%**
Total Sugars 12g	
Includes 10g Added Sugars	**20%**
Protein 3g	
Vitamin D 2mcg	10%
Calcium 260mg	20%
Iron 8mg	45%
Potassium 240mg	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.

Nutrition Facts

64 servings per container

Serving size **1 tbsp (14g)**

Amount per serving

Calories **130**

	% DV*
Total Fat 14g	**18%**
Saturated Fat 2g	**10%**
Trans Fat 2g	
Polyunsaturated Fat 4g	
Monounsaturated Fat 6g	
Sodium 0mg	**0%**
Total Carbohydrate 0g	**0%**
Protein 0g	

Not a significant source of cholesterol, dietary fiber, total sugars, added sugars, vitamin D, calcium, iron, and potassium

* %DV = %Daily Value

Nutrition Labeling for Small Packages

- Our regulations refer to “small packages” as having the total surface area available to bear labeling of less than 12 square inches (21 CFR 101.9(j)(13)(i))

- The term “Intermediate-sized package” refers to a package that has a total surface area available to bear labeling of 40 or less square inches. (21 CFR 101.9(d)(1))

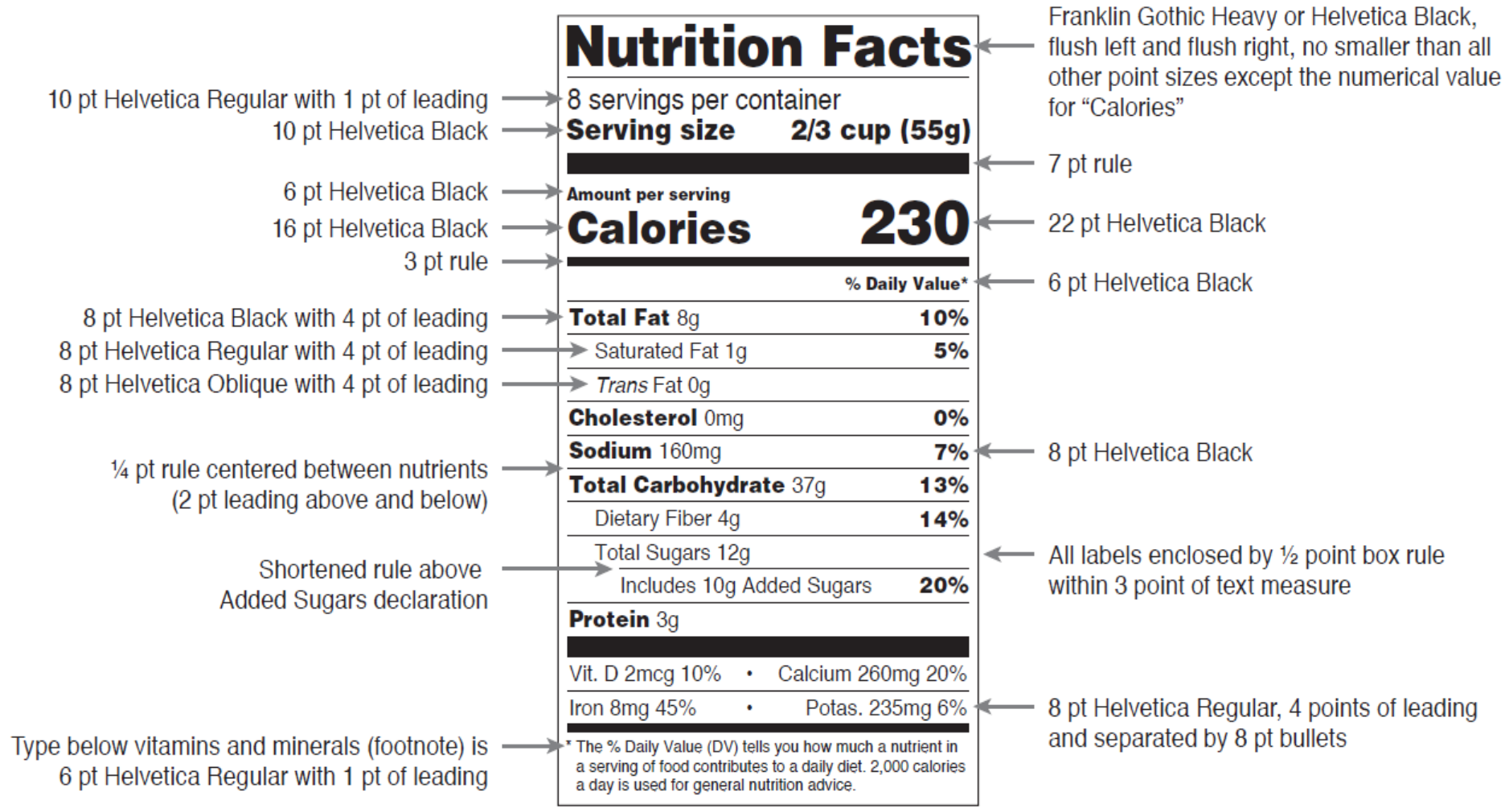
- Generally, there are 3 packages sizes:

- < 12 sq. in. = small

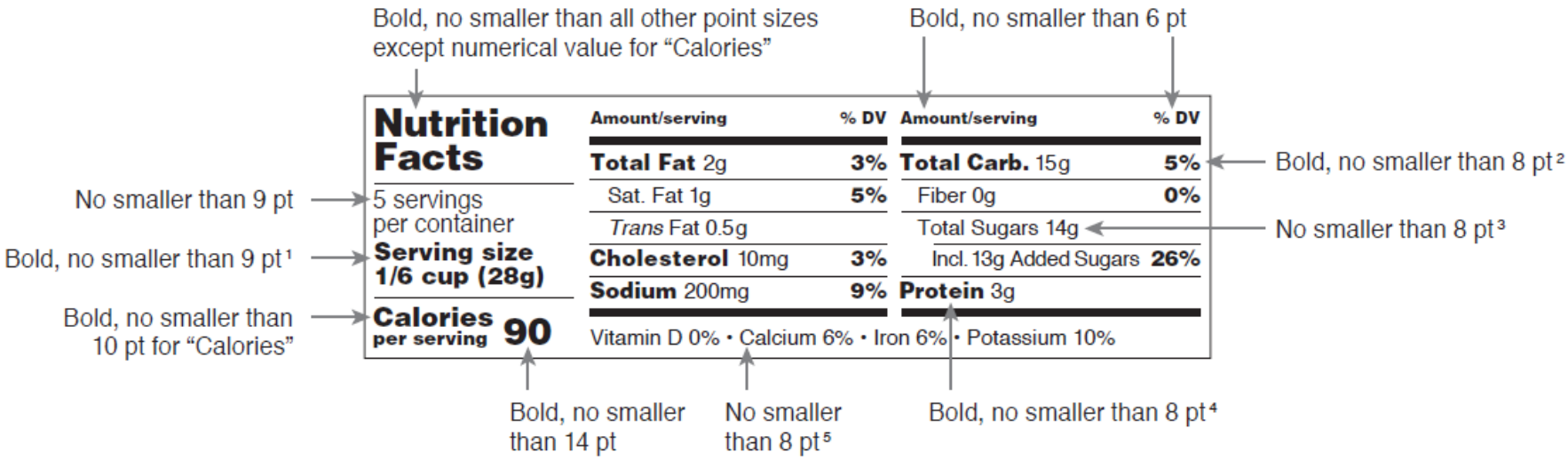
- 12-40 sq. in. = intermediate sized package

- > 40 sq. in. = regular size package

This is an example of a standard vertical display



Tabular Display for Small or Intermediate Size Packages



† Text in bold font is Helvetica Black; text not bolded is Helvetica Regular in all instances

[1] "Serving size" declaration may be decreased to no smaller than 8 pt bold if additional space is needed for the declaration

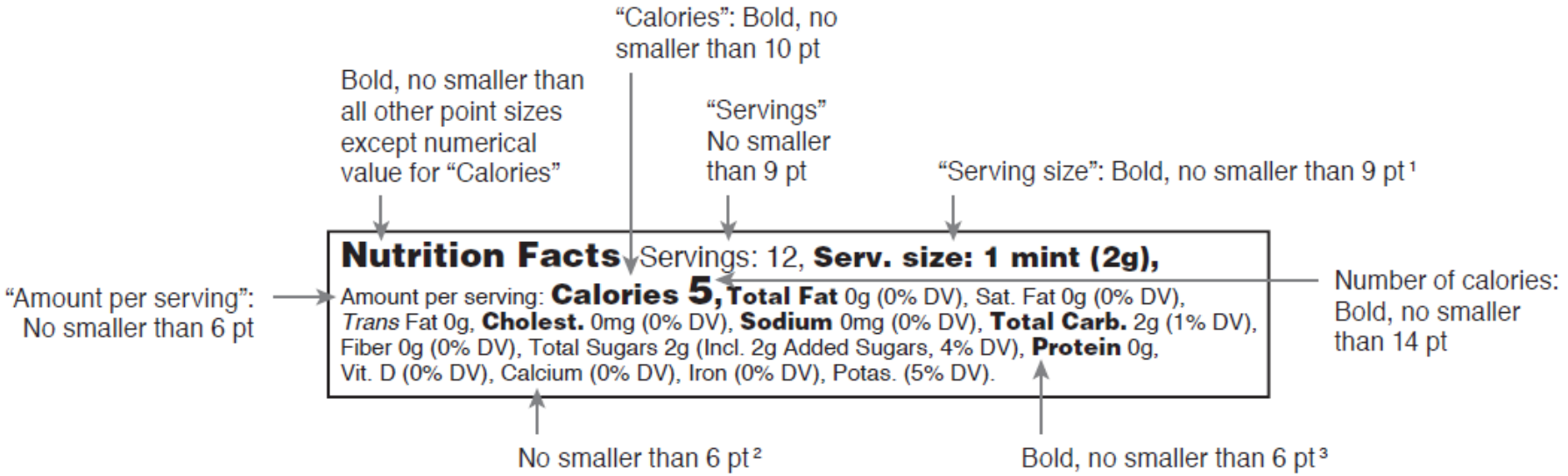
[2] % DV values for nutrients between thick bars: Bold, no smaller than 8 pt

[3] Sat. Fat, *Trans* Fat, Fiber, Total Sugars, Added Sugars, voluntary nutrients (if listed) and all g/mg values: No smaller than 8 pt

[4] Total Fat, Cholesterol, Sodium, Total Carb. and Protein: Bold, no smaller than 8 pt

[5] Vitamin D, Calcium, Iron, Potassium, voluntary nutrients (if listed) and their % DV values: No smaller than 8 pt

Linear Display for Small or Intermediate Size Packages



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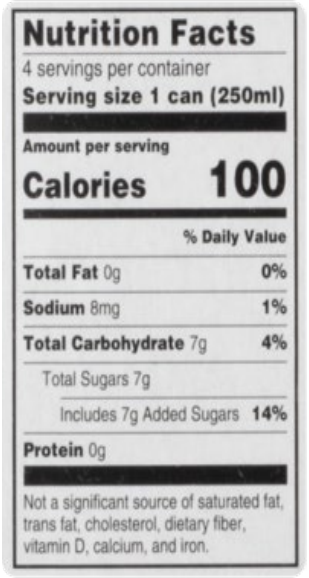
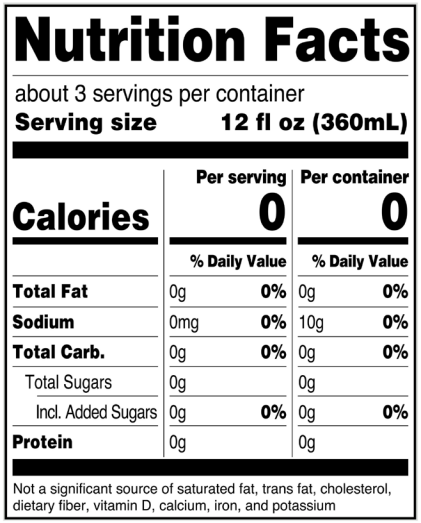
[2] Sat. fat, *Trans* Fat, Fiber, Total Sugars, Added Sugars, Vit. D, Calcium, Iron, Potas., voluntary nutrients (if listed) and all g/mg values and % DV values: No smaller than 6 pt

[3] Total Fat, Cholest., Sodium, Total Carb., Protein: Bold, no smaller than 6 pt

Nutrition Labeling: Serving Size (21 CFR 101.9(b) and 21 CFR 101.12)

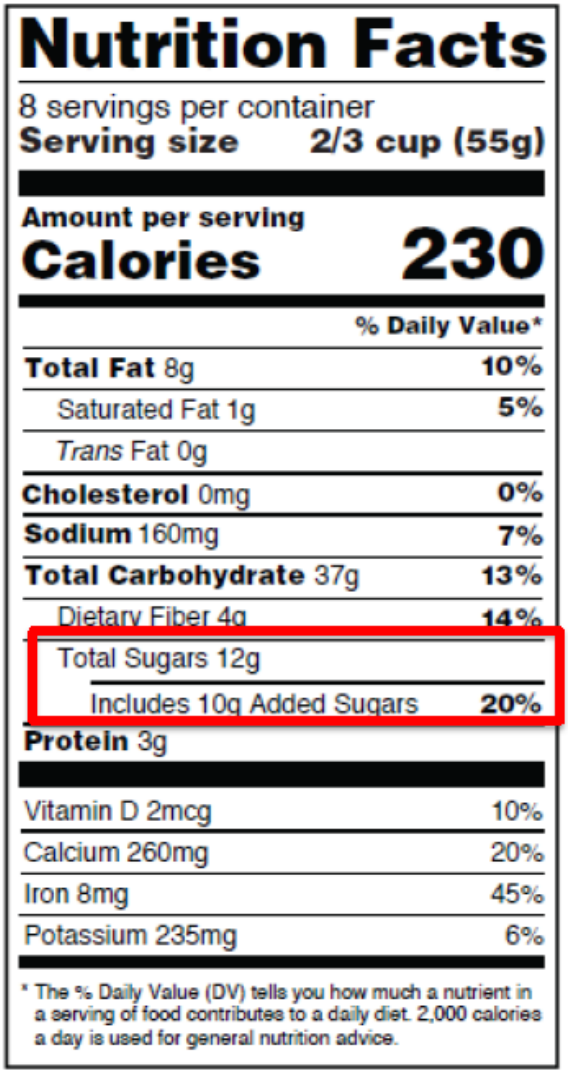
- Serving size is expressed in common household measure, e.g. fluid ounces, or for single serving containers a description of the container, e.g. “1 can”
- Serving size is based on the Reference Amounts Customarily Consumed (RACC) and amount of food in package
- RACC for Beverages, carbonated and noncarbonated beverages, wine coolers, water is 360 mL (21 CFR 101.12)
- Single serving container contains less than 200 percent of the RACC





Added Sugars Is Mandatory

- Defined as sugars that are either added during the processing of foods, or are packaged as such, and include sugars (free, mono- and disaccharides), sugars from syrups and honey, and sugars from concentrated fruit or vegetable juices that are in excess of what would be expected from the same volume of 100 percent fruit or vegetable juice of the same type
- Examples: syrups, brown sugar, HFCS, invert sugar, maltose, trehalose, honey, molasses, sucrose, lactose, concentrated fruit juice



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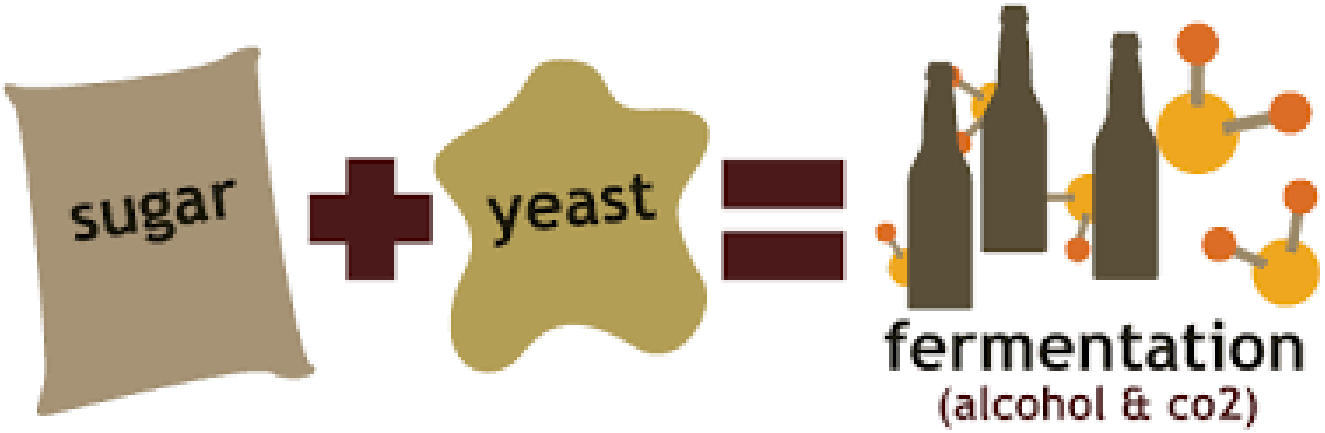
Protein 3g	
Vitamin D 2mcg	10%
Calcium 260mg	20%
Iron 8mg	45%
Potassium 235mg	6%

* The % Daily Value (DV) tells you how much a nutrient in a serving of food contributes to a daily diet. 2,000 calories a day is used for general nutrition advice.

Added Sugars Determination

- Up to manufacturer to determine which ingredients provide added sugars
- If the fermented beverage contains only sugars that meet our definition of added sugars, then the amount of sugars present in a serving after fermentation must be declared as both the total and added sugars.

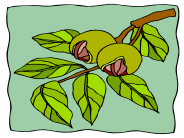


Added Sugars Determination

- If the fermented beverage contains both sugars that do and do not meet our definition of added sugars, you can determine the total sugars analytically. For added sugars:
  - a reasonable approximation of the amount of added sugars in the finished product; or
  - Declare the amount of added sugars added prior to fermentation and make and keep records to verify the amount (21 CFR 101.9(g)); or,
  - If you have no way to determine a reasonable approximation of the amount of added sugars in the finished food, but have reason to believe that a significant reduction of added sugars took place during fermentation, you may submit a petition, under 21 CFR 10.30, to request an alternative means of compliance.
- See “Nutrition and Supplement Facts Labels: Questions and Answers Related to the Compliance Date, Added Sugars, and Declaration of Quantitative Amounts of Vitamins and Minerals: Guidance for Industry”

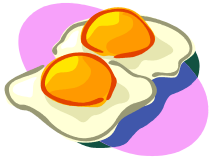
Allergen Labeling

- Section 403(w) of the FD&C Act
- Major food allergens: Sesame (1/1/23), Milk, Egg, Fish, Crustacean Shellfish, Tree Nuts, Wheat, Peanuts, Soybeans



- Requires specific label declarations for major food allergens for all foods regulated by FDA except:
  - raw agricultural commodities (fresh fruits and vegetables)
  - ingredients exempt from the definition of a major food allergen
  - Highly refined oils

- For fish, Crustacean shellfish, and tree nuts, label declaration is satisfied by the name of the food source of the allergen, e.g. “almonds” not “tree nuts”
- No requirement for advisory labeling e.g. “May Contain”



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, partially hydrogenated 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.

Any Cookie Company
College Park, MD 20740

OPTION 2

Cocoa Crispers Bar
Chocolate Candy with Crisped Rice

Nutrition Facts
Serving Size 1 Bar (60g)
Calories 230
Fat Cal. 100
*Percent Daily Values (DV) are based on a 2,000 calorie diet.

Amount/serving	%DV*	Amount/serving	%DV*
Total Fat 12g	**18%**	**Potassium** 230mg	**3%**
Saturated Fat 7g	**36%**	**Total Carb.** 29g	**10%**
Trans Fat 0g		Fiber <1g	**3%**
Cholesterol 10mg	**0%**	Sugars 24g	
Sodium 65mg	**3%**	**Protein** 2g	

Vitamin A 0% • Vitamin C 0% • Calcium 6% • Iron 0%

Ingredients: Milk Chocolate (Sugar, Milk, Cocoa Butter, Chocolate, Vanilla), Corn Syrup, Whey, Cocoa Powder, Crisped Rice (Rice, Sugar, Salt, Malt), Flour, Soy Protein, Ovalbumin, Natural Flavor.

Manufactured by: Sweetz Inc.
101 Main Street, Baltimore, MD 21201

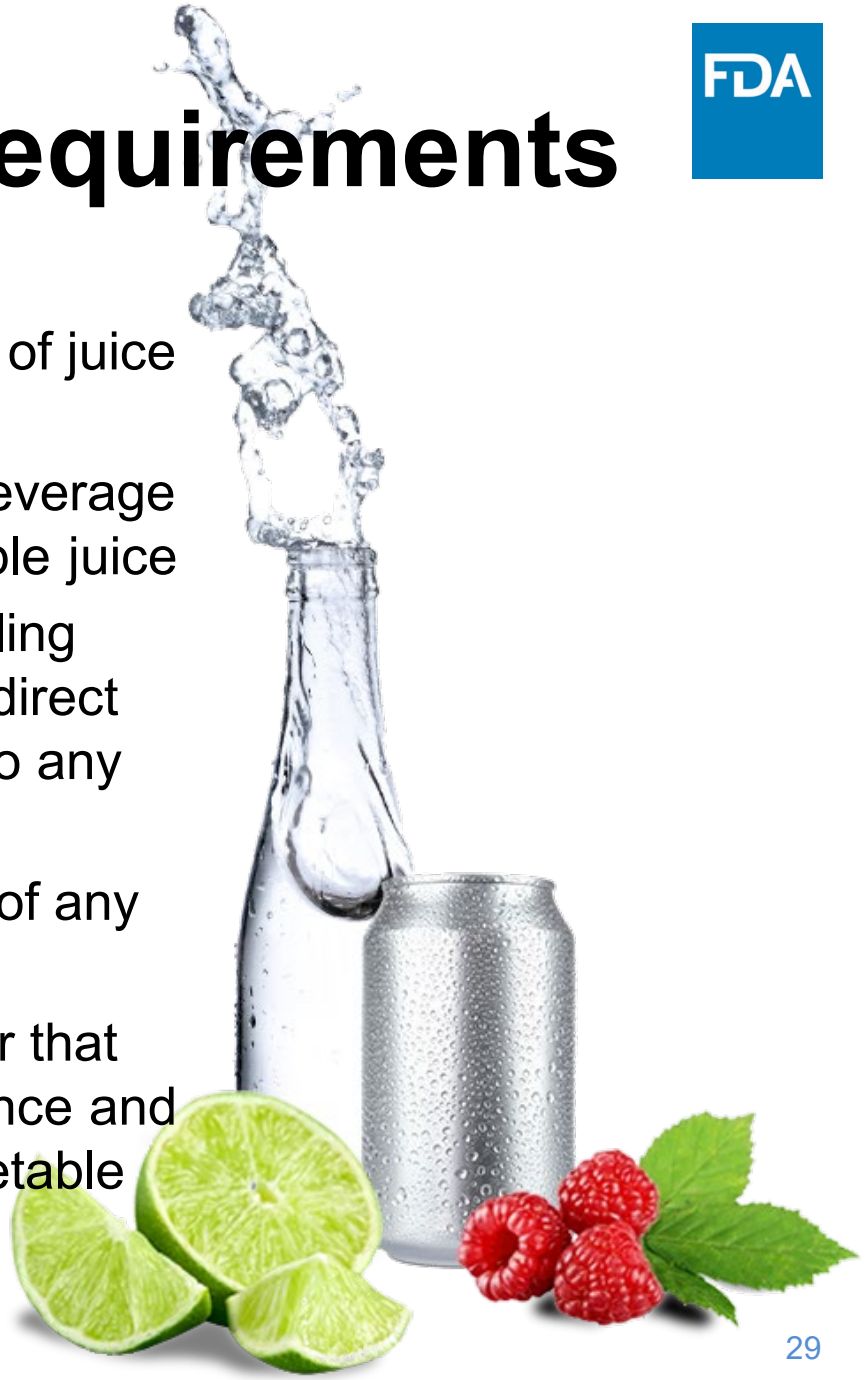
Ingredients: Milk Chocolate (Sugar, Milk, Cocoa Butter, Chocolate, Vanilla), Corn Syrup, Whey, Cocoa Powder, Crisped Rice (Rice, Sugar, Salt, Malt), Wheat Flour, Soy Protein, Ovalbumin (Egg), Natural Peanut Flavor.

OR

Ingredients: Milk Chocolate (Sugar, Milk, Cocoa Butter, Chocolate, Vanilla), Corn Syrup, Whey, Cocoa Powder, Crisped Rice (Rice, Sugar, Salt, Malt), Flour (Wheat), Soy Protein, Ovalbumin (Egg), Natural Flavor (Peanut).

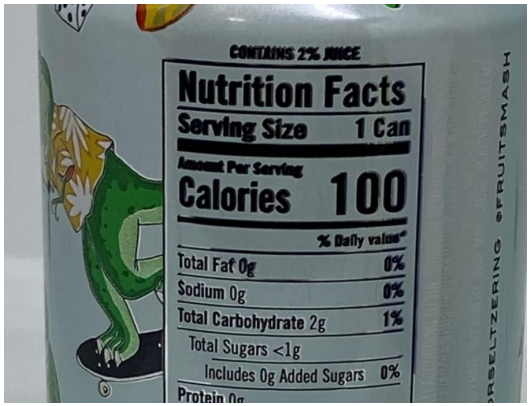
% Juice labeling requirements

- When is a declaration of the total % of juice required? (21 CFR 101.30)
  - Any food that purports to be a beverage that contains any fruit or vegetable juice
    - Advertisement, label or labeling bears name of or indirect or direct representation with respect to any fruit or vegetable juice
  - Label or labeling bears vignette of any fruit or vegetable
  - Product contains color and flavor that gives the beverage the appearance and taste of containing a fruit or vegetable juice



% Juice labeling requirements

- Exemption (21 CFR 101.30(c))
  - ✓ contains minor amounts of juice for flavoring AND
  - ✓ labeled with a flavor description using the terms “flavor,” “flavored,” or “flavoring” AND
  - ✓ does not use the term “juice” on the label other than ingredient list, have no explicit vignette depicting the fruit or vegetable from which the flavor derives and have no specific physical resemblance to juice or distinctive juice characteristic such as pulp
- Fermented juice does not count toward the total % percentage ((21 CFR 101.30(k)/Question A3, Guidance for Industry: Questions and Answers on Juice HACCP Regulation (Sept. 2003))



Nutrient Content Claims

- Defined in 21 CFR 101.13

- Claims about the level of a nutrient

- Types of claims:
  - Expressed ("low fat") or Implied ("high in oat bran")
  - Inherent Claims ("Milk, a product naturally low in sodium")
  - Relative Claims ("Reduced Fat," "Light," "Less")

Nutrient Content Claims

- General Requirements, 21 CFR 101.13
- Specific Requirements, 21 CFR 101.54-101.69, (Subpart D)
- 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 specific claim including nutrient levels
- Generally based on reference amount customarily consumed (RACC) 21 CFR 101.12
- May be other required information
- Example: “Sugar free” (21 CFR 101.60(c)(1))
  - <0.5g sugar per RACC and labeled serving
  - Food contains no ingredient that is a sugar or understood to contain sugars unless ingredient is followed by asterisk that refers to a statement that the ingredient adds a trivial amount of sugar
  - it is labeled “low calorie” or “reduced calorie” or
  - it is labeled as “not a reduced calorie food,” “not a low calorie food,” or “not for weight control”

What is a Health Claim?

- 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 whole grains (three servings or 48 grams per day), as part of a low saturated fat, low cholesterol diet, may reduce the risk of diabetes mellitus type 2."

Fortification Policy (21 CFR 104.20)

- Establish a uniform set of principles that would serve as a model for rational addition of nutrients to foods
- Random fortification could result in over- or under fortification; and deceptive or misleading claims
- Discourages indiscriminate addition of nutrients to food
- Not appropriate to fortify
  - Fresh produce
  - Meat, poultry, or fish products
  - Sugars
  - Snack foods such as candies and carbonated beverages
  - Alcoholic beverages
- Urged to use these principles when adding nutrients to foods
- Some nutrients are limited by food additive or GRAS regulations regarding the foods that may be fortified and to what level to which they may be fortified (e.g., folic acid (21 CFR 172.345) & Vitamin D (21 CFR 172.380, 21 CFR 184.1950))
- Although fortification policy is guidance in most situations, it is mandatory for:
  - Nutrient content claim for “More” 21 CFR 101.54(e)
  - Nutrient content claim for “Healthy” 21 CFR 101.65(d)

Statements about Alcohol Content

- There are no FDA labeling regulations for these statements
- The Federal Food, Drug, and Cosmetic Act requires all labeling to be truthful and not misleading (section 403(a)(1) of the Act)

FDA recommendations (CPG Sec 510.400):

- **"Dealcoholized"/"alcohol removed"**: should appear in SOI preceding the type of wine from which it was derived and be followed by "contains less than 0.5 percent alcohol by volume"; "non-alcoholic" can also used in addition to but not in lieu of these terms
- **"Non-alcoholic":** beverages that contain <0.5% ABV
- **"Alcohol free":** no detectable alcohol

- **% ABV**: voluntary, truthful/not misleading statements permitted under section 403(a)(1), highly recommended to alert consumers to presence of alcohol when they would not expect the food to contain alcohol

- When alcohol is added in the formulation of a food, alcohol must be declared as an ingredient by the common or usual name (21 CFR 101.4)

Statements about Geographic Origin

- Food labeling statements regarding geographical origin must not be false or misleading (section 403(a)(1) of the Act and 21 CFR 101.18)
- Examples of permitted statements:
    1. A truthful representation of geographical origin
    2. A trademark or trade name provided that as applied to the article in question its use is not deceptively misdescriptive because,
        i. Has been so long and exclusively used by a manufacturer or distributor that it is generally understood by the consumer to mean the product of a particular manufacturer or distributor; or
        ii. Is so arbitrary or fanciful that it is not generally understood by the consumer to suggest geographic origin
    3. A part of the name required by applicable Federal law or regulation
    4. A name whose market significance is generally understood by the consumer to connote a particular class, kind, type, or style of food rather than to indicate geographical origin

Gluten-Free Labeling

- Gluten is a protein found in wheat, rye, and barley
- In the US, 3 million people suffer from celiac disease
- Gluten-free food labeling final rule was published in August 2013 (21 CFR 101.91)
- Hydrolyzed & Fermented Foods final rule 2020
  - No scientifically valid method to detect and quantify gluten in these foods
  - Record keeping required
- Qs/As: https://www.fda.gov/food/food-labeling-nutrition/questions-and-answers-gluten-free-food-labeling-final-rule

Resources

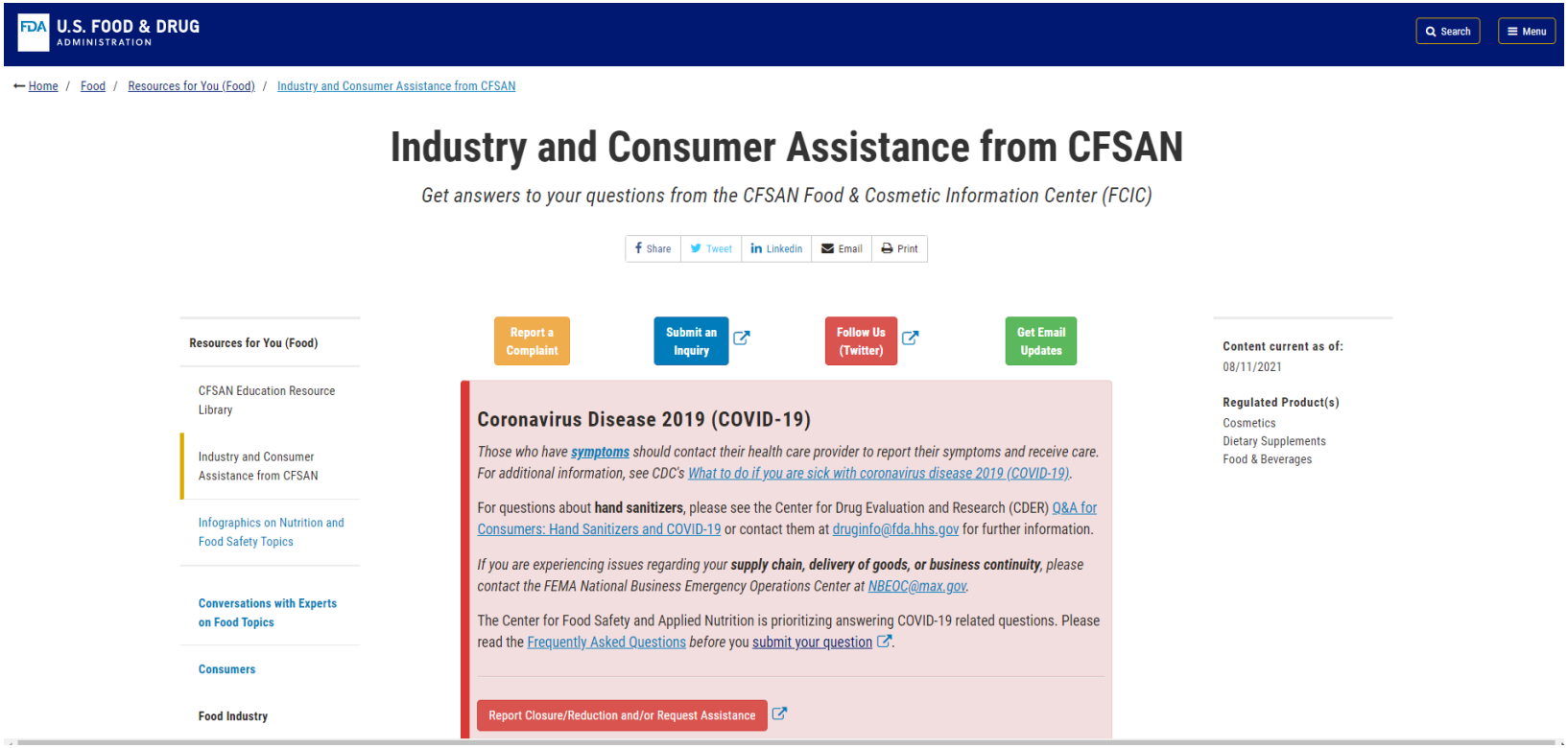
- A Food Labeling Guide (https://www.fda.gov/regulatory-information/search-fda-guidance-documents/guidance-industry-food-labeling-guide)
- Changes to the Nutrition Facts Label (https://www.fda.gov/food/food-labeling-nutrition/industry-resources-changes-nutrition-facts-label)
- CFSAN Education Resource Library (https://www.fda.gov/food/resources-you-food/cfsan-education-resource-library)
- Guidance for Industry: Questions and Answers on FDA's Fortification Policy (https://www.fda.gov/regulatory-information/search-fda-guidance-documents/guidance-industry-questions-and-answers-fdas-fortification-policy)
- Guidance for Industry: Labeling of Certain Beers Subject to the Labeling Jurisdiction of the Food and Drug Administration (https://www.fda.gov/regulatory-information/search-fda-guidance-documents/guidance-industry-labeling-certain-beers-subject-labeling-jurisdiction-food-and-drug-administration)
- CPG Sec 510.400 Dealcoholized Wine and Malt Beverages – Labeling (https://www.fda.gov/regulatory-information/search-fda-guidance-documents/cpg-sec-510400-dealcoholized-wine-and-malt-beverages-labeling)
- CPG Sec 510.450 Labeling - Diluted Wines and Cider with Less Than 7% Alcohol (https://www.fda.gov/regulatory-information/search-fda-guidance-documents/cpg-sec-510450-labeling-diluted-wines-and-cider-less-7-alcohol)

Website

- www.fda.gov
- Use the search feature, “food labeling,” “search guidances,” “food industry resources”

Questions

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



Questions?