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Module 4: Labels

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Module 4: Labels

- Part 1: Required label components
- Part 2: Other label issues

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Part 1: Required label components

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Label Components

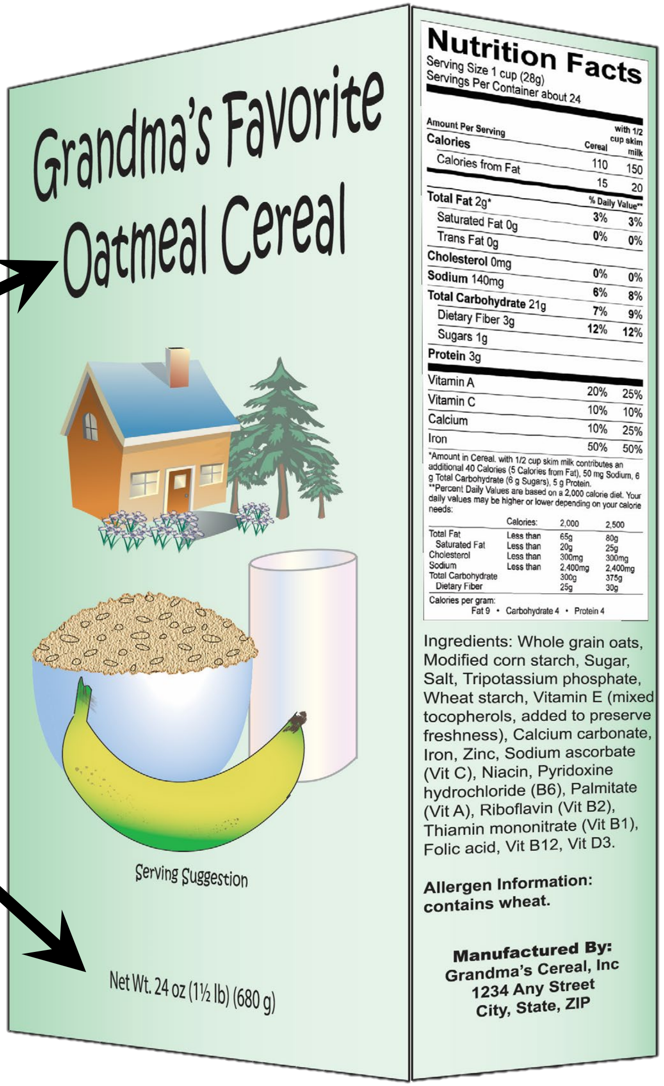
- All labels must include the required label items
  - USDA reviews and approves labels before they can be used
  - FDA expects that your labels are correct, but doesn’t review first
- Other items to include (as long as there’s enough room)
  - Brand logo or picture
  - UPC code
  - Lot code and use-by/best-by date
  - Marketing information – your story

Required Label Components

Principal Display Panel

Statement of Identity

Net weight statement



Statement of Identity

- Many foods have a legally established name that must be used (CFR21 §101.3)
- All others must use "common or usual name"
- Other requirements include:
  - Form of food (e.g. sliced, cubed, crushed)
  - "___% Juice" for any drink showing fruit or vegetables on the label

Go to https://ecfr.gov to view or search most up-to-date regulations

Standards of Identity Exist for:

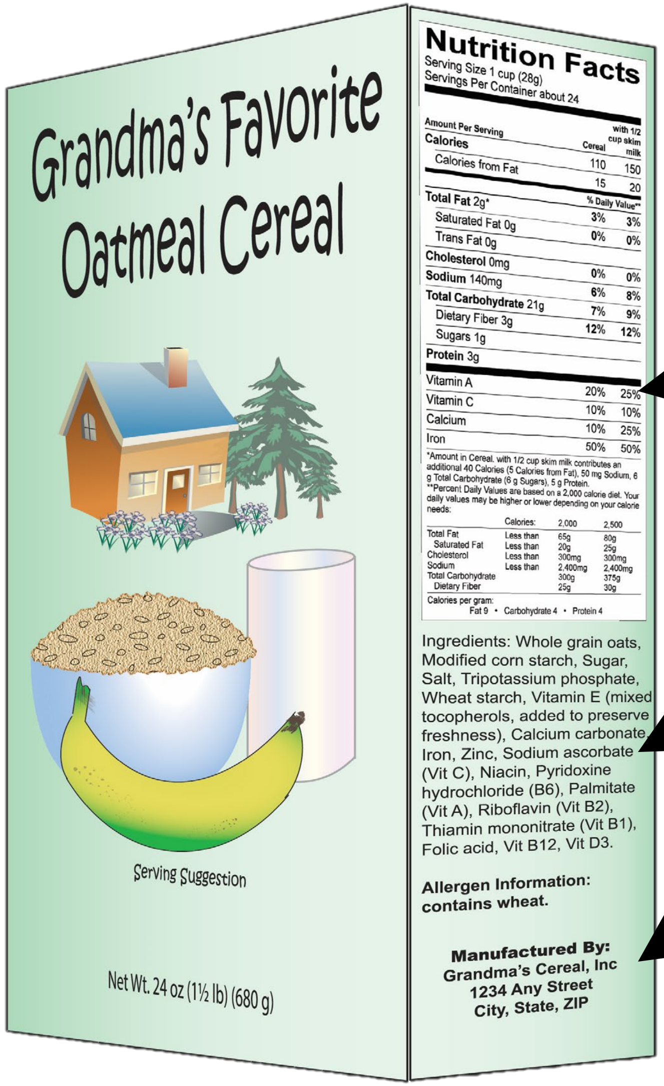
§ 131 Milk & cream
§ 133 Cheese
§ 135 Frozen desserts
§ 136 Bakery products
§ 137 Cereal flours
§ 139 Macaroni & noodles
§ 145 Canned fruit
§ 146 Canned fruit juice
§ 150 Jellies & preserves
§ 152 Fruit Pies
§ 155 Canned vegetables
§ 156 Vegetable juices
§ 158 Frozen vegetables
§ 160 Eggs & egg products
§ 161 Fish & shellfish
§ 163 Cacao products
§ 164 Tree nuts & peanuts
§ 165 Beverages
§ 166 Margarine
§ 168 Sweeteners & syrups
§ 169 Dressings & flavorings

Net Content Statement

- Specific requirements for placement and font size, dependent on package dimensions (21CFR §101.7)
- Specification of weight or volume
  - From 1-4 lbs, must be shown as: ounces (lbs) or fl oz (qts or pts)
  - Above 4 lbs, must be shown as: pounds or gallons
- Some states require SI (metric) units be listed parenthetically after US measure
  - Utah reference: NIST Handbook 130, 2022 ed (R70-920-2)

NIST is the National Institute of Standards and Technology, they create "model code" as examples of rules that can be adopted by other agencies.

Required Label Components

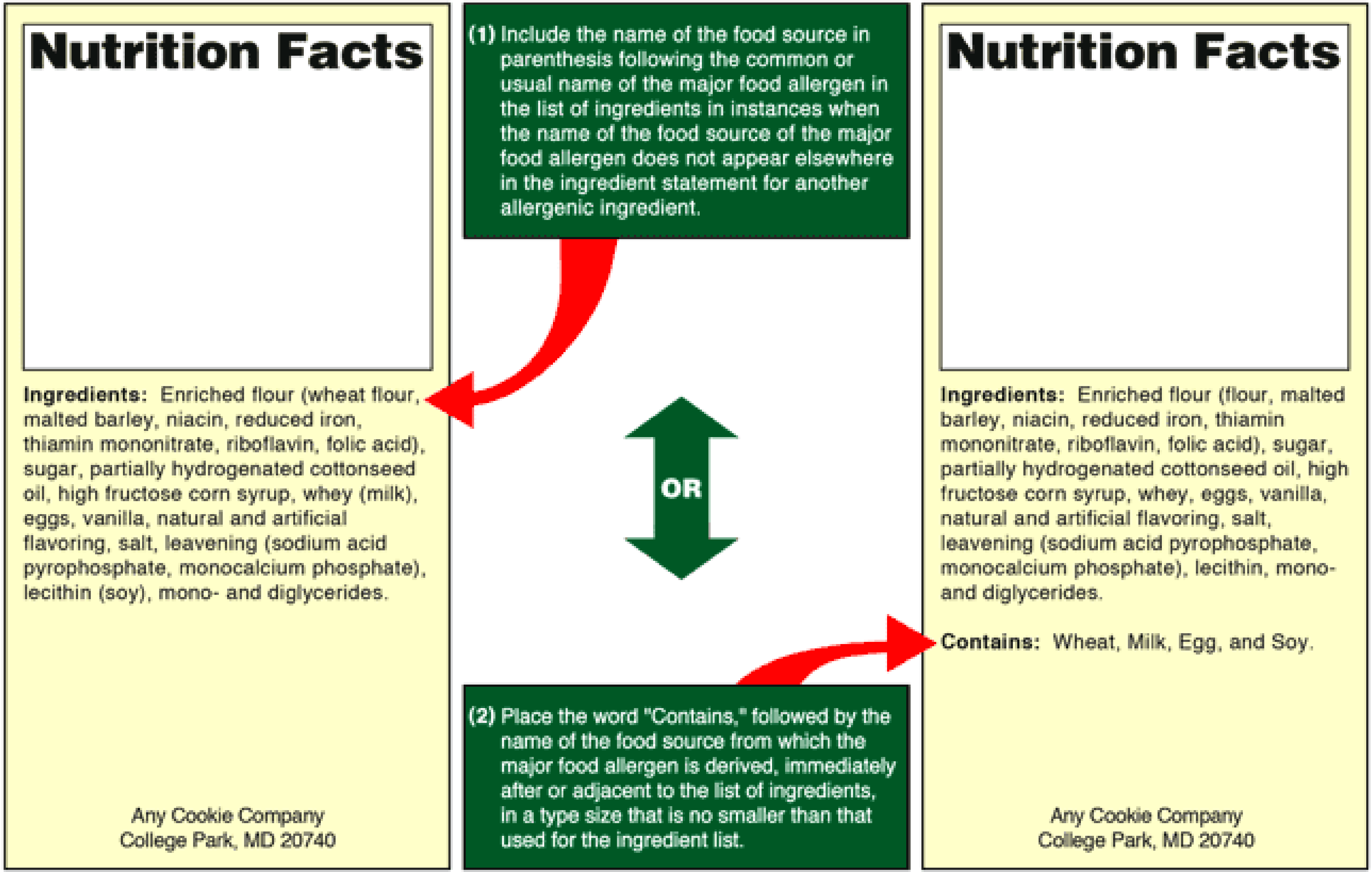


Information Panel

- Nutrition Facts panel
- Ingredient statement (including allergens)
- Producer name & address

Ingredient Statement

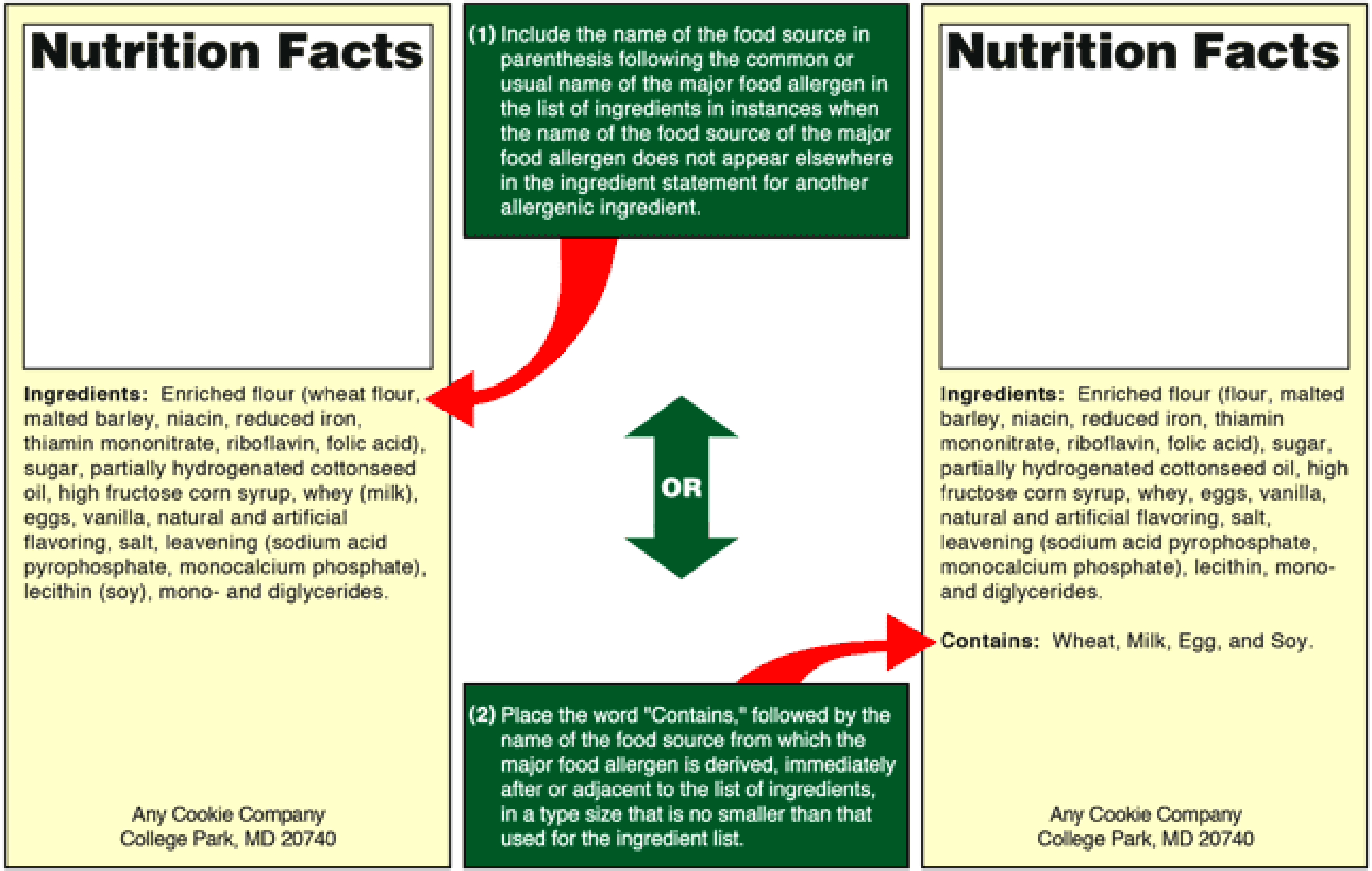
- Ingredients must be listed in order by weight (21CFR §101.4)
- Must list function of any preservatives
  - "Ascorbic Acid to promote color retention"
- "Spices", "Natural Flavor", "Artificial Flavor" can be grouped
  - *Except:* vegetable items (e.g. garlic), salt, MSG, and colorants (e.g. paprika)
- Certified colors must be specified
  - "Red 40" or "FD&C Red 40"
- Allergens listed separately or incorporated into ingredient statement



All ingredients MUST be in the ingredient statement. Allergens can be identified parenthetically.

If a **Contains** statement is used, ALL allergenic ingredients must be included.

Allergen Statement



- Wheat
- Dairy
- Eggs
- Tree Nuts (by name)
- Peanuts
- Soy
- Molluscan Shellfish
- Finfish (by name)
- Sesame

Nutrition Facts

- The rules for nutrition facts are very complex – don't try to make the panel yourself!
- Several options available for nutrition facts panels:
  - Online subscription programs
  - One-time purchase programs
  - Consultants or companies that charge a per-panel fee (usually around $100)

Photo source: FDA

Small Business Exemptions

- Retailer Exemptions: 21CFR§101.9(j)(1)

Nutrition Labeling: Retailer Exemption		Annual Food Sales ONLY (Includes food resold and food manufactured)	
		Up to $50,000	$50,001 or more
Total Annual Sales (Includes food and non-food items)	Up to $500,000	**EXEMPT*** Nutrition labeling IS NOT required	**EXEMPT*** Nutrition labeling IS NOT required
	$500,001 or more	**EXEMPT*** Nutrition labeling IS NOT required	**COVERED** Nutrition labeling IS required

* Does not apply if you make ANY health-related claims on your package (e.g. Low Fat, Healthy (or heart-shaped graphics), High in Iron, Sugar-Free).

Small Business Exemptions

- Manufacturer Exemptions: 21CFR§101.9(j)(18)

Nutrition Labeling: Low-Volume Exemption	Annual Units Produced and Full-Time Equivalent Employees (FTEs)	
	<10,000 Units **and** <10 FTEs	<100,000 Units **and** <100 FTEs
Products do not include imports	**EXEMPT*** • Nutrition labeling IS NOT required • Exemption notice IS NOT required	**EXEMPT*** • Nutrition labeling IS NOT required • Exemption notice IS required
Products include imports	**EXEMPT*** • Nutrition labeling IS NOT required • Exemption notice IS required	**EXEMPT*** • Nutrition labeling IS NOT required • Exemption notice IS required

* Does not apply if you make ANY health-related claims on your package (e.g. Low Fat, Healthy (or heart-shaped graphics), High in Iron, Sugar-Free).

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Other FDA Components

Optional Regulated Claims

- Nutrient Content Claims (e.g. high in, low in, free, good source of)
- Health Claims and Implied Health Claims (disease risk reduction)
- Qualified Health Claims (less scientific evidence)
- “Fresh”, “Gluten-free”

Special Programs

- Organic – USDA or State programs
- Bioengineered – USDA program

FDA Food Labeling guide available on their website, link in resource page

Organic Labeling

- "100% Organic"
  - Only organic ingredients (except water and salt)
- "Organic"
  - 95% organic ingredients, no sulfites
- "Contains organic ________:
  - 75% organic ingredients, no sulfites, cannot use USDA organic seal
- Organic ingredients can always be designated in ingredient statement

Natural Labeling

- No specific legal definition from FDA
  - Currently reviewing public comments on whether it should be more tightly regulated
  - USDA has stricter requirements for meat products
- Cannot contain artificial or synthetic ingredients
  - Colors
  - Flavors
  - Preservatives

National Bioengineered Food Disclosure Standard

- Bioengineered food/ingredient disclosure must be placed on label in a conspicuous manner
  - BIOENGINEERED symbol
  - “Bioengineered food” “bioengineered food ingredient” or similar
- Foods/Ingredients that do not qualify for an exemption but do not the BE definition
  - DERIVED FROM BIOENGINEERING symbol or equivalent text

Recalls for Labeling Issues

Required Allergens

- Wheat, soy, eggs, milk, tree nuts, peanuts, shellfish, finfish (Food Allergen Labeling & Consumer Protection Act of 2004)
- Sesame required as of Jan 1, 2023 (Food Allergy Safety, Treatment, Education, and Research Act of 2021)

	2019	2020	2021	2022	2023 (to April)
FDA	6	21	87	91	31
USDA	32	16	10	15	9

Lot Codes and Product Records

- Lot codes help you track your product in case there is a need to recall it from the market
- You should keep records linked to each lot code
  - Product name
  - Batch lot number
  - Ingredients used in the batch
  - Package description or size
  - Where it was sold (or the company it was sold to)
  - Date or date range it was sold
  - Amount sold (number of packages or cases)
  - Delivery company name (if a 3rd party service was used)

Records should be kept for ingredients too, including lot numbers and where/when purchased.

Best-By or Use-By Dates

- FDA and USDA do not currently have authority to create date labeling regulations for most foods

Grocery Marketing Association proposal:

- "Best if Used By" to indicate that quality may not be optimal
  - Shelf stable foods, pasteurized dairy, frozen foods
- "Use By" for perishables that may become unsafe
  - Applies to some refrigerated foods (e.g. hummus, guacamole)

Some states have additional requirements for perishable foods (e.g. milk, shell fish). Current information on state requirements can be found on the ReFED website – this link is in the resource materials

Other Label Issues

- Many common claims are not regulated by FDA or USDA
  - “Handmade”, “Small Batch”, “Nothing Artificial”, “No Preservatives”
- These and others have been the focus of recent lawsuits
  - Label graphics imply that a food is “healthy”
  - “Greek Yogurt” not made in Greece
  - “Evaporated cane juice” instead of “Sugar”
  - “Made in USA” when some ingredients are foreign
- No way to predict what may trigger a lawsuit, but if it *could* be misleading, someone will think it is!

Questions?

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