PACKAGING COMPLIANCE

FIELD GUIDE

PRO TIPS FOR FOOD ENTREPRENEURS

BROUGHT TO YOU BY

+

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.

CHUCK COTTER
Holland & Hart / Partner
Food & Beverage Team Lead
(303) 473-2735
CACotter@hollandhart.com

JENI LAMB ROGERS
Holland & Hart / Associate
Food & Beverage Regulatory Compliance Specialist
(303) 295-8329
JLRogers@hollandhart.com

LEE GRAY
Holland & Hart / Partner
Food & Beverage Product Liability & Recall Specialist
(303) 290-1602
LGray@hollandhart.com

ADAM SPRIGGS
Nucleus Maximus / Founder
(419) 705-1248
Adam@nucleusmaximus.com

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 does not cover dietary supplements or 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]

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, punishable by a criminal fine or one year of imprisonment.[12]

TABLE OF CONTENTS

PACKAGING OVERVIEW & TERMINOLOGY

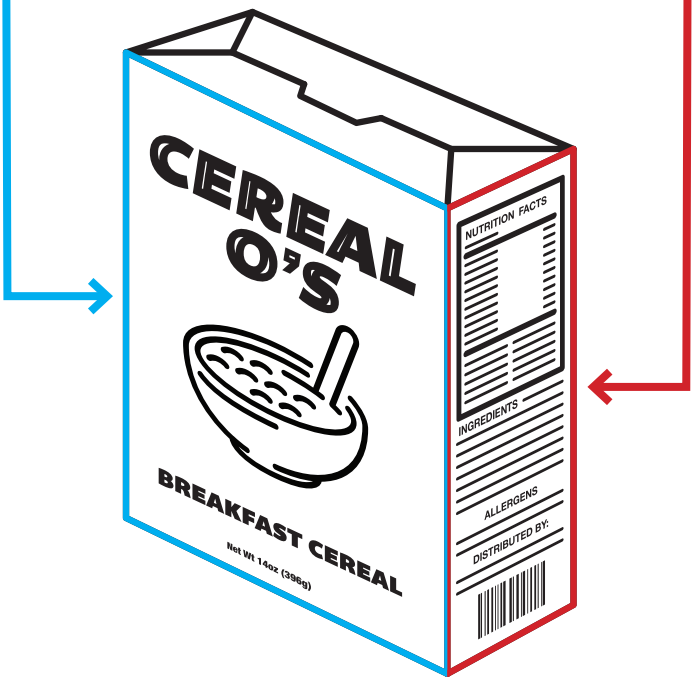
Before diving in, let's get aligned on some essential packaging terminology that all packaged food products must have:

1: PDP (PRINCIPAL DISPLAY PANEL)

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

2: INFORMATION PANEL

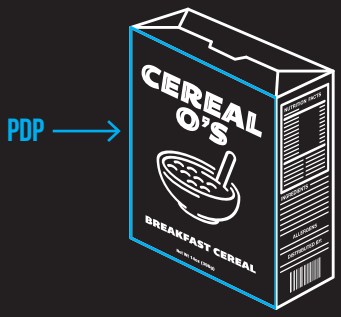
Must be located on nearest adjacent panel to the PDP that can accommodate the required information.



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

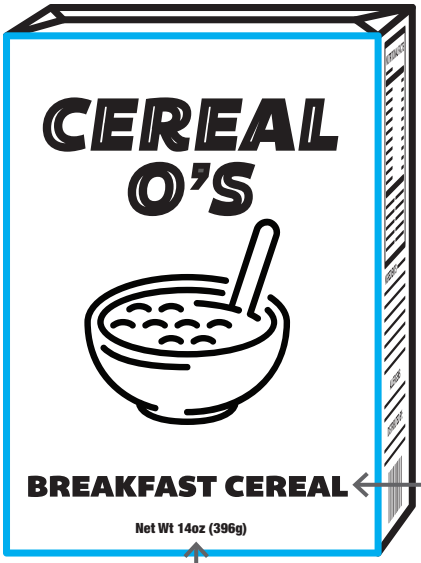
1

PRINCIPAL DISPLAY PANEL (PDP) REQUIREMENTS



PRINCIPAL DISPLAY PANEL (PDP)

PDP



1: SOI (STATEMENT OF IDENTITY)[14]

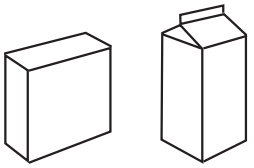
2: NET QUANTITY OF CONTENTS[15]

PDP SIZE REQUIREMENTS

PDP SIZES

FOR RECTANGULAR PACKAGING:

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

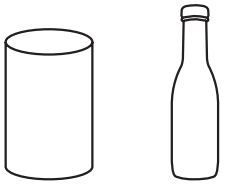


BOXES CARTONS

FOR CYLINDRICAL PACKAGING:

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

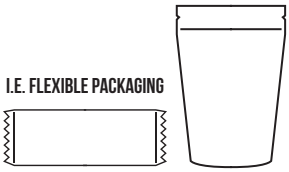
Any bottled or canned food in cylindrical packaging (ex. jarred salad dressing or canned beverages).



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]



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.

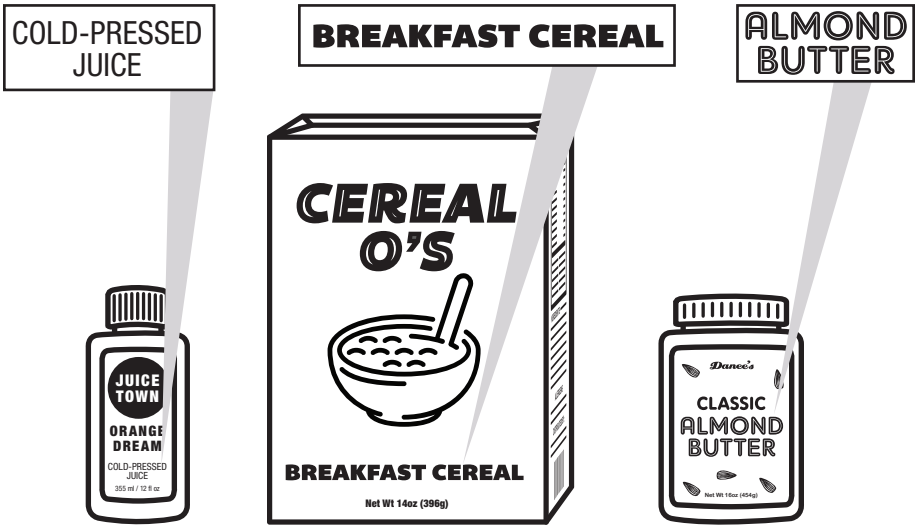
For compliance purposes, it's always best to ensure your PDP encompasses the entire front-facing panel (most brands prefer to design their packaging this way). If your packaging falls outside of these norms and your PDP won't encompass the entire front panel, check in with a food regulatory attorney.

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 products. If your product has a standard of identity established by the FDA, you must use it.[19] (See the Appendix 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).[20]

A common name is one established by usage.[21] 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."[22]

Where no common name exists for the product, an appropriately descriptive term may be used.[23]

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.[24] 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 not covered by this guide).

HOW TO DISPLAY YOUR SOI:[25]

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

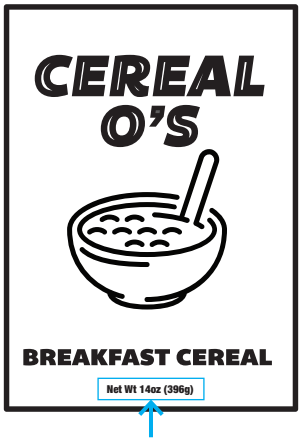
- A SOI must be a "principal feature" of the PDP.
- Must be at least half the size of the largest element printed on the label.
- Must be in lines parallel to the package (always straight, horizontal).
- Must be in **bold** typeface.
- Your artwork must not hide or detract from the prominence of your SOI, or any other FDA required information.[26]

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.[27]

**If your package contains multiple items, always include the count and the weight or liquid measure.*[28]

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



NET WEIGHT

NET CONTENTS

SOLID (or semisolid, viscous, a mixture of solid and liquid in weight).[29]

- 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)

LIQUID[30]

- 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:[31]

- Fractions – must be reduced to lowest terms and be in form of halves, quarters, eighths, sixteenths, or thirty-seconds.[32]
- Decimal—cannot be more than two decimal places.[33]

MUST BE EXPRESSED IN PROPER ORDER:[34]

- 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 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.

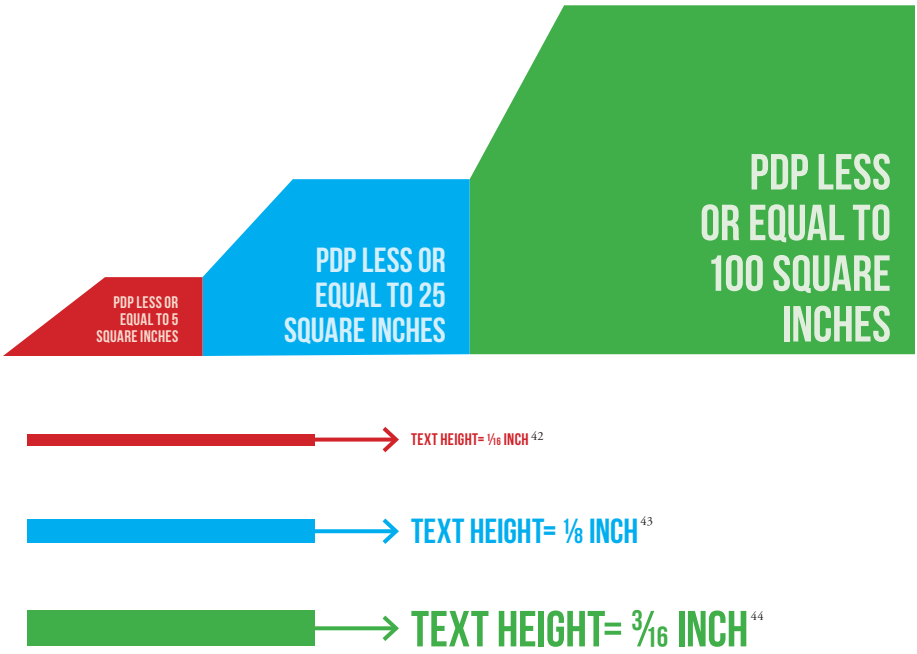
NET QUANTITY OF CONTENTS

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

- Must be featured on the PDP.[35]
- Must be in **bold** typeface.[36]
- Must be in lines parallel to the package bottom.[37]
- May appear on more than one line.[38]
- Letters must not be more than three times as high as they are wide.[39]
- 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.[40]

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.[41]



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.[45]
- A space equal to the width of the "N" used from printed information on either side of the declaration.[46]

PLACEMENT:

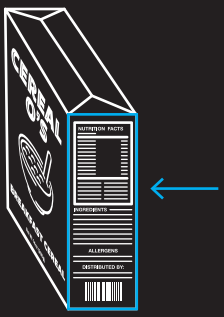
- For packages with a PDP greater than 5 square inches, Net Wt. must be in the bottom 30% of the PDP.[47]
- For packages with PDP less than 5 square inches, Net Wt. need not to be in the bottom 30%.[48]

SPECIAL RULES APPLY FOR:

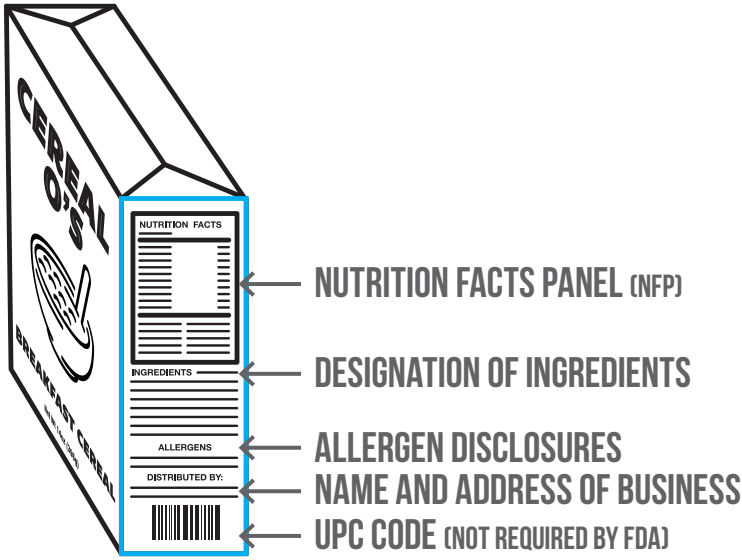
- Pickles
- Multi-Unit Packages

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.[49]
- In some cases, this could be the back of the product.
- If the PDP is on the top, any surface immediately adjacent.[50]

THERE ARE TWO NARROW EXCEPTIONS WHERE A NUTRITION FACTS PANEL (NFP) IS NOT REQUIRED:[51]

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

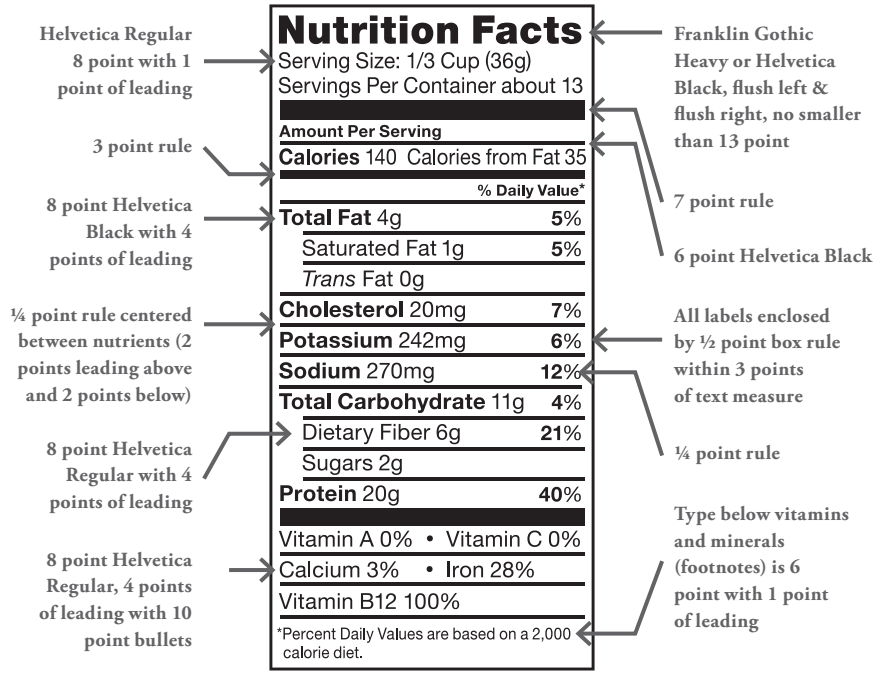
If one of these exemptions applies to you, **no nutrition claims** may be made about the food in its labeling or advertising. Sales for these exemptions are calculated based on the last two years of data, or if the business has not been in operation for two years, upon reasonable sales estimates.

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).[52]
- Use a single easy-to-read type style.
- Use upper and lowercase letters.[53]

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 only be disclosing information pertaining to 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?

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	
Vitamin D 2mcg	10%
5 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 label 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	

*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.

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

DUAL COLUMN VERTICAL

Nutrition Facts

2 servings per container
Serving size **1 cup (255g)**

Calories	Per serving 220		Per container 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	8g	**21%**	12g	**43%**
Total Sugars	7g		14g	
Incl. Added Sugars	4g	**8%**	8g	**16%**
Protein	9g		18g	
Vitamin D	5mcg	25%	10mcg	50%
Calcium	200mg	15%	400mg	30%
Iron	1mg	6%	2mg	10%
Potassium	470mg	10%	940mg	20%

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

DUAL COLUMN 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	8g	**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.

DECLARATION OF INGREDIENTS

HOW TO DISPLAY 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 <u>many</u> 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.

INGREDIENT'S 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

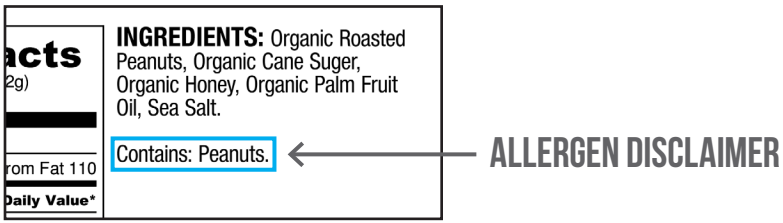
The most common cause of recalls due to misbranding is for undisclosed allergens. Because these present a serious risk to the health of those with food allergies, this is one of the most important disclosures made on a package.[72] FDA focuses on disclosure of eight "major food allergens," commonly referred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

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

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

RECOMMENDED CLEAR AREA

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

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]

PRODUCT COMPOSITION	WHAT CLAIMS CAN BE MADE?	USE USDA SEAL?	USE CERTIFIER SEAL?	WHERE PERMITTED CLAIMS OR CLAIM OR SEALS CAN BE USED?
100% organic ingredients	• 100% organic (Product Name)[92]	Yes[93]	Yes[94]	On any labeling or marketing material[95]
95% or more organic ingredients	• 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]	Yes[98]	Yes[99]	
70% or more organic ingredients	• _% 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]	Yes[104]	Yes[105]	
Less than 70% organic ingredients	• _% organic ingredients[106]	Yes[107]	No[108]	On information panel only[109]

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

GREEN: PMS 348
BROWN: PMS 175

B/W LOGO

BLACK: K=100%
WHITE

B/W LOGO WITH TRANSPARENT BACKGROUND

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

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

B/W LOGO

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.

- 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

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

COMPACT LOGO FOR PACKAGING FROM GFCO

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

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

PMS COLOR

2-COLOR
BLACK
PMS 376C

PMS COLOR ALT

2-COLOR
BLACK
PMS 375U

GRAYSCALE LOGO

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:

37% OF PRODUCT

4

APPENDIX: SOURCES/ CITATIONS

SOURCES / CITATIONS

APPENDIX

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.

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 Food & Drug Admin., 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. § 101.3(b)(1).
[20] 21 C.F.R. § 101.3(b)(2).
[21] 21 C.F.R. § 101.3(b)(2).
[22] 21 C.F.R. § 102.5(d).
[23] 21 C.F.R. § 101.3(b)(3).
[24] 21 U.S.C. § 343(g); see, e.g. Food & Drug Admin., Warning Letter to Awesome Foods, Inc., (Dec. 15, 2009) (citing company for failing to conform for the standard of identity promulgated for parmesan cheese).
[25] 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.
[26] 21 C.F.R. § 101.15.
[27] 21 C.F.R. § 101.105(a).
[28] 21 C.F.R. § 101.105(c).
[29] 21 C.F.R. § 101.105(b); § 101.105(j)(3) (must use Net Weight); §101.105(n) for abbreviations.
[30] 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.
[31] 21 C.F.R. § 101.105(d).
[32] 21 C.F.R. § 101.105(d).
[33] 21 C.F.R. § 101.105(d).
[34] 21 C.F.R. § 101.105(k).
[35] 21 C.F.R. § 101.105(a).
[36] 21 C.F.R. § 101.105(h).
[37] 21 C.F.R. § 101.105(f).
[38] 21 C.F.R. § 101.105(f).
[39] 21 C.F.R. § 101.105(h)(1).
[40] Food & Drug Admin. Compliance Policy Guide Section 140.500 Metric Declaration of Quantity of Contents on Product Labels.; https://www.fda.gov/ICECI/ComplianceManuals/CompliancePolicyGuidanceManual/ucm073844.htm
[41] 21 C.F.R. § 101.105(h)(3)(i)(4).
[42] 21 C.F.R. § 101.105(h)(3)(i)(1).
[43] 21 C.F.R. § 101.105(h)(3)(i)(2).
[44] 21 C.F.R. § 101.105(h)(3)(i)(3).
[45] 21 C.F.R. § 101.105(f).
[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. § 101.2(a).
[50] 21 C.F.R. § 101.2(a).
[51] 21 C.F.R. § 101.9(j)(1)(i); § 101.9(j)(1)(ii).
[52] 21 C.F.R. § 101.9(d)(1)(i).
[53] 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).
[54] Food Labeling: Revision of the Nutrition and Supplement Fact Labels, 81 Fed. Reg. 33742 (May 27, 2016).
[55] 81 Fed. Reg. 33742.
[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).

BROUGHT TO YOU BY

NUCLEUS MAXIMUS AND HOLLAND & HART