PACKAGING COMPLIANCE

FIELD GUIDE

PRO TIPS FOR FOOD ENTREPRENEURS

BROUGHT TO YOU BY

HOLLAND & HART LLP + NUCLEUS MAXIMUS

Ensuring your package falls in line with official rules and guidelines can require hours of Googling and note taking, and even then – despite your sincerest efforts, walking the tightrope of compliance can be a treacherous journey.

The good folks at Holland & Hart, a leading law firm to food brands, and Nucleus Maximus, a leading package design agency to food brands, have teamed up to simplify the process.

In this handy guide, we outline the fundamental packaging compliance topics today's food brands should be aware of, and tips for how to keep your most valuable brand asset out of regulatory red tape and hot water.

If you'd like to discuss the legal standing of your packaging please contact the team at Holland & Hart, for package design - say hello to your friends at Nucleus Maximus.

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DISCLAIMER

This publication was created to provide you with accurate information concerning the limited subject matters covered. However, all content was not necessarily prepared by persons licensed to practice law in a particular jurisdiction. This publication is not a substitute for the advice of an attorney. Every product package comes with unique circumstances and intricacies, and you should seek the services of a competent attorney to assure compliance with all current applicable laws and regulations.

We at Holland & Hart believe we are providing this publication with your permission. This guide is designed to provide general information on pertinent legal topics. The statements made are provided for educational purposes only. They do not constitute legal advice nor do they necessarily reflect the views of Holland & Hart LLP or any of its attorneys other than the authors. This guide is not intended to create an attorney-client relationship between you and Holland & Hart LLP. If you have specific questions as to the application of the law to your activities, you should seek the advice of your legal counsel.

This packaging guide provides only a brief introduction to dietary supplements and claims. Claims about your product may be regulated by the FDA or the Federal Trade Commission (FTC), or in some cases both agencies. Some states, such as California, also have additional regulations about product claims. If you are making claims about your product in your labeling or advertising, you should seek the advice of a food regulatory attorney.

IS THIS GUIDE FOR ME?

Both the U.S. Food & Drug Administration (FDA) and the United States Department of Agriculture (USDA) Food Safety Inspection Service (FSIS) regulate the labeling of food products in the United States.

This guide is intended for packaged products regulated by the FDA only.

MEAT OR POULTRY PRODUCT?

MEAT:

Products made from domesticated livestock species[1]

POULTRY:

Products made from domesticated bird species[2]

REGULATED BY USDA FSIS

- Must submit label for agency preapproval unless a generic label applies[3]
- Not the focus of this guide

MEAT OR POULTRY INGREDIENTS?

INGREDIENT EXAMPLE:

Chicken noodle soup, meat sauce with beef flavor, etc.

WARNING!

- Could be regulated USDA FSIS or FDA depending on the percentage of meat or poultry used at formulation
- Consider this when you formulate your product

***This guide only covers FDA.**

ALL OTHER PACKAGED FOODS AND BEVERAGES

INGREDIENT EXAMPLE:

Dairy products, juice, nut butters, snack bars, etc.[4]

**Special Rules apply to Dietary Supplements, these are introduced in Appendix 2.*

THIS GUIDE IS FOR YOU!

- Covers FDA label compliance only

MISBRANDING

FDA's authority to regulate food packaging comes from the Federal Food Drug and Cosmetic Act (FDCA), which is a federal criminal statute.[5] For food packaging, FDA is mostly concerned with products being "misbranded," which generally means that a product's labeling must not be "false or misleading."[6] There are a number of additional ways a product may be misbranded under the FDCA itself, and FDA has promulgated numerous regulations, a violation of which may also lead to a misbranding action. The notes throughout this guide cite different portions of the FDCA and the Code of Federal Regulations that set out FDA labeling requirements. The FDA may discover that a product is misbranded through random market surveys, FDA inspection of a registered food facility, a consumer civil suit, or consumer complaints over a misleading label.

FDA has broad authority to enforce misbranding violations. As a preliminary measure, it may issue a Warning Letter, which gives the food manufacturer 15 days to identify how it will fix a problem.[7] For more serious violations, FDA may request or mandate a recall[8] (for example, if a product is misbranded because it contains an undisclosed allergen), seize product and mark it for destruction,[9] withdraw a food facility's registration so that it may no longer operate,[10] or bring a criminal enforcement action.[11] Misbranding is a prohibited act, and a misdemeanor violation is punishable by a criminal fine of up to $100,000 for an individual or $200,000 for a corporation and or one year of imprisonment.[12]

TABLE OF CONTENTS

CHAPTER 1: PRINCIPAL DISPLAY PANEL REQUIREMENTS

CHAPTER 2: INFORMATION PANEL REQUIREMENTS

CHAPTER 3: CERTIFICATIONS & SEALS

CHAPTER 4: FDA MARKETING / MESSAGING

CHAPTER 5: APPENDIX / SOURCES / CITATIONS

PACKAGING OVERVIEW & TERMINOLOGY

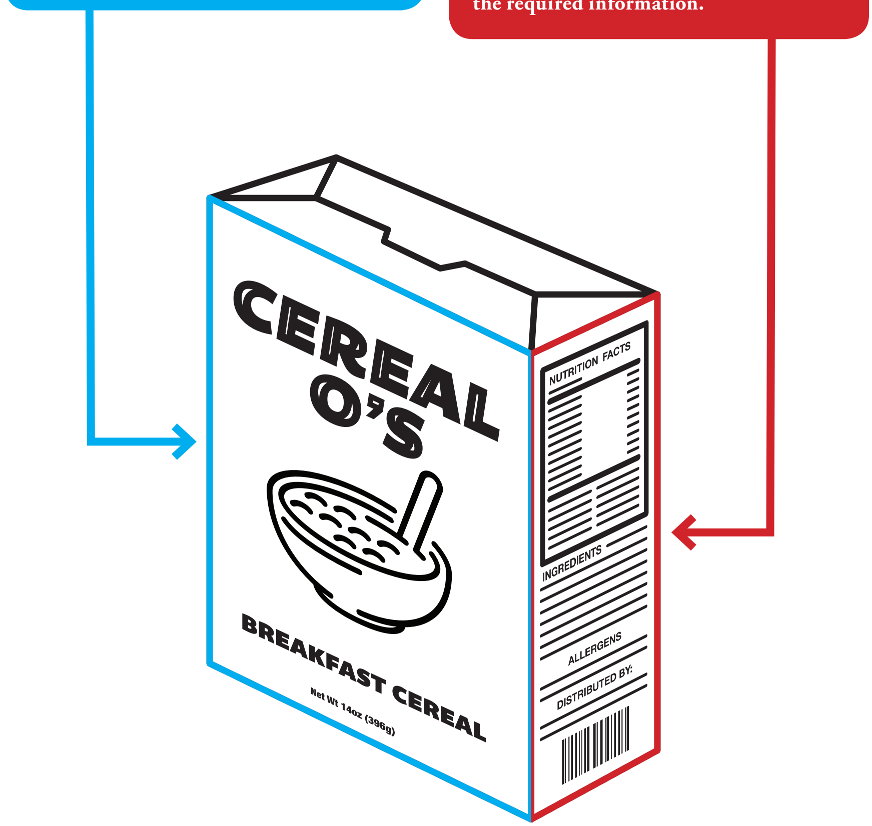
Before diving in, let's get aligned on some essential packaging terminology that all packaged food products must have:

1: PDP (PRINCIPAL DISPLAY PANEL)

Panel most likely to be seen by consumer at the point of purchase.

2: INFORMATION PANEL

Must be located on nearest adjacent panel to the PDP that can accommodate the required information.

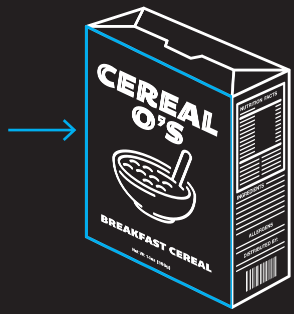


All FDA required information must be displayed on either of these panels.[13]

1

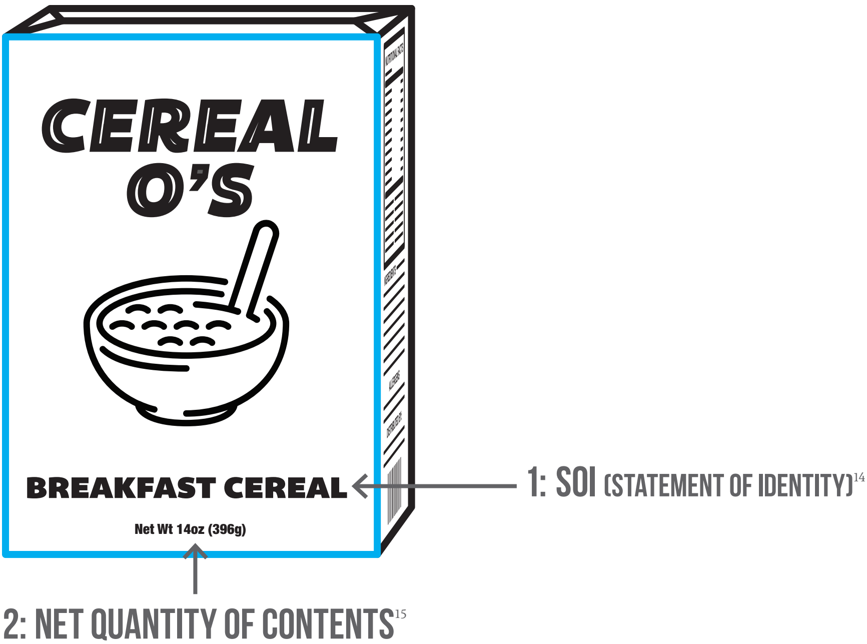
PRINCIPAL DISPLAY PANEL (PDP) REQUIREMENTS

PDP



PRINCIPAL DISPLAY PANEL (PDP)

PDP

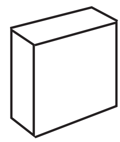


PDP SIZE REQUIREMENTS

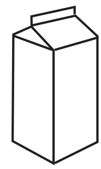
PDP SIZES

FOR RECTANGULAR PACKAGING:

The PDP is required to encompass the entire front-facing panel.[16]



BOXES

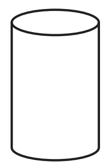


CARTONS

FOR CYLINDRICAL PACKAGING:

The PDP is required to encompass at least 40% of the surface area (height of container x circumference).[17]

Any bottled or canned food in cylindrical packaging (ex. jarred salad dressing or canned beverages).



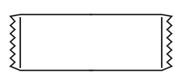
CANS

BOTTLES

FOR OTHER PACKAGING:

The PDP is required to encompass at least 40% of the surface area, or if there is an obvious PDP, the entirety of that panel.[18]

I.E. FLEXIBLE PACKAGING



WRAPS

POUCHES

TIPS THAT APPLY TO ANY AND ALL INFORMATION DISPLAYED ON A PDP:

- All information on a PDP must be displayed conspicuously.
- Do not use a typeface where the letters are less than 1/16 of an inch.
- Your artwork must not hide or detract from the prominence of required label statements.[19]

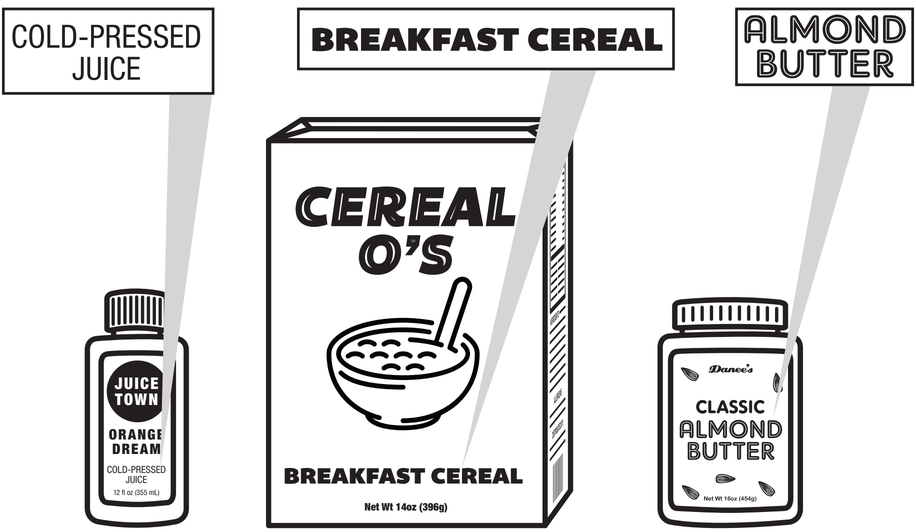
As a rule of thumb, it's always best to ensure your PDP encompasses the entire front-facing panel (most brands prefer to design their packaging this way). If your packaging falls outside of these norms and your PDP won't encompass the entire front panel, check in with a food regulatory attorney.

STATEMENT OF IDENTITY (SOI)

ALL PACKAGED GOODS MUST INCLUDE A STATEMENT OF IDENTITY (SOI):

In layman's terms, a SOI is a simplified declaration of what you make. The purpose of a SOI is to provide shoppers standardized terminology to help them understand the product offered inside the package.

HERE ARE SOME EXAMPLES OF SOI IN ACTION:



HOW TO DETERMINE YOUR SOI:

The FDA has established a standard statement of identity for most major categories of food and beverage products. If your product has a standard of identity established by the FDA, you must use it.[20] (See the Appendix 1 for a list of food categories for which FDA has standardized food regulations).

If not established by regulation, does your product have a common name? If so, using this common name (ex. almond butter above) as part of your existing product communication on your packaging also serves as a SOI (where you would not need to feature a separate SOI).[21]

A common name is one established by usage.[22] It must be uniform to all similar or identical products and cannot be confusingly similar to the name of another product.

STATEMENT OF IDENTITY (SOI)

If the nature of the product is obvious, a fanciful name commonly used by the public for such food may be used. Most of the time this is not an option. The most common example is the "Vanilla Wafer."[23]

Where no common name exists for the product, an appropriately descriptive term may be used.[24]

DON'T PLAY COPY CAT

Some brands look to other brands in their category to arrive at the appropriate SOI. However, we suggest you should seek legal advice as to whether there is a specific identity for your product and whether your product adheres to that standard of identity.

Failing to use or adhere to an appropriate standard of identity may subject you to a Warning Letter or misbranding action by the FDA.[25] Additionally, the ability to make claims about a product is, at times, linked to the statement of identity (product claims generally require legal advice and are only introduced by this guide).

HOW TO DISPLAY YOUR SOI:[26]

Here's the visual guidelines laid out by the FDA:

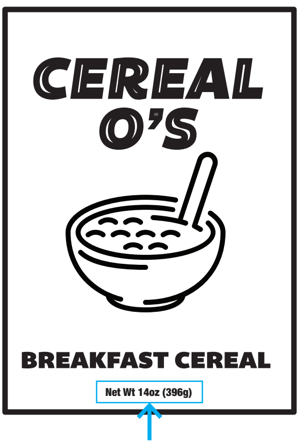
- A SOI must be a "principal feature" of the PDP.
- Must be at least half the size of the largest element printed on the label.
- Must be in lines parallel to the package (always straight, horizontal).
- Must be in **bold** typeface.
- Your artwork must not hide or detract from the prominence of your SOI, or any other FDA required information.[27]

NET QUANTITY OF CONTENTS

The net quantity of contents (net quantity statement) is the statement on the label which provides the amount of food in the container or package.[28]

**If your package contains multiple items, always include the count and the weight or liquid measure.*[29]

THE TYPE OF PRODUCT YOU HAVE DETERMINES HOW YOU DECLARE YOUR NET QUANTITY OF CONTENTS:



NET WEIGHT

SOLID (or semisolid, viscous, a mixture of solid and liquid in weight).[30]

- Must use "Net Weight" or "Net Wt."
  - May use all uppercase, all lowercase or upper and lowercase letters.
- Must disclose by avoirdupois pound and ounce
- You can either spell out or abbreviate as:
  - Pound (lb)
  - Ounce (oz)
- After disclosure using pounds and ounces, may also disclose by the metric or imperial system.
- You can either spell out or abbreviate as:
  - Kilogram (kg)
  - Milligram (mg)
  - Gram (g)

NET CONTENTS

LIQUID[31]

- May use "Net" or "Net Contents" or no prefix at all.
- Feature in liquid measure using the avoirdupois system.
- You can either spell out or abbreviate as:
  - U.S. gallon (gal)
  - Pint (pt)
  - Quart (qt)
  - Fluid ounce (fl oz)
- After required disclosure using the avoirdupois system, may disclose using metric or imperial system.
- You can either spell out or abbreviate as:
  - Liter (L)
  - Milliliter (mL)

NET QUANTITY OF CONTENTS

NET WEIGHT OR NET CONTENTS CAN BE IN FRACTIONS OR DECIMALS:[32]

- Fractions – must be reduced to lowest terms and be in form of halves, quarters, eighths, sixteenths, or thirty-seconds.[33]
- Decimal—cannot be more than two decimal places.[34]

MUST BE EXPRESSED IN PROPER ORDER:[35]

- Number of oz or fl oz, (identification by weight or liquid measure (1 pound or 1 pint, etc.), any remainder in common decimals or fractions).

SOLID EX: NET WT. 24 OZ (1 LB 8 OZ); NET WT. 24 OZ (1 ½ LB); NET WT. 24 OZ. (1.5 LB)

- For liquid measure, must be in the largest whole unit to express that quantity.
- For liquid measure, when specifying the unit in parentheses, you may not skip units of measure to avoid confusing or misleading customers. A pint is the proper unit of measure between a qt and fluid ounce, as depicted in the correct example. The statement must also be in bold face type.

SOLID EXAMPLES:

CORRECT	INCORRECT
Net Wt. 24 oz (1½ lb) **Net Wt. 6 oz (170g)** **Net Wt. 24 oz (1 lb 8 oz)**	Net wt. 1.5 lb (24 oz) Why it is wrong: • Must list ounces first, then follow by weight units in parantheses. These cannot be flipped. • Not in bold face type.

LIQUID EXAMPLES:

CORRECT	INCORRECT
Net 56 fl oz (1 qt 1 ½ pt) **Net 56 fl oz (1 qt 1 pt 8oz)** **Net 15.2 fl oz (450 mL)**	Net 56 fl oz (1qt 24 oz) Why it is wrong: • You may not skip units of measure. A pint is the proper unit of measure between a qt and fluid ounce. • Not in bold face type.

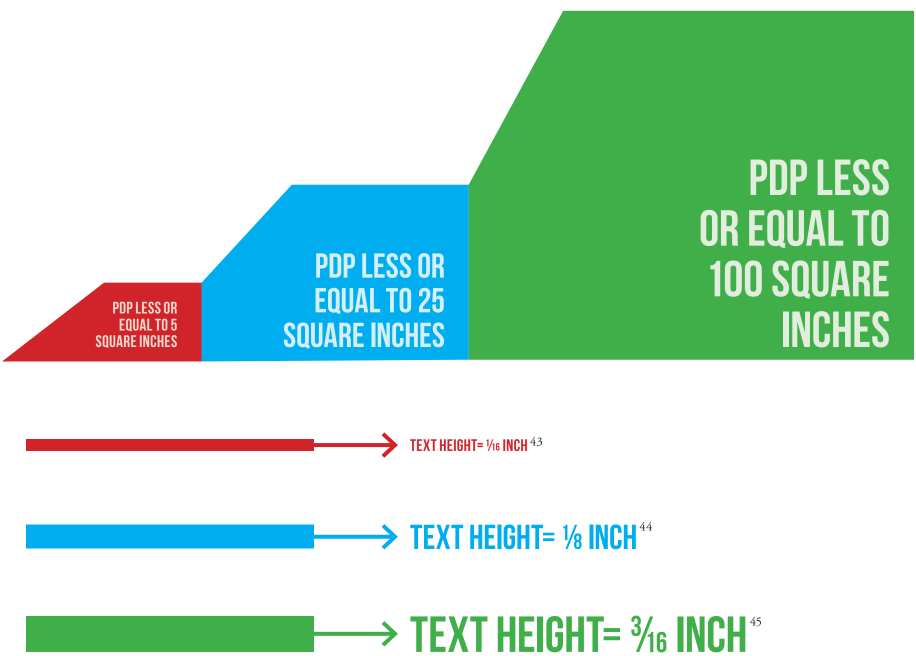
NET QUANTITY OF CONTENTS

HOW TO DISPLAY YOUR NET QUANTITY OF CONTENTS ON YOUR PACKAGE:

- Must be featured on the PDP.[36]
- Must be in **bold** typeface.[37]
- Must be in lines parallel to the package bottom.[38]
- May appear on more than one line.[39]
- Letters must not be more than three times as high as they are wide.[40]
- All abbreviated symbols should be lower-case, except for liter / milliter (L and mL)
- Periods should not be used after the symbol.
- Symbols for units are the same in singular and plural.[41]

TYPE SIZE:

- Type size must be in relation to the size of the PDP.
- Text size must be larger with larger packages.
- If blown, embossed, or molded onto glass or plastic, must be 1/16 inch larger for all categories.[42]



NET QUANTITY OF CONTENTS

SPACING:

Must be separated from other content on the PDP by:

- A space equal to the height of the lettering used in the declaration from other printed information above and below.[46]
- A space equal to the width of the "N" used from printed information on either side of the declaration.[47]

PLACEMENT:

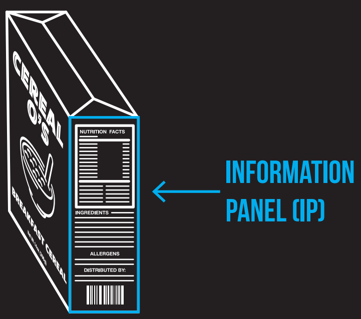
- For packages with a PDP greater than 5 square inches, Net Wt. must be in the bottom 30% of the PDP.[48]
- For packages with PDP less than 5 square inches, Net Wt. need not to be in the bottom 30%.[49]

SPECIAL RULES APPLY FOR:

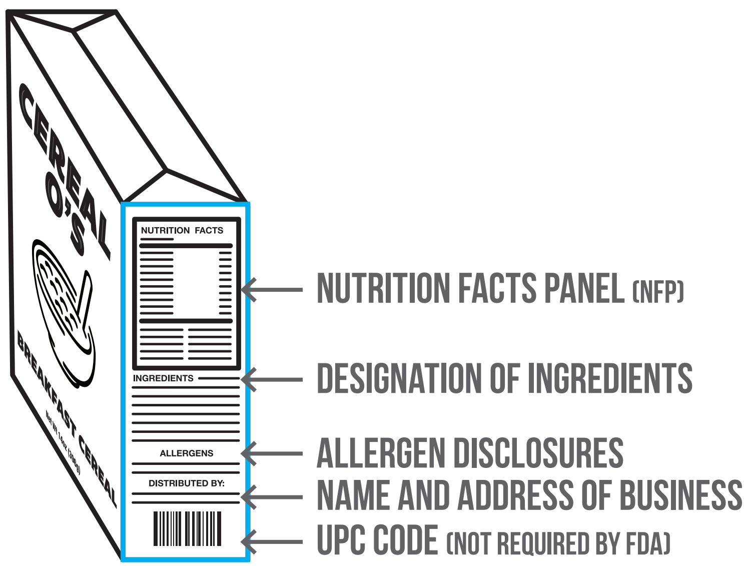
- Pickles
- Multi-Unit Packages

2

INFORMATION PANEL (IP) REQUIREMENTS



INFORMATION PANEL



INFORMATION PANEL (IP) REQUIREMENTS:

- The IP must be located on the nearest adjacent panel to the right of the PDP that can accommodate the required information.[50]
- In some cases, this could be the back of the product.
- If the PDP is on the top, any surface immediately adjacent.[51]
- All information must be in typeface at least 1/16 inch high.[52]

THERE ARE TWO NARROW EXCEPTIONS WHERE A NUTRITION FACTS PANEL (NFP) IS NOT REQUIRED:[53]

- Product sold directly to consumers with gross sales of less than $500,000 annually.
- Total product sales are less than $50,000 annually.

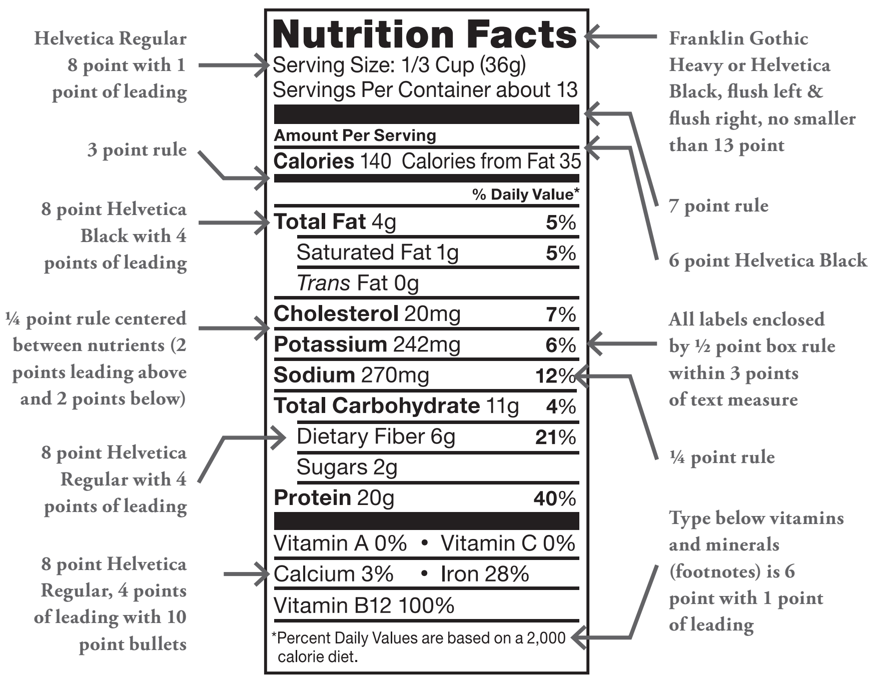
If you meet the criteria for and wish to use one of these exemptions, **no nutrition claims** may be made about the food in its labeling or advertising. Sales for these exemptions are calculated based on the last two years of data, or if the business has not been in operation for two years, upon reasonable sales estimates.

CURRENT NUTRITION FACTS PANEL (NFP)

NUTRITION FACTS PANEL (NFP) FORMATTING REQUIREMENTS:

- Must be set off by hairlines in a box.
- Information must be all black or one color type.
- Printed on a white or other neutral contrasting background (where practicable).[54]
- Use a single easy-to-read type style.
- Use upper and lowercase letters.[55]

CURRENT NUTRITION FACTS PANEL



NEW NUTRITION FACTS PANEL

OUT WITH THE OLD, IN WITH THE NEW NUTRITION FACTS PANEL:

For the purposes of helping you comply with the new FDA Nutrition Facts Panel, we'll provide examples using the new standards. Even though the new regulations have yet to go into effect, you should consider designing packaging in accord with the new regulations to avoid duplicating costs.

WHEN DO I HAVE TO HAVE TO MOVE TO THE NEW NFP?

Originally, FDA required manufacturers with more than 10 million in sales to have adopted the new panel by July 26, 2018, and manufacturers with less than 10 million in sales to have adopted the new panel the following year.

On June 13, 2017, however, FDA announced it would be **delaying the compliance date for the Nutrition Facts Panel** because it had not been able to provide guidance documents on the determination of added sugar or fiber. If your product contains either, you should meet with a regulatory attorney about the decision to use the new panel.

NEW NUTRITION FACTS PANEL

CURRENT PANEL

Nutrition Facts
Serving Size: 1/3 Cup (36g)
Servings Per Container about 13

Amount Per Serving	
Calories 140 Calories from Fat 35	
	% Daily Value*
Total Fat 4g	5%
Saturated Fat 1g	5%
Trans Fat 0g	
Cholesterol 20mg	7%
Potassium 242mg	6%
Sodium 270mg	12%
Total Carbohydrate 11g	4%
Dietary Fiber 6g	21%
Sugars 2g	
Protein 20g	40%
Vitamin A 0% • Vitamin C 0%	
Calcium 3% • Iron 28%	
Vitamin B12 100%	

*Percent Daily Values are based on a 2,000 calorie diet.

NEW PANEL

Nutrition Facts

1	8 servings per container **Serving size**	**2/3 cup (55g)**
2	**Amount per serving** **Calories**	**230**
		% Daily Value*
3	**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	
4	Includes 10g Added Sugars	**20%**
	Protein 3g	
5	Vitamin D 2mcg	10%
	Calcium 260mg	20%
	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.	

CHANGES TO NUTRITION FACTS PANEL:

1 SERVINGS

- Number of "servings per container" and "Serving Size" have increased.
  - Nutrition Facts Panel calculations must be scaled as well to reflect this serving size increase.
- Larger and bolder type.
- Odd serving sizes between 1-2 (example 1.5) are no longer accurate, and will default to "1 serving," likely increasing nutrition content per serving.

2 CALORIES

- Larger and bolder type.

3 FATS

- "Calories from Fat" is now optional.

4 ADDED SUGARS

- In grams and as a percent Daily Value (%DV).

5 NUTRIENTS

- Must include Vitamin D and Potassium.
- Vitamin A and C are now optional.

6 NEW FOOTNOTE

- Better explains the meaning of %DV.

NEW NUTRITION FACTS PANEL

NUTRITION FACTS PANEL BASICS:

Only those nutrients or food components listed by FDA for mandatory or voluntary disclosure may be listed within the nutrition label.[56] If you intend to make a claim about any voluntary nutrient, vitamin, or mineral, you must list that nutrient on your label, and there are likely additional requirements for the content of the that nutrient, vitamin, or mineral for the claim to be made in compliance with law.

THE NUTRIENTS MUST BE LISTED IN THE FOLLOWING ORDER:[57]

An * indicates that disclosure is voluntary.

- Calories
- Calories from saturated fat*
- Total fat
- Cholesterol
- Sodium
- Fluoride*
- Total carbohydrate
- Dietary fiber
- Soluble fiber*
- Insoluble fiber*
- Total sugars
- Added sugars
- Sugar alcohol*
- Protein

MANDATORY VITAMINS AND MINERALS, IN ORDER:[58]

- Vitamin D
- Calcium
- Iron
- Potassium

VOLUNTARY ADDITIONAL VITAMINS AND MINERALS THAT MAY BE DISCLOSED, IN ORDER, AFTER THE MANDATORY VITAMINS AND MINERALS:[59]

- Vitamin A
- Vitamin C
- Vitamin E
- Vitamin K
- Thiamin
- Riboflavin
- Niacin
- Vitamin B6
- Folate
- Vitamin B12
- Biotin
- Pantothenic Acid
- Phosphorus
- Iodine
- Magnesium
- Zinc
- Selenium
- Copper
- Manganese
- Chromium
- Molybdenum
- Chloride
- Choline

PRACTICE TIP

Because FDA has not required this information previously, your suppliers may not have information on Potassium, Vitamin D, and added sugars. If desired, you should start asking suppliers for this information immediately and begin working with a food lab to have an appropriate analysis of your final product performed.

NEW NUTRITION FACTS PANEL

NUTRITIONAL ANALYSIS AS PART OF YOUR MARKETING AND COMPLIANCE STRATEGY:

Nutrition labeling should be a critical part of your marketing strategy. Legally, you can only make some nutrient-content and health claims if your product meets certain nutritional criteria and if you disclose these values on your nutrition label. We urge that you consider meeting with a food regulatory attorney prior to making any such claims to know what kind of professional nutritional analysis you should obtain for your product, what claims you may be able to make, and to know what records you must keep to comply with the regulations.

SELECTED ADDITIONAL NUTRITION PANEL FORMS:

The new Nutrition Facts Panel regulations also provide a variety of alternative label forms for use on particular products, not all of which are featured here. For example, if your product is a variety pack, or has a different nutritional content when prepared as directed or as promoted on the label, or contains insignificant amounts of a number of nutrients, the FDA has additional labeling formats not shown here.

SMALL PACKAGES:

For small packages, a tabular format may be used for package designs without sufficient vertical space (approximately 3 inches) to accommodate the vertical label.[60]

DUAL COLUMN PANELS FOR PACKAGES WITH MULTIPLE SERVINGS :

A major change from the prior regulations is that for products that are packaged and sold individually, where the package contains between 200%-300% of the serving size, a dual column label is required displaying the nutritional information per serving and for the whole container. FDA provided sample formats for this in the traditional column form and tabular form.[61]

TABULAR FORMAT

Nutrition Facts
10 servings per container
Serving size **2 slices (56g)**
Calories per serving **170**

Amount/serving	% Daily Value*	Amount/serving	% Daily Value*
Total Fat 1.5g	**2%**	**Total Carbohydrate** 36g	**13%**
Saturated Fat 0.5g	**3%**	Dietary Fiber 2g	**7%**
Trans Fat 0.5g		Total Sugars 1g	
Cholesterol 0mg	**0%**	Includes 1g of Added Sugars	**2%**
Sodium 280mg	**12%**	**Protein** 4g	

Vitamin D 0mcg 0% • Calcium 80mg 6% • Iron 1mg 6% • Potassium 470mg 10%
Thiamin 15% • Riboflavin 8% • Niacin 10%

*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 TABULAR

Nutrition Facts
2 servings per container
Serving size **1 cup (255g)**
Calories **220** per serving | **440** per container

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

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.

DECLARATION OF INGREDIENTS

WHERE TO DECLARE YOUR INGREDIENTS ON YOUR PACKAGE:

The ingredients must be listed on the PDP or IP.[62] They are usually listed on the IP accompanying the nutrition panel.

LISTING ORDER:

All manufactured food products must list the ingredients they contain in descending order by weight, meaning the ingredient that makes up the greatest percentage by weight is listed first, and the ingredient that makes up the lowest percentage of product by weight is listed last.[63] The descending order requirement does not apply to ingredients that make up 2% or less of the product by weight, but all such ingredients must be preceded by a qualifying statement, such as:

- "Contains _______ percent or less of _______."
- "Less than _______ percent of _______."[64]

TYPE SIZE:

The ingredients must be listed in a font size no less than 1⁄16 inch in height based on the lowercase letter "o".[65]

USING THE PROPER NAME FOR INGREDIENTS

There are many specific rules about naming conventions used for ingredients, so it is best to consult a food regulatory attorney to ensure that you are following these rules precisely. Failing to appropriately label ingredients is a common citation in FDA Warning Letters.

INGREDIENTS NAMES:

In general, you must disclose the ingredient by its common name,[66] but spices, artificial and natural flavorings, colorings, and preservatives,[67] as well as ingredients which themselves have a Standard of Identity promulgated by FDA or USDA must be disclosed in accord with certain rules.[68] Additionally, there are more than twenty other exceptions to this rule about common naming conventions.

FOOD ADDITIVES:

A food additive is any substance that is added to food such that it becomes a component of the food or otherwise affects the characteristics of a food.[69] Manufacturers are responsible for only using food additives that are Generally Recognized as Safe (GRAS) or have been approved in accord with FDA's premarket notification process.[70] For example, color additives need to be preapproved by FDA.[71] A food regulatory attorney can verify that your ingredients meet these requirements.

ALLERGEN DISCLOSURES

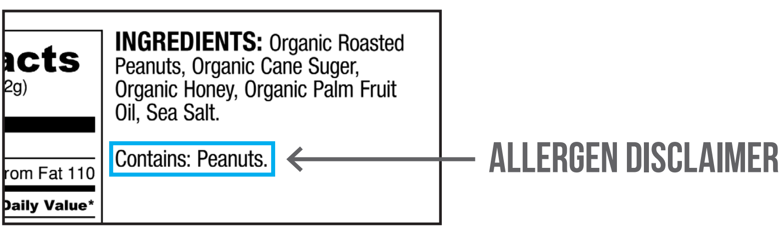
The most common cause of recalls due to misbranding is for undisclosed allergens. Because these present a serious risk to the health of those with food allergies, this is one of the most important disclosures made on a package.[72] FDA focuses on disclosure of eight "major food allergens," commonly referred to as "the big 8".

THE BIG 8:

- Milk
- Egg
- Fish
- Crustacean Shellfish
- Tree nuts
- Wheat
- Peanuts
- Soybeans[73]

If your product contains one of these allergens, to avoid being misbranded the product labeling must state "Contains" followed by the food source from which the allergen is derived (above), with some limited exceptions.[74] For particular categories such as fish, crustacean shellfish, and tree nuts, the label must disclose the specific species or type.[75]

HERE IS AN EXAMPLE OF ALLERGENS IN ACTION:



PLACEMENT AND TYPE SIZE:

The allergen disclosure must be made immediately after or adjacent to the list of ingredients in the same size font used for the ingredients.[76]

It does not matter whether the introduction of a product containing a food allergen was accidental. If the product contains a major allergen, and that allergen is not disclosed, whether it be from putting the wrong label on a product or from cross-contact between food surfaces containing the allergen, if it is not declared on the label the product is misbranded and subject to recall.

NAME AND PLACE OF BUSINESS AND COUNTRY OF ORIGIN

NAME AND PLACE OF BUSINESS

FORMATTING RULES:

The Name and Place of Business of the manufacturer must be disclosed on the PDP or IP.[77] Usually listed on the IP.

INCLUDES THE NAME OF THE BUSINESS, STREET ADDRESS, CITY, STATE, AND ZIP CODE:[78]

- Corporations must be named by their actual corporate name, with the name of the subdivision of the corporation immediately before or after.[79]
- Individuals, partnerships, and associations should use the name under which they conduct business.[80]

WHEN THE FOOD IS NOT MANUFACTURED BY THE COMPANY IDENTIFIED ON THE LABEL, THEN THE NAME MUST BE SET OFF BY AN ACCURATE QUALIFYING PHRASE:

- "Manufactured for" _________
- "Distributed by" _________[81]

LABEL MAY LIST THE PRINCIPAL PLACE OF BUSINESS FOR A COMPANY WHERE COMPANY MANUFACTURES, PACKS, OR DISTRIBUTES PRODUCT AT A LOCATION OTHER THAN THE PRINCIPAL PLACE OF BUSINESS:

- This cannot be misleading.[82]

COUNTRY OF ORIGIN

Customs and Border Patrol (CBP) regulations require disclosure of the Country of Origin on the final product package for delivery to the consumer. The FDA has also stated that a violation of the CBP regulations could result in the label violating the general prohibition against being false or misleading in any particular.[83] Additionally, a product is misbranded when there is "any representation that expresses or implies a geographical origin of the food or any ingredient of the food except when such representation is… a truthful representation of the geographic origin."[84] One circumstance where a package could be misleading is if only the distributor is listed, or if the information about the manufacturer and distributor are separated such that one would have the impression that they were purchasing a U.S. product.

Country of Origin information and US distributor information should be in close proximity to one another and of similar font size and prominence to avoid misleading the consumer.

INTERVENING MATERIAL ON IP

DON'T CLUTTER IT UP!

FDA prohibits the inclusion of ANY information (including pictures or claims) between required content on the information panel.[85]

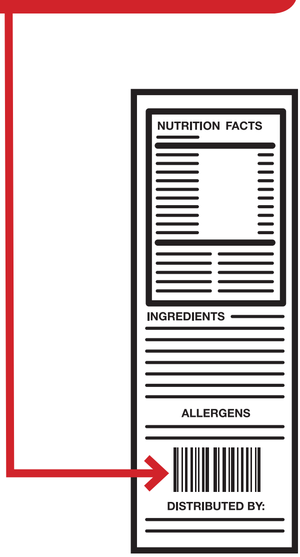
This rule is broken all the time, but it doesn't mean that it won't land you in trouble.

EXAMPLES:

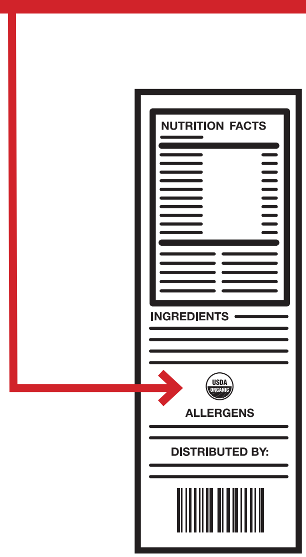
- Picture or graphic between the nutrition panel and the ingredients or the Name and Place of Business of the manufacturer.
- Claims between the ingredients and the Name and Place of Business of the manufacturer.
- Certification seals (Organic, Non-GMO Project, etc.) between the ingredients and the name and place of business of the manufacturer.
- UPC codes between ingredients and Name and Place of Business of the manufacturer.

EXAMPLES OF INTERVENING MATERIAL ON THE INFORMATION PANEL:

1: INTERVENING MATERIAL BETWEEN REQUIRED ALLERGENS AND DISTRIBUTED BY INFORMATION



2: INTERVENING MATERIAL BETWEEN REQUIRED INGREDIENTS AND ALLERGENS.



UPC CODE INFORMATION

UPC barcodes are are often found on information panels, however are not required by the FDA. **UPC codes must not be placed in between any of the required information panel information.**

CORRECT AND INCORRECT EXAMPLES OF UPC CODE PLACEMENT:

CORRECT

INCORRECT

UPC CODE INFORMATION

UPC SIZE:

- Recommended size: 1.5" W x 1.06" H.
  - Can be truncated to .5" H (width should remain at 1.5").
- Can be reduced to 80% and can be increased up to 200% without significantly jeopardizing reliable scanning.

UPC COLORS:

- First choice: 100% black bars on a white field.
- Optional: Other color combinations (ex. dark brown).
- Never: Red bars or light colors.

MINIMUM CLEAR AREA

1.5"

100% UPC A MINIMUM CLEAR ZONE
(1.5"W X 1.06"H)

1.5"

100% UPC A MINIMUM CLEAR ZONE & MAXIMUM TRUNCATION*
(1.5"W X 0.5"H)

RECOMMENDED CLEAR AREA

1.675"

100% UPC A RECOMMENDED CLEAR ZONE
(1.675"W X 1.06"H)

1.675"

100% UPC A RECOMMENDED CLEAR ZONE & MAXIMUM TRUNCATION*
(1.675"W X 0.5"H)

VANITY CODE USAGE:

- Must meet color & size standards to be scannable.
- Examples of functional and decorative bar codes:

3

CERTIFICATIONS & SEALS

CERTIFICATIONS & SEALS

The purpose of this chapter is to outline fundamental guidelines to help your brand comply with each certifier's packaging requirements.

Use of these certifications and seals prior to verification is prohibited. To learn more about the verification process for each certifying body, contact that organization directly or consult with a food regulatory attorney.

USDA ORGANIC

WHAT IS ORGANIC?

The National Organic Program (NOP) was created by the Organic Foods Production Act of 1990 and is managed and enforced by the USDA Agricultural Marketing Service. The Act and regulations limit the use of the term "organic" and the organic seal to certified producers of crops and livestock and handlers of processed products. A facility that manufactures processed organic products must obtain an organic handlers certification, which requires the submission of an annual plan and annual on-site inspection[86] by an approved certifier (Ex: CCOF or QAI).[87]

*Knowingly labeling a product as organic not in accordance with the Act or regulations carries a penalty of up to $11,000 per violation.[88]

ALL PROCESSED ORGANIC PRODUCTS MUST HAVE BEEN PRODUCED WITHOUT THE USE OF:

- Synthetic substances (with limited exceptions)
- Prohibited nonsynthetic substances
- Nonorganic processed products (with limited exceptions)
- Genetic engineering
- Ionizing radiation
- Sewage sludge[89]

ORGANIC CLAIMS:

For a packaged product, what kind of organic claim you can make depends on what percentage of is made up of organic ingredients.

The percentage of organic ingredients must be calculated by the handler that affixes the label on the consumer package, and verified by the handler certifier.[90] In general, the percentage is calculated by:

$$\frac{\text{weight of organic ingredients} - (\text{weight water} + \text{salt})}{\text{weight of all ingredients} - (\text{weight water} + \text{salt})}$$ [91]

<table>
<tr><th>PRODUCT COMPOSITION</th><th>WHAT CLAIMS CAN BE MADE?</th><th>USE USDA SEAL?</th><th>USE CERTIFIER SEAL?</th><th>WHERE PERMITTED CLAIMS OR CLAIM OR SEALS CAN BE USED?</th></tr>
<tr><td>100% organic ingredients</td><td>• 100% organic (Product Name)[92]</td><td>Yes[93]</td><td>Yes[94]</td><td rowspan="3">On any labeling or marketing material[95]</td></tr>
<tr><td>95% or more organic ingredients</td><td>• Organic (Product Name)[96]
• _% organic, no larger than half the size of the largest font on the panel & must use uniform font, size, and color without highlighting[97]</td><td>Yes[98]</td><td>Yes[99]</td></tr>
<tr><td>70% or more organic ingredients</td><td>• _% organic[100]
• Made with organic (specified ingredient (s) or specified food group(s)[101]
• May only identify up to three groups or ingredients[102]
• All claims must be no larger than half the size of the largest font on that panel & use uniform font, size, and color without highlighting for any claim[103]</td><td>No[104]</td><td>Yes[105]</td></tr>
<tr><td>Less than 70% organic ingredients</td><td>• _% organic ingredients[106]</td><td>No[107]</td><td>No[108]</td><td>On information panel only[109]</td></tr>
</table>

USDA ORGANIC

ALL PRODUCTS WITH ANY "ORGANIC" CLAIM MUST ALSO BE ACCOMPANIED BY AN APPROPRIATE INGREDIENT DISCLOSURE:

• All products must label all organic ingredients as "organic ________" or use an asterisk or other reference mark for each organic ingredient indicate the ingredient is organically produced.

• Water and salt cannot be identified as organic.[110]

"100% ORGANIC," "ORGANIC," AND "MADE WITH ORGANIC" PRODUCTS MUST IDENTIFY THE HANDLER CERTIFIER:

• Below the mandatory name, place, and business of the manufacturer (see following certifiers page), must state the name of the certifying agent.

• May include the business address, internet address, or telephone number of the certifying agent as well.[111]

USDA ORGANIC

USDA ORGANIC SEAL ART GUIDELINES:

100% organic and organic products may only use the organic seal in the format and manner specified in by regulation:

- Seal on white background, brown outer, green field.[112]
- Black on white or transparent background.[113]
- May or may not use the four lines to look like a green field.[114]
- USDA seal must be more prominent than any certifier seal used.[115]

USE CERTIFIED LOGO ONLY

Don't mess around with the USDA Organic Logo whatsoever. It is a federally regulated certification.

- If the USDA seal is used, it appears in one of three approved color schemes: black and clear, black and white, or green center with brown rim.
- The USDA logo must be on a background that is white or a lighter color.

OFFICIAL	B/W LOGO	B/W LOGO WITH TRANSPARENT BACKGROUND
USDA ORGANIC	USDA ORGANIC	USDA ORGANIC
GREEN: PMS 348 BROWN: PMS 175	BLACK: K=100% WHITE	BLACK WHITE TRANSPARENCY

QUALITY ASSURANCE INTERNATIONAL (QAI)

QAI is a commonly used certifier, we've outlined the art guidelines pertaining to featuring their seal below. If you are using a different certifying agent, be sure to consult with the organization in advance of featuring their seal.

OFFICIAL

B/W LOGO

NO RESTRICTION ON BACKGROUND COLOR

• Should be same or smaller than USDA seal.[116]

≤

CALIFORNIA CERTIFIED ORGANIC FARMERS (CCOF)

CCOF is a commonly used certifier. We've outlined the art guidelines pertaining to featuring their seal below. If you are using a different certifying agent, be sure to consult with the organization in advance of featuring their seal.

• Should be in a more prominent location and size than certifier's seal (ex. CCOF).

OFFICIAL

GREEN: PMS 357
YELLOW: PMS 130

1-COLOR LOGO

CCOF 1-COLOR LOGO CAN BE ANY COLOR

• Should be same or smaller than USDA seal.[117]

NON-GMO PROJECT

WHEN TO USE:

- You must obtain verification before using the Non-GMO Project Verification Trademark on product or marketing materials.
- Add "Verification Mark," for all products except meat and liquid eggs.
- Visit nongmoproject.org for more information.

OFFICIAL

B/W LOGO

5-COLOR
BLACK: PMS BLACK
ORANGE: PMS 144C
GREEN: PMS 363C
LIGHT BLUE: PMS 283C
DARK BLUE: PMS 2747C

1-COLOR GRAYSCALE

- If printed in single color (or black and white) must match the following:

1-COLOR OPTIONS ON DARK

1-COLOR OPTIONS ON WHITE

- Must not appear smaller than 3/8" in height.

3/8"

- Must not be modified to eliminate URL or any part of artwork on packaging.

CERTIFIED GLUTEN FREE

WHEN TO USE:

- You must obtain certification before using Certified Gluten-Free mark on any products.
- Visit gfco.org for more information.

OFFICIAL

Certified GF ® Gluten-Free

BLACK: K=100
WHITE: C=0 M=0 Y=0 K=0

COMPACT LOGO FOR PACKAGING FROM GFCO

GF

BLACK: K=100
WHITE: C=0 M=0 Y=0 K=0

- Must maintain clear area without imagery / graphic around logo.
- Image should be in proportion to package design (neither overpowering or lost in overall design).

- Preferred is PDP near other certification marks.
- Alternative is near nutrition panel without violating the prohibition on intervening material.

- For printed use (including packaging), GFCO may be printed without the copyright symbol.
- Optional: additional info (ex. GFCO website / contact info) may be added to label with GFCO approval.

FAIR TRADE CERTIFIED

WHEN TO USE:

- Use of the Fair Trade Certified mark on products prior to certification is prohibited.
- Visit fairtradeusa.com for more information.

OFFICIAL	PMS COLOR	PMS COLOR ALT	GRAYSCALE LOGO
PROCESS COLOR (CMYK) GREEN: C=50 M=0 Y=100 K=0 LIGHT GREEN: C=25 M=0 Y=50 K=0 BLACK: C=0 M=0 Y=0 K=100	2-COLOR BLACK PMS 376C	2-COLOR BLACK PMS 375U	1-COLOR GRAYSCALE

SIZE MINIMUM (OR 5% OF PDP)

⅛ CLEAR SAFE SPACE

- Must be placed on the PDP.

- Variations are available, must seek approval from Fair Trade USA.

Examples:

FAIR TRADE CERTIFIED TEA	FAIR TRADE CERTIFIED INGREDIENT	FAIR TRADE CERTIFIED INGREDIENTS	FAIR TRADE CERTIFIED ROSES
37% OF PRODUCT			

4

FDA MARKETING / MESSAGING

FDA MARKETING / MESSAGING

THE DO'S AND DON'TS!

Class action lawsuits are filed against food and beverage makers of every size nearly every day related to alleged misrepresentations made about the products. Many of these cases relate to "natural," "organic," health, and structure / function claims. This chapter will help you identify potential pitfalls in marketing your products and, hopefully, minimize the risk of noncompliance with FDA regulations or potential lawsuits. A food product is misbranded—and subject to FDA action or civil lawsuits—if its labeling is false or misleading.[118]

In this regard, labeling may be false or misleading either

• Expressly (by what is said about the product).

• By omission (what the labeling fails to say).

A PICTURE IS WORTH A THOUSAND WORDS… OR A LAWSUIT

The combination of words and graphics may create a claim that the food maker did not intend. For example, a consumer class action was allowed to proceed against a food maker for making false claims where the label used the words "Fruit Juice Snacks" combined with the pictures of certain fruits, because the combination created a claim that the juices from pictured fruits were present in the food.[119] Although a more recent case in another state based on this same theory was dismissed,[120] the potential for lawsuits in some jurisdictions suggests that manufacturers should be aware of the risks from unintended claims from the combination of words and graphics.

LABEL VS. LABELING

RESPONSIBILITY GOES WELL BEYOND THE "LABEL":

Although they may sound similar, there are important differences between a food product's label and its labeling. As discussed throughout this book, several specific items (such as statement of identity, net quantity, and nutritional facts panel) are required on the actual product label. The "label" itself is the display of written, printed, or graphic matter upon the immediate container, not including package liners, of any article.[121] The term "labeling" is much broader than the label, and includes the label and all other written, printed, or graphic matter (1) upon any article or any of its containers or wrappers, or (2) accompanying such article."[122] Generally, these terms are defined as broadly as possible.

Thus, labeling includes all written, printed or graphic matter found on:

- The product label.
- Any insert included in the packaging.
- The company's websites.
- Any in-store advertising, including:
  - Posters
  - Displays
  - Pamphlets

WHY DOES THIS MATTER? ALL LABELING IS CONSIDERED IN EVALUATING A CLAIM:

Claims are determined by considering the combination of all words and graphics found on any portion of the label and labeling. This is best known as the "overall net takeaway test." Thus, food makers should be sure that there are no unintended, or unsubstantiated, representations or claims in the graphics used on labels or the combination of graphics and words elsewhere on the label or labeling.

YOU DON'T SAY... CLAIMS MAY ALSO BE IMPLIED

Graphics alone may unintentionally create an implied claim. The label of a well-known orange juice brand included a picture of an orange pierced with a drinking straw. Consumers filed a class action claiming that the graphic implied that the product was fresh-squeezed when it was actually pasteurized, stored, and later artificially colored and flavored prior to packaging. The claim was allowed to proceed even though the word "PASTEURIZED" was printed on the front label, because of the implied representation that the product was 100% pure and natural orange juice.[123]

BIG TICKET CLAIMS

Two of the most frequent claims that lead to either FDA warning letters or class action lawsuits are use of:

- “Natural”
- "Healthy"

Most of these lawsuits concerning alleged false or misleading claims are settled without going to trial, so there are few reported decisions that explore the issues related to food claims. Regardless, in addition to bad press, defending such lawsuits requires payment of significant legal bills and settlements often involve payments of millions of dollars. Thus, food makers must use extreme caution in evaluating what marketing claims to make about its food products, and should assure that any claim is properly substantiated. Further, since these issues are very fact-specific, we urge you to consult with a food regulatory attorney to better assess the potential issues for using “natural” or “healthy” in your food labeling.

KNOW WHEN NOT TO MAKE A CLAIM. QUESTIONS TO ASK WHEN EVALUATING WHETHER TO MAKE A CLAIM INCLUDE:

- What are the benefits to making this claim?
- What is the basis for believing these benefits exist?
- What are the risks (litigation or FDA action) or downsides (counterproductive disclaimers) of making the claim?
  - Are there existing lawsuits related to similar claims?
  - What are potential legal fees or exposure for such a lawsuit?
  - How might the brand suffer if we are sued (regardless of outcome)?
- Weigh identified benefits versus risks / exposure?

“NATURAL”

Although it has provided a “policy,” the FDA has not provided a formal definition of “natural” as it has for many other labeling terms. The FDA’s policy considers the term “natural” to mean that nothing artificial or synthetic (including all color additives regardless of source) has been included in, or has been added to, a food that would not normally be expected to be in that food. Importantly, this “policy” does not address food production methods (including use of pesticides) or processing or manufacturing methods, such as thermal technologies, pasteurization, or irradiation. The FDA accepted public comments between late 2015 through May 2016 concerning its potential definition of the term “natural,” but has not yet indicated any timeline when—or if—it may provide a rule or guidance in this area. Until such time, food makers should be weary of using any new “natural” claims in product labeling.

Although many lawsuits have been put on hold by courts to await the long-promised FDA guidance, some cases remain active and provide some useful instruction for food makers. The majority of these cases relate to use of genetically modified organisms (“GMOs”), artificial flavorings or preservatives, and certain processing techniques.

Generally speaking, most cases allege that the use of the word “natural” or “all-natural” on food labels is misleading if any portion of the food is touched by scientific modification such as bioengineered, artificial or synthetic ingredients.[124] Although virtually all of these cases have been settled prior to trial, often for millions of dollars, the risk of litigation strongly indicates that manufacturers should avoid using the term "natural" on product labeling unless it is certain that none of the ingredients are synthetic or contain any GMOs.

"HEALTHY"

Unlike "natural," the FDA has provided specific guidance and a definition for the term "healthy" for food labeling. That said, the FDA has begun a public process to redefine the "healthy" nutrient content claim, but the current definition will continue to apply until this process is complete (which could be some time).

You may use the term "healthy" or related terms (such as "health," "healthful," "healthfully," "healthier," and "healthiest") as an implied nutrient content claim in labeling of a food that is useful in creating a diet that is consistent with dietary recommendations if:[125]

- The food meets all of the following general conditions for fat, saturated fat, cholesterol, and other nutrients (but which may be different for certain items):

"HEALTHY"

IF THE FOOD IS...	THE FAT LEVEL MUST BE...	THE SATURATED FAT LEVEL MUST BE...	THE CHOLESTEROL LEVEL MUST BE...	THE FOOD MUST CONTAIN...
(A) A raw fruit or vegetable (B) A single-ingredient or a mixture of frozen or canned fruits and vegetables (C) An enriched cereal-grain product that conforms to a standard of identity in part 136, 137 or 139 of this chapter	Low fat (3 g or less of fat per reference amount customarily consumed ("RA"), which must be >30 g)[126]	Low saturated fat (1 g or less of saturated fatty acids[127] per RA and ≤ 15% of calories from saturated fatty acids)	60 mg or less cholesterol per labeled serving ("LS")[128]	N/A
(D) A raw, single-ingredient seafood or game meat	Less than 5 g total fat per RA and per 100 g	Less than 2 g saturated fat per RA and per 100 g	Less than 95 mg cholesterol per RA and per 100 g	At least 10 % of the daily referenced value ("DRV") per RA of one or more of vitamin A, vitamin C, calcium, iron, protein, or fiber

Chart continued on next page.

"HEALTHY"

IF THE FOOD IS...	THE FAT LEVEL MUST BE...	THE SATURATED FAT LEVEL MUST BE...	THE CHOLESTEROL LEVEL MUST BE...	THE FOOD MUST CONTAIN...
(E) A meal product (weighing ≥ 10 oz per labeled serving)[129] or a main dish product (≥ 6 oz per labeled serving)[130]	Low fat (3 g or less of fat per 100 g, and ≤ 30% of calories from fat)[131]	Low saturated fat (1 g or less of saturated fatty acids per 100 g and ≤ 10% of calories from saturated fat)[132]	90 mg or less cholesterol per LS	At least 10 % of the DRV per LS of 2 nutrients (for a main dish product) or of 3 nutrients (for a meal product) of: vitamin A, vitamin C, calcium, iron, protein, or fiber
(F) A food not specifically listed in this table	Low fat (3 g or less of fat per RA, which must be >30 g)[133]	Low saturated fat (1 g or less of saturated fatty acids per RA and ≤ 15% of calories from saturated fatty acids)[134]	60 mg or less cholesterol per LS[135]	At least 10 percent of the RDI or the DRV per RA of one or more of vitamin A, vitamin C, calcium, iron, protein or fiber

- The food meets the following conditions for sodium:

"HEALTHY"

IF THE FOOD IS...	THE SODIUM LEVEL MUST BE...
(A) A food with a RA that is greater than 30 g or 2 tbsp.	480 mg or less sodium per RA and per LS
(B) A food with a RA that is equal to or less than 30 g or 2 tbsp.	480 mg or less sodium per 50 g
(C) A meal product (weighing ≥ 10 oz per labeled serving)[136] or a main dish product (≥ 6 oz per labeled serving)[137]	600 mg or less sodium per LS

In addition to meeting the above nutrient conditions, the "healthy" nutrient content claim must also include an explicit or implicit claim or statement about a nutrient (such as "healthy, contains 3 grams of fat") that suggests the food, because of its nutrient content, may be useful in creating a diet that is consistent with dietary recommendations.

FDA has indicated that, in addition to the circumstances outlined above, it will exercise enforcement discretion (not pursue legal action) against products using the term healthy that are not low in fat as long as the fat profile is made up of predominantly mono and polyunsaturated fats and that such fat content is declared on the label.[138]

NUTRIENT CONTENT CLAIMS

A nutritional content claim ("NCC") is a claim on a food product that directly or by implication characterizes the level of a nutrient in the food (such as, "low fat," "high fiber," "low sodium," or "contains 100 calories")[139]. FDA regulations list numerous specific nutrient level requirements that must be met in order to make a NCC. Importantly, you may not make a NCC unless it (or its synonym) is specifically defined in these FDA regulations.

NCC FORMATTING REQUIREMENTS:

• Type size of the NCC may not be more than twice the type size of the Statement of Identity

• Nor may the font type be unduly prominent compared to that used for the SOI.[140]

DISCLOSURE STATEMENT REQUIREMENTS:

When a NCC is made and a nutrient in that food exceeds certain prescribed levels, a disclosure statement is also required that identifies the excessive nutrient (e.g. "See nutrition information for sodium content")[141]. Generally, these prescribed levels are as follows:

DISCLOSURE STATEMENT REQUIREMENTS

IF THE FOOD IS...	THE PRESCRIBED LEVELS PER LABELED SERVING ARE...
A meal product (weighing ≥ 10 oz per labeled serving)[142]	26 g of fat, 8 g of saturated fat, 120 mg of cholesterol, or 960 mg of sodium[143]
A main dish product (≥ 6 oz per labeled serving)[144]	19.5 g of fat, 6.0 g of saturated fat, 90 mg of cholesterol, or 720 mg of sodium[145]
Other food, or foods with small serving sizes, per 50 g	13 g of fat, 4 g of saturated fat, 60 mg of cholesterol, or 480 mg of sodium[146]

The disclosure statement must be:

• Right next to the NCC.

• In legible **boldface** type.

• In distinct contrast to other printed or graphic matter.

• In a type size at least as large as the net quantity of contents declaration.[147]

Claims may be made for nutrients that do not have an established daily value, but must identify the amount of the nutrient without characterizing that amount.[148] Thus, for example, you may make a claim such as "x grams of omega3 fatty acids," "Contains x grams of omega-3 fatty acids per serving" or "Provides x g of omega-3 fatty acids" but may not state "High in omega-3 fatty acids" or "good source of omega-3 fatty acids."[149]

NUTRIENT CONTENT CLAIMS

("FREE," "LOW," "REDUCED / LESS")

FREE	LOW	REDUCED / LESS	COMMENTS
Synonyms include: "Zero," "No," "Without," "Trivial Source of," "Dietarily Insignificant Source of" Definitions for "Free" for meals and main dishes are the stated values per labeled serving but are not defined for calories	Synonyms include: "Little," ("Few" for Calories), "Contains a Small A mount of," "Low Source of"	Synonyms include: "Lower" ("Fewer" for Calories) "Modified" may be used in SOI Definitions for meals and main dishes are same as for individual foods on a per 100 g basis	For "Free," "Very Low," or "Low," must indicate if food meets a definition without benefit of special processing, alteration, formulation or reformulation; e.g., "broccoli, a fat-free food" or "celery, a low c alorie food"

DEFINITIONS OF PERMITTED NCC

NUTRIENT	FREE	LOW	REDUCED / LESS	COMMENTS
CALORIES	Less than 5 cal. per RA and per labeled serving.[150]	40 cal. or less per RA (and per 50 g if RA is small).[151] Meals and main dishes: 120 cal. or less per 100 g.[152]	At least 25% fewer calories per RA than an appropriate reference food (for meals and main dishes, at least 25% fewer calories per 100 g).[153] Reference food may not be "Low Calorie." Uses term "Fewer" rather than "Less."	"Light" or "Lite": if 50% or more of the calories are from fat, fat must be reduced by at least 50% per RA. If less than 50% of calories are from fat, fat must be reduced at least 50% or calories reduced at least 1/3 per RA.[154] "Light" or "Lite" meal or main dish product meets definition for "Low Calorie" or "Low Fat" meal and is labeled to indicate which definition is met.[155]

Chart continued on next page.

NUTRIENT CONTENT CLAIMS

DEFINITIONS OF PERMITTED NCC

NUTRIENT	FREE	LOW	REDUCED / LESS	COMMENTS
TOTAL FAT	Less than 0.5 g RA and per labeled serving (or for meals and main dishes, less than 0.5 g per labeled serving).[156] Contains no ingredient that is fat or understood to contain fat, except if the ingredient listed in the ingredient statement has an asterisk that refers to footnote (e.g., "* adds a trivial amount of fat").	3 g or less per RA (and per 50 g if RA is small).[157] Meals and main dishes: 3 g or less per 100 g and not more than 30% of calories from fat.[158]	At least 25% less fat per RA than an appropriate reference food (or for meals and main dishes, at least 25% less fat per 100 g).[159] Reference food may not be "Low Fat."	"__% Fat Free": may be used if food meets the requirements for "Low Fat."[160] 100% Fat Free: food must be "Fat Free."[161] "Light" meal or main dish product meets definition for "Low Calorie" or "Low Fat" meal and is labeled to indicate which definition is met.[162]
SATURATED FAT	Less than 0.5 g each of saturated fat and trans fatty acids per RA and main dishes, or labeled serving).[163] Contains no ingredient that is saturated fat or understood to contain saturated fat, except if the ingredient listed in the ingredient statement has an asterisk that refers to footnote (e.g., "* adds a trivial amount of saturated fat").	1 g or less per RA and 15% or less of calories from saturated fat.[164] Meals and main dishes: 1 g or less per 100 g and less than 10% of calories from saturated fat.[165]	At least 25% less saturated fat per RA than an appropriate reference food (or for meals and main dishes, at least 25% less saturated fat per 100 g).[166] Reference food may not be "Low Saturated Fat."	Next to all saturated fat claims, must declare the amount of cholesterol if 2 mg or more per RA; and the amount of total fat if more than 3g per RA (or 0.5 g or more of total fat per RA for "Saturated Fat Free") (or for meals and main dishes, per labeled serving).[167]

Chart continued on next page.

NUTRIENT CONTENT CLAIMS

DEFINITIONS OF PERMITTED NCC

NUTRIENT	FREE	LOW	REDUCED / LESS	COMMENTS
CHOLESTEROL	Less than 2 mg per RA and per labeled serving (or for meals and main dishes, per labeled serving).[168] Contains no ingredient that is cholesterol or understood to contain cholesterol, except if the ingredient listed in the ingredient statement has an asterisk that refers to footnote (e.g., "* adds a trivial amount of cholesterol").	20 mg or less per RA (and per 50 g of food if RA is small).[169] Meals and main dishes: 20 mg or less per 100 g.[170]	At least 25% less cholesterol per RA than an appropriate reference food (or for meals and main dishes, per 100 g).[171] Reference food may not be "Low Cholesterol."	Cholesterol claims only allowed when food contains 2 g or less saturated fat per RA; or for meals and main dish products, per labeled serving size for "Free" claims or per 100 g for "Low" and "Reduced / Less" claims. Must declare the amount of total fat next to cholesterol claim when fat exceeds 13 g per RA and labeled serving (or per 50 g of food if RA is small), or when the fat exceeds 19.5 g per labeled serving for main dishes or 26 g for meal products.[172]

Chart continued on next page.

NUTRIENT CONTENT CLAIMS

DEFINITIONS OF PERMITTED NCC

NUTRIENT	FREE	LOW	REDUCED / LESS	COMMENTS
SODIUM	Less than 5 mg per RA and per labeled serving (or for meals and main dishes, per labeled serving).[173] "Salt Free" must meet criteria for "Sodium Free."[174] Contains no ingredient that is sodium chloride or understood to contain sodium, except if the ingredient listed in the ingredient statement has an asterisk that refers to footnote (e.g., "* adds a trivial amount of sodium").	140 mg or less per RA (and per 50 g if RA is small).[175] Meals and main dishes: 140 mg or less per 100 g.[176] "Very Low Sodium": 35 mg or less per RA (and per 50 g if RA is small). For meals and main dishes: 35 mg or less per 100 g.[177]	At least 25% less sodium per RA than an appropriate reference food (or for meals and main dishes, per 100 g).[178] Reference food may not be "Low Sodium."	"Light" (for sodium reduced products): if food is "Low Calorie" and "Low Fat" and sodium is reduced by at least 50%.[179] "Light in Sodium": if sodium is reduced by at least 50% per RA.[180] For meals and main dishes, "Light in Sodium" meets definition for "Low in Sodium."[181] "No Salt Added" and "Unsalted" must declare "This is Not A Sodium Free Food" on information panel if food is not "Sodium Free."[182] "Lightly Salted": 50% less sodium than normally added to reference food and if not also "Low Sodium," then "Not a low sodium food" must be adjacent to nutrition label or information panel.[183]

Chart continued on next page.

NUTRIENT CONTENT CLAIMS

DEFINITIONS OF PERMITTED NCCS

NUTRIENT	FREE	LOW	REDUCED / LESS	COMMENTS
SUGARS	"Sugar Free": Less than 0.5 g sugars per RA and per labeled serving (or for meals and main dishes, per labeled serving).[184] Disclose calorie profile (e.g., "Low Calorie"). Contains no ingredient that is a sugar or understood to contain sugars, except if the ingredient listed in the ingredient statement has an asterisk that refers to footnote (e.g., "* adds a trivial amount of sugar").	Not Defined. May not be used.	At least 25% less sugars per RA than an appropriate reference food (or for meals and main dishes per 100 g).[185]	"No Added Sugars" and "Without Added Sugars" are allowed if no sugar or sugar-containing ingredient is added during processing. Only use if food is not "Low" or "Reduced Calorie."[186] The terms "Unsweetened" and "No Added Sweeteners" remain as factual statements.[187] The claim does not refer to sugar alcohols, which may be present.

THE "JELLY BEAN RULE"

"Jelly Bean Rule"—*You can't fortify jelly beans to make them "healthy"*

Two points to remember:

- FDA has a general policy against fortifying candy, snack foods, and carbonated beverages[188] and
- Just because a product is low in fat, cholesterol, and sodium, it cannot claim to be "healthy" or make a specific claim about a particular nutrient in a product, unless, in the recommended serving, the product also contains 10% of the daily value of :
  - A vitamin
  - A mineral
  - Protein
  - Fiber
  - Potassium[189]

EXAMPLES OF PRODUCTS THAT RECEIVED FDA WARNING LETTERS:

- Chocolates "fortified with calcium"[190]
- "Chocolate Syrup with Calcium" and "Sugar Free Syrup with Vitamin and Mineral Fortification"[191]
- Soft drink "enhanced with … antioxidants from Green Tea & Vitamin C"[192]

EXAMPLES OF PRODUCTS WHERE JELLY BEAN RULE VIOLATIONS GAVE RISE TO A CONSUMER CLASS ACTION:

- Fruit snacks[193]
- Flavored water[194]

HEALTH CLAIMS

Claims about potential health-related benefits can be very powerful in marketing food products in today's health-conscious marketplace. Due to this power, and the potential for consumers to be deceived by misleading claims, the FDA has provided detailed regulations governing when and how such claims may be made in product labeling. As with other types of claims, we urge you to consult with a food regulatory attorney to better assess the potential risks for using health claims in your food labeling—or to assure that you are not inadvertently making an unsubstantiated health claim.

Generally speaking, as defined by the FDA, a health claim is any claim made on the label or in labeling of a food that characterizes the relationship of any substance to a disease or health-related condition. These claims may be either unqualified or qualified, and be made expressly or impliedly. Importantly, health claims may be found to exist whether intended or not. All new health claims require pre-market approval by FDA. Health claims are made in a variety of ways, including:

- Reference to "third parties" (such as the American Heart Association),
- Written statements (such as a brand name including the term "heart")
- Symbols (e.g., a heart symbol)
- Vignettes[195]

Implied health claims include those statements, symbols, vignettes, or other forms of communication that suggest, within the context in which they are presented, that a relationship exists between the presence or level of a substance in the food and a disease or health-related condition.

Health claims are different from dietary guidance statements. While health claims characterize the relationship between a food or ingredient and a disease, statements of dietary guidance do not contain both of these elements (although it may contain one element or another). Dietary guidance statements typically refer to a broad class or category of foods (i.e., a grouping that is not readily characterized compositionally) and not to a specific substance.

Some examples help demonstrate these differences:

EXAMPLES OF HOW HEALTH CLAIMS ARE DIFFERENT FROM DIETARY GUIDANCE STATEMENTS

HEALTH CLAIM	DIETARY GUIDANCE
"Three grams of soluble fiber from oatmeal daily in a diet low in saturated fat and cholesterol may reduce the risk of heart disease. This cereal has 2 grams per serving." "Diets low in saturated fat and cholesterol that include 25 grams of soy protein a day may reduce the risk of heart disease."	"Consuming at least 3 or more ounce-equivalents of whole grains per day can reduce the risk of several chronic diseases." "Carrots are good for your health." "Calcium is good for you."

HEALTH CLAIMS

NLEA AUTHORIZED HEALTH CLAIMS:

Under the Nutrition Labeling and Education Act , certain health claims are provided for by FDA regulations, but must be used in accordance with that regulation. Such claims are limited to claims about disease risk reduction, and may not concern the diagnosis, cure, mitigation, or treatment of disease. In addition, these health claims must be reviewed and evaluated by FDA prior to use on food labeling in the market.

Generally, these authorized health claims include:

• Calcium / Vitamin D and Osteoporosis[196]

• Dietary Fat and Cancer[197]

• Sodium and Hypertension[198]

• Dietary Saturated Fat and Cholesterol and risk of Coronary Heart Disease[199]

• Fiber-Containing Grain Products, Fruits, and Vegetables and Cancer[200]

• Soluble Fiber-Containing Foods and Risk of Coronary Heart Disease[201]

• Soy Protein and Risk of Coronary Heart Disease[202]

Each of these type of claims have specific requirements for the food itself (e.g., high in calcium or low fat) as well as the wording of the claim. All approved claims have specific model claim statements that may be used, when appropriate (e.g., "Development of cancer depends on many factors. A diet low in total fat may reduce the risk of some cancers.").

AUTHORITATIVE STATEMENT CLAIMS:

FDA also permits food makers to make claims based on current, published, authoritative statements from certain federal scientific bodies. In practice , approval of such claims has proven difficult to obtain.

Generally, there are several requirements for such an "authoritative statement":

• The statement relates to the relationship between a nutrient and a disease or health-related condition.

• It is published by an accepted scientific body (identified below).

• It is currently in effect.

• It is not a statement of an employee of the scientific body made in their individual capacity.

• It reflects a consensus within the identified scientific body (if published by a subdivision of one of the Federal scientific bodies).

• It is based on a deliberative review by the scientific body of the supporting scientific evidence.[203]

Recognized scientific bodies are:

– National Academy of Sciences (NAS) or its subdivisions

– National Institutes of Health (NIH)

– Centers for Disease Control and Prevention (CDC)

– The Surgeon General within Department of Health and Human Services

– The Food and Nutrition Service

– The Food Safety and Inspection Service

– The Agricultural Research Service within the Department of Agriculture

In addition to statements from the Federal scientific bodies, food makers may also rely upon other "authoritative statements," but must submit a notice to FDA of its intent 120 days prior to placing the claim on labeling in the market. This notice must contain:

- The exact words used in the claim.
- A concise description of the basis relied upon for determining that the requirements for an authoritative statement have been satisfied.
- A copy of the authoritative statement referred to.
- A balanced representation of the scientific literature relating to the relationship between a nutrient and a disease or health-related condition to which the claim refers.[204]

NLEA AUTHORIZED HEALTH CLAIMS AND AUTHORITATIVE STATEMENT CLAIMS MUST MEET "SIGNIFICANT SCIENTIFIC AGREEMENT"

FDA assesses new proposed authorized health claims and authoritative statement claims against the high standard of "Significant Scientific Agreement," which requires consensus among experts based on scientific studies indicating such a certain state of the science that new research is unlikely to reverse the claim.[205] Once the authoritative statement is provided to the FDA, it may authorize use of the health claims if it "determines, based on the totality of publicly available scientific evidence (including evidence from well- designed studies conducted in a manner which is consistent with generally recognized scientific procedures and principles), that there is significant scientific agreement among experts qualified by scientific training and experience to evaluate such claims, that the claim is supported by such evidence."[206]

QUALIFIED HEALTH CLAIMS:

Food makers whose claim cannot meet significant scientific agreement, may instead petition the agency for a qualified health claim ("QHC"). A QHC is just that— a health claim that has been qualified to reflect supporting science so as not to mislead consumers.[207] Although QHCs are still based on the totality of publicly available evidence, the scientific support does not have to be as strong as that for regular health claim.

FDA requirements for QHCs are similar to regular health claims in many respects. Food makers must submit a pre-market petition to FDA setting forth:

- Preliminary Requirements, including:[208]
  - Relationship between substance and disease or health-related condition.
  - How substance is a food, food ingredient, or component that has been shown to be safe and lawful at levels necessary to justify a claim.[209]
  - How substance contributes taste, aroma, nutritive value, or a technical effect as a food additive (e.g., anticaking agent, antioxidant, color).[210]
- Summary of Scientific data, including:[211]
  - Totality of publicly-available scientific evidence (including results of well-designed studies),
  - Public health benefit from use of the claim.
  - Analysis of potential effect of use of the claim on food consumption.
  - Prevalence of disease or health-related condition, if appropriate.
- Analytical data to show amount of the substance / ingredient that is present in representative foods.[212]
- Proposed model health claim(s) for use on labeling, which should include:[213]
  - Brief statement of the relevant conclusion of the summary.
  - Statement of how substance helps consumer attain goal associated with the health benefit provided.
- Copies of all supporting materials, including:[214]
  - Scientific data supporting a claim.
  - Computer literature searches.
  - All research articles relied upon for support of petition (in English).
  - Information concerning adverse consequences pertinent to any segment of the U.S. population.
- A claim for categorical exclusion or an environmental assessment.[215]

An example of a QHC is Omega3 Fatty Acids; Coronary Heart Disease related to qualified fish products. In this regard, the approved QHC states:

> Supportive but not conclusive research shows that consumption of EPA and DHA omega-3 fatty acids may reduce the risk of coronary heart disease. One serving of [Name of the food] provides [ ] gram of EPA and DHA omega-3 fatty acids. [See nutrition information for total fat, saturated fat, and cholesterol content.][216]

STRUCTURE / FUNCTION CLAIMS

STRUCTURE / FUNCTION CLAIMS:

In addition to the health claims described above, dietary supplements may include labeling statements that describe the role of a nutrient or dietary ingredient intended to affect the normal structure or function of the human body.[217] For example, "calcium builds strong bones" is a structure / function claim. Structure / function claims may also characterize the means by which a nutrient or dietary ingredient acts to maintain such structure or function (e.g., "fiber maintains bowel regularity," or "antioxidants maintain cell integrity."

Importantly, these claims may not relate to a disease (e.g., cardiovascular disease) or state of health leading to dysfunction (e.g., hypertension). If they do, then the FDA will treat the dietary supplement as a "drug," subjecting it to a whole host of drug-related regulations and requirements.

If a dietary supplement label includes a structure / function claim, it must also include specific "disclaimer" in boldface type and either placed next to or tied to the claim by an asterisk:[218]

Unlike health claims described above, structure / function claims do not require pre-market approval. But the manufacturer must have substantiation that the claim is truthful and not misleading, and must submit a notification with the text of the claim to FDA no later than 30 days after marketing the dietary supplement with the claim.[219] For an introduction to additional labeling requirements for dietary supplements, please see Appendix 2.

Although the statutory provisions described above only apply to dietary supplements, such structure / function claims may be made on conventional foods as long as the effects are derived from the nutritive value of the food. FDA has indicated that it is likely to interpret the dividing line between structure / function claims and disease claims in a similar manner for conventional foods as for dietary supplements.[220]

There are two significant differences between use of structure / function claims on nutritional supplements and foods. Conventional food makers need not use the above "disclaimer," nor do they need to notify FDA about their structure / function claims.

These statements have not been evaluated by the Food and Drug Administration. This product is not intended to diagnose, cure, treat, or prevent any disease.

5

APPENDIX:
SOURCES / CITATIONS

APPENDIX

APPENDIX 1

COMMON STANDARD OF IDENTITY CATEGORIES:

As mentioned in the Standards of Identity section, FDA has promulgated specific regulations for certain categories of standardized and non-standardized foods. This is not intended to be a complete list, but includes food categories where you should consult a regulatory attorney and align your processes with the regulations promulgated for that food to avoid a misbranding action.

STANDARDIZED FOODS	NONSTANDARDIZED FOODS
• Dairy[1] • Frozen desserts[2] • Bakery products[3] • Macaroni and Noodle products[4] • Canned fruit[5] & canned fruit juices[6] • Fruit butters, jellies, etc.[6] • Canned vegetables[7] • Vegetable juice[9] • Eggs and Egg products[10] • Fish & shellfish[11] • Cacao products[12] • Tree and Nut products[13] • Beverages[14] • Sweeteners and table sirups (FDA's spelling, not ours!)[15] • Food dressings and flavorings[16]	• Peanut spreads[17] • Frozen "heat and serve" dinners[18] • Foods packaged for use in preparing "main dishes" or "dinners"[19] • Juice – very specific requirements!!![20] • Certain types of fish and seafood[21]

1 See 21 C.F.R. § 131 (milk and cream—including yogurt); § 133 (cheese and related products).
2 See 21 C.F.R. § 135.3.
3 See 21 C.F.R. § 136; see also 21 C.F.R § 137 (cereal flours).
4 See 21 C.F.R. § 139.
5 See 21 C.F.R. § 145.
6 See 21 C.F.R. § 136.
7 See 21 C.F.R. § 150.
8 See 21 C.F.R. § 155.
9 See 21 C.F.R. § 156.
10 See 21 C.F.R. § 160.
11 See 21 C.F.R. § 161.
12 See 21 C.F.R. § 163.
13 See 21 C.F.R. § 164.
14 See 21 C.F.R. § 165.
15 See 21 C.F.R. § 168.
16 See 21 C.F.R. § 169.
17 21 C.F.R. § 102.23.
18 21 C.F.R. § 102.26.
19 21 C.F.R. § 102.28.
20 21 C.F.R. § 102.33.
21 See 21 C.F.R. §§ 102.45–.57.

APPENDIX

APPENDIX 2

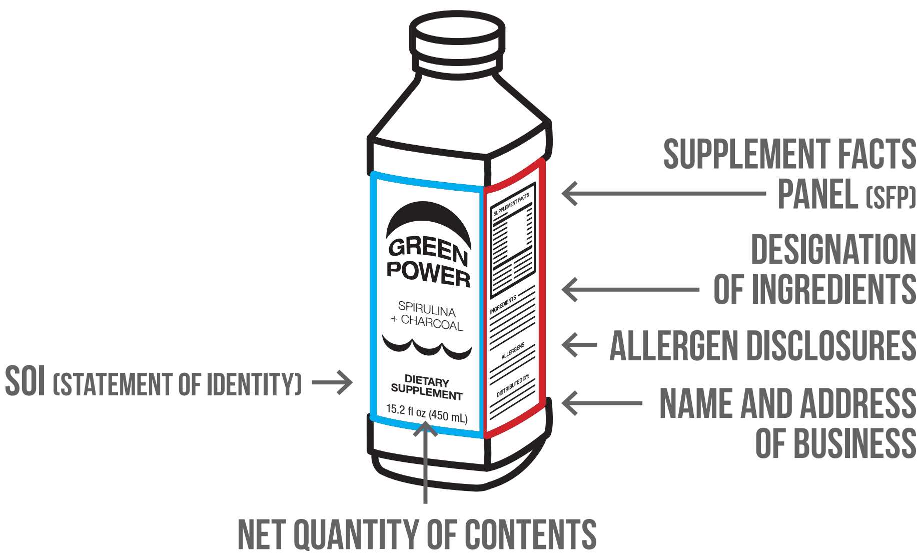
INTRODUCTION TO DIETARY SUPPLEMENTS:

This Appendix covers some of the basic differences between how dietary supplements are labeled compared to conventional foods.

Are you using a box and a bottle in your packaging? The same information must appear on both, including any additional warnings and information about serious adverse event reporting requirements.

PRINCIPAL DISPLAY PANEL (PDP)

INFORMATION PANEL (IP)



PRINCIPAL DISPLAY PANEL (PDP)

Must include:

1. STATEMENT OF IDENTITY (SOI):

- "Dietary Supplement."
- A description of the dietary ingredients in the product may replace the word "dietary."[1]
- Examples:
  - Dietary Supplement
  - Vitamin A Supplement
  - Herbal Supplement
- The same size and prominence requirements apply as to food products. *See page 11.*

2. NET QUANTITY OF CONTENTS:

- In addition to weight or liquid measure, a count of the number of units in the container is appropriate.[2]
- Examples:
  - **30 Capsules**
  - **20 Tablets**
  - **10 Packets**
- Same requirements for bold face type and typeface height apply.

INFORMATION PANEL (IP)

MUST INCLUDE:

- Supplement Facts Panel
- Declaration of Ingredients
- Allergen Disclosures (same rules as conventional foods, page 24)
- Name and Place of Business of Manufacturer
- Serious Adverse Event Reporting Contact
- Applicable Required Warnings

HOW TO DISPLAY YOUR IP

All information must measure at least 1/16 inches high.[3]
Dietary supplements must bear a "Supplement Facts" and not a "Nutrition Facts" panel.

APPENDIX

Key Differences between Nutrition Facts and Supplement Facts Panel:

NUTRITION FACTS PANEL	SUPPLEMENT FACTS PANEL
• Must NOT list ingredients without a Reference Daily Intake (RDI) or Daily Reference Value (DRV) • Must NOT list the source of an ingredient within the panel • Must NOT list the part of the plant from which ingredient is derived • MUST list ingredients for which there are Zero amounts of nutrients	• MUST list dietary ingredients without a RDI or DRV[4] • MAY list the source of an ingredient in parentheses after the ingredient in the panel[5] • MUST list the part of the plant from which the dietary ingredient is derived in the panel[6] • Must NOT list nutrients with zero amounts[7]

NEW SUPPLEMENT FACTS PANEL:

Like the new Nutrition Facts Panel, FDA will begin requiring the disclosure of:

- Total Sugars
- Vitamin D
- Potassium

FDA no longer requiring disclosure of:

- Vitamin A
- Vitamin C
- Calories from fat

There have also been some order changes for the disclosure of dietary ingredients.[8]

FORMATTING:

FDA has stated that it will not require calories in bold or extrabold font and in typeface 2 points larger than other text in the label, and will correct the error codified in regulation at some point in time.[9]

APPENDIX

An example of the new label is provided below:

EXAMPLE 1

(i) Multiple vitamins (Includes voluntary listing of vitamin D in IUs)

Supplement Facts

Serving Size 1 Gelcap
Servings Per Container 100

	Amount Per Serving	% Daily Value
Vitamin A (as retinyl acetate and 50% as beta-carotene)	900 mcg	100%
Vitamin C (as ascorbic acid)	90 mg	100%
Vitamin D (as cholecalciferol)	20 mcg (800 IU)	100%
Vitamin E (as dl-alpha tocopheryl acetate)	15 mg	100%
Thiamin (as thiamin mononitrate)	1.2 mg	100%
Riboflavin	1.3 mg	100%
Niacin (as niacinamide)	16 mg	100%
Vitamin B_6 (as pyridoxine hydrochloride)	1.7 mg	100%
Folate	400 mcg DFE (240 mcg folic acid)	100%
Vitamin B_{12} (as cyanocobalamin)	2.4 mcg	100%
Biotin	3 mcg	10%
Pantothenic Acid (as calcium pantothenate)	5 mg	100%

Other ingredients: Gelatin, lactose, magnesium stearate, microcrystalline cellulose, FD&C Yellow No. 6, propylene glycol, preservatives (propylparaben and sodium benzoate).

Like the new Nutrition Facts Panel, FDA has indefinitely delayed the compliance date for when the new panel will go into effect. You should consult a food regulatory attorney about the your decision to use the old or new panel.

DECLARATION OF INGREDIENTS:

Ingredients may be declared differently on Supplements compared with food products. FDA distinguishes between ingredients and dietary ingredients in the requirements for ingredients.

Ingredients is the broader category, while dietary ingredients contribute some sort of nutritive value to the product – even if there is no established daily value for the ingredient.

Unlike with conventional foods, if a dietary ingredient is listed in the Supplement Facts Panel, the dietary ingredient does not need to be included in the ingredient declaration below as well.[10] If all the ingredients are listed in the Supplement Facts Panel, then no additional ingredient disclosure is required.[11]

If some ingredients are listed in the Supplement Facts Panel, but ingredients such as fillers, remain to be disclosed, the ingredient listing must be preceded by "Other Ingredients:…," as in the example above.

If you choose to list all ingredients, the list should be preceded with "Ingredients:…"[12] When

EXAMPLE 2

(iii) Multiple vitamins in packets (Includes voluntary listing of vitamin D in IUs)

Supplement Facts

Serving Size 1 Packet
Servings Per Container 10

	AM Packet		PM Packet	
Amount Per Serving		**% Daily Value**		**% Daily Value**
Vitamin A	450 mcg	50%	450 mcg	50%
Vitamin C	90 mg	100%	90 mg	100%
Vitamin D	20 mcg (800 IU)	100%		
Vitamin E	15 mg	100%		
Thiamin	1.2 mg	100%	1.2 mg	100%
Riboflavin	1.3 mg	100%	1.3 mg	100%
Niacin	16 mg	100%	16 mg	100%
Vitamin B_6	1.7 mg	100%	1.7 mg	100%
Folate	200 mcg DFE (120 mcg folic acid)	50%	200 mcg DFE (120 mcg folic acid)	50%
Vitamin B_{12}	1.2 mcg	50%	1.2 mcg	50%
Biotin			3 mcg	10%
Pantothenic Acid	2.5 mg	50%	2.5 mg	50%

Ingredients: Sodium ascorbate, ascorbic acid, calcium pantothenate, niacinamide, dl-alpha tocopheryl acetate, microcrystalline cellulose, dextrin, starch, mono- and diglycerides, vitamin A acetate, magnesium stearate, gelatin, FD&C Blue #1, FD&C Red #3, artificial colors, thiamin mononitrate, pyridoxine hydrochloride, citric acid, lactose, sorbic acid (preservative), tricalcium phosphate, sodium benzoate (preservative), sodium caseinate, preservatives (methylparaben, potassium sorbate, BHA, BHT), ergocalciferol, cyanocobalamin, and artificial flavors.

These examples are not included in this guide, but additional rules apply and FDA has provided sample formats for when:

- A supplement is intended for children.
- A supplement is intended for children and adults.
- A supplement includes different capsules to be taken at different times (EX: an AM and a PM tablet).
- A supplement includes a proprietary blend of ingredients

You should consult regulatory counsel to advise about requirements for labeling of such products.

APPENDIX

INGREDIENT NAMING CONVENTIONS AND NEW DIETARY INGREDIENTS:

There are particular naming conventions for ingredients in dietary supplements. For example, dietary ingredients of botanical origin must be disclosed in accord with their listing in the 2000 edition of the *Herbs of Commerce*,[14] and list the part of the plant from which they are sourced in parentheses following the identity of the ingredient, and in English.[15]

Additionally, if a dietary ingredient in the supplement you are marketing was not marketed before October 15, 1994, is not covered by an existing New Dietary Ingredient filing, or is in a form that is chemically altered from how the substance is available in the conventional food supply, a New Dietary Ingredient filing may be required.[16] This is a controversial area in labeling and packaging law, and rapidly changing.

Because of the intricacies involved in disclosing ingredients, especially in determining if a New Dietary Ingredient filing is required, you should consult a regulatory attorney to review your ingredient listing.

ALLERGEN DISCLOSURES:

The same requirements for the disclosure of allergens for foods also apply to the labeling of dietary supplements, *see page 24*.

NAME, PLACE, AND BUSINESS OF THE MANUFACTURER & SERIOUS ADVERSE EVENT REPORTING LABELING REQUIREMENTS:

Dietary supplements must follow the same rules as conventional foods in the labeling for name place and business of the manufacturer, but an additional law comes into play. The Dietary Supplement and Nonprescription Drug Consumer Protection Act requires that the label of all dietary supplements include

- A domestic address or
- Domestic phone number

Through the provision of this information the "responsible person" must be able to receive reports of serious adverse events associated with the consumption of its products.[17] If the name and address that appears on the label is that of a person other than the responsible person, this requires the inclusion of additional contact information. If an address is used instead of a phone number, the address must include the full street address or P.O. Box, city, state, and zip code of the responsible person.[18]

The FDCA does not require, but FDA guidance recommends the inclusion of a "clear, prominent statement" directing consumers that they may report any serious adverse event to the contact provided.[19]

You should consult a regulatory attorney to ensure that you have identified an appropriate responsible person and have procedures in place to make serious adverse event reports to the FDA. If you are using a co-manufacturer or a retailer's contact information will appear on your label, it is best to allocate serious adverse event reporting requirements contractually with the advice of legal counsel.

APPENDIX

WARNINGS:

Iron containing supplements must include the following on the information panel:[20]

WARNING: Accidental overdose of iron-containing products is a leading cause of fatal poisoning in children under 6. Keep this product out of reach of children. In case of accidental overdose, call a doctor or poison control center immediately.

Warnings also apply to:

- High protein supplements marketed for weight loss.[21]
- Supplements containing high levels of psyllium husk.[22]

PRACTICE TIP

The prohibition on intervening material also applies to dietary supplement labeling. However, with more required information, the information panel requires careful planning.

1 21 U.S.C. § 321(ff)(2)(C), 21 U.S.C. § 343(s)(2)(B) and 21 CFR § 101.3(g).
2 21 C.F.R. § 101.105.
3 21 C.F.R. § 101.2(c).
4 21 C.F.R. § 101.136(b)(2).
5 21 C.F.R. § 101.136(d).
6 21 C.F.R. § 101.136(d)(1).
7 21 C.F.R. § 101.136(b)(2).
8 21 C.F.R. § 101.36(b)(2)(i)(B)).
9 See 81 Fed. Reg. 33742, 33939 Revision of the Nutrition and Supplement Facts Labels, (May 27, 2016).
10 21 CFR § 101.36(d).
11 21 CFR § 101.4(a)(1).
12 21 CFR § 101.4(g).
13 21 C.F.R. § 101.4(a).
14 Food &; Drug Admin., Food Labeling: Ingredient Labeling of Dietary Supplements That Contain Botanicals, 68 Fed. Reg. 51693, 51695 (Aug. 28, 2003).
15 21 C.F.R. § 101.4(h)(1).
16 See Food &; Drug Admin., Premarket Notification for a New Dietary Ingredient, 62 Fed. Reg. 50774 (Sep. 23, 1997); Food &; Drug Admin., Draft Guidance for Industry: Dietary Supplements: New Dietary Ingredient Notifications and Related Issues, (August 2016), https://www.fda.gov/downloads/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/UCM515733.pdf.
17 21 U.S.C. § 343(y).
18 Food &; Drug Admin., Guidance for Industry: Questions and Answers Regarding the Labeling of Dietary Supplements as Required by the Dietary Supplement and Nonprescription Drug Consumer Protection Act (Revised September 2009), https://www.fda.gov/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/ucm179018.htm
19 Id.
20 21 C.F.R § 101.179(e).
21 21 C.F.R § 101.17(d)
22 21 C.F.R. § 101.17(f).

SOURCES / CITATIONS

[1] 21 U.S.C. § 601.
[2] 21 U.S.C. § 453.
[3] 21 U.S.C. § 607(d) (meat) & 457(c).
[4] 21 U.S.C. § 301 et seq.
[5] 21 U.S.C. § 301 et seq.
[6] 21 U.S.C. § 343(a)(1) (defining misbranding); § 331(b) (defining delivery of misbranded product into interstate commerce as a prohibited act).
[7] See Inspections, Compliance, Enforcement & Criminal Investigations: Warning Letters, https://www.fda.gov/ICECI/EnforcementActions/WarningLetters/ucm2005393.htm#moreinfo.
[8] 21 U.S.C. § 350l(a) (voluntary recall); § 350l(b)(1) (mandatory recall authority).
[9] 21 U.S.C. § 334 (seizure authority).
[10] 21 U.S.C. § 350d(b).
[11] 21 U.S.C. § 333.
[12] 21 U.S.C. § 333(a)(1) (explaining criminal fines and potential for one year of imprisonment for a first time offense).
[13] 21 C.F.R. § 101.2(a)(3).
[14] 21 C.F.R. 101.3(a)
[15] 21 C.F.R. § 101.105.
[16] 21 C.F.R. § 101.1(a).
[17] 21 C.F.R. § 101.1(b).
[18] 21 C.F.R. § 101.1(b).
[19] 21 C.F.R. 101.2(c).
[20] 21 C.F.R. § 101.3(b)(1).
[21] 21 C.F.R. § 101.3(b)(2).
[22] 21 C.F.R. § 101.3(b)(2).
[23] 21 C.F.R. § 102.5(d).
[24] 21 C.F.R. § 101.3(b)(3).
[25] 21 U.S.C. § 343(g); see, e.g. Warning Letter to Awesome Foods, Inc., (Dec. 15, 2009) (citing company for failing to conform for the standard of identity promulgated for parmesan cheese).
[26] 21 C.F.R. §101.3(a) (principle feature); §101.3(d) (parallel to the package bottom, bold typeface); Food & Drug Admin., A Food labeling guide, Guidance for Industry, at 7, http://www.fda.gov/downloads/Food/GuidanceRegulation/UCM265446.pdf.
[27] 21 C.F.R. § 101.15.
[28] 21 C.F.R. § 101.105(a).
[29] 21 C.F.R. § 101.105(c).
[30] 21 C.F.R. § 101.105(b); § 101.105(j)(3) (must use Net Weight); §101.105(n) for abbreviations.
[31] 21 C.F.R. § 101.105(a); § 105(b)(2) (for units of measure); § 101.105(j)(3) (must use Net or Net Contents); §101.105(n) for abbreviations.
[32] 21 C.F.R. § 101.105(d).
[33] 21 C.F.R. § 101.105(d).
[34] 21 C.F.R. § 101.105(d).
[35] 21 C.F.R. § 101.105(k).
[36] 21 C.F.R. § 101.105(a).
[37] 21 C.F.R. § 101.105(h).
[38] 21 C.F.R. § 101.105(f).
[39] 21 C.F.R. § 101.105(f).
[40] 21 C.F.R. § 101.105(h)(1).
[41] Compliance Policy Guide Section 140.500 Metric Declaration of Quantity of Contents on Product Labels.; https://www.fda.gov/ICECI/ComplianceManuals/CompliancePolicyGuidanceManual/ucm073844.htm
[42] 21 C.F.R. § 101.105(h)(3)(i)(4).
[43] 21 C.F.R. § 101.105(h)(3)(i)(1).
[44] 21 C.F.R. § 101.105(h)(3)(i)(2).
[45] 21 C.F.R. § 101.105(h)(3)(i)(3).
[46] 21 C.F.R. § 101.105(f).
[47] 21 C.F.R. § 101.105(f).
[48] 21 C.F.R. § 101.105(f).
[49] 21 C.F.R. § 101.105(f).
[50] 21 C.F.R. § 101.2(a).
[51] 21 C.F.R. § 101.2(a).
[52] 21 C.F.R. § 101.2(c).
[53] 21 C.F.R. § 101.9(j)(1)(i); § 101.9(j)(1)(ii).
[54] 21 C.F.R. § 101.9(d)(1)(i).
[55] 21 C.F.R. § 101.9(d)(1)(ii)(A); § 101.9(d)(1)(ii)(B); § 101.9(d)(1)(ii)(C); § 101.9(d)(1)(ii)(D).
[56] 21 C.F.R. § 101.9(c).
[57] 21 C.F.R. § 101.9(c).
[58] 21 C.F.R. § 101.9(c)(8)(ii).
[59] 21 C.F.R. § 101.9(c)(8)(iv).
[60] 21 C.F.R. § 101.9 (11)(iii).
[61] 21 C.F.R. § 101.9(b)(12)(i).
[62] 21 C.F.R. § 101.2(b).

SOURCES / CITATIONS

[63] 21 C.F.R. § 101.4(a)(1).
[64] 21 C.F.R. § 101.4(a)(2).
[65] 21 C.F.R. § 101.2(c).
[66] 21 C.F.R. § 101.4(b).
[67] 21 C.F.R. § 101.4(b)(1); § 101.22.
[68] 21 C.F.R. § 101.4(b)(2).
[69] 21 U.S.C. § 321(s).
[70] 21 U.S.C. § 321(s).
[71] 21 U.S.C. § 321(s)(3).
[72] 21 U.S.C. § 343(w).
[73] 21 U.S.C. § 321(qq)(1).
[74] 21 U.S.C. § 343(w)(1)(a).
[75] 21 U.S.C. § 343(w)(2).
[76] 21 U.S.C. § 343(w)(1)(a).
[77] 21 C.F.R. § 101.2(b).
[78] 21 C.F.R. § 101.5(d).
[79] 21 C.F.R. § 101.5(b).
[80] 21 C.F.R. § 101.5(b).
[81] 21 C.F.R. § 101.5(c).
[82] 21 C.F.R. § 101.5(e).
[83] FDA, Inspections, Compliance, Enforcement, and Criminal Investigations: Compliance Policy Guide Sec. 560.200 Country of Origin Labeling, https://www.fda.gov/iceci/compliancemanuals/compliancepolicyguidancemanual/ucm074567.htm
[84] 21 C.F.R. § 101.18.
[85] 21 C.F.R. § 101.2(e).
[86] See generally 7 C.F.R § 205.270 (organic handling requirements); §205.400 (requiring annual submission of handling system plan); §205.403 (requiring annual onsite inspection).
[87] See generally 7 C.F.R. § 205.500(a).
[88] 7 C.F.R § 205.100(c)(1) as amended by 7 C.F.R. § 3.91(b)(1)(xxxvii) (adjusting penalty for inflation).
[89] 7 C.F.R. § 205.105.
[90] 7 C.F.R. § 205.302(c).
[91] See 7 C.F.R. § 205.302. Specific formulas exist for solid ingredients, liquid ingredients, and combination products.
[92] 7 C.F.R. § 205.303(a)(1).
[93] 7 C.F.R. § 205.303(a)(4).
[94] 7 C.F.R. § 205.303(a)(5).
[95] 7 C.F.R. § 205.303(a); §304(a).
[96] 7 C.F.R. § 205.303(a)(1).
[97] 7 C.F.R. § 205.303(a)(2)
[98] 7 C.F.R. § 205.303(a)(4).
[99] 7 C.F.R. § 205.303(a)(5).
[100] 7 C.F.R. § 205.304(a)(2).
[101] 7 C.F.R. § 205.304(a)(1)(i) (All ingredients must be organically produced).
[102] 7 C.F.R. § 205.304(a)(1)(ii) (The food groups are: beans, fish, fruits, grains, herbs, meats, nuts, oils, poultry, seeds, spices, sweeteners, and vegetables or processed milk products. All ingredients of each food group must be organically produced.)
[103] 7 C.F.R. § 205.304(a)(1)(i); §304.(a)(1)(ii).
[104] 7 C.F.R. § 205.304(a)(1)(iii); § 304(a)(2).
[105] 7 C.F.R. § 205.304(c).
[106] 7 C.F.R. § 205.304(a)(3).
[107] 7 C.F.R. § 205.305(a)(2).
[108] 7 C.F.R. § 205.305(b)(1).
[109] 7 C.F.R. § 205.305(b)(2).
[110] 7 C.F.R. § 205.305(a)(2).
[111] 7 C.F.R. § 205.303(b)(1); § 304(b)(1); § 305(a)(1).
[112] 7 C.F.R. § 205.303(b)(2); § 304(b)(2).
[113] 7 C.F.R. § 205.311(b)(1).
[114] 7 C.F.R. § 205.311(b)(2).
[115] 7 C.F.R. § 205.311(b)(3).
[116] 7 C.F.R. § 205.303(a)(5).
[117] 7 C.F.R. § 205.303(a)(5).
[118] 21 U.S.C. § 343(a).
[119] Williams v. Gerber Products Company, 552 F.3d 934, 938 (9th Cir. 2008).
[120] Henry v. Gerber Products Company, Civ. No. 3:15-cv- 02201 (D. Ore. Dec. 7 2016).
[121] 21 U.S.C. § 321(k).
[122] 21 U.S.C. § 321(m).
[123] Lynch, et al. v. Tropicana Products, Inc. , et al., Civ. No. 2:11-cv- 07382-DMC- JAD (D.N.J. June 12, 2013).
[124] See, e.g., Ramsaran v. Tabatchnick Fine Foods Inc., Civ. No. 0:17-cv- 60794 (S.D. Fla. Apr. 24, 2017), Eggnatz at al. v. The Kellogg Company, et al., Civ. No. 1:12-cv- 21678 (S.D. Fla. Sept. 5, 2014), Frito-Lay North America Inc. "All Natural" MDL Litigation, Civ. No. 1:12-md- 02413 (E.D.N.Y. Nov. 10, 2015).
[125] 21 CFR § 101.65(d).
[126] 21 CFR § 101.62(b)(2).

SOURCES / CITATIONS

[127] 21 CFR § 101.62(c)(2).
[128] 21 CFR § 101.13(h).
[129] 21 CFR § 101.13(l).
[130] 21 CFR § 101.13(m).
[131] 21 CFR § 101.62(b)(3).
[132] 21 CFR § 101.62(c)(3).
[133] 21 CFR § 101.62(b)(2).
[134] 21 CFR § 101.62(c)(2).
[135] 21 CFR § 101.13(h).
[136] 21 CFR § 101.13(l).
[137] 21 CFR § 101.13(m).
[138] Food &; Drug Admin., Use of the Term Healthy in Labeling of Human Food Products: Guidance for Industry, (September 2016), https://www.fda.gov/downloads/food/guidanceregulation/guidancedocumentsregulatoryinformation/ucm521692.pdf.
[139] 21 CFR § 101.13(a) and (b).
[140] 21 CFR § 101.13(f).
[141] 21 CFR § 101.13(h)(1).
[142] 21 CFR § 101.13(l).
[143] 21 CFR § 101.13(h)(2).
[144] 21 CFR § 101.13(m).
[145] 21 CFR § 101.13(h)(3).
[146] 21 CFR § 101.13(h)(1).
[147] 21 CFR § 101.13(h)(4)(i)(ii).
[148] 21 CFR §§ 101.54(a) and (c) and 101.13(i)(3).
[149] 21 CFR §§ 101.54(a) and (c) and 101.13(i)(3).
[150] 21 CFR § 101.60(b)(1).
[151] 21 CFR § 101.60(b)(2).
[152] 21 CFR § 101.60(b)(3).
[153] 21 CFR §§ 101.60(b)(4) &; (5).
[154] 21 CFR § 101.56(b).
[155] 21 CFR § 101.56(d).
[156] 21 CFR § 101.62(b)(1).
[157] 21 CFR § 101.62(b)(2).
[158] 21 CFR § 101.62(b)(3).
[159] 21 CFR §§ 101.62(b)(4) &;(5).
[160] 21 CFR § 101.62(b)(6).
[161] 21 CFR § 101.62(b)(2)(iii).
[162] 21 CFR § 101.56(d).
[163] 21 CFR § 101.62(c)(1).
[164] 21 CFR § 101.62(c)(2).
[165] 21 CFR § 101.62(c)(3).
[166] 21 CFR §§ 101.62(c)(4) &;(5).
[167] 21 CFR § 101.62(c).
[168] 21 CFR § 101.62(d)(1).
[169] 21 CFR § 101.62(d)(2).
[170] 21 CFR § 101.62(d)(3).
[171] 21 CFR §§ 101.62(d)(4) &;(5).
[172] 21 CFR § 101.62(d)(1).
[173] 21 CFR § 101.61(b)(1).
[174] 21 CFR § 101.61(c)(1).
[175] 21 CFR § 101.61(b)(4).
[176] 21 CFR § 101.61(b)(5).
[177] 21 CFR §§ 101.61(b)(2) &; (3).
[178] 21 CFR §§ 101.61(b)(6) &; (7).
[179] 21 CFR § 101.56(c)(1).
[180] 21 CFR § 101.56(c)(2).
[181] 21 CFR § 101.56(d)(2).
[182] 21 CFR § 101.61(c)(2).
[183] 21 CFR § 101.56(g).
[184] 21 CFR § 101.60(c)(1).
[185] 21 CFR §§ 101.60(c)(5) &; (6).
[186] 21 CFR § 101.60(c)(2).
[187] 21 CFR § 101.60(c)(3).
[188] 21 C.F.R.§ 104.20.
[189] See 21 C.F.R. § 101.54.
[190] FDA, WARNING LETTER TO GOETZE'S CANDY COMPANY, March 4, 2011 http://www.fda.gov/ICECI/EnforcementActions/WarningLetters/ucm247011.htm.
[191] FDA, WARNING LETTER TO THE HERSHEY COMPANY, Feb. 14, 2012, http://www.fda.gov/ICECI/EnforcementActions/WarningLetters/ucm314829.htm.

SOURCES / CITATIONS

[192] FDA, WARNING LETTER TO DR. PEPPER SNAPPLE GROUP, http://www.fda.gov/ICECI/EnforcementActions/WarningLetters/ucm224571.htm.
[193] Atik, et al. v. Welch Foods, Inc., et al., Civ. No. 1:15-cv- 05405-MKB- VMS (E.D.N.Y. Sept. 30, 2016).
[194] In Re Glaceau Vitamin Water Marketing and Sales Practice Litigation &; Ackerman v. Coca-Cola Company, Civ. No. 11-2355 (E.D.N.Y. Apr. 7, 2016) (in which Coca-Cola agreed to pay $2,730,000 to consumers).
[195] 21 CFR § 101.14(a)(1).
[196] 21 CFR § 101.72.
[197] 21 CFR § 101.73.
[198] 21 CFR § 101.74.
[199] 21 CFR § 101.75.
[200] 21 CFR §§ 101.76 and 101.78.
[201] 21 CFR §§ 101.77 and 101.81.
[202] 21 CFR § 101.82.
[203] FDA, Guidance for Industry: Notification of a Health Claim or Nutrient Content Claim Based on an Authoritative Statement of a Scientific Body (https://www.fda.gov/food/guidanceregulation/guidancedocumentsregulatoryinformation/ucm056975.htm).
[204] 21 U.S.C. §343(r)(3)(C)(ii).
[205] 21 U.S.C. §343(r)(3)(B)(i), 21 CFR §101.14(c).
[206] 21 U.S.C. §343(r)(3)(B)(i).
[207] Food &; Drug Admin., Guidance for Industry: Interim Procedures for Qualified Health Claims in the Labeling of Conventional Human Food and Human Dietary Supplements, (July 2003) (updated July 1, 2016) https://www.fda.gov/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/ucm053832.htm.
[208] 21 CFR 101.70(f)(A).
[209] 21 CFR 101.14(b)(3)(ii).
[210] 21 CFR 170.3(o).
[211] 21 CFR 101.70(f)(B).
[212] 21 CFR 101.70(f)(C).
[213] 21 CFR 101.70(f)(D).
[214] 21 CFR 101.70(f)(E).
[215] 21 CFR 101.70(f)(F).
[216] Letter Responding to Health Claim Petition dated November 3, 2003 (Martek Petition): Omega-3 Fatty Acids and Reduced Risk of Coronary Heart Disease (Docket No. 2003Q-0401), https://www.fda.gov/food/ingredientspackaginglabeling/labelingnutrition/ucm072932.htm.
[217] 21 U.S.C. §343(r)(6).
[218] 21 CFR §§ 101.93(c) &; (d).
[219] 21 CFR § 101.93(a)(1).
[220] https://www.fda.gov/Food/IngredientsPackagingLabeling/LabelingNutrition/ucm2006881.htm#conventional.

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