Regulatory Considerations and Resources

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CalPoly Product Development & Innovation Short Course August 2025

A suggested check list for the product developer, student teams and entrepreneurs

- Brand name, product name
- Process outline
- General Label guidance: Ingredient listing, claims
- Compliance with food safety standards/ California regulations

Please consult regulatory expert for final guidance

BRAND/PRODUCT NAME

Is your product or brand name unique and free to use?

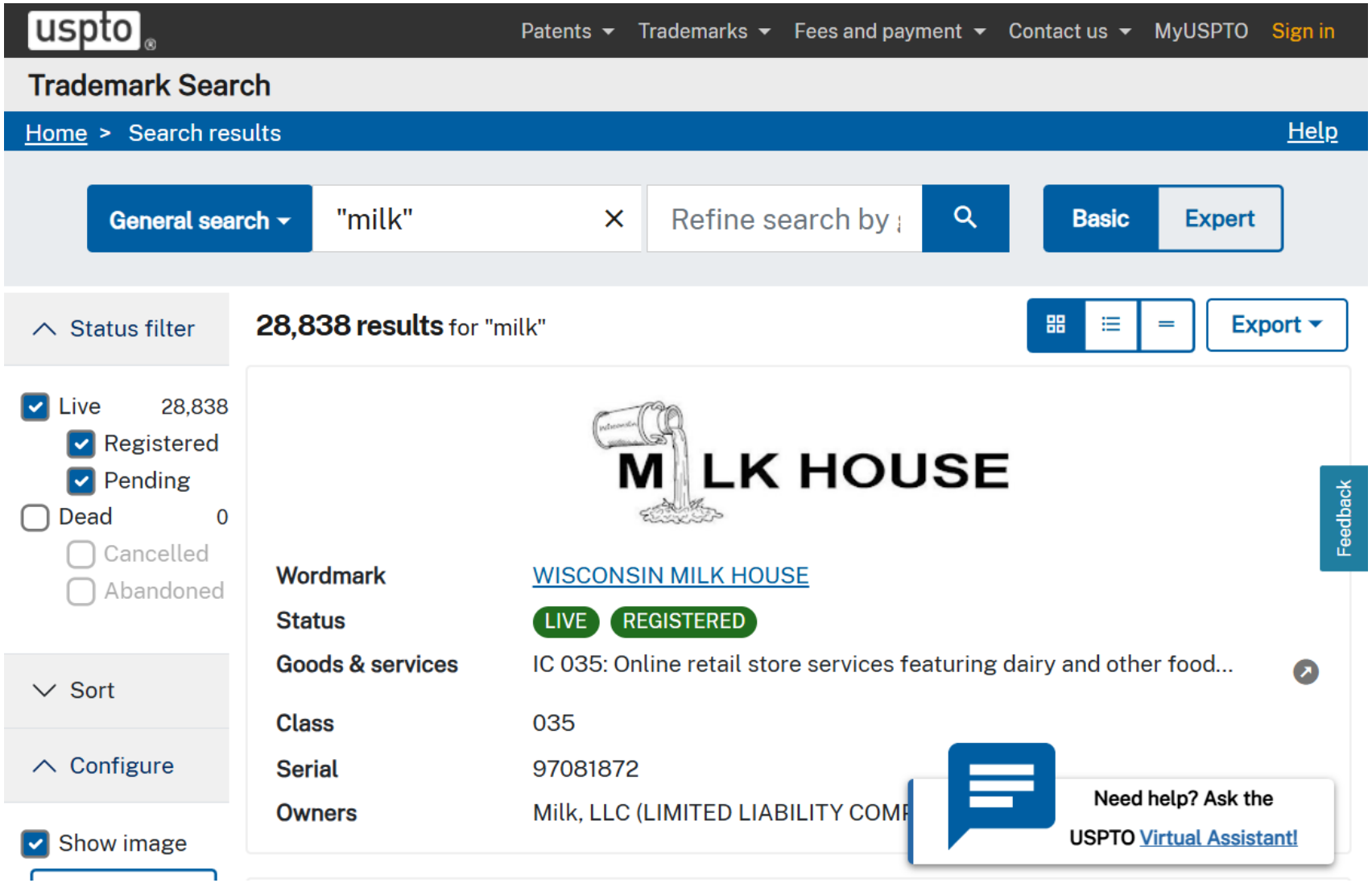
Check trademarks: https://www.uspto.gov/

(FREE)

Also check guidance on use of **product name!** (see : FDA regulations)

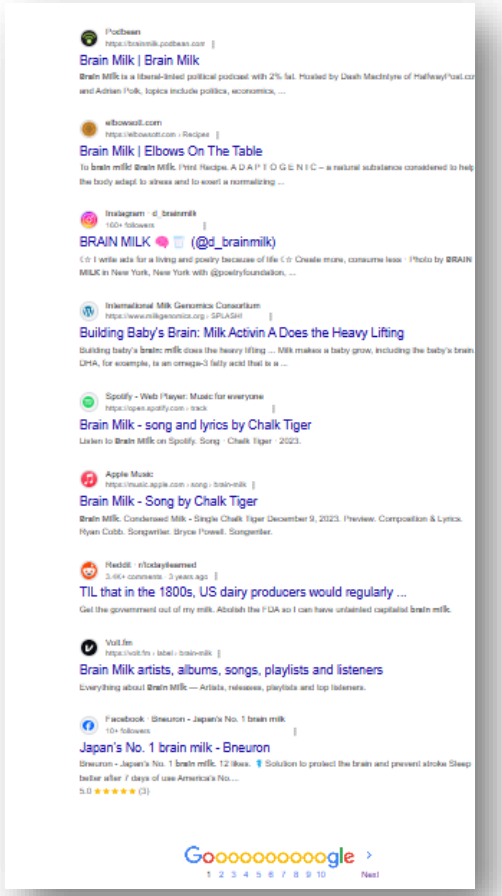
FREE TOOL

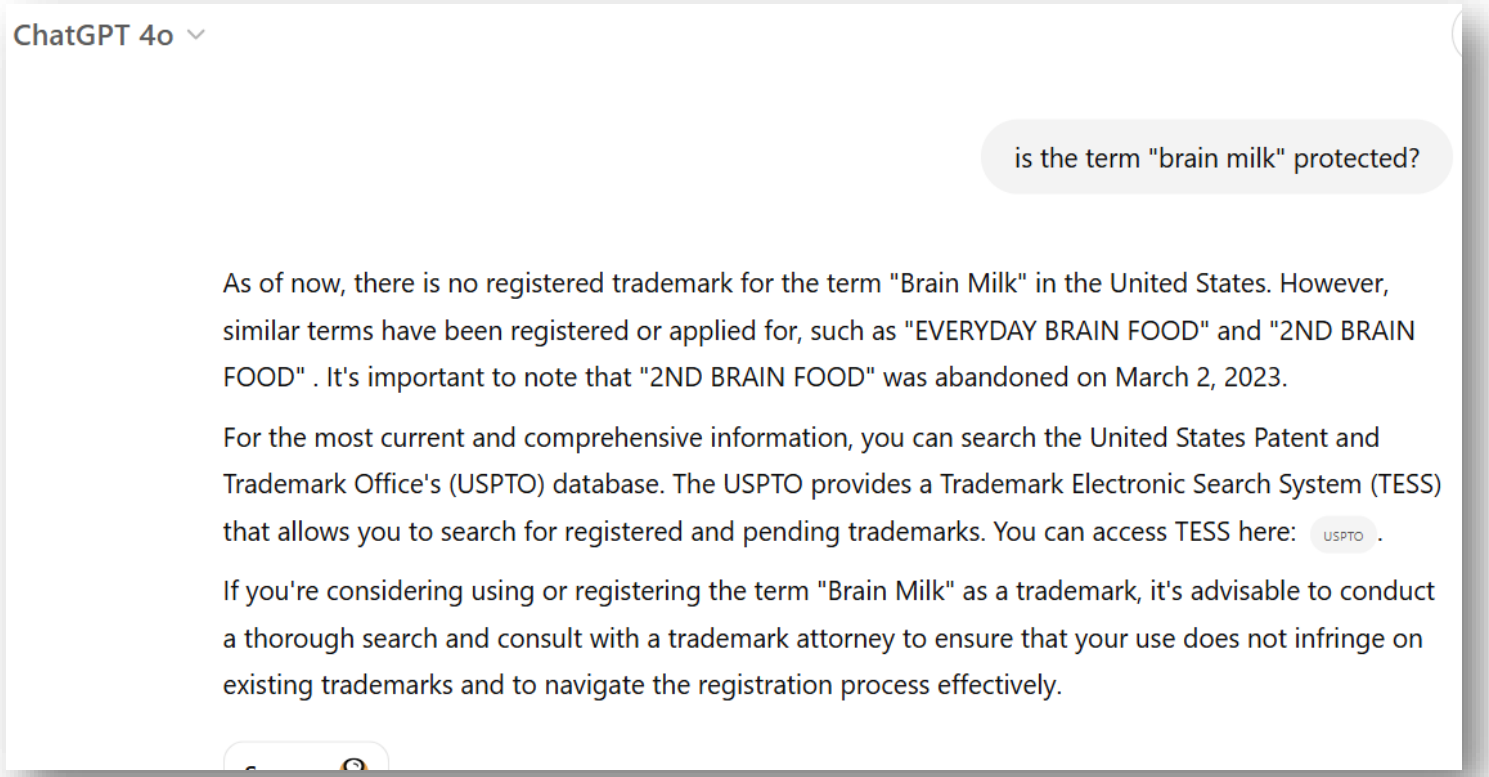
CALIFORNIA DAIRY INNOVATION CENTER



Google it!
Ok to use AI – but double check!

Example: “Brain Milk”



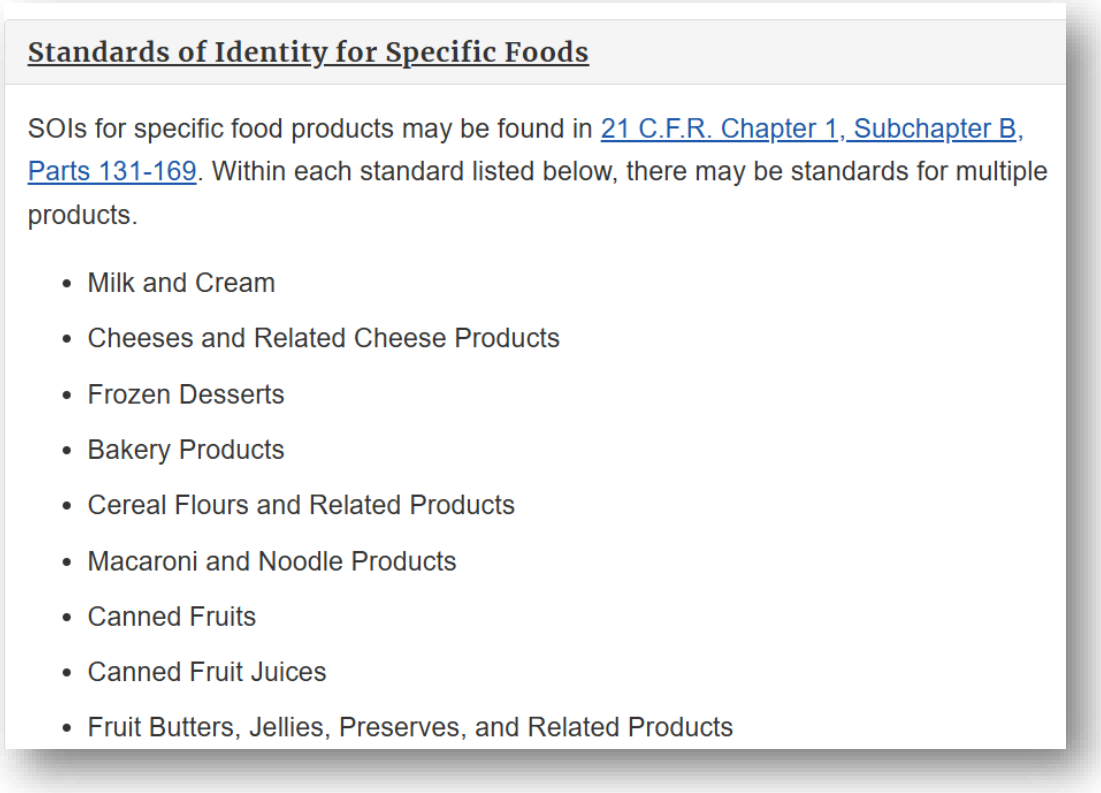


Standards of Identity

If your product is covered by a Standard of Identity, you must comply with it!

https://www.ecfr.gov/current/title-21/chapter-I/subchapter-B

If not, find an alternative, acceptable common name – but check, double check!



Standards of Identity for Specific Foods

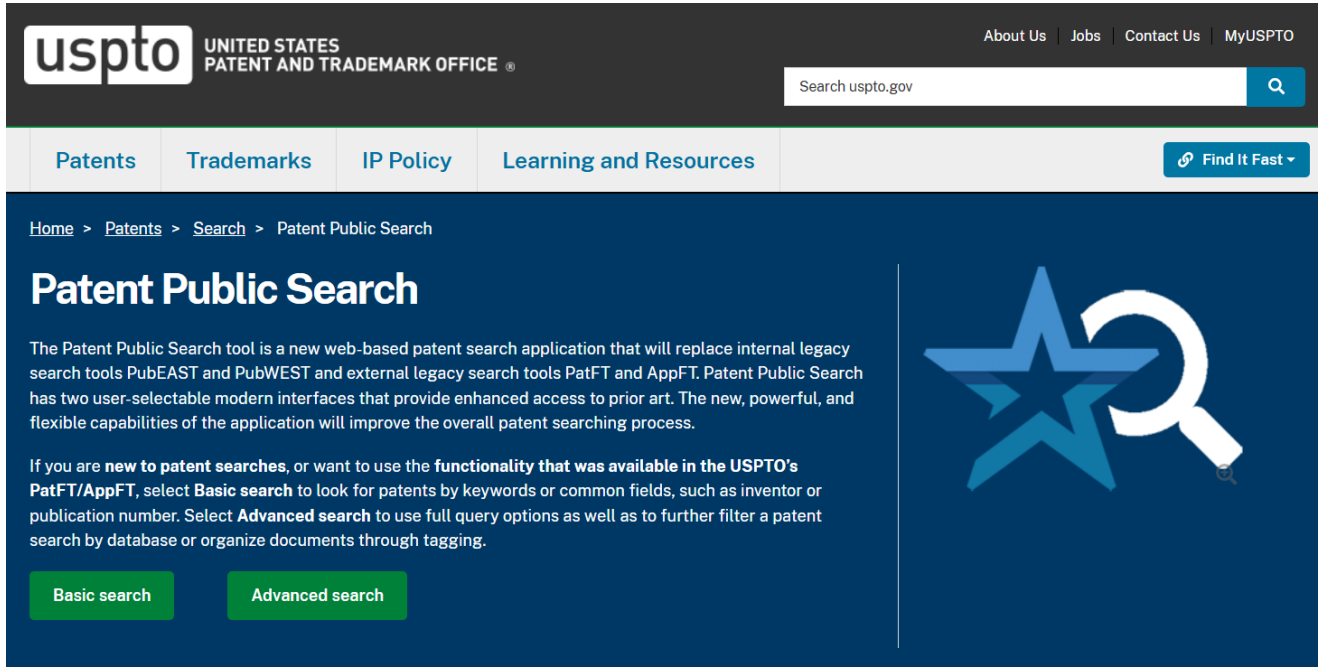
SOIs for specific food products may be found in 21 C.F.R. Chapter 1, Subchapter B, Parts 131-169. Within each standard listed below, there may be standards for multiple products.

- Milk and Cream
- Cheeses and Related Cheese Products
- Frozen Desserts
- Bakery Products
- Cereal Flours and Related Products
- Macaroni and Noodle Products
- Canned Fruits
- Canned Fruit Juices
- Fruit Butters, Jellies, Preserves, and Related Products

Process

Always a good idea to check existing patents for process IP.

- https://www.uspto.gov/patents/search/patent-public-search



Process

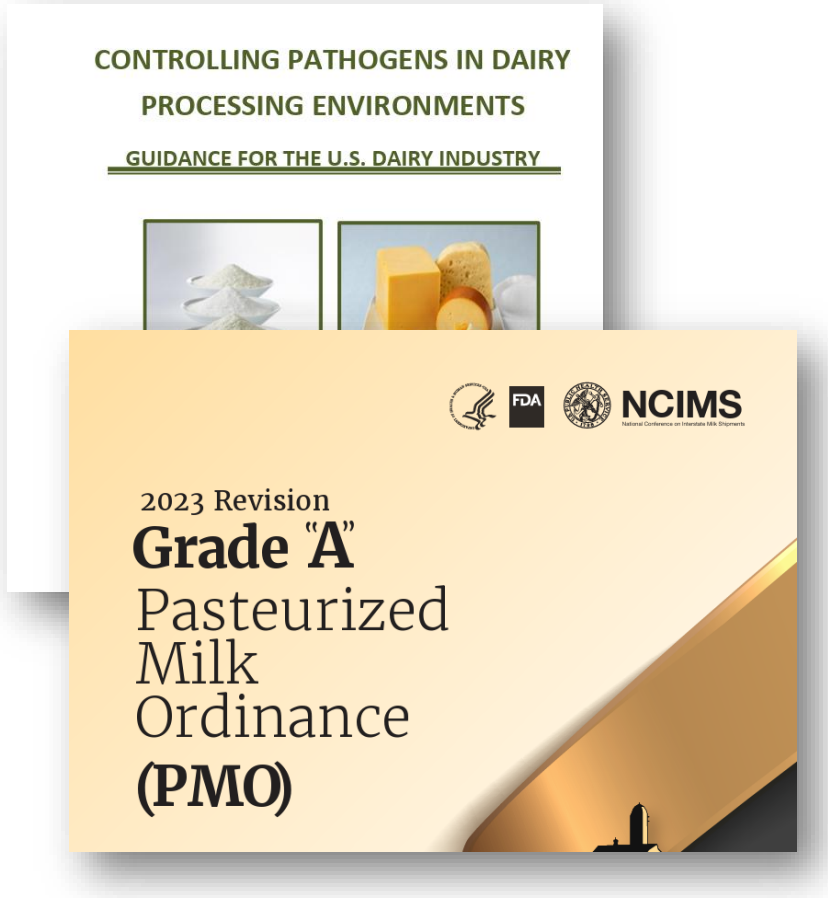
Dairy products are highly regulated!

Planned sanitary design/heat treatment

More info at: https://www.usdairy.com/about-us/innovation-center/food-safety/guidance-documents

Pasteurized Milk Ordinance (PMO). Among the PMO's many provisions are requirements for laboratory testing of milk and dairy products for quality and safety.

https://www.fda.gov/food/milk-guidance-documents-regulatory-information/national-conference-interstate-milk-shipments-ncims-model-documents



CLAIMS

Avoid using anything which implies your product can cure or prevent a disease!

- The **Food, Drug, and Cosmetic Act (FDCA)** prohibits disease claims on foods and dietary supplements unless the product has gone through the rigorous **New Drug Application (NDA)** process.

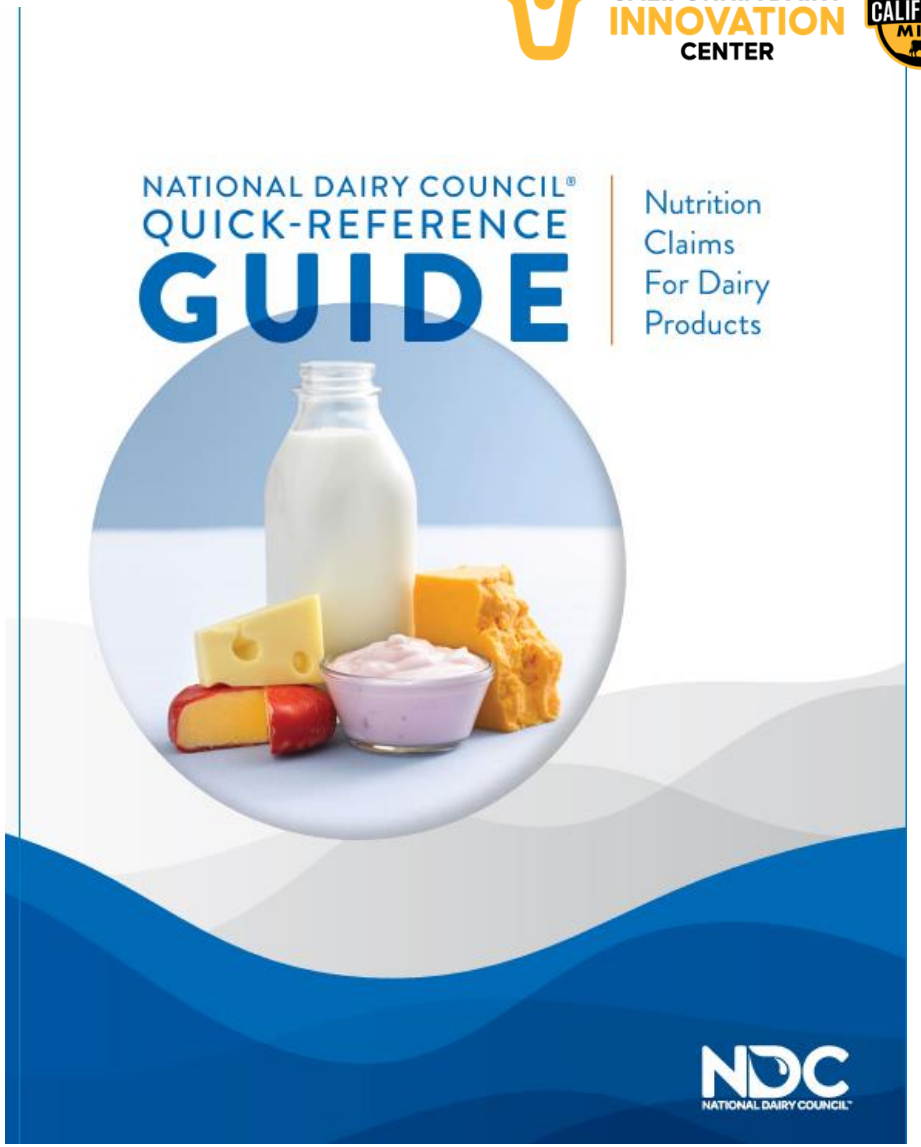
Most useful tool:

https://www.usdairy.com/research-resources

DAIRY MANAGEMENT INC.™

CALIFORNIA DAIRY INNOVATION CENTER

REAL CALIFORNIA MILK



More on claims

Dietary supplements can make **structure/function claims** (e.g., "supports immune health"), but not disease claims (e.g., "cures the flu").

https://www.fda.gov/food/nutrition-food-labeling-and-critical-foods/structurefunction-claims#conventional

Health claims must be authorized by the FDA and supported by significant scientific agreement.

Not just your label!

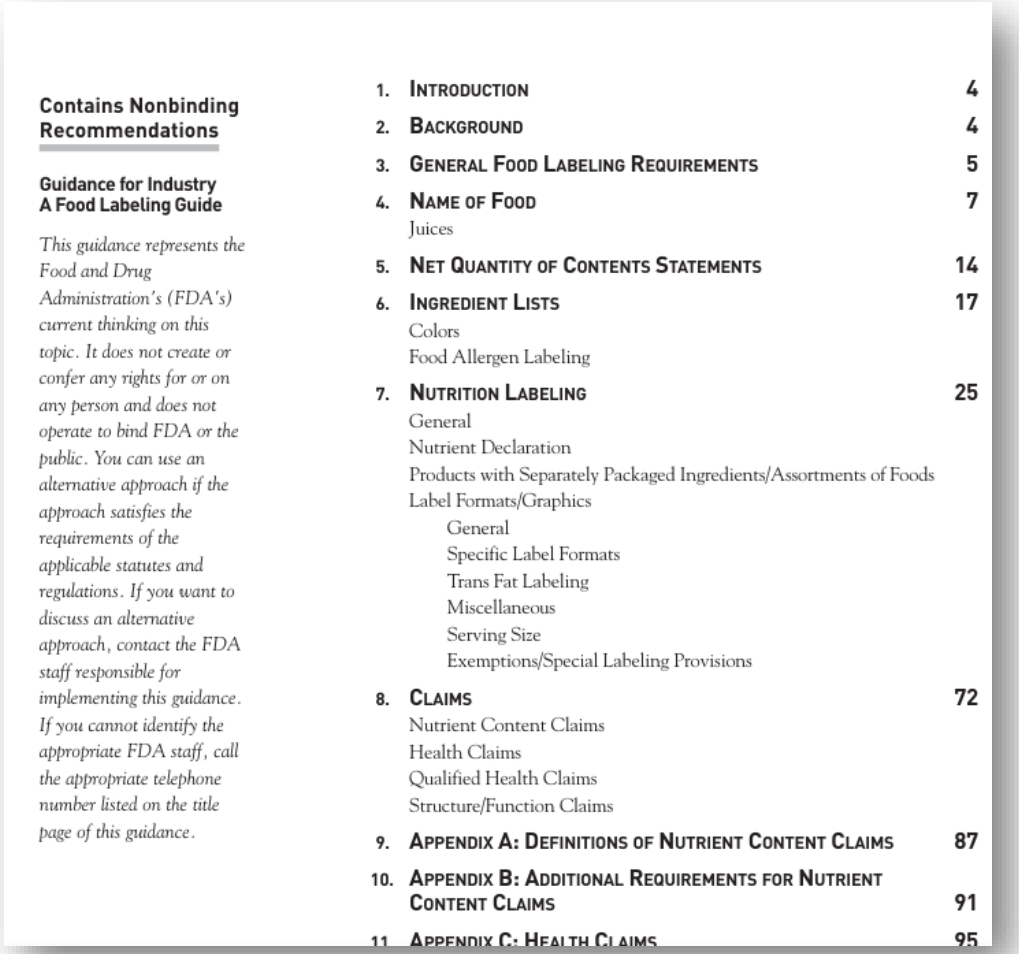
The Federal Trade Commission (FTC) enforces truth-in-advertising laws, meaning any claim (in your marketing materials, communications, website, etc.) must be backed by competent and reliable scientific evidence.

- **Structure/Function Claims**: "Supports cardiovascular health" (instead of "Lowers blood pressure")
- **Qualified Health Claims** (if FDA-approved): "May reduce the risk of heart disease" (requires disclaimer)
- **Nutrient Content Claims**: "Good source of calcium for strong bones“

Designing your product label

Name of the food, ingredient list, allergens, nutrition facts + serving size (theoretical)

Recommended resource:
https://www.fda.gov/regulatory-information/search-fda-guidance-documents/guidance-industry-food-labeling-guide



Contains Nonbinding Recommendations

Guidance for Industry
A Food Labeling Guide

This guidance represents the Food and Drug Administration's (FDA's) current thinking on this topic. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. You can use an alternative approach if the approach satisfies the requirements of the applicable statutes and regulations. If you want to discuss an alternative approach, contact the FDA staff responsible for implementing this guidance. If you cannot identify the appropriate FDA staff, call the appropriate telephone number listed on the title page of this guidance.

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Designing your product label

Name of the food, ingredient list, allergens, nutrition facts + serving size (theoretical)

4. Name Of Food

1. **What is the name of the food statement called and where must it be placed?**

   Answer: The statement of identity is the name of the food. It must appear on the front label, or PDP as well as any alternate PDP. *21 CFR 101.3*

2. **Should the statement of identity stand out?**

   Answer: Use prominent print or type for the statement of identity. It shall be in bold type. The type size must be reasonably related to the most prominent printed matter on the front panel and should be one of the most important features on the PDP. Generally, this is considered to be at least 1/2 the size of the largest print on the label. *21 CFR 101.3(d)*

3. **What name should be used as the statement of identity?**

   Answer: The name established by law or regulation, or in the absence thereof the common or usual name of the food, if the food has one, should be used a the statement of identity. If there is none, then an appropriate descriptive name, that is not misleading, should be used. Brand names are not considered to be statements of identity and should not be unduly prominent campared to the statement of identity. *21 CFR 101.3(b)* & *(d)*

4. **Where should the statement of identity be placed on the label?**

   Answer: Place the statement of identity on the PDP in lines generally parallel to the base of the package. *21 CFR 101.3(d)*

5. **When are fanciful names permitted as the statement of identity?**

   Answer: When the nature of the food is obvious, a fanciful name commonly used and understood by the public may be used. *21 CFR 101.3(b)(3)*

6. **Is it necessary to use the common or usual name instead of a new**

6. Ingredient Lists

1. **What is the ingredient list?**

   Answer: The ingredient list on a food label is the listing of each ingredient in descending order of predominance.

   "INGREDIENTS: Pinto Beans, Water, and Salt"

   21 CFR 101.4(a)

2. **What is meant by the requirement to list ingredients in descending order of predominance by weight?**

   Answer: Listing ingredients in descending order of predominance by weight means that the ingredient that weighs the most is listed first, and the ingredient that weighs the least is listed last (see illustration for question 3 below). *21 CFR 101.4(a)*

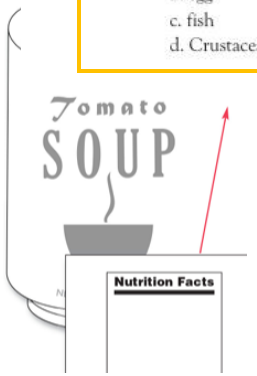
3. **Where is the ingredient list placed on the label?**

   Answer: The ingredient list is placed on the same label panel as the name and address of the manufacturer, packer or distributor. This may be either the information panel or the PDP. It may be before or after the nutrition label and the name and address of the manufacturer, packer or distributor. *21 CFR 101.4*

   See also section 3, question 7 of this guidance for information on intervening material on the information panel.

4. **What type size is required for ingredient lists?**

   Answer: Use a type size that is at least 1/16 inch in height (based on the lower case "o") and that is prominent, conspicuous, and easy to read. See the type size, prominence, and clarity requirements for information panel labeling discussed in section 3, question 6 of this guidance. *21 CFR 101.2(c)*



Food Allergen Labeling

General Information

F1. What is the Food Allergen Labeling and Consumer Protection Act of 2004?

Answer: The Food Allergen Labeling and Consumer Protection Act of 2004 (FALCPA) (or Title II of Public Law 108-282) is a law that was enacted in August 2004. Among other issues, FALCPA addresses the labeling of all packaged foods regulated by the FDA. We recommend that producers of meat products, poultry products, and egg products, which are regulated by the U.S. Department of Agriculture (USDA), contact appropriate USDA agency staff regarding the labeling of such products. Also see Information about Food Allergens for more information about the agency's food allergen activities and related guidance documents that address additional FALCPA questions and answers. *http://www.fda.gov/Food/LabelingNutrition/FoodAllergensLabeling/default.htm*

F2. What is a "major food allergen?"

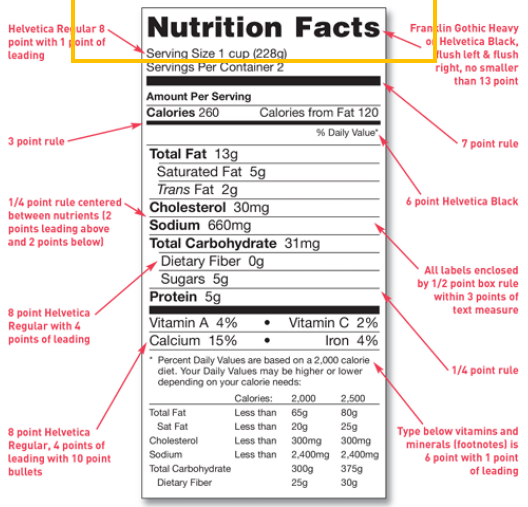
Answer: Under FALCPA, a "major food allergen" is an ingredient that is one of the following eight foods or food groups or an ingredient that contains protein derived from one of them:

a. milk
b. egg
c. fish
d. Crustacean shellfish

Answer: Format requirements are specified in *21 CFR 101.9(d)*. For example, the nutrition information must be set off in a box by use of hairlines and must be all black or one color type, printed on a white or other neutral contrasting background whenever practical. *21 CFR 101.9(d)(1)(i)*

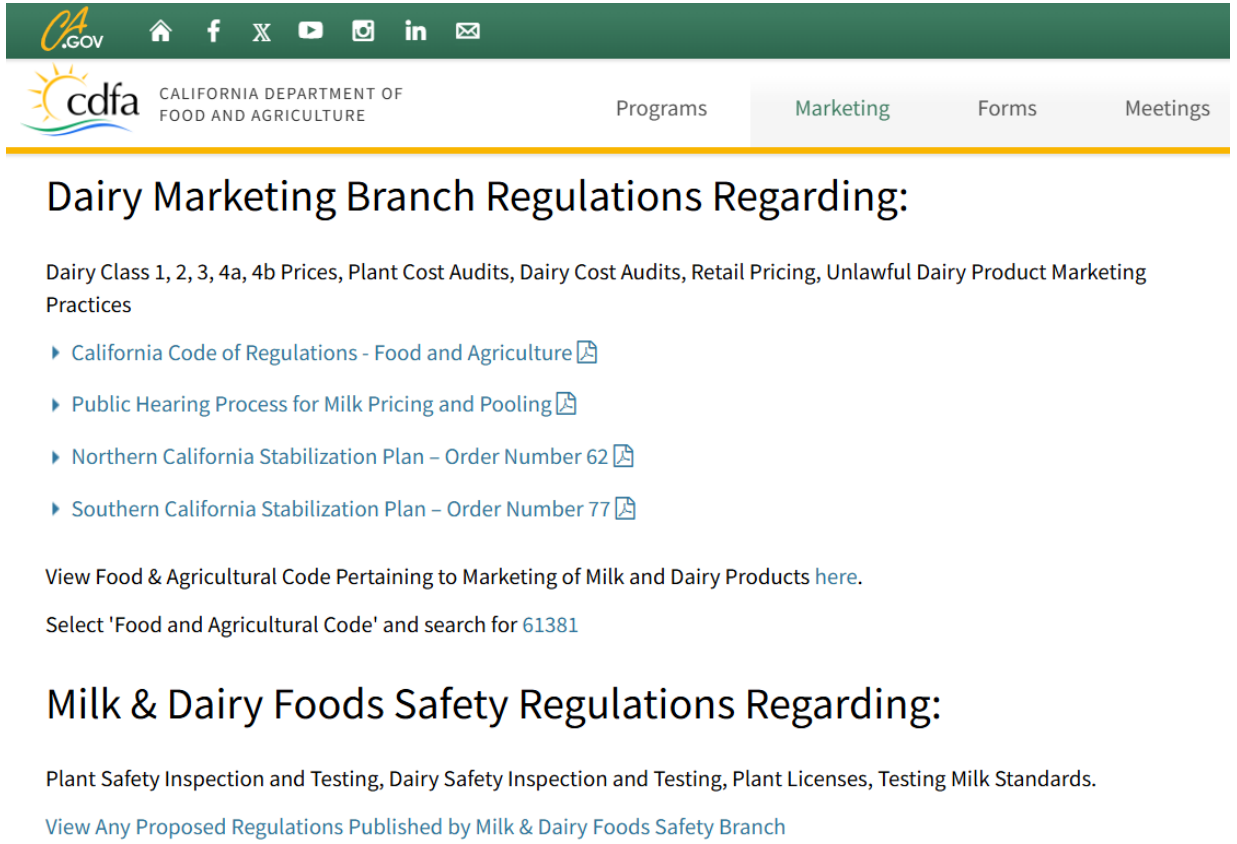
FDA urges that the nutrition information be presented using the graphic specifications set forth in appendix B to part 101 (see below).

Example of Graphic Enhancements used by FDA



California-specific regulations

- https://www.cdfa.ca.gov/dairy/proposed_regs.html



CA.GOV

cdfa CALIFORNIA DEPARTMENT OF FOOD AND AGRICULTURE

Programs | Marketing | Forms | Meetings

Dairy Marketing Branch Regulations Regarding:

Dairy Class 1, 2, 3, 4a, 4b Prices, Plant Cost Audits, Dairy Cost Audits, Retail Pricing, Unlawful Dairy Product Marketing Practices

- California Code of Regulations - Food and Agriculture
- Public Hearing Process for Milk Pricing and Pooling
- Northern California Stabilization Plan – Order Number 62
- Southern California Stabilization Plan – Order Number 77

View Food & Agricultural Code Pertaining to Marketing of Milk and Dairy Products here.

Select 'Food and Agricultural Code' and search for 61381

Milk & Dairy Foods Safety Regulations Regarding:

Plant Safety Inspection and Testing, Dairy Safety Inspection and Testing, Plant Licenses, Testing Milk Standards.

View Any Proposed Regulations Published by Milk & Dairy Foods Safety Branch

Thank you!

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