

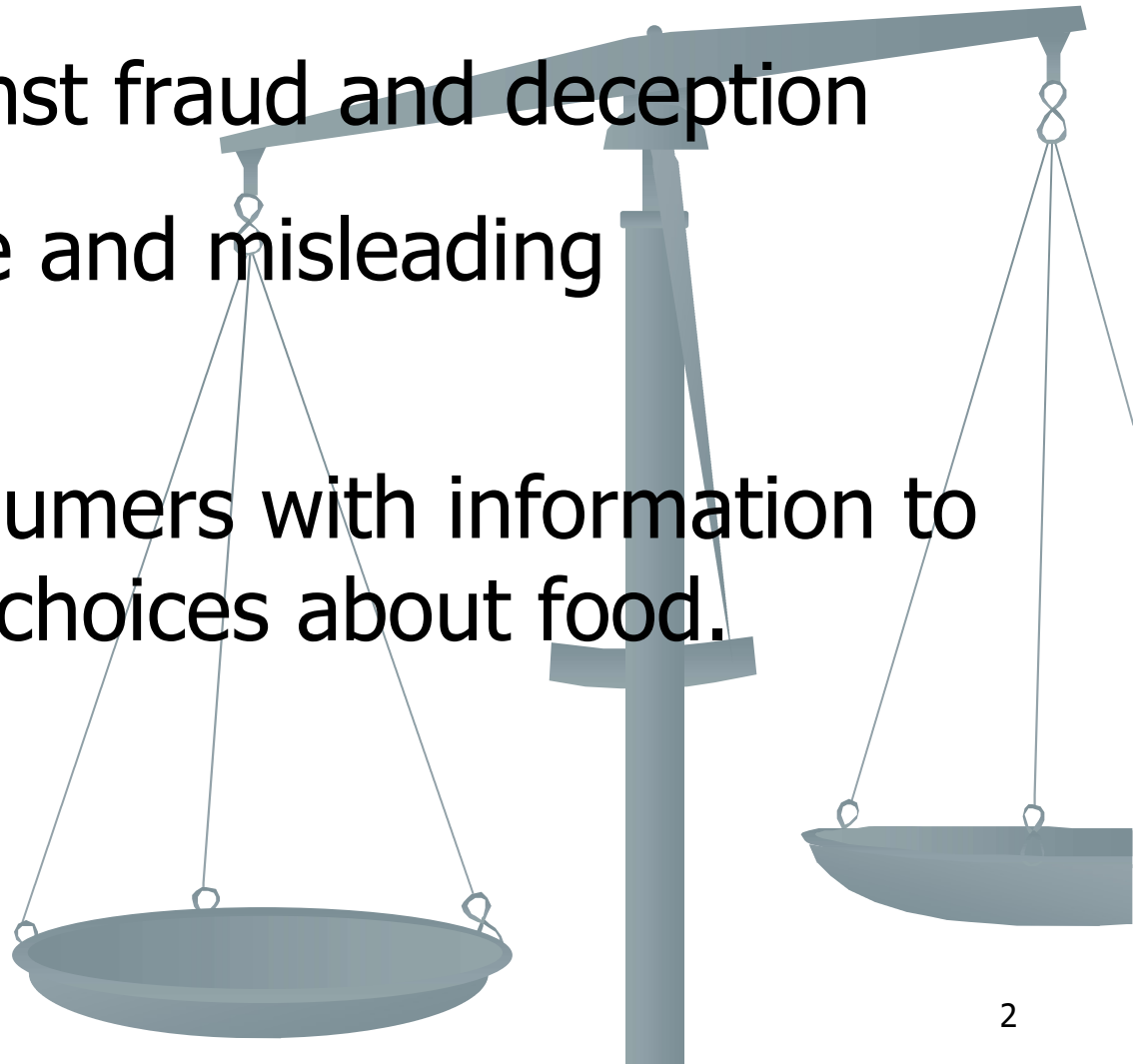
Food Labeling Regulations

John Khouryieh, PhD
Food Laws & Regulations
Western Kentucky University



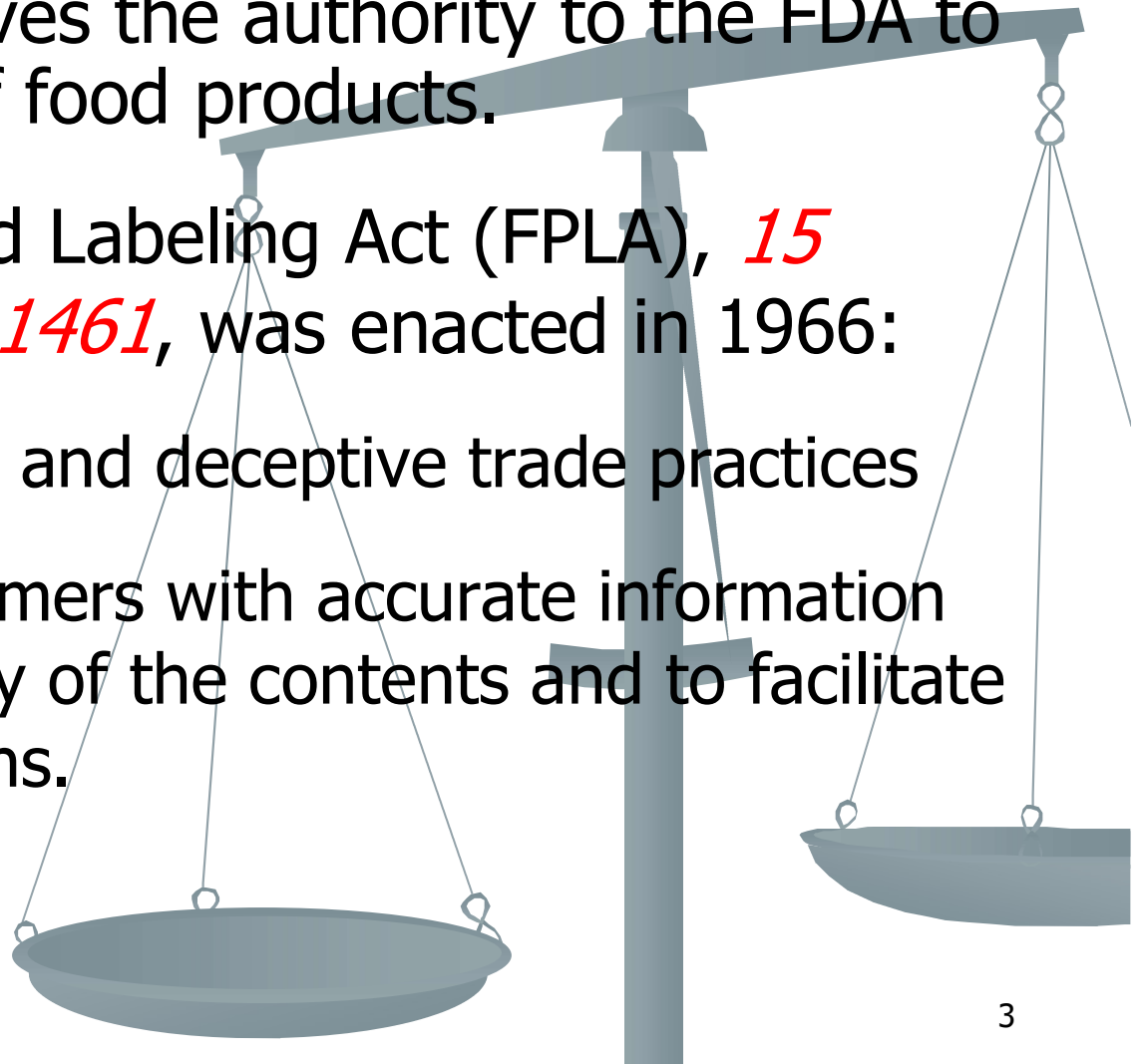
Why Food Labeling Regulations?

- To protect against fraud and deception
- To prevent false and misleading statements
- To provide consumers with information to make informed choices about food.



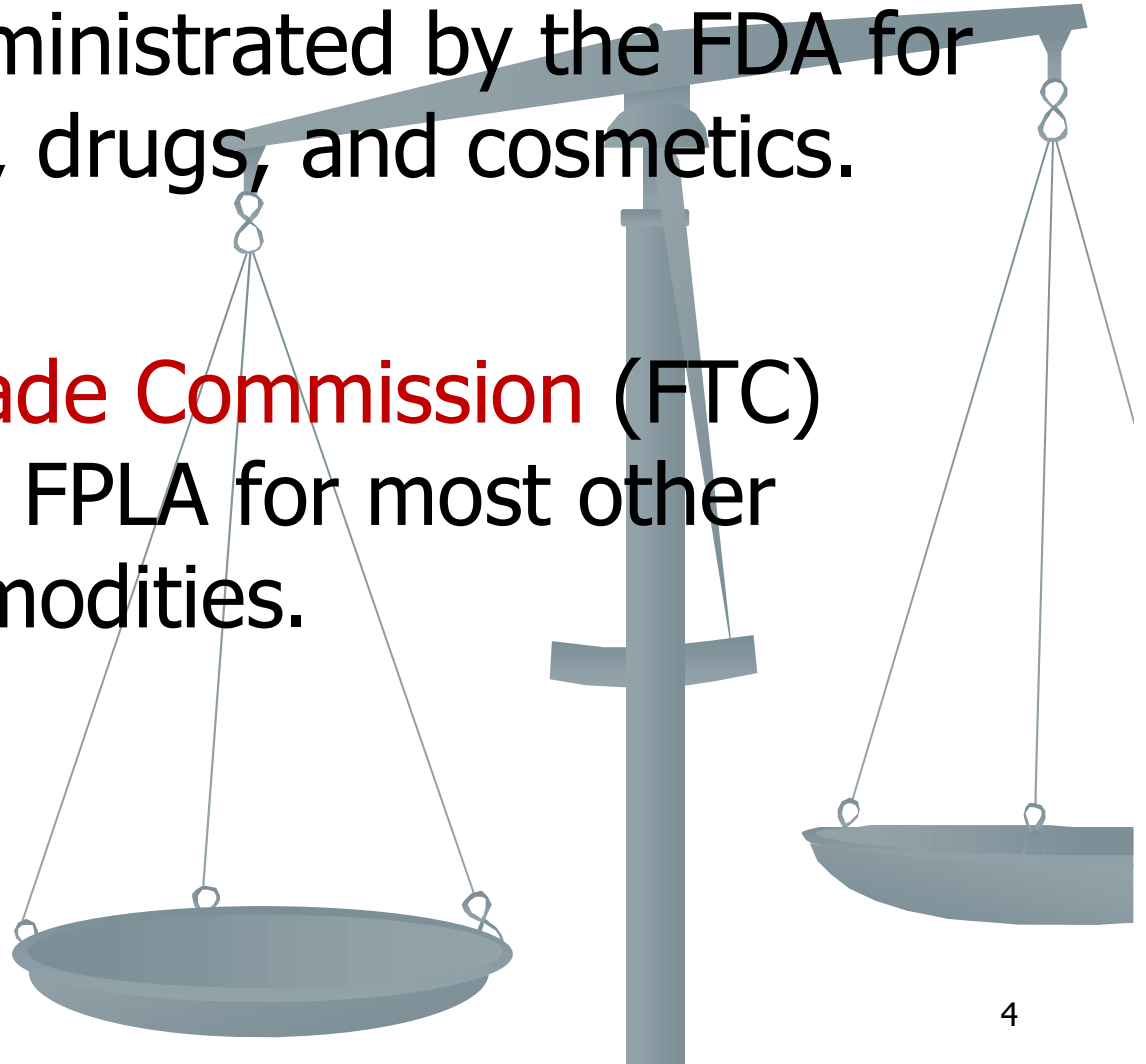
Legal Authorities

- The **FD&C Act** gives the authority to the FDA to compel labeling of food products.
- Fair Packaging and Labeling Act (FPLA), *15 U.S.C. § § 1451-1461*, was enacted in 1966:
 - to prevent unfair and deceptive trade practices
 - to provide consumers with accurate information as to the quantity of the contents and to facilitate value comparisons.



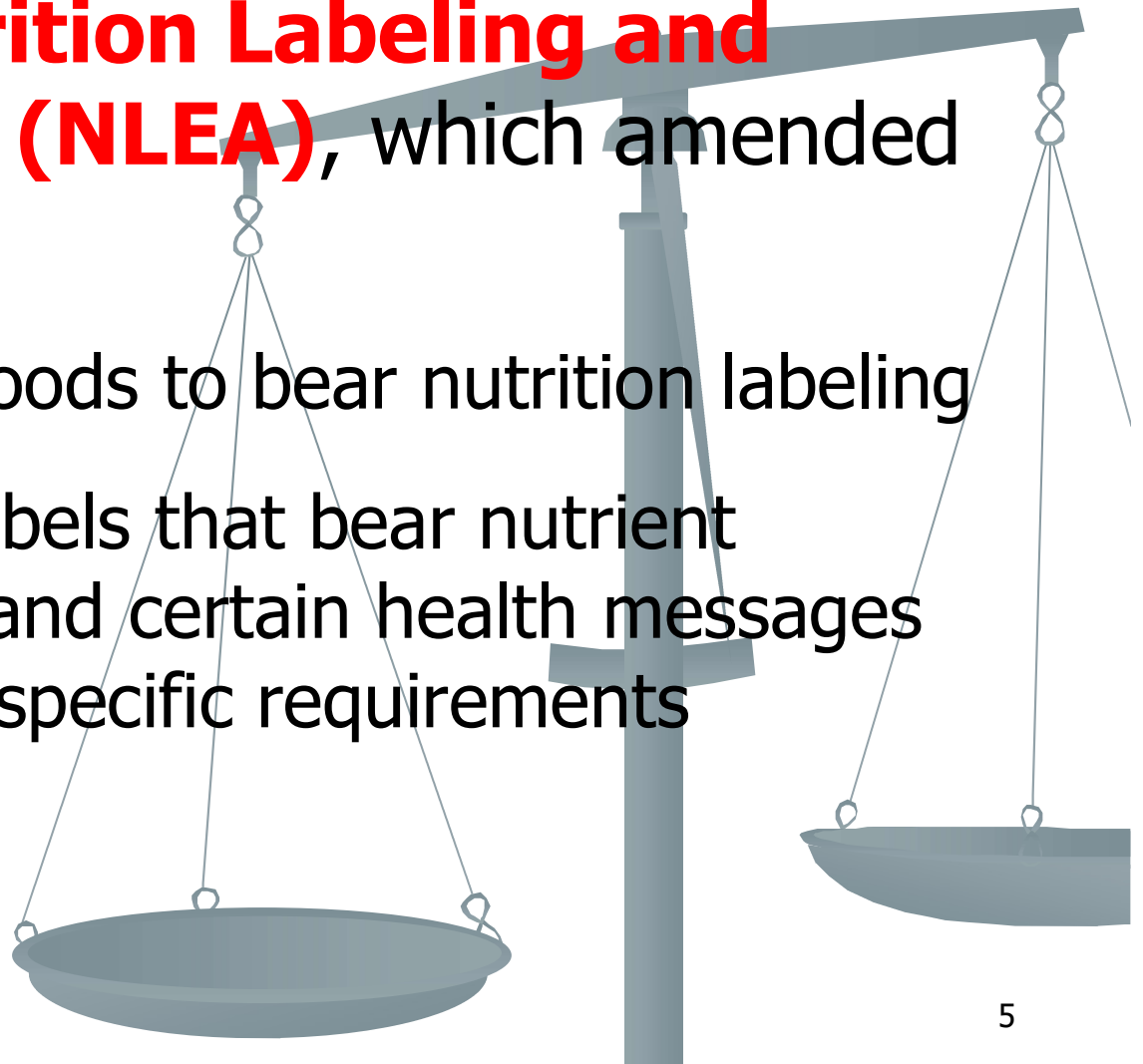
Legal Authorities

- The FPLA is administered by the FDA for labels on foods, drugs, and cosmetics.
- The **Federal Trade Commission** (FTC) administers the FPLA for most other consumer commodities.



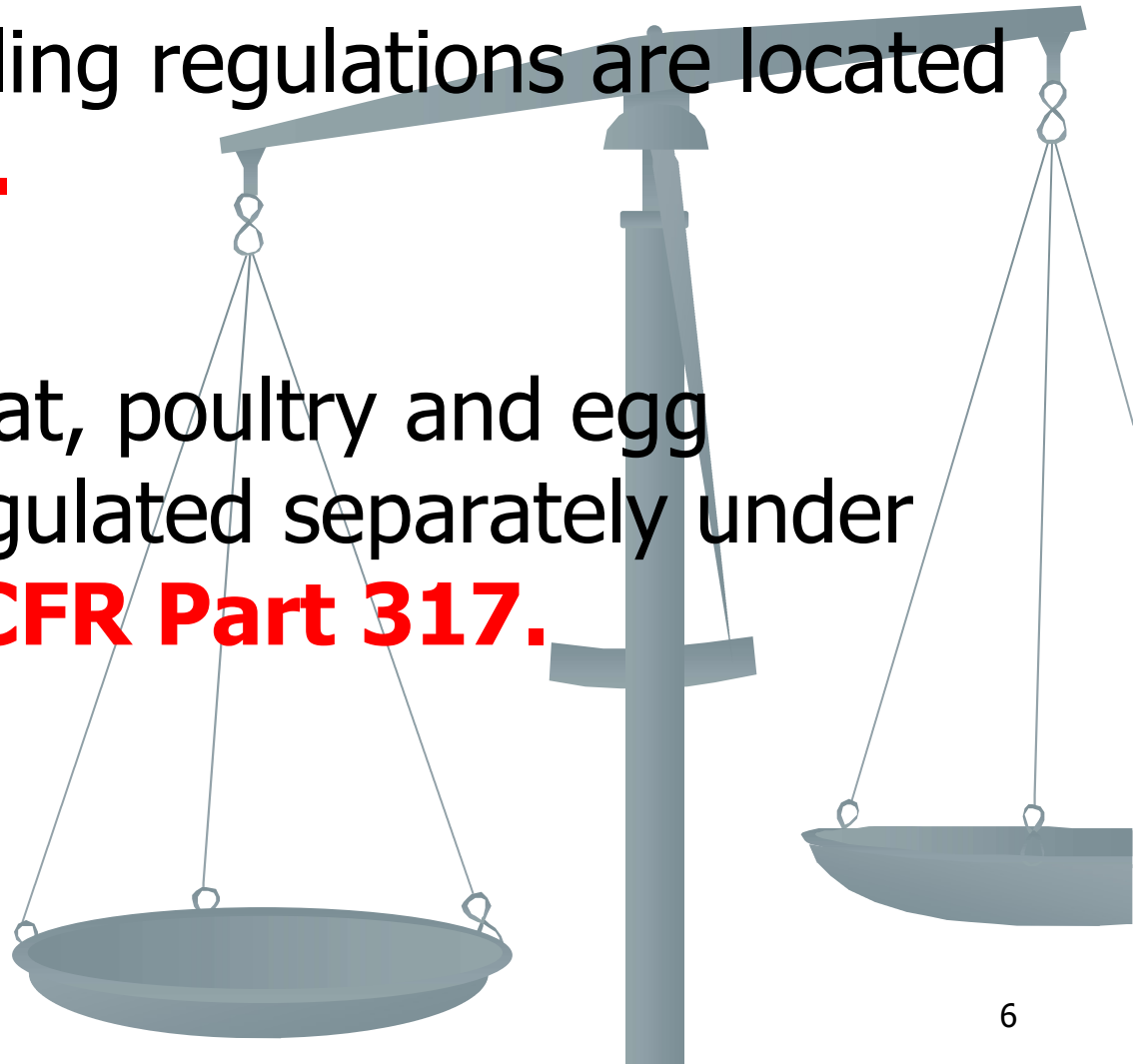
Legal Authorities

- The **1990 Nutrition Labeling and Education Act (NLEA)**, which amended the FD&C Act,
 - requires **most** foods to bear nutrition labeling
 - requires food labels that bear nutrient content claims and certain health messages to comply with specific requirements



Legal Authorities

- FDA's food labeling regulations are located in **21 CFR 101.**
- Labeling for meat, poultry and egg products are regulated separately under the USDA in **9 CFR Part 317.**

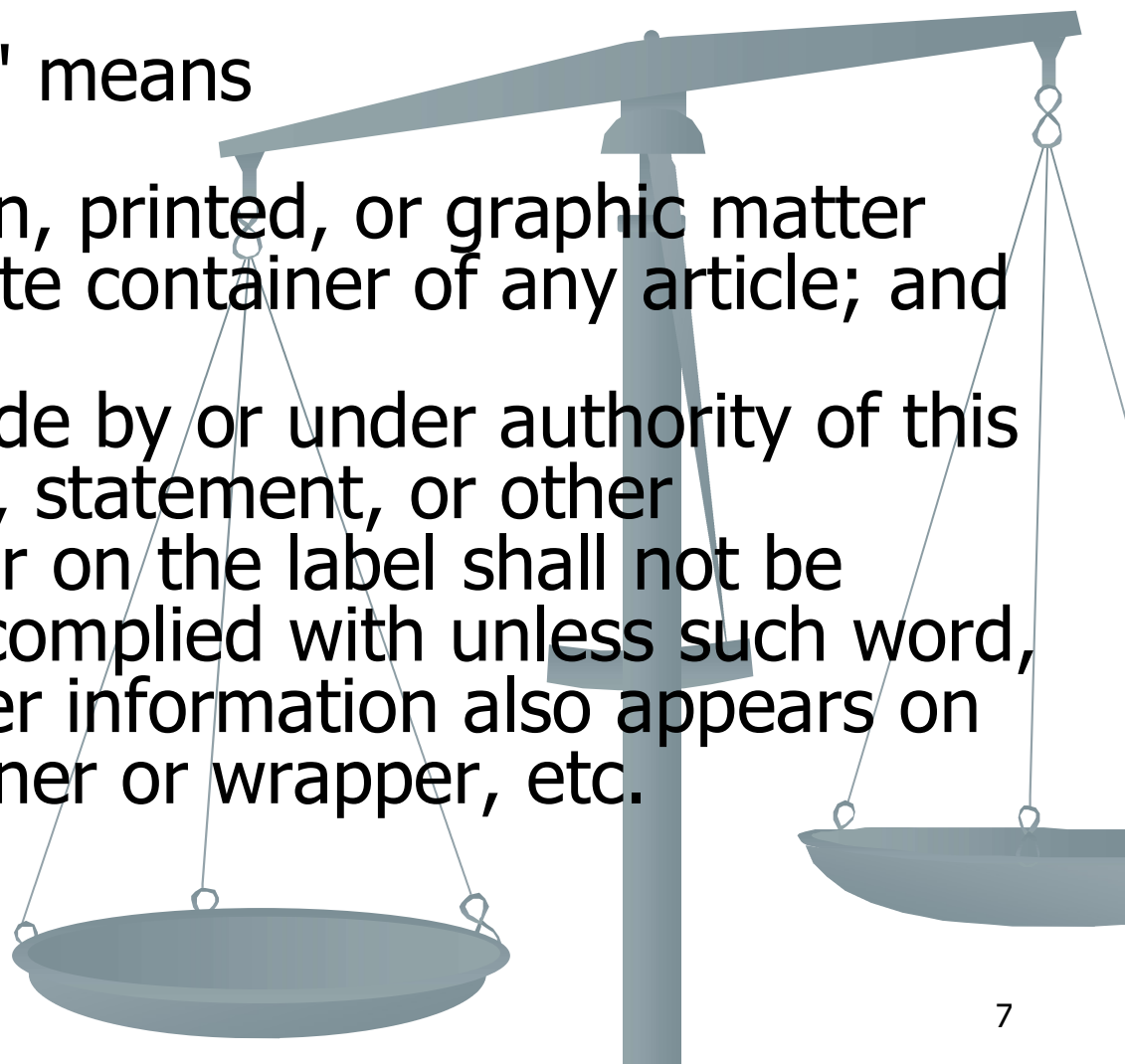


Labeling Terminology

FD&C Act SEC. 201 or [21 U.S.C. § 321]

(k) The term "**label**" means

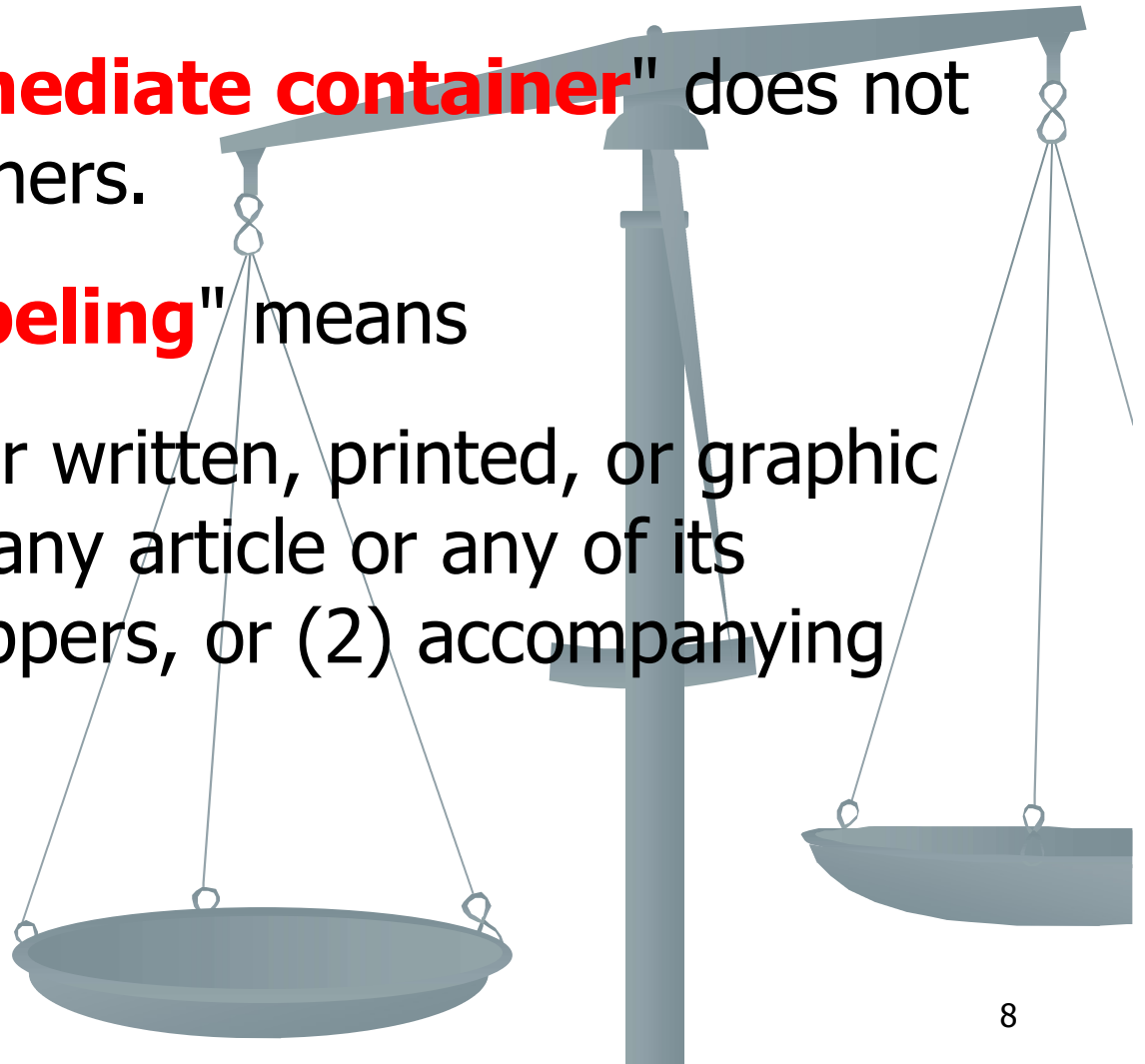
- a display of written, printed, or graphic matter upon the immediate container of any article; and
- a requirement made by or under authority of this Act that any word, statement, or other information appear on the label shall not be considered to be complied with unless such word, statement, or other information also appears on the outside container or wrapper, etc.



Labeling Terminology

FD&C Act SEC. 201. or [21 U.S.C. § 321]

- (l) The term "**immediate container**" does not include package liners.
- (m) The term "**labeling**" means
all labels and other written, printed, or graphic matters (1) upon any article or any of its containers or wrappers, or (2) accompanying such article.



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- (100) General
- (101) Food labeling**
- (102) Common or usual name for nonstandardized foods
- (104) Nutritional quality guidelines for foods
- (105) Foods for special dietary use

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21 CFR 101 – Food Labeling

 U.S. Department of Health & Human Services

 **U.S. Food and Drug Administration**

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TITLE 21--FOOD AND DRUGS
CHAPTER I--FOOD AND DRUG ADMINISTRATION
DEPARTMENT OF HEALTH AND HUMAN SERVICES
SUBCHAPTER B--FOOD FOR HUMAN CONSUMPTION
PART 101 [FOOD LABELING](#)

[Subpart A--General Provisions](#)
[§ 101.1](#) - Principal display panel of package form food.
[§ 101.2](#) - Information panel of package form food.
[§ 101.3](#) - Identity labeling of food in packaged form.
[§ 101.4](#) - Food; designation of ingredients.
[§ 101.5](#) - Food; name and place of business of manufacturer, packer, or distributor.
[§ 101.9](#) - Nutrition labeling of food.
[§ 101.10](#) - Nutrition labeling of restaurant foods.
[§ 101.12](#) - Reference amounts customarily consumed per eating occasion.
[§ 101.13](#) - Nutrient content claims--general principles.
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[§ 101.15](#) - Food; prominence of required statements.
[§ 101.17](#) - Food labeling warning, notice, and safe handling statements.
[§ 101.18](#) - Misbranding of food.

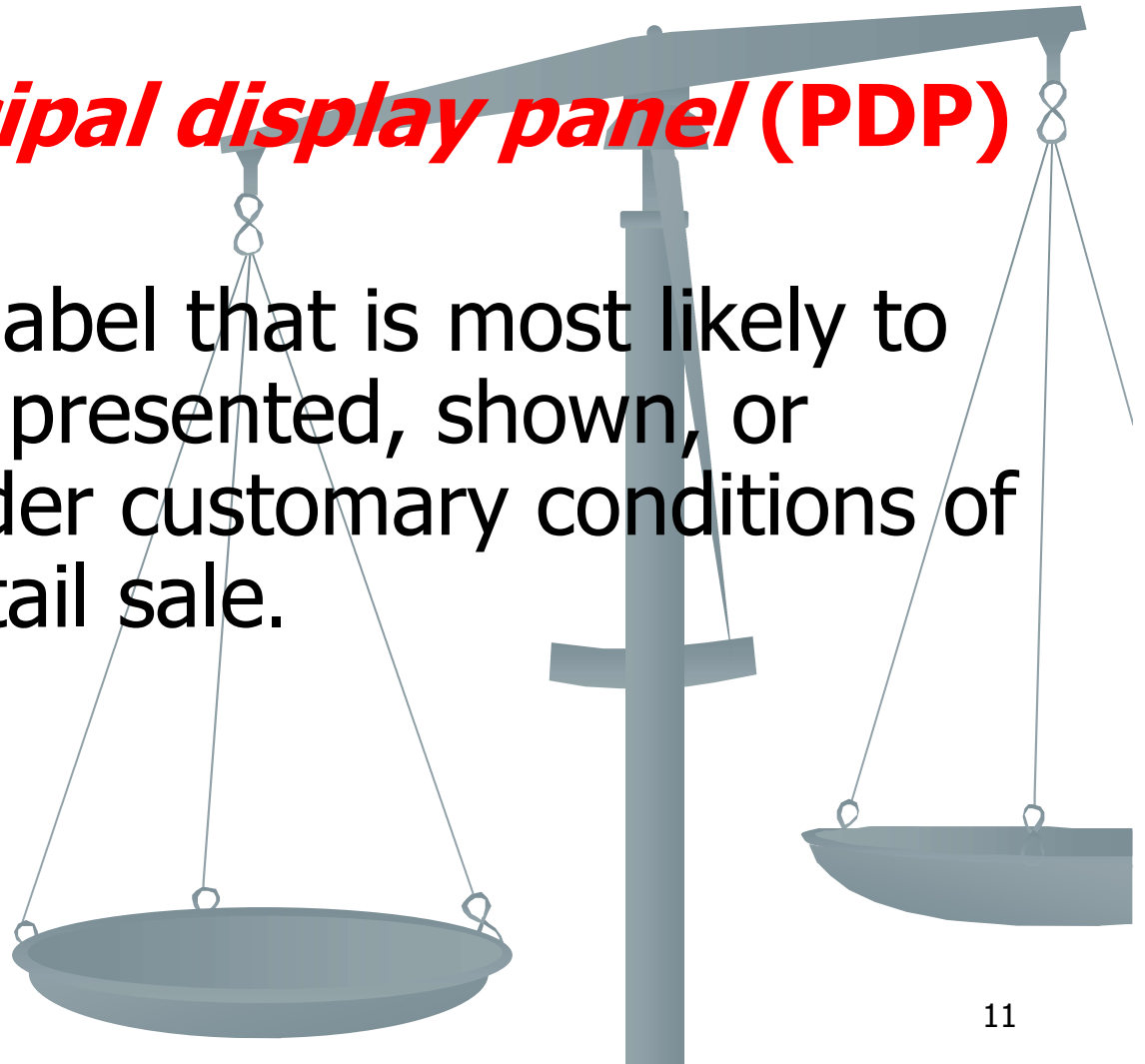
[Subpart B--Specific Food Labeling Requirements](#)
[§ 101.22](#) - Foods; labeling of spices, flavorings, colorings and chemical preservatives.
[§ 101.30](#) - Percentage juice declaration for foods purporting to be beverages that contain fruit or vegetable juice.

[Subpart C--Specific Nutrition Labeling Requirements and Guidelines](#)
[§ 101.36](#) - Nutrition labeling of dietary supplements.
[§ 101.42](#) - Nutrition labeling of raw fruit, vegetables, and fish.
[§ 101.43](#) - Substantial compliance of food retailers with the guidelines for the voluntary nutrition

Principal Display Panel

21 CFR § 101.1

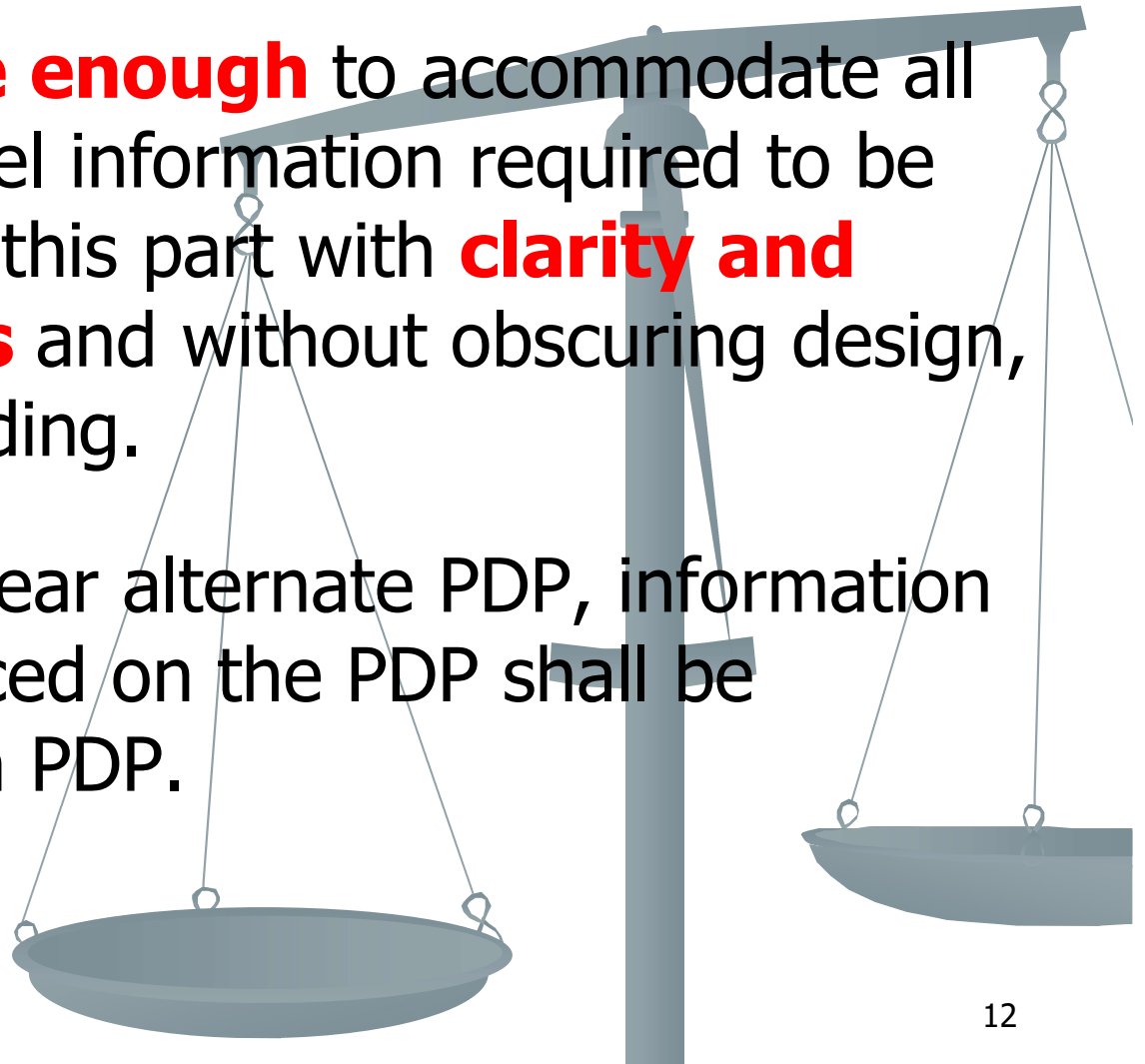
- The term ***principal display panel (PDP)*** means
 - the part of a label that is most likely to be displayed, presented, shown, or examined under customary conditions of display for retail sale.



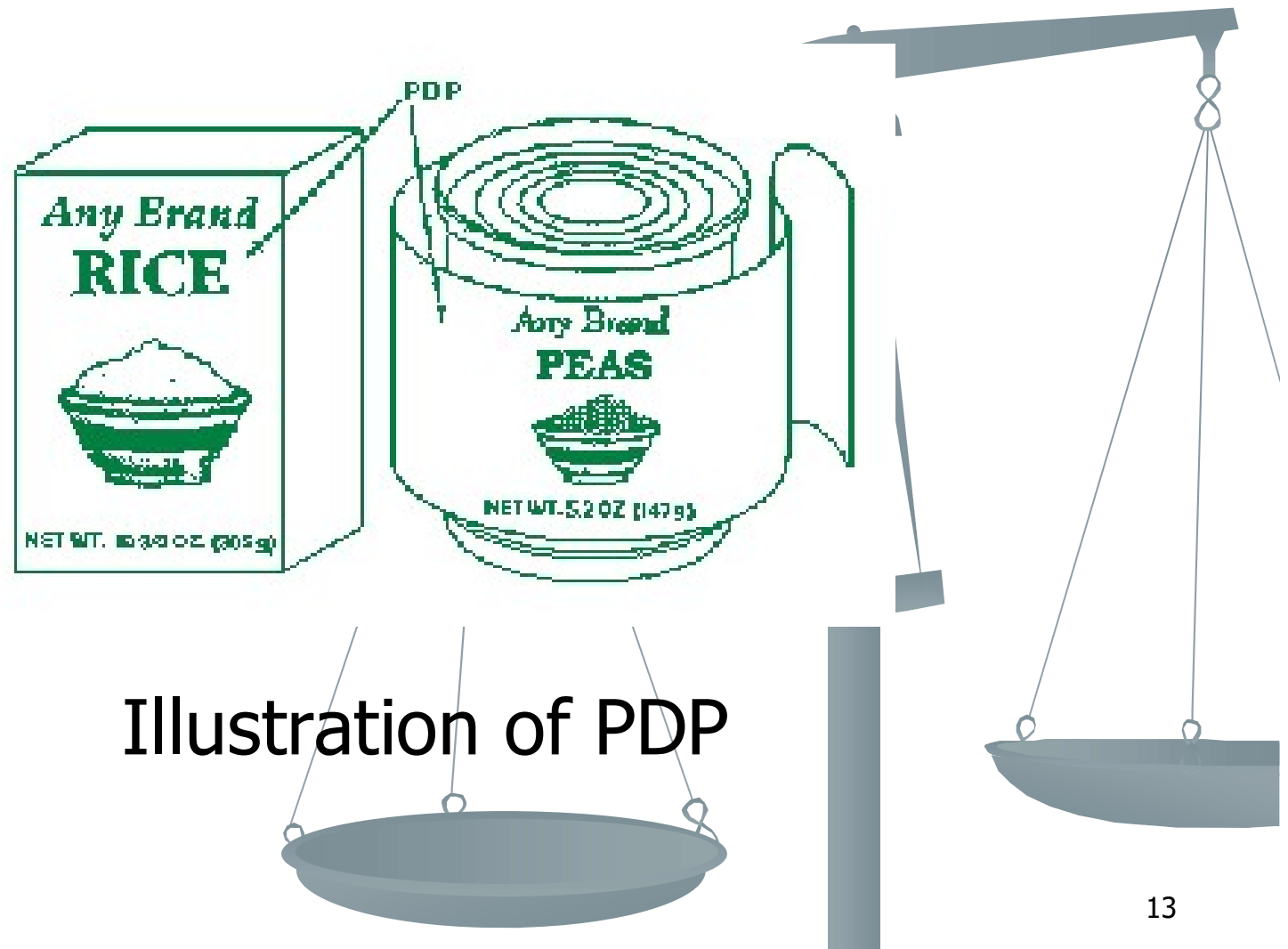
PDP

21 CFR § 101.1

- PDP shall be **large enough** to accommodate all the mandatory label information required to be placed thereon by this part with **clarity and conspicuousness** and without obscuring design, vignettes, or crowding.
- Where packages bear alternate PDP, information required to be placed on the PDP shall be duplicated on each PDP.

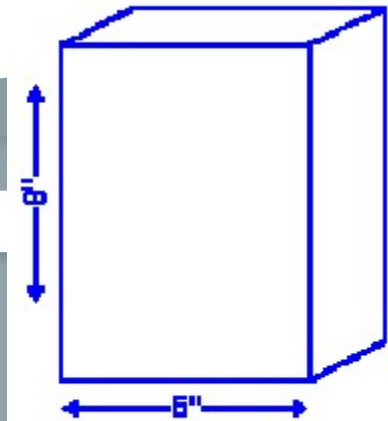


PDP



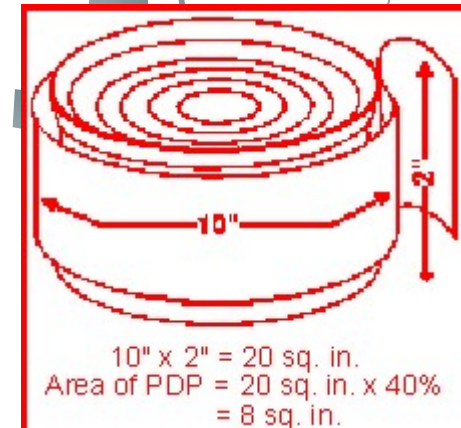
Area of PDP (21 CFR 101.1)

- The area of a rectangular or square PDP on a carton is the height multiplied by the width (both in inches or both in centimeters).



Area of PDP = $6" \times 8" = 48$ sq. in.

- To calculate the area of the PDP for a cylindrical container, use 40% of the product of the height by the circumference.

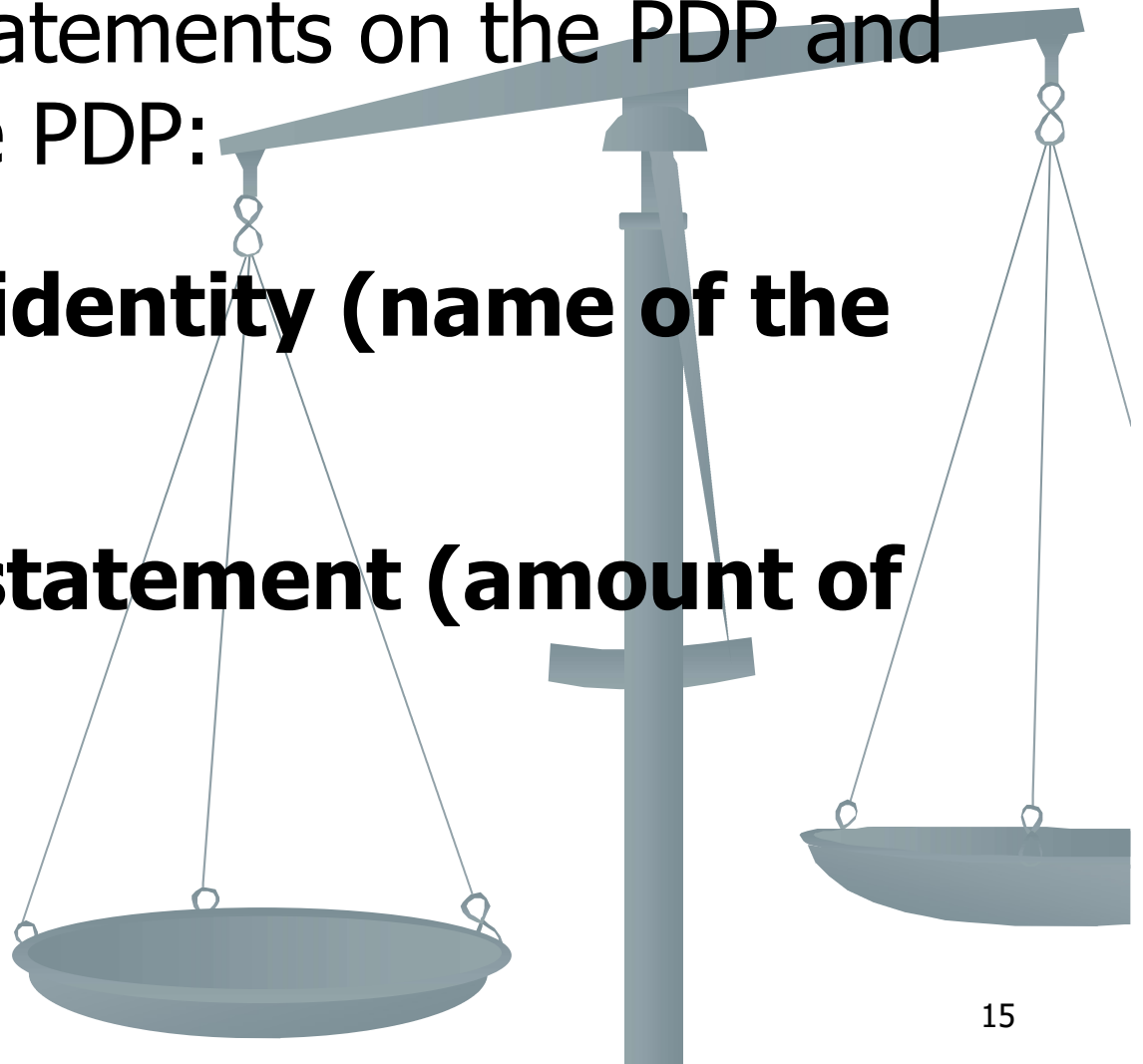


$10" \times 2" = 20$ sq. in.
Area of PDP = 20 sq. in. $\times 40\%$
= 8 sq. in.

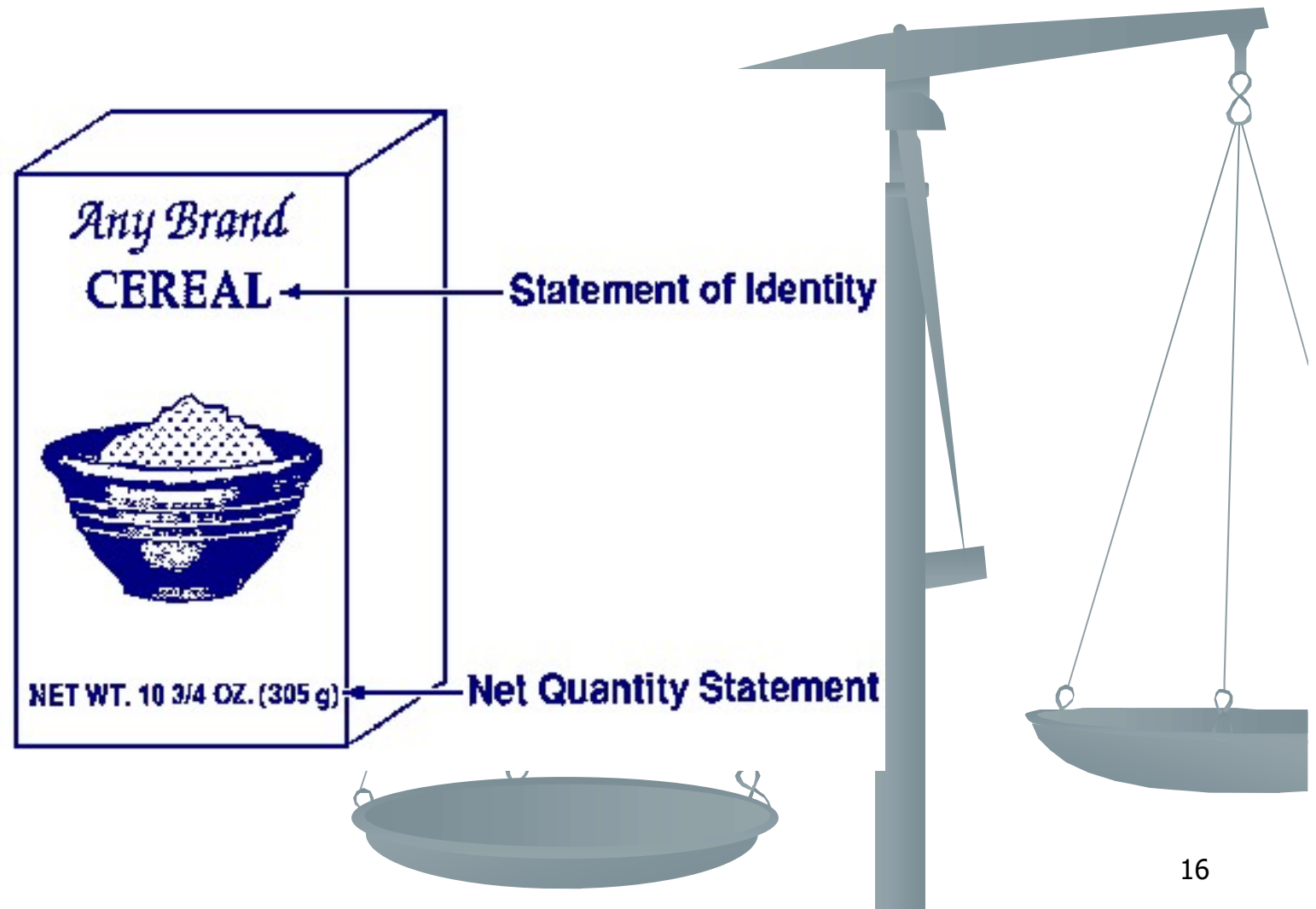
PDP (21 CFR § 101.1)

Required Label statements on the PDP and on the alternate PDP:

- **Statement of identity (name of the food)**
- **Net quantity statement (amount of product)**



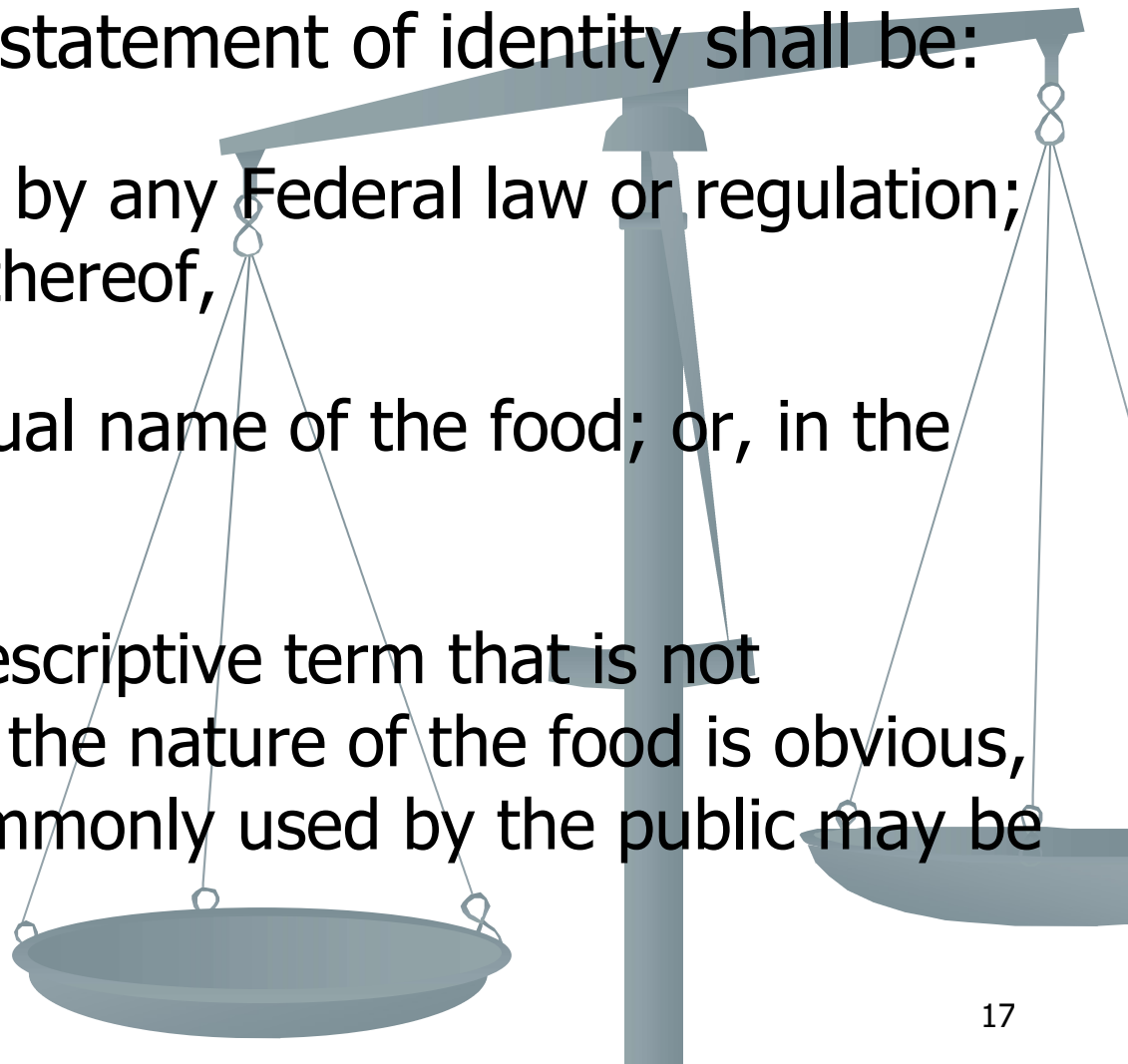
PDP



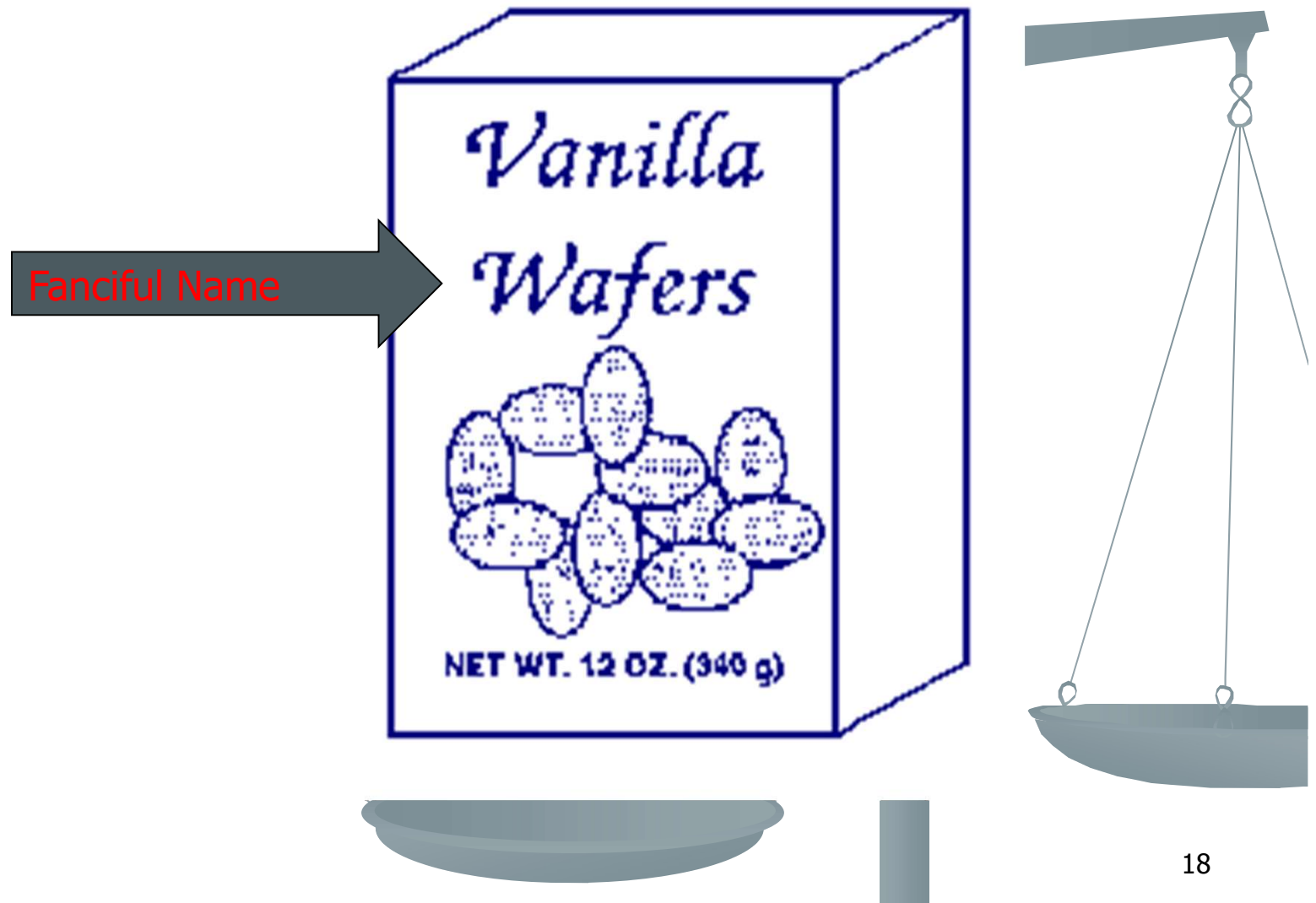
Statement of Identity

21 CFR 101.3(b)

- The name used as statement of identity shall be:
 - (1) The name required by any Federal law or regulation; or, in the **absence** thereof,
 - (2) The common or usual name of the food; or, in the **absence** thereof,
 - (3) An appropriately descriptive term that is not misleading, or when the nature of the food is obvious, a **fanciful** name commonly used by the public may be used.



Statement of Identity

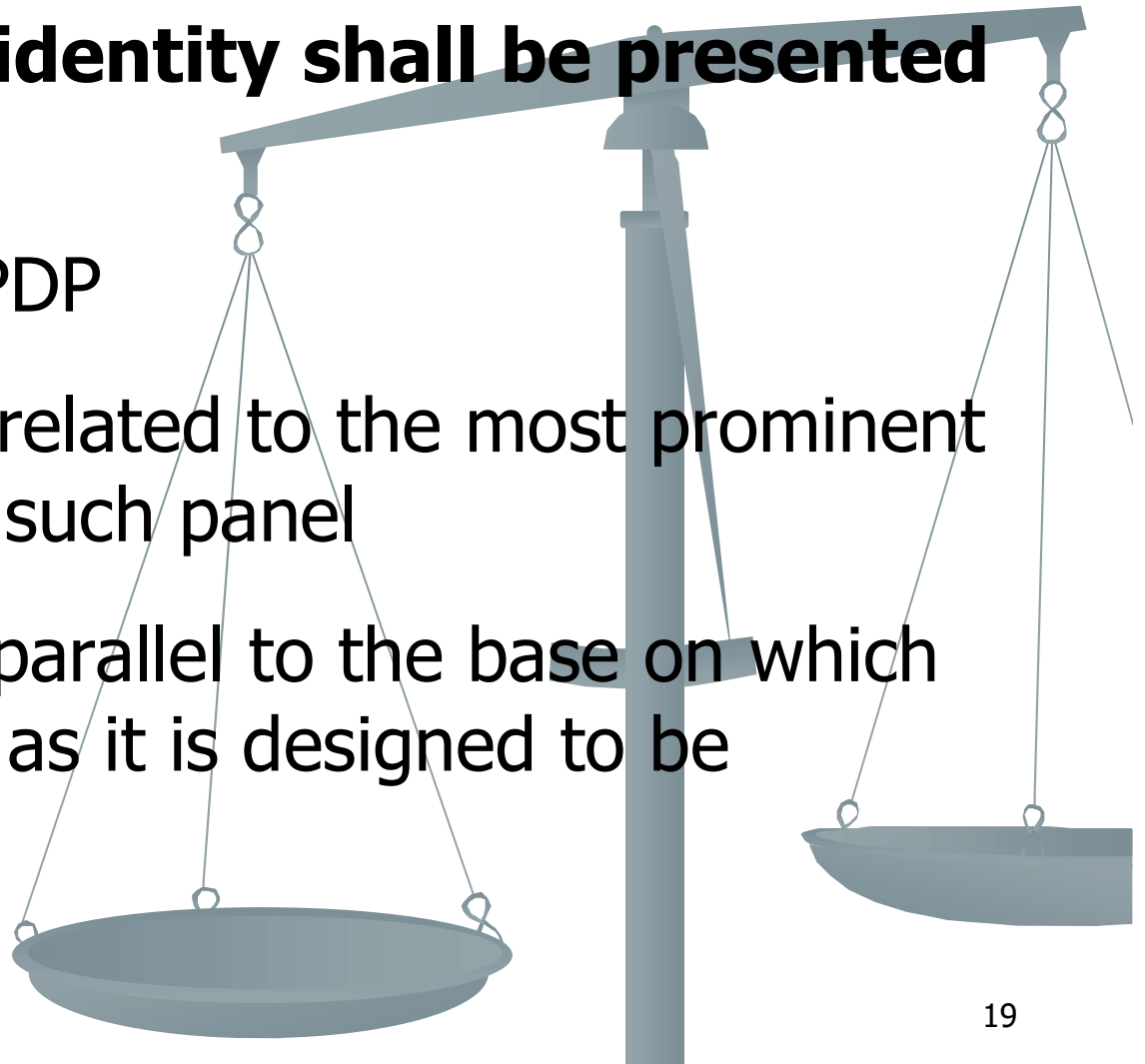


Statement of Identity

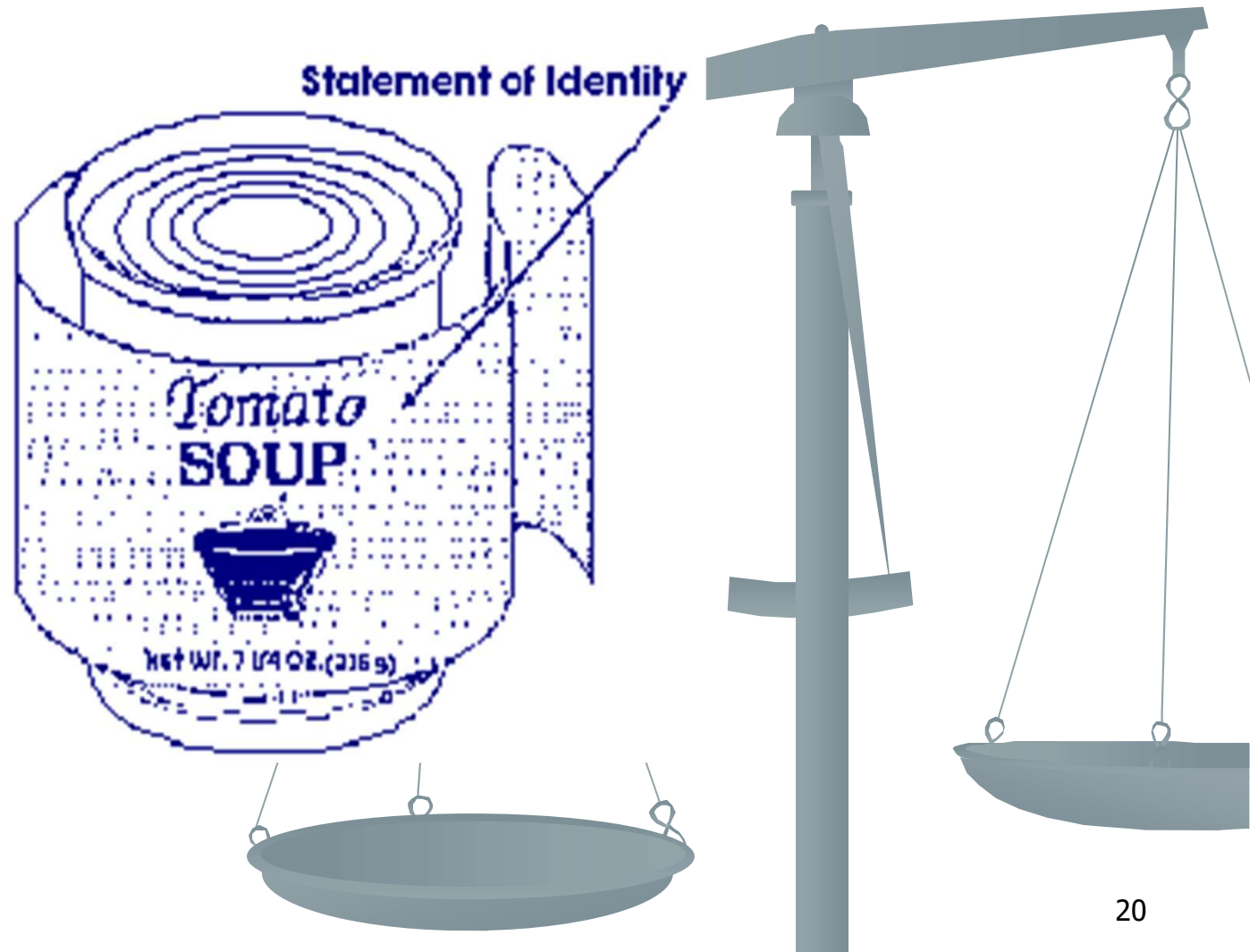
21 CFR 101.3 (d)

The statement of identity shall be presented in:

- Bold type on the PDP
- A size reasonably related to the most prominent printed matter on such panel
- In lines generally parallel to the base on which the package rests as it is designed to be displayed



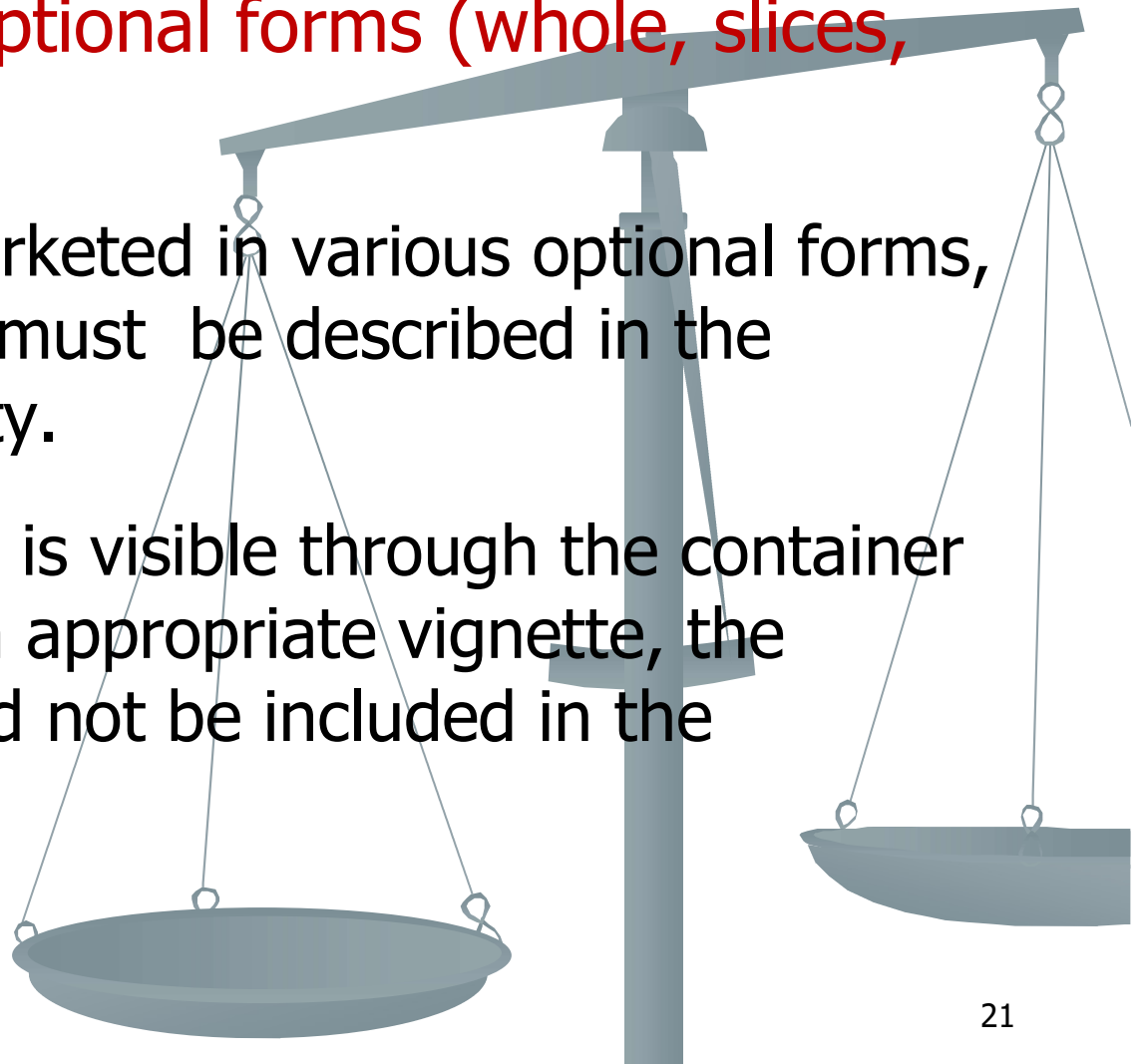
Statement of Identity



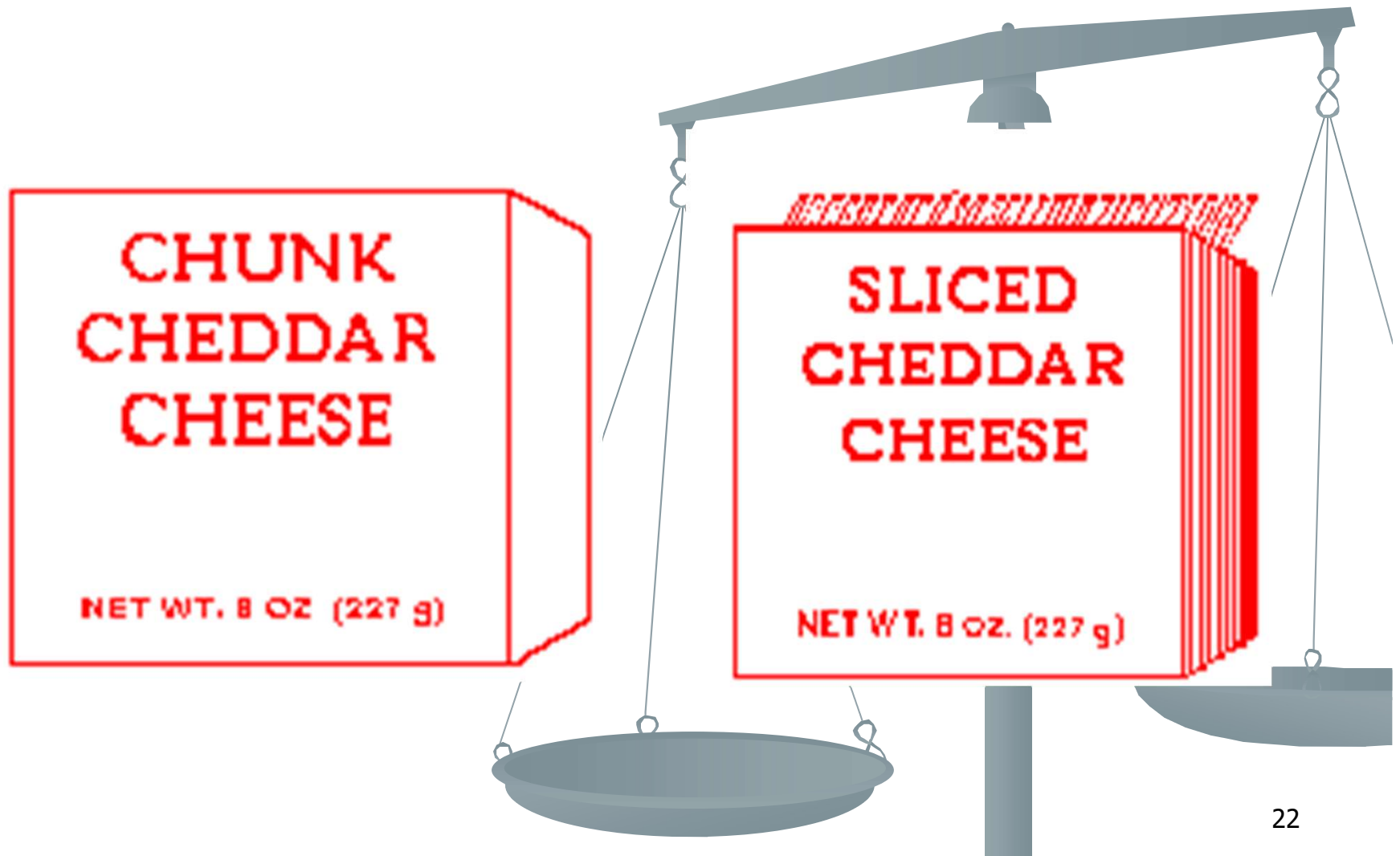
Statement of Identity

21 CFR 101.3(c) - Optional forms (whole, slices, diced, etc.)

- Where a food is marketed in various optional forms, the particular form must be described in the statement of identity.
- If the optional form is visible through the container or is depicted by an appropriate vignette, the particular form need not be included in the statement.



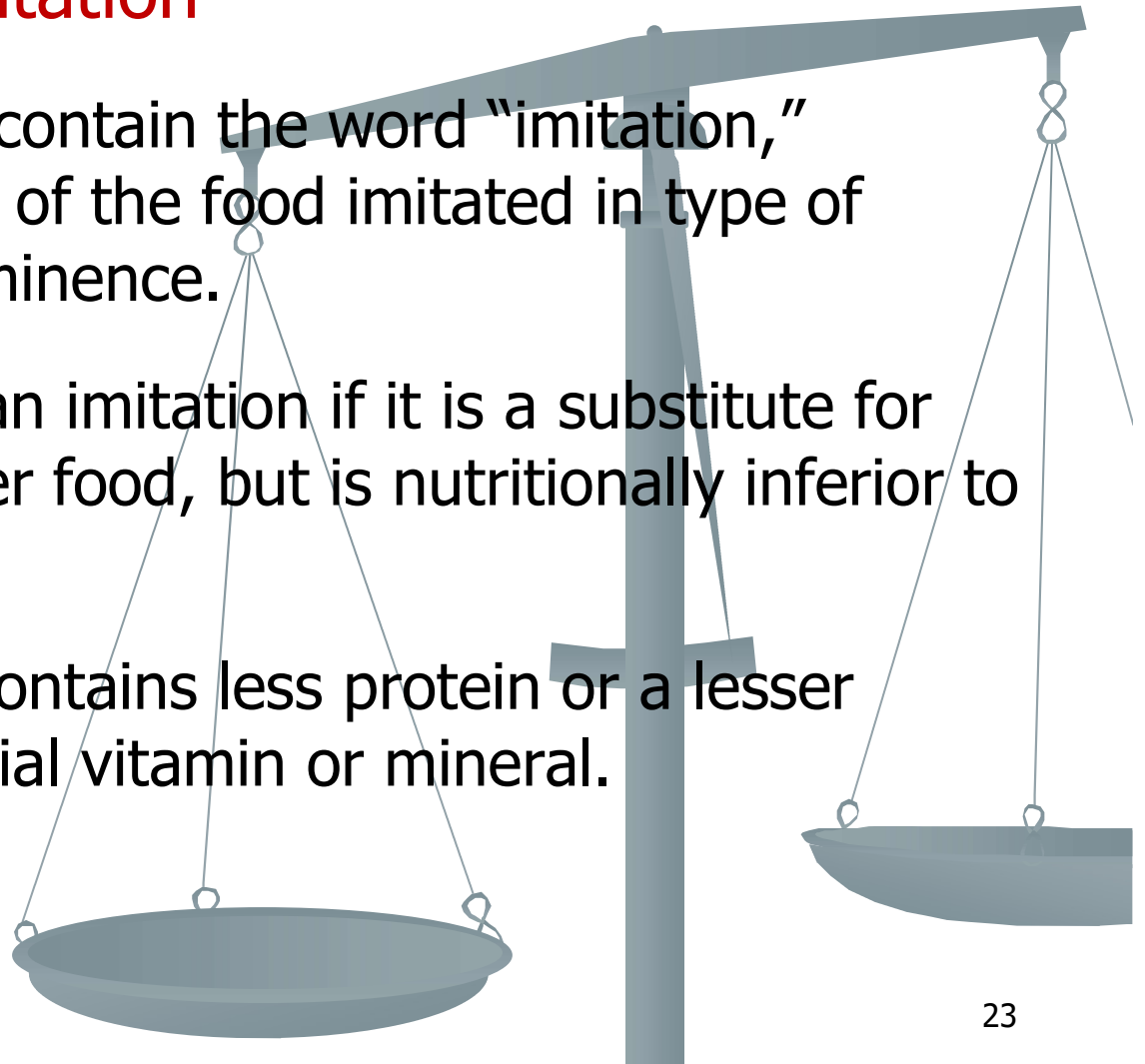
Statement of Identity



Statement of Identity

21 CFR 101.3(e)- Imitation

- Imitation foods must contain the word “imitation,” followed by the name of the food imitated in type of uniform size and prominence.
- A food is considered an imitation if it is a substitute for and resembles another food, but is nutritionally inferior to that food.
- Nutritionally inferior contains less protein or a lesser amount of any essential vitamin or mineral.



Statement of Identity



Statement of Identity

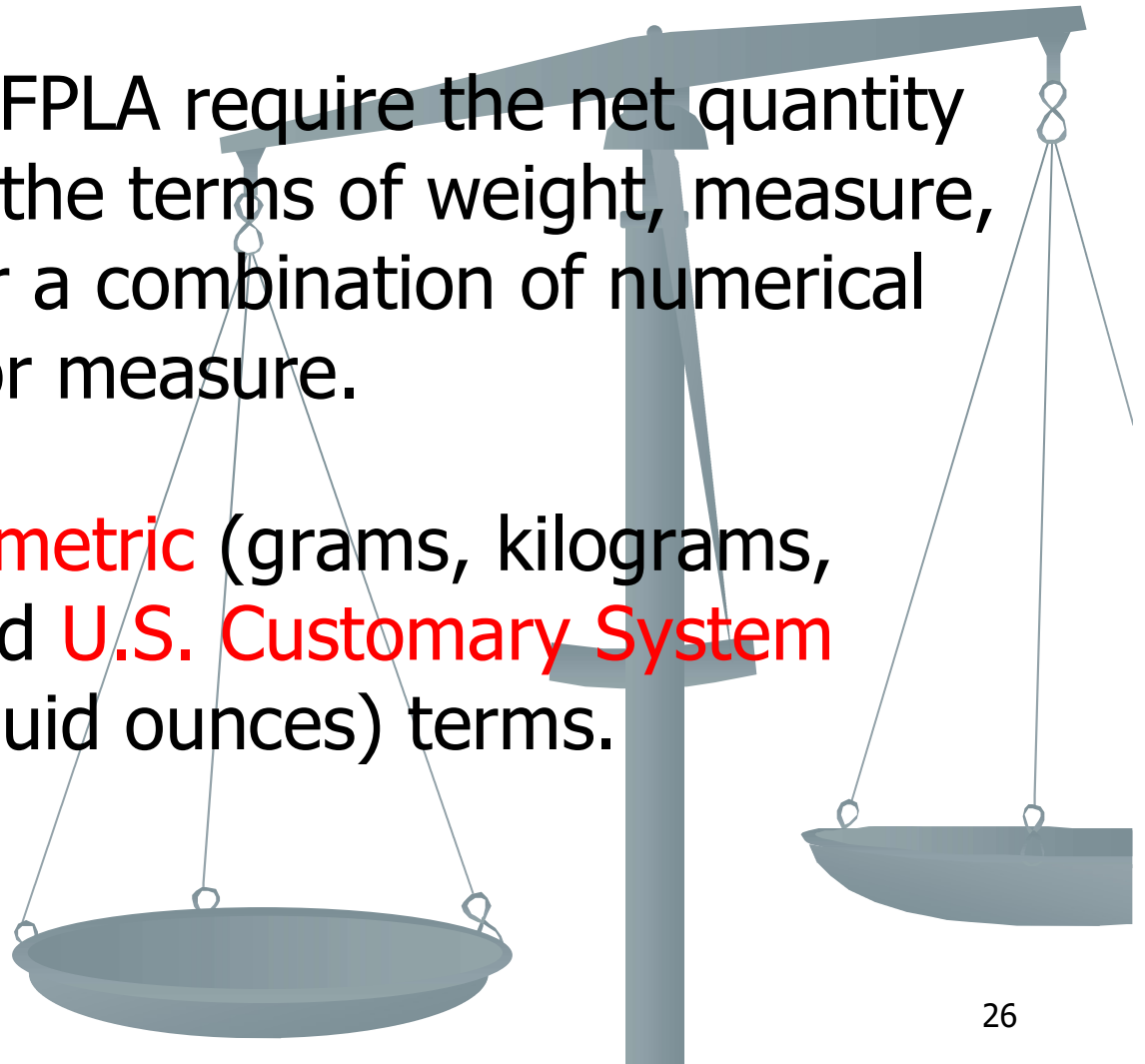
- Food standards for specific foods can be found in **21 CFR 131-169**.



Net Quantity

(21 CFR 101.105)

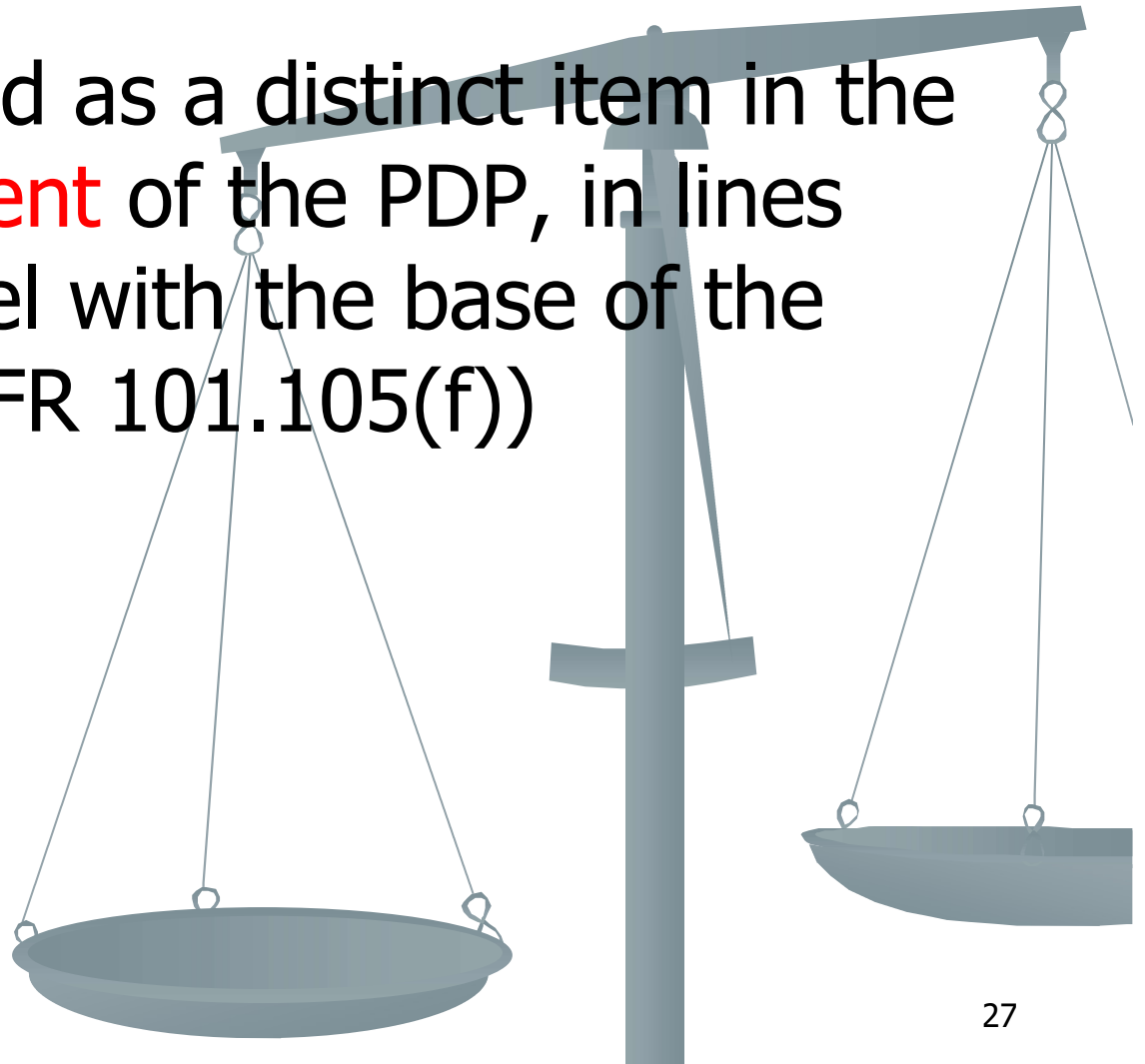
- The FD&C Act and FPLA require the net quantity to be expressed in the terms of weight, measure, numerical count, or a combination of numerical count and weight or measure.
- It must be in both **metric** (grams, kilograms, milliliters, liters) and **U.S. Customary System** (ounces, pounds, fluid ounces) terms.



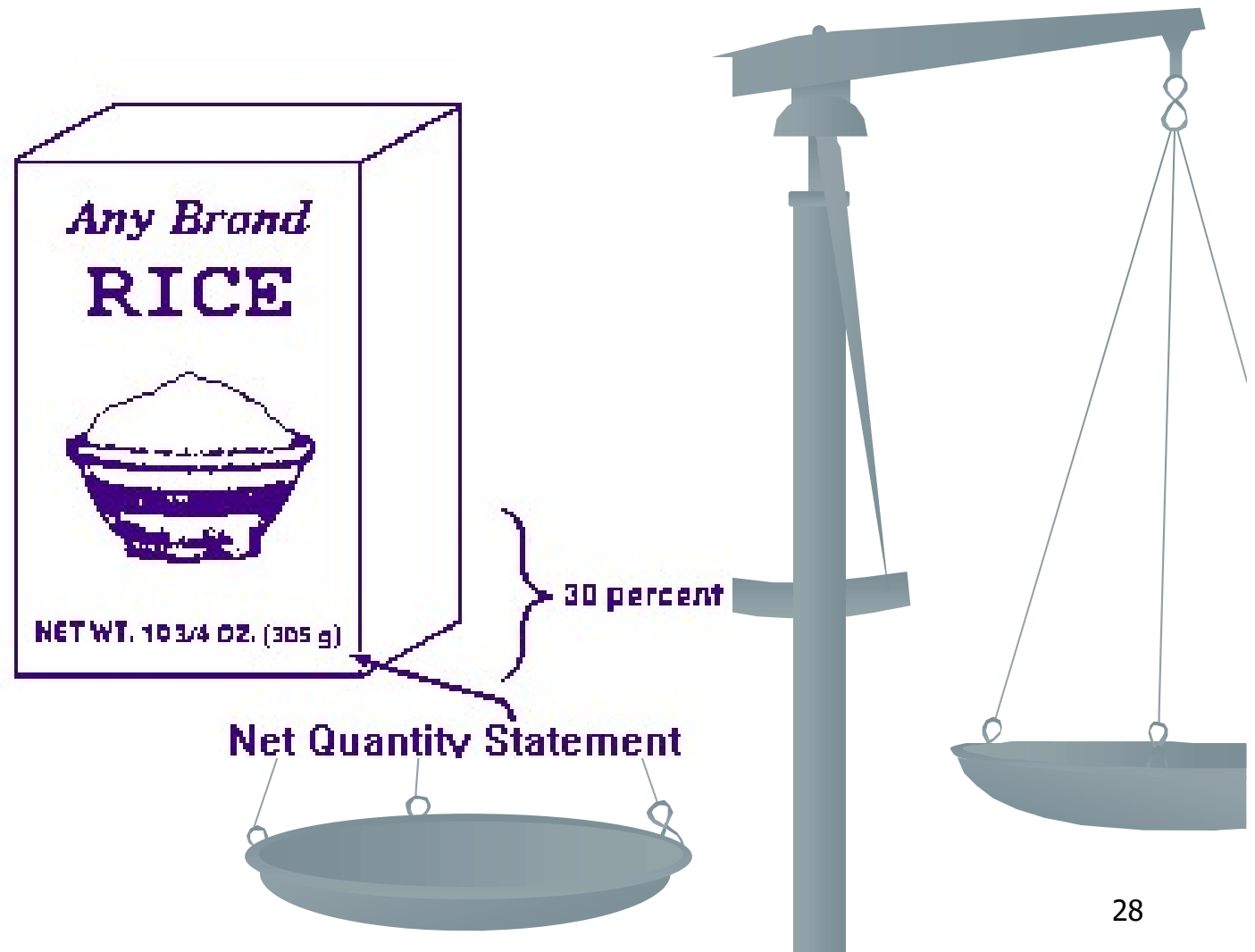
Net Quantity

21 CFR 101.105

- It shall be placed as a distinct item in the **bottom 30 percent** of the PDP, in lines generally parallel with the base of the container (21 CFR 101.105(f))

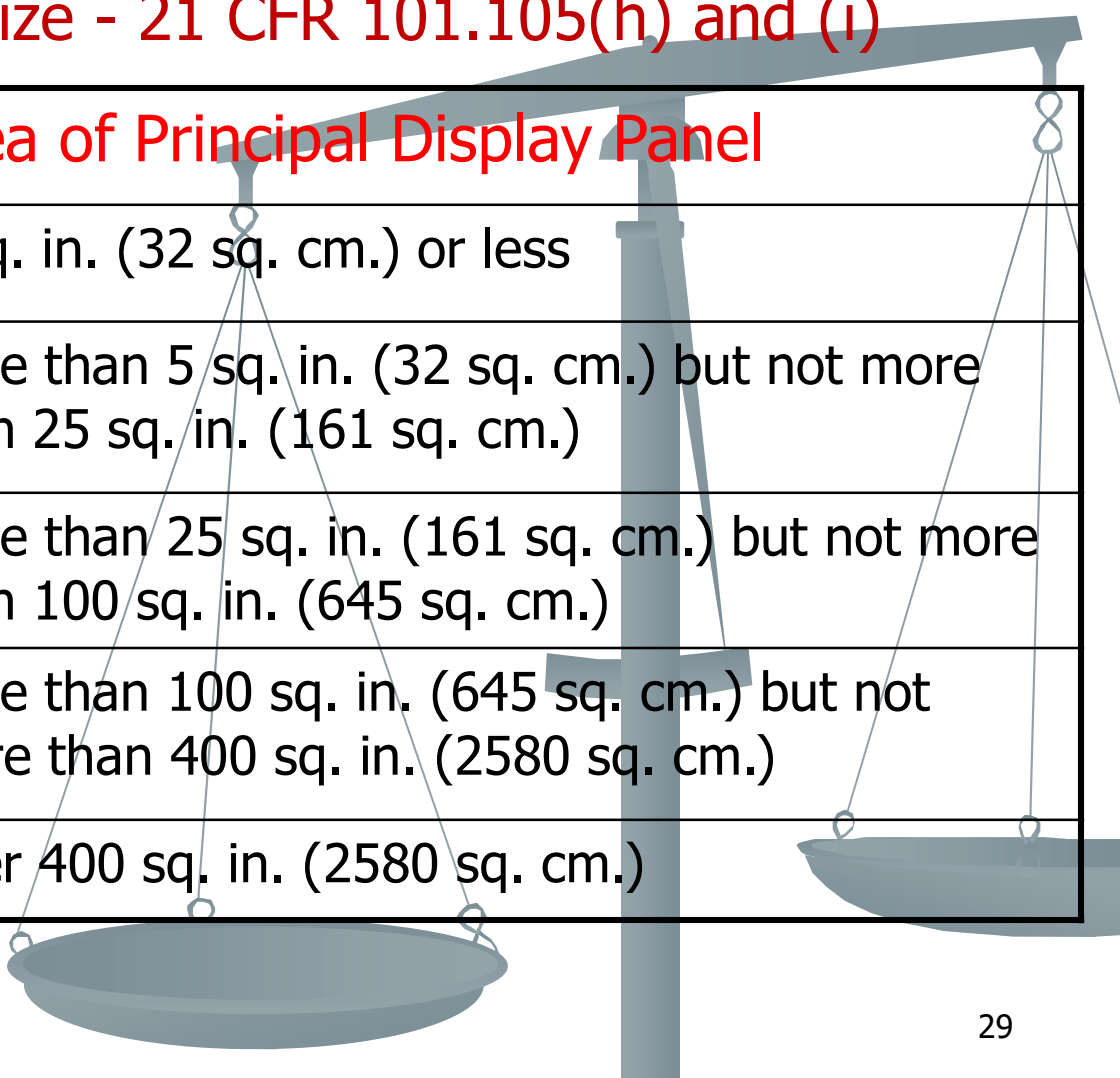


Net Quantity



Net Quantity

Minimum Type Size - 21 CFR 101.105(h) and (i)

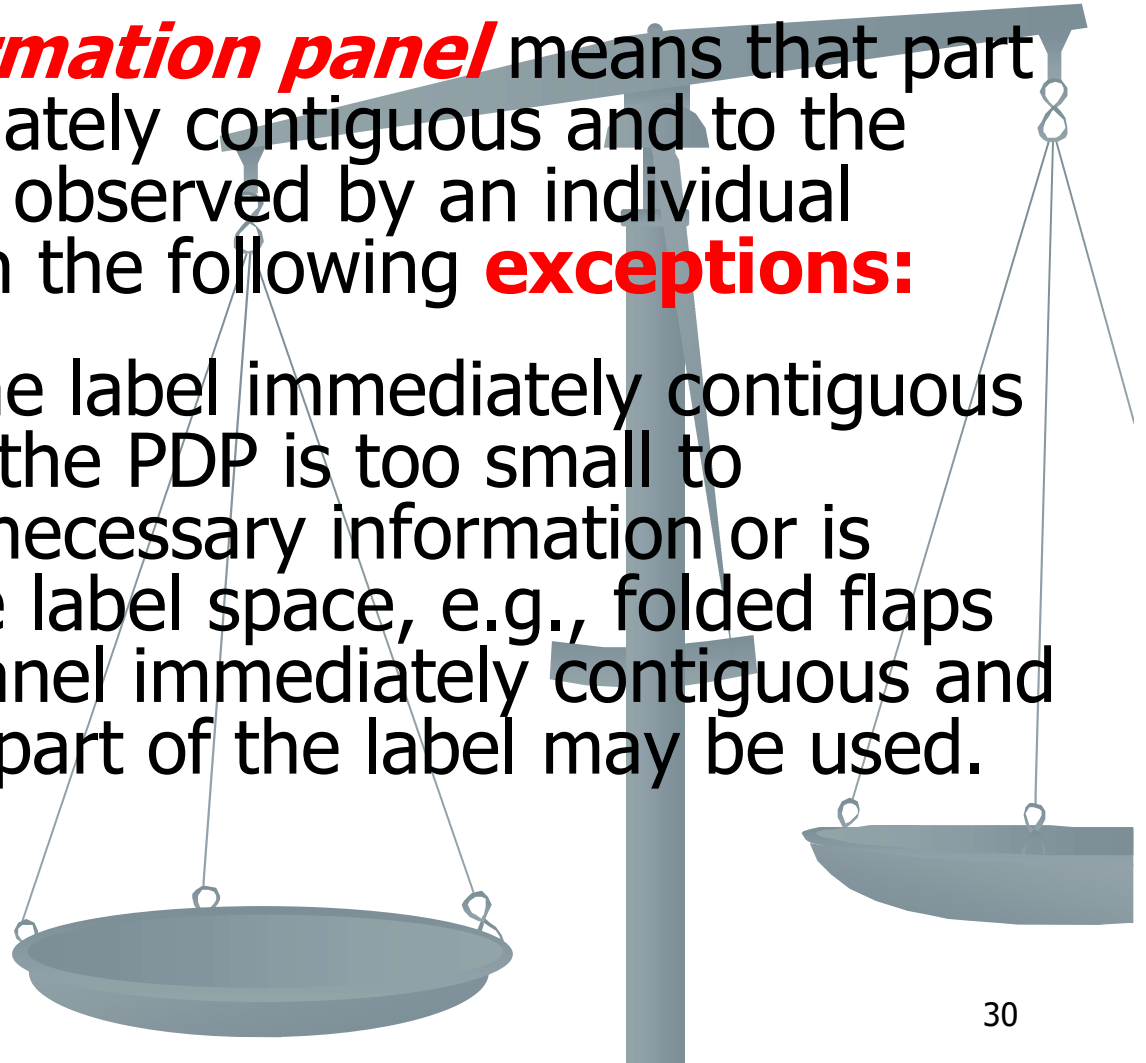


Minimum Type Size	Area of Principal Display Panel
1/16 in. (1.6 mm)	5 sq. in. (32 sq. cm.) or less
1/8 in. (3.2 mm)	More than 5 sq. in. (32 sq. cm.) but not more than 25 sq. in. (161 sq. cm.)
3/16 in. (4.8 mm)	More than 25 sq. in. (161 sq. cm.) but not more than 100 sq. in. (645 sq. cm.)
1/4 in. (6.4 mm)	More than 100 sq. in. (645 sq. cm.) but not more than 400 sq. in. (2580 sq. cm.)
1/2 in. (12.7 mm)	Over 400 sq. in. (2580 sq. cm.)

Information Panel

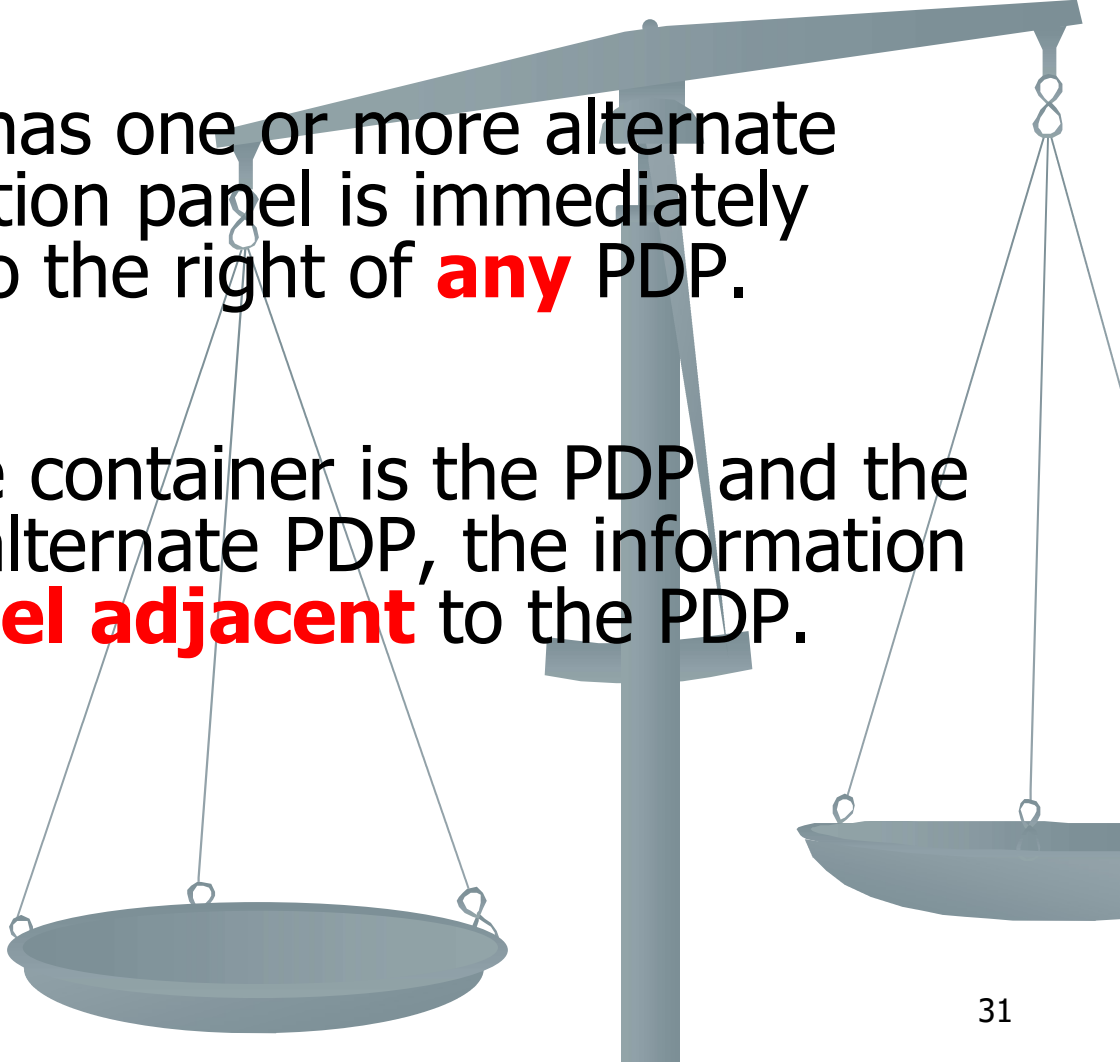
21 CFR § 101.2

- (a) The term ***information panel*** means that part of the label immediately contiguous and to the right of the PDP as observed by an individual facing the PDP with the following **exceptions**:
- (1) If the part of the label immediately contiguous and to the right of the PDP is too small to accommodate the necessary information or is otherwise unusable label space, e.g., folded flaps or can ends, the panel immediately contiguous and to the right of this part of the label may be used.

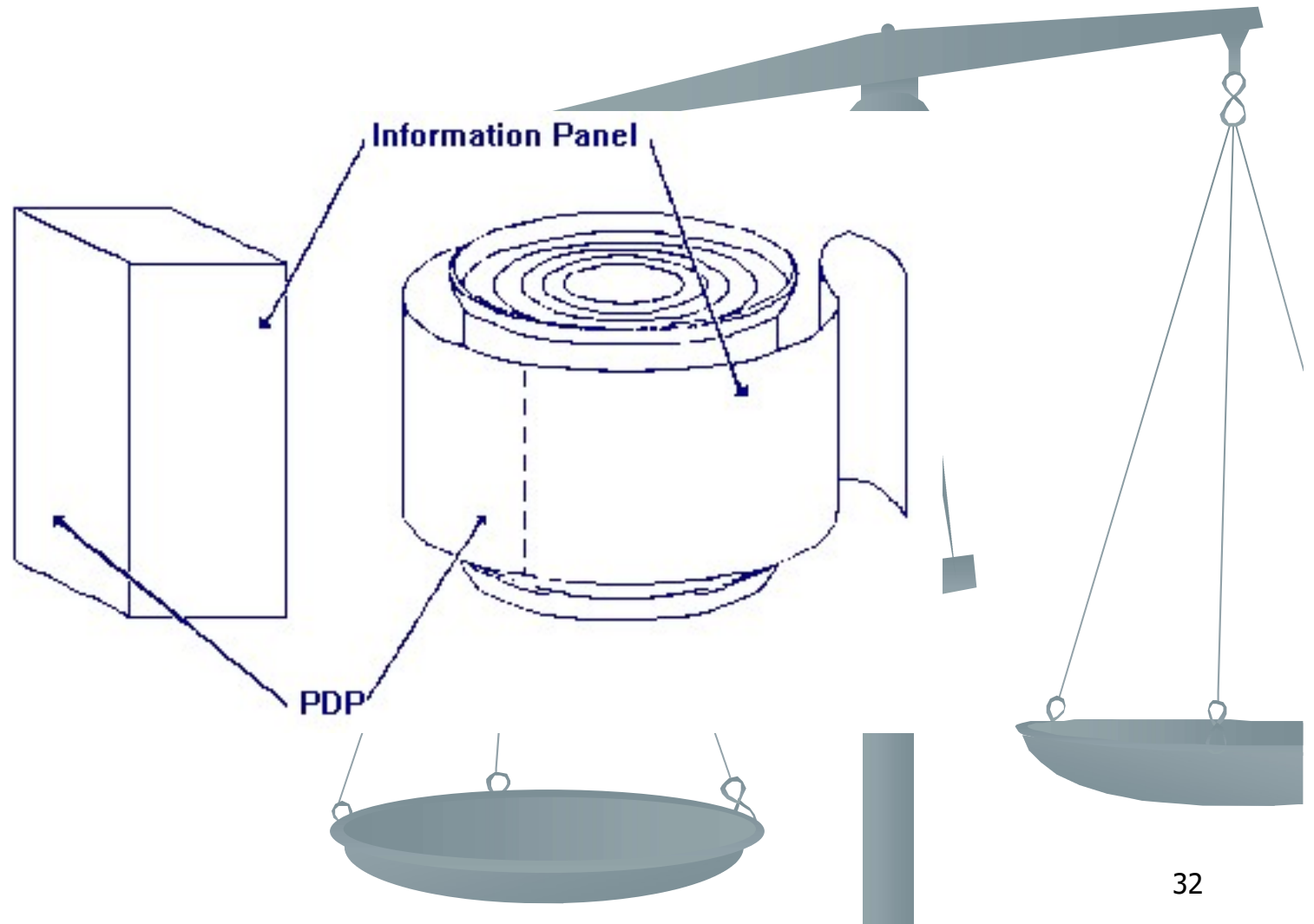


Information Panel

21 CFR § 101.2

- 
- (2) If the package has one or more alternate PDP, the information panel is immediately contiguous and to the right of **any** PDP.
- (3) If the top of the container is the PDP and the package has no alternate PDP, the information panel is **any panel adjacent** to the PDP.

Information Panel

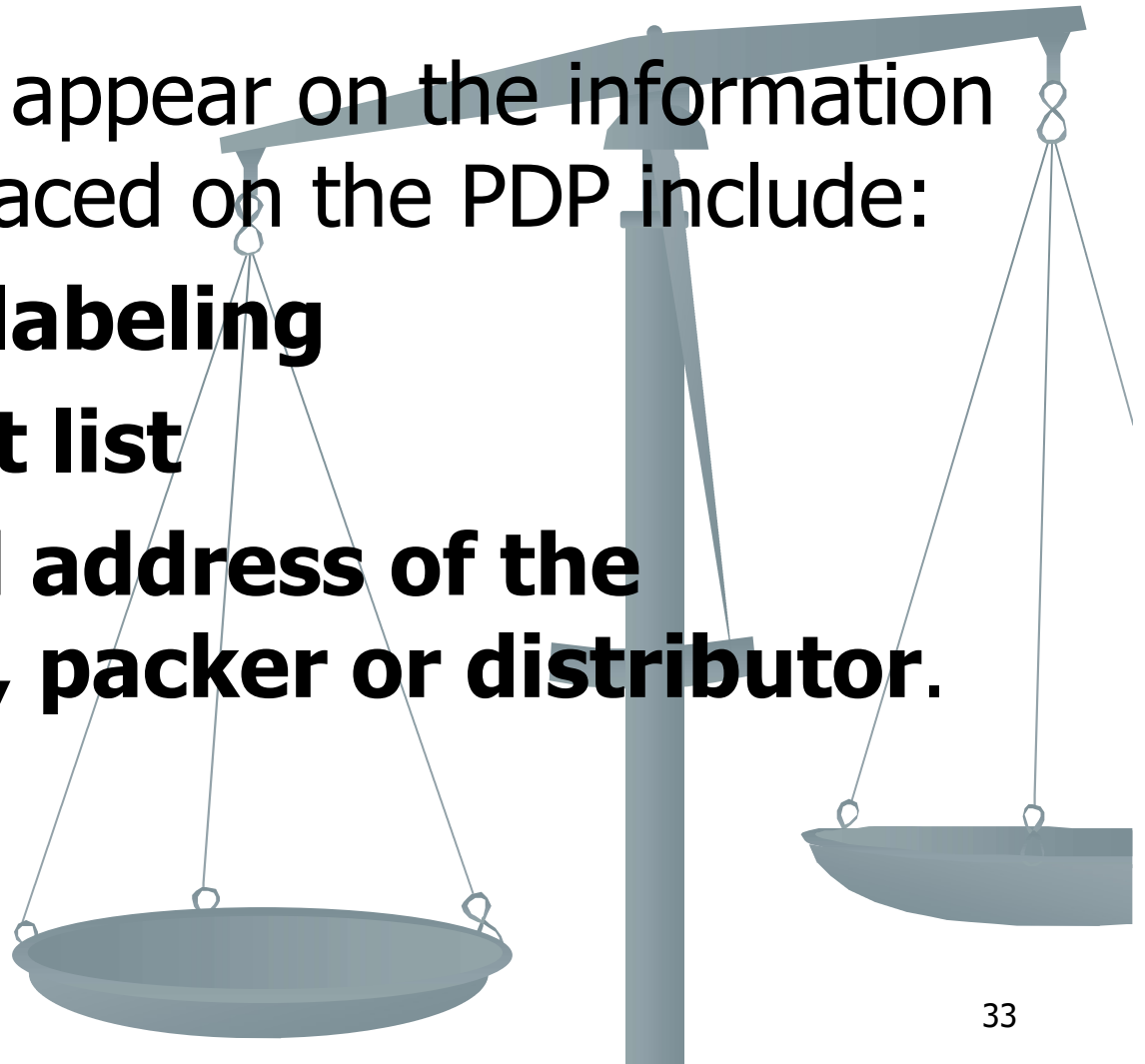


Information Panel

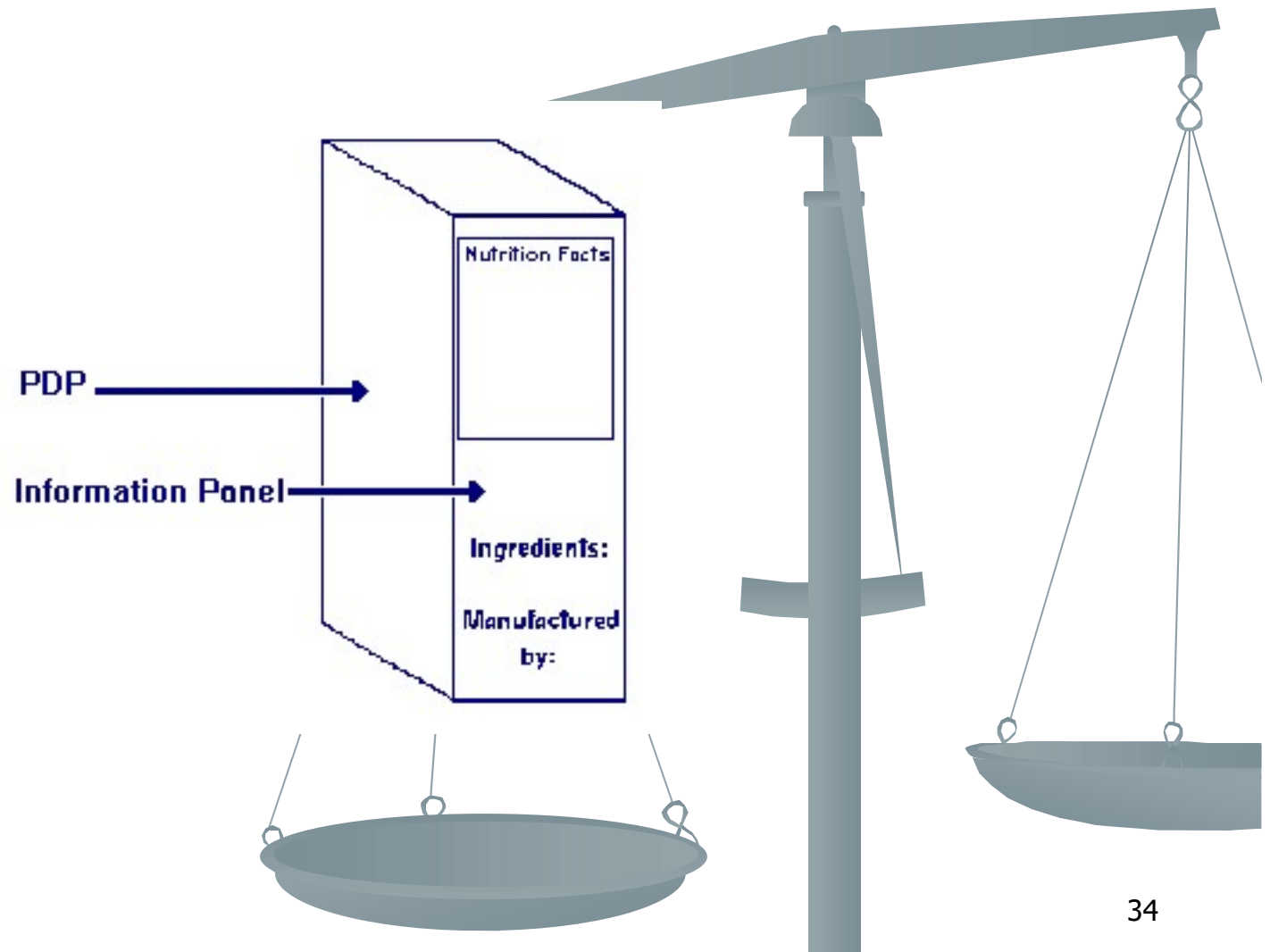
(21 CFR 101.2(b) and (d))

Information must appear on the information panel, unless placed on the PDP include:

- **The nutrition labeling**
- **The ingredient list**
- **The name and address of the manufacturer, packer or distributor.**



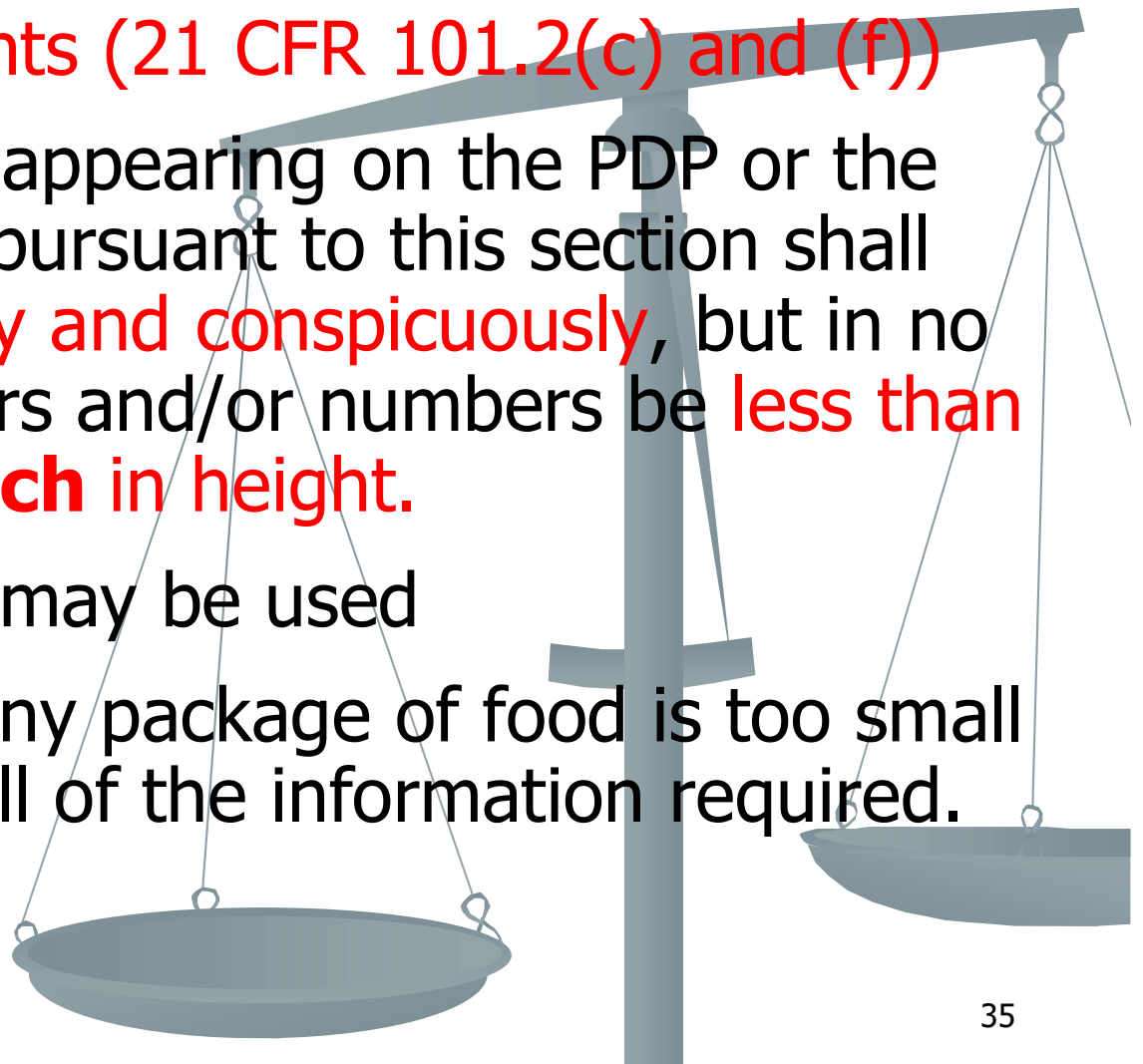
Information Panel



Information Panel

Type size requirements (21 CFR 101.2(c) and (f))

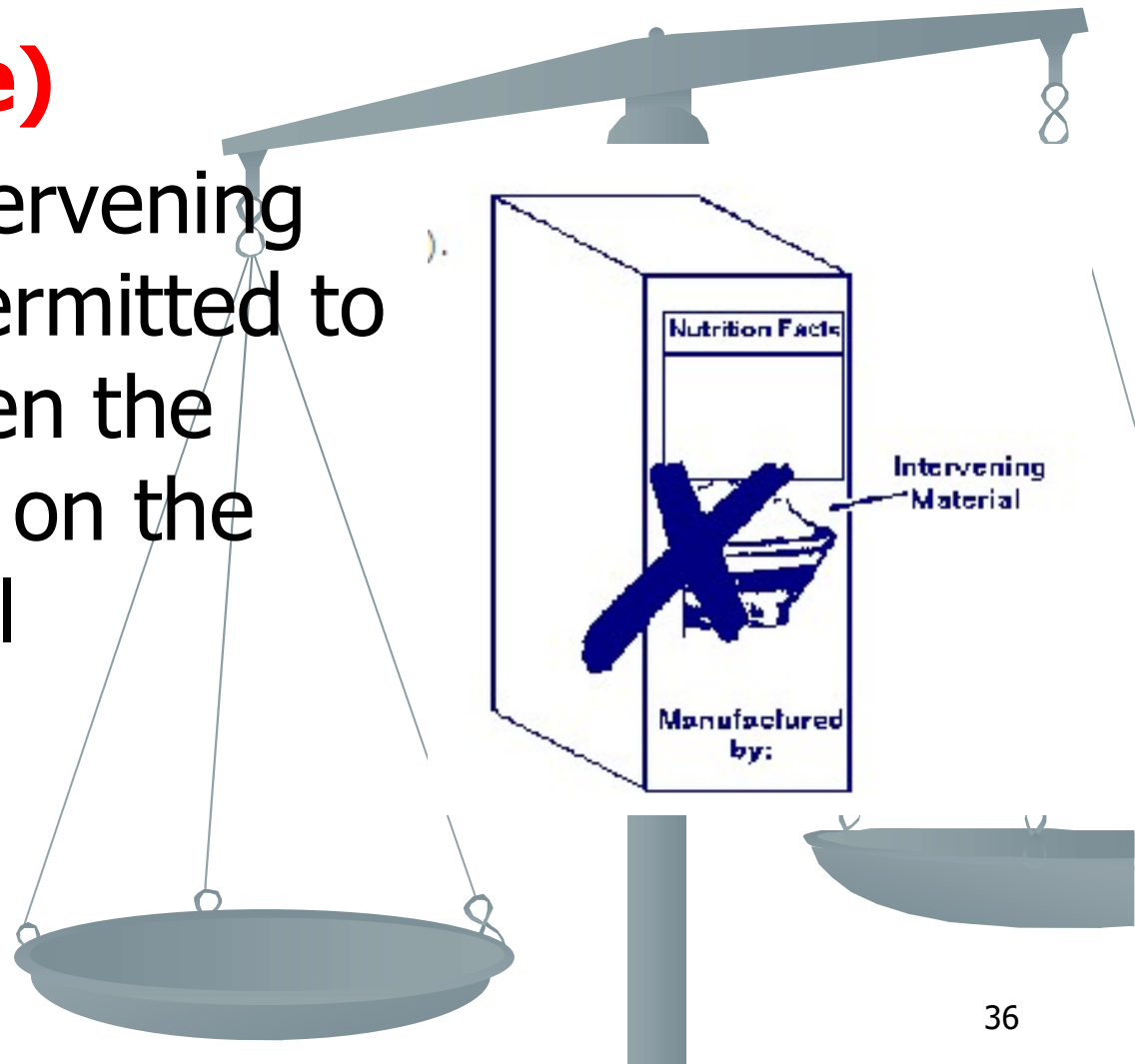
- (c) All information appearing on the PDP or the information panel pursuant to this section shall appear **prominently and conspicuously**, but in no case may the letters and/or numbers be **less than one-sixteenth inch in height**.
- Smaller type sizes may be used
- (f) If the label of any package of food is too small to accommodate all of the information required.



Information Panel

- **21 CFR 101.2(e)**

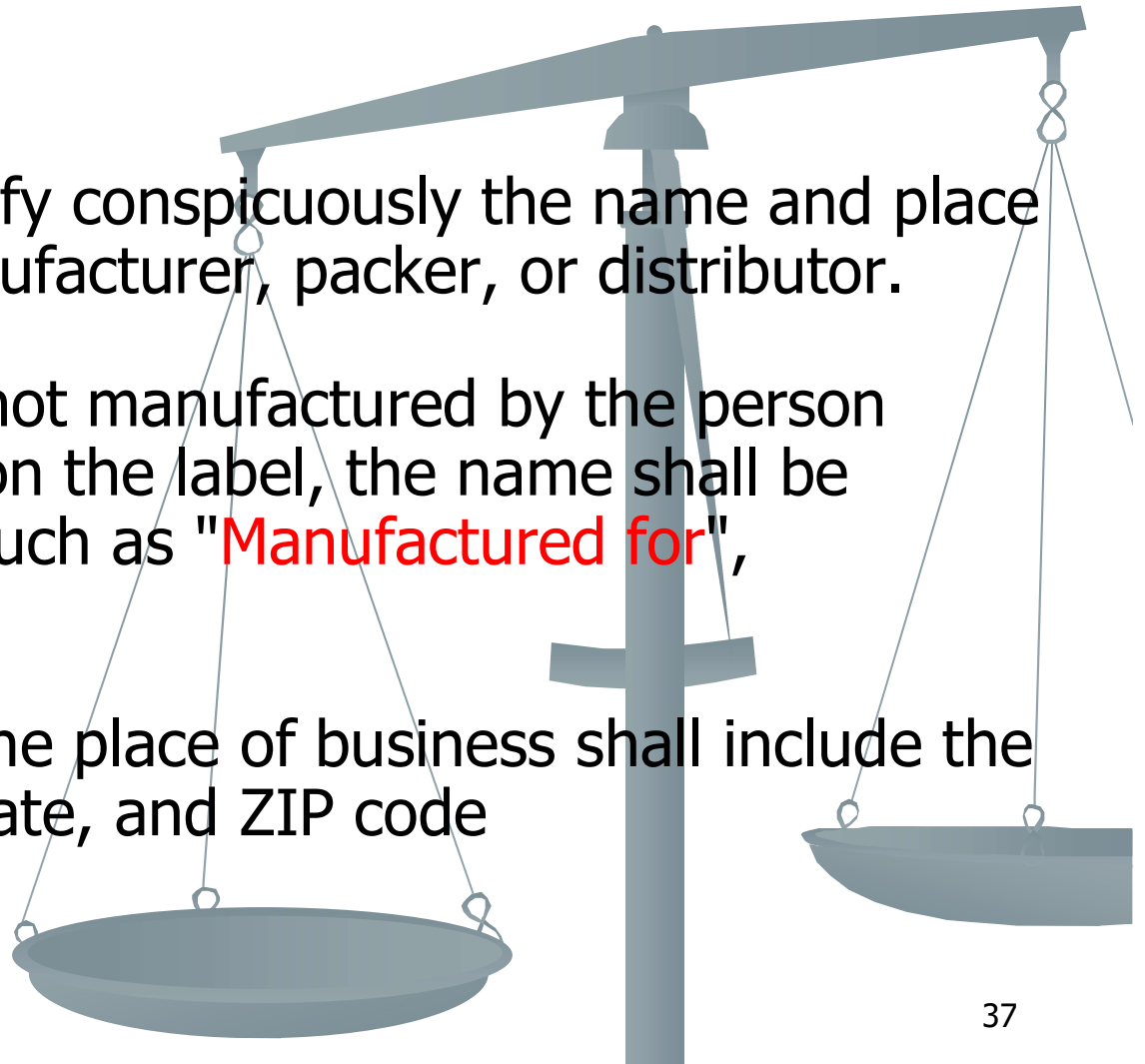
Nonessential, intervening material is not permitted to be placed between the required labeling on the information panel



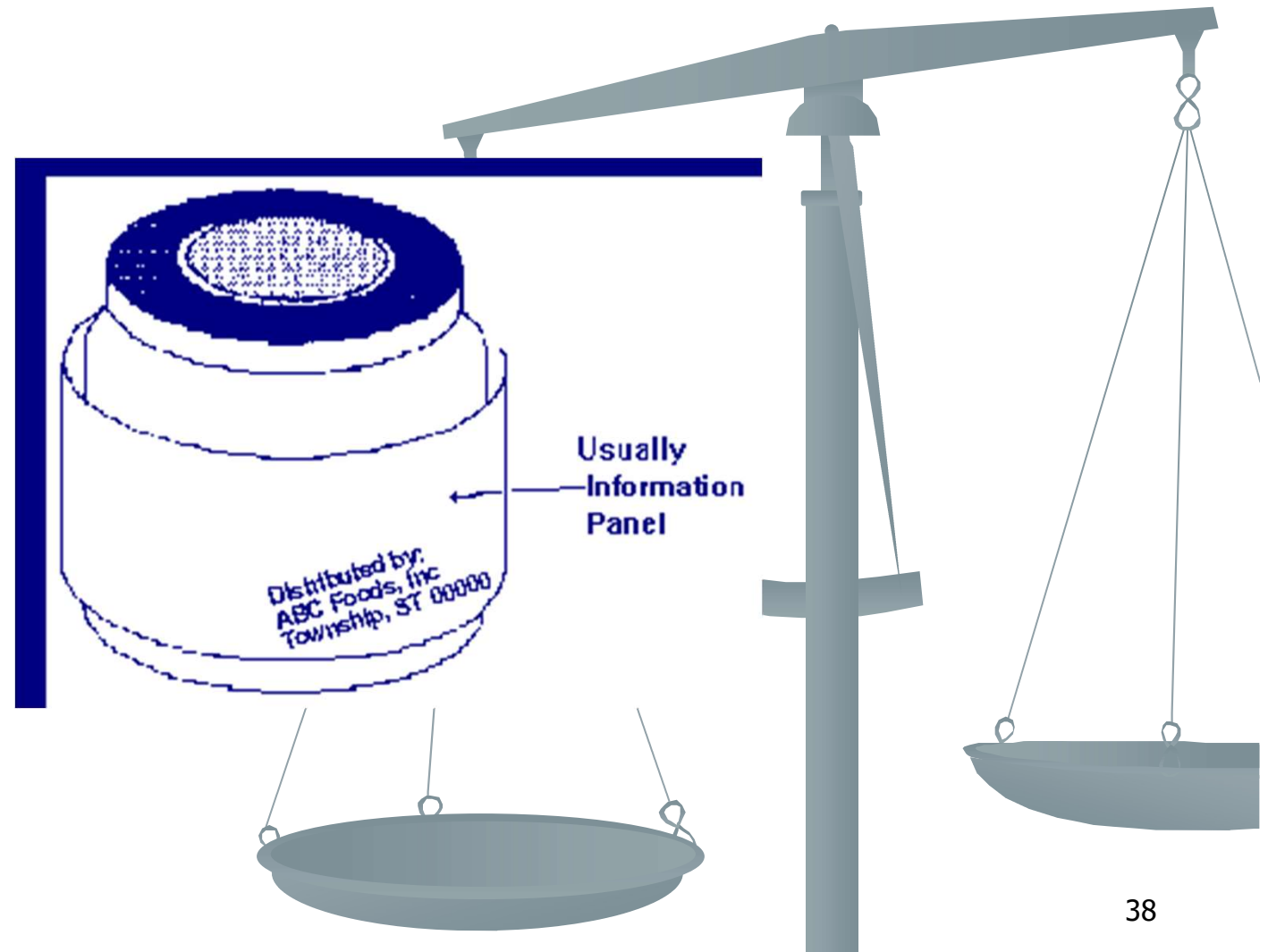
Name and Place of Business of Manufacturer, Packer, or Distributor

21 CFR 101.5

- a) The label shall specify conspicuously the name and place of business of the manufacturer, packer, or distributor.
- (c) Where the food is not manufactured by the person whose name appears on the label, the name shall be qualified by a phrase such as "**Manufactured for**", "**Distributed by**".
- (d) The statement of the place of business shall include the street address, city, State, and ZIP code



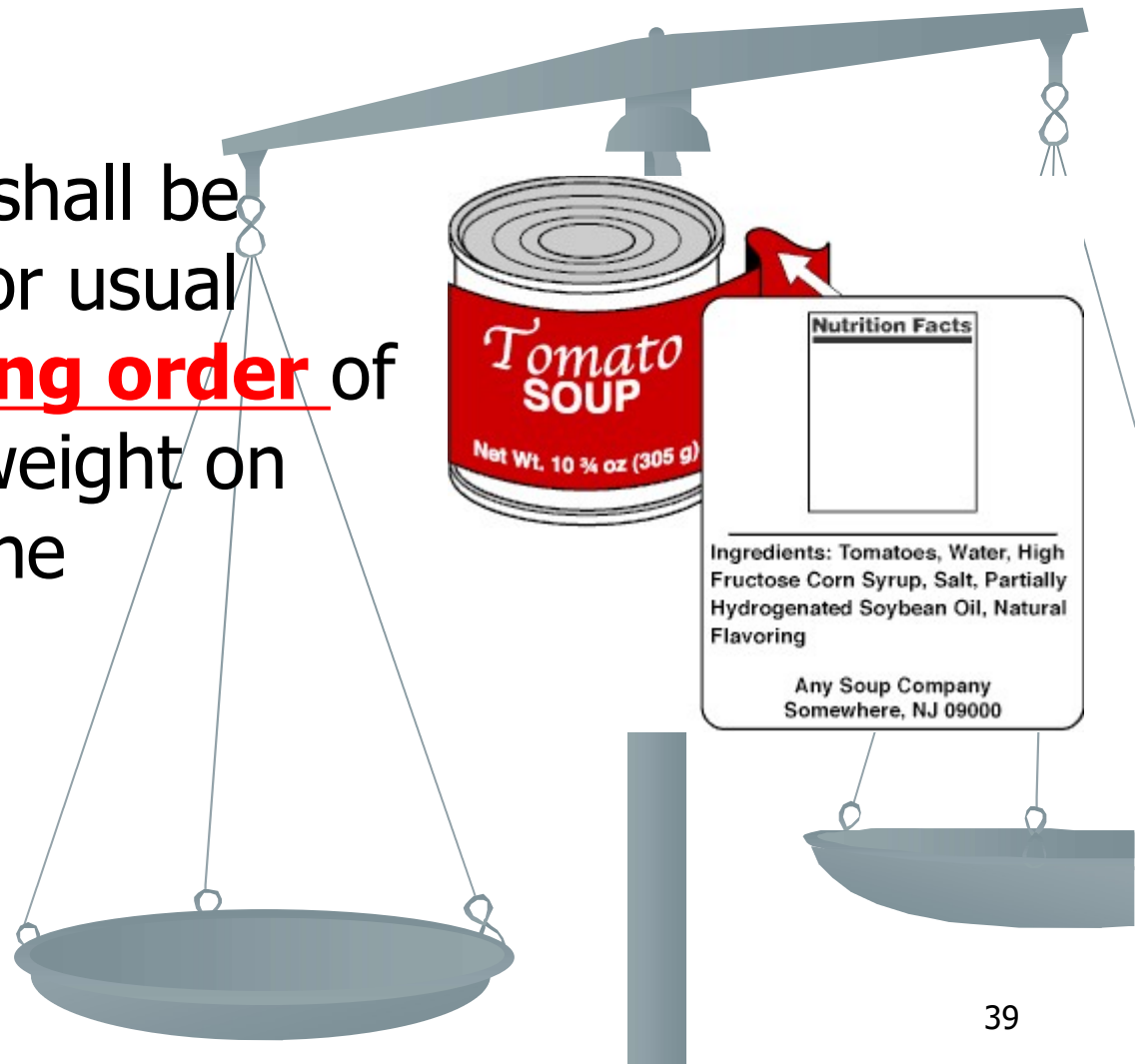
Name and Place of Business of Manufacturer, Packer, or Distributor



Ingredient List

21 CFR 101.4

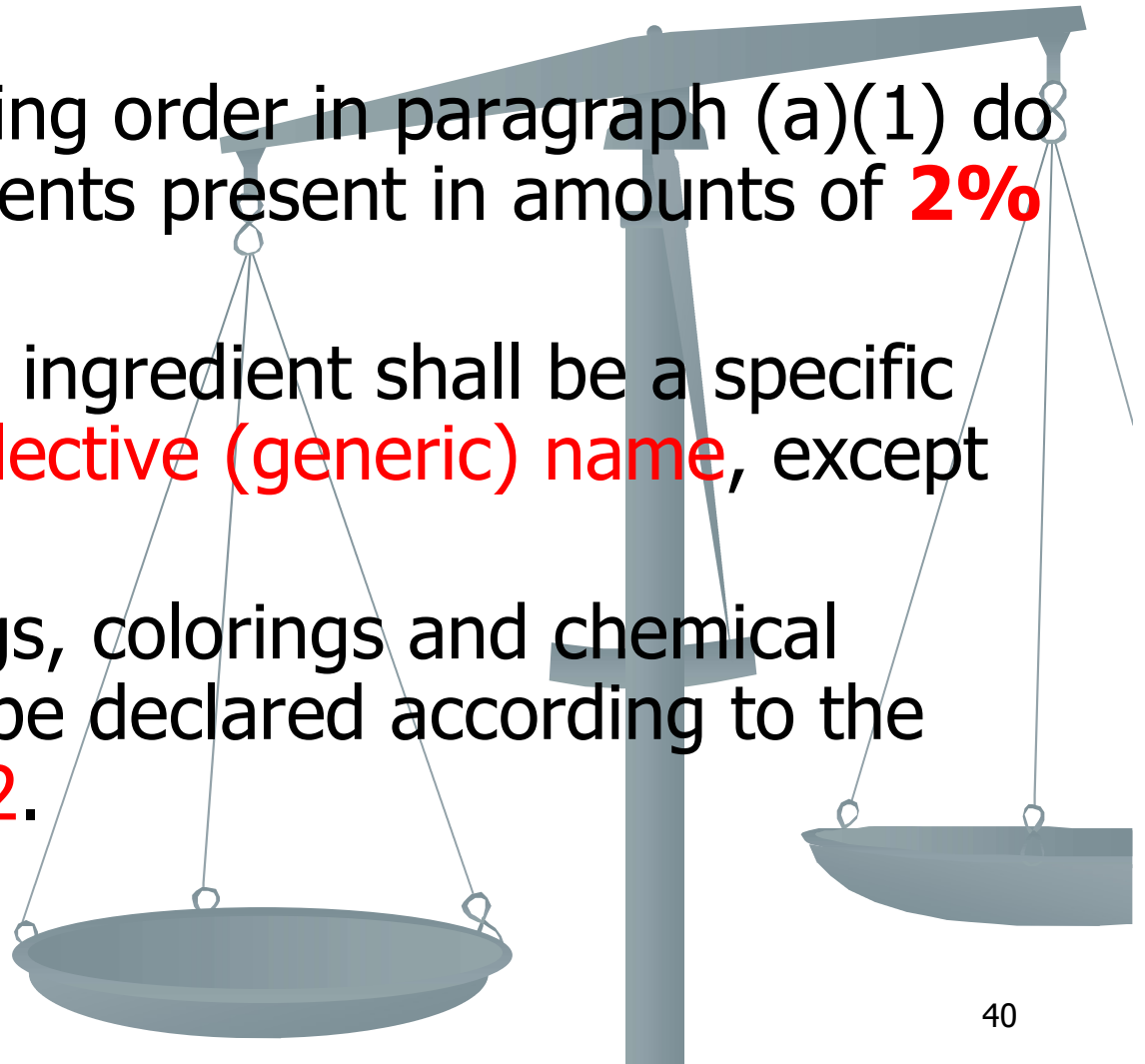
- (a)(1) Ingredients shall be listed by common or usual name in descending order of predominance by weight on either the PDP or the information panel.



Ingredient List

21 CFR 101.4

- (a)(2) The descending order in paragraph (a)(1) do not apply to ingredients present in amounts of **2% or less.**
- (b) The name of an ingredient shall be a specific name and **not a collective (generic) name**, except that:
 - (1) Spices, flavorings, colorings and chemical preservatives shall be declared according to the provisions of **101.22.**



Ingredient List

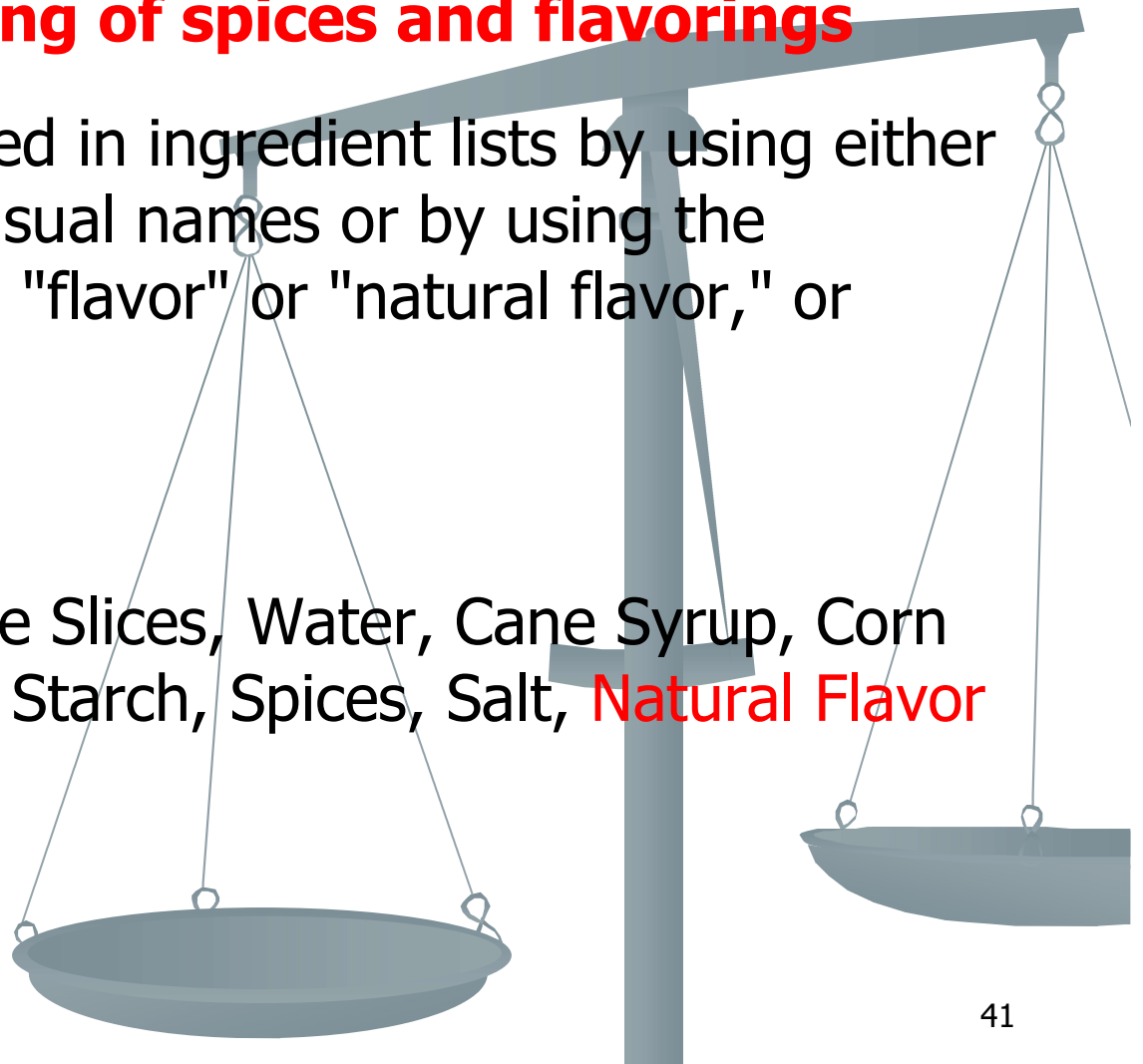
21CFR101.22 -Labeling of spices and flavorings

- These may be declared in ingredient lists by using either specific common or usual names or by using the declarations "spices," "flavor" or "natural flavor," or "artificial flavor."

- **Example:**

"INGREDIENTS: Apple Slices, Water, Cane Syrup, Corn Syrup, Modified Corn Starch, Spices, Salt, **Natural Flavor and Artificial Flavor**"

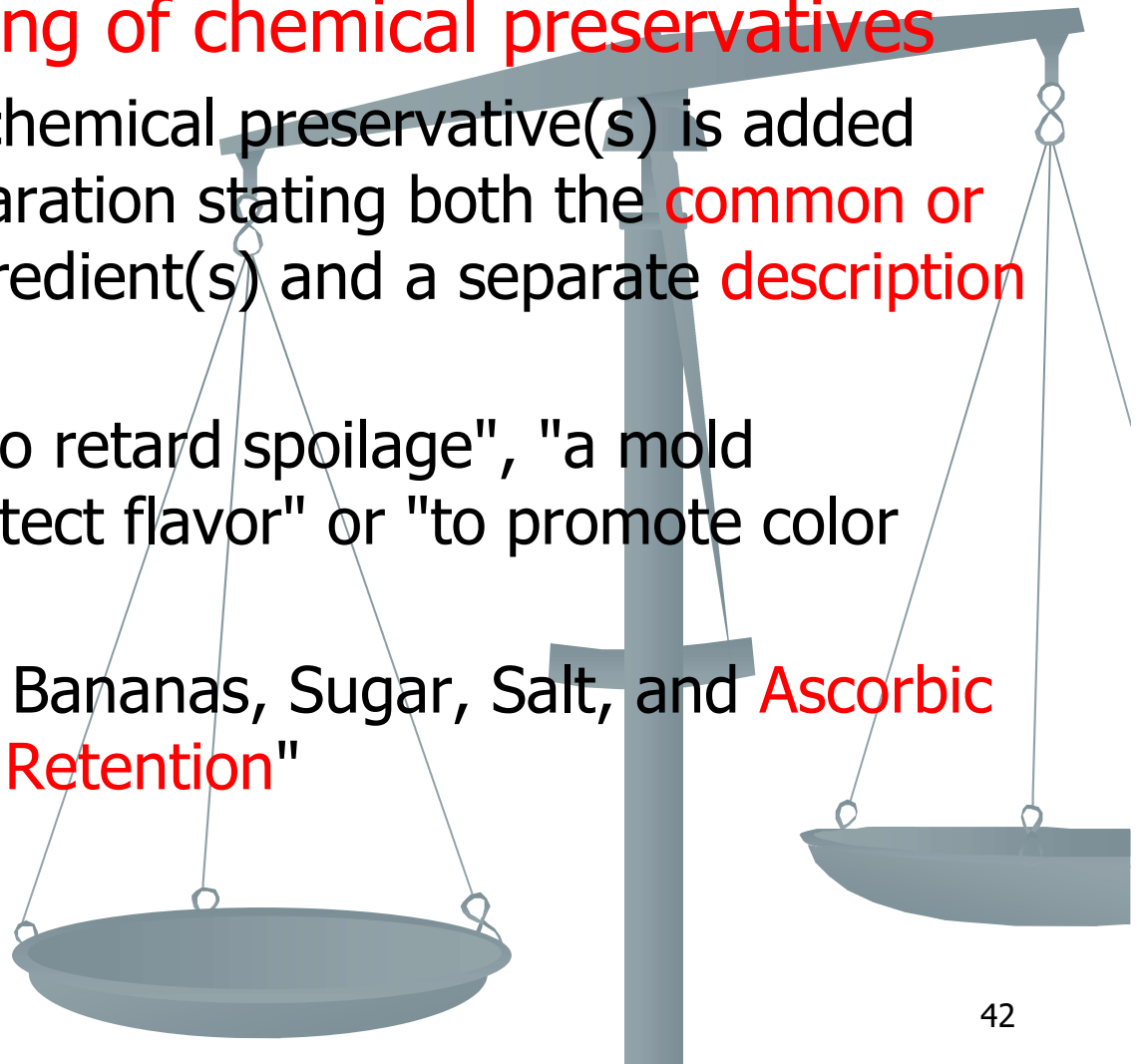
21 CFR 101.22(h)(1)



Ingredient List

21CFR101.22 - Labeling of chemical preservatives

- (j) A food to which a chemical preservative(s) is added shall bear a label declaration stating both the **common or usual name** of the ingredient(s) and a separate **description of its function**
- e.g., "preservative", "to retard spoilage", "a mold inhibitor", "to help protect flavor" or "to promote color retention".
- "INGREDIENTS: Dried Bananas, Sugar, Salt, and **Ascorbic Acid to Promote Color Retention**"



Ingredient List

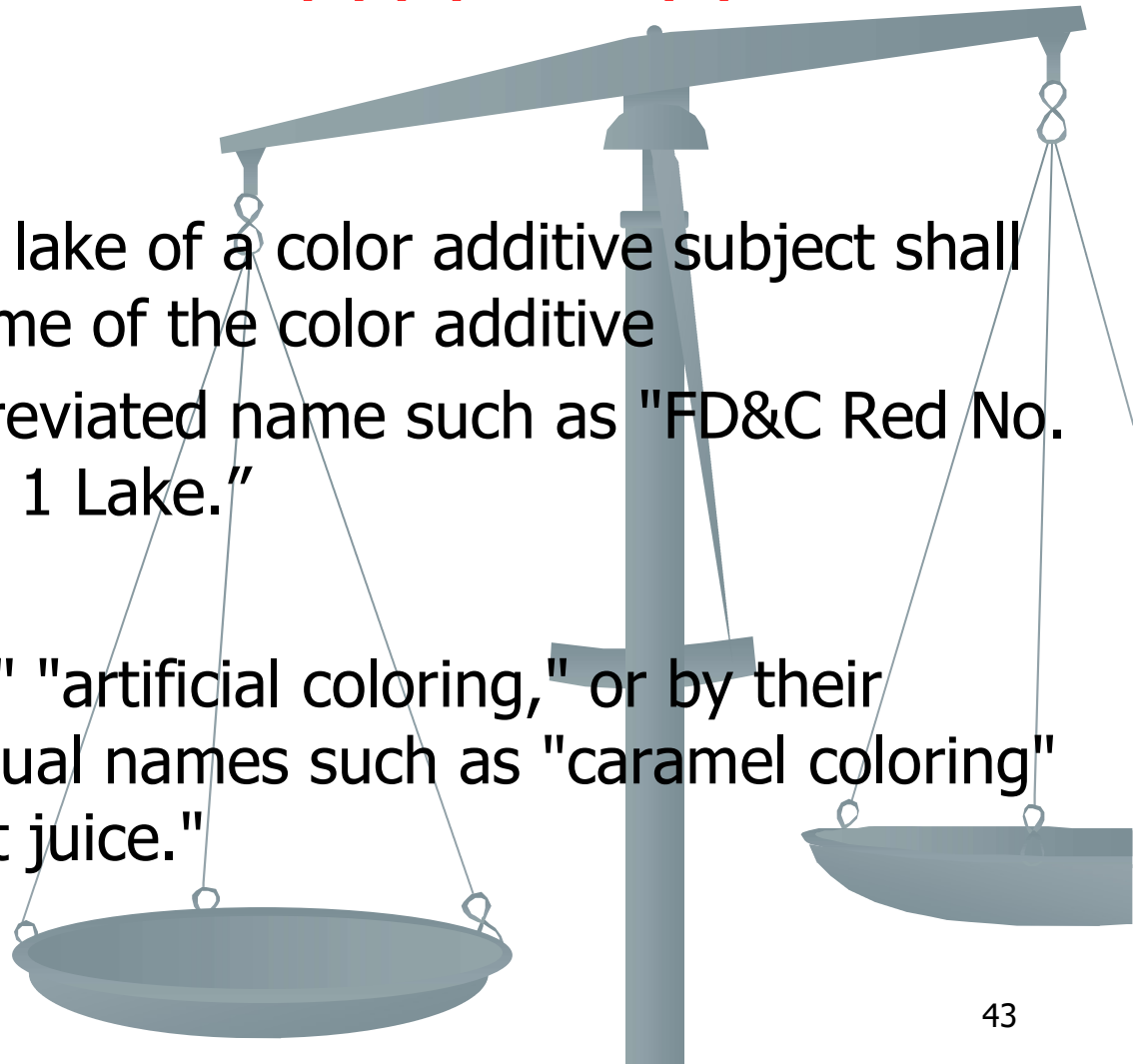
Artificial colors -21CFR 101.22(k)(1) and (2),
21CFR74

1. Certified colors:

- A color additive or the lake of a color additive subject shall be declared by the name of the color additive
- List by specific or abbreviated name such as "FD&C Red No. 40", "Red 40" or "Blue 1 Lake."

2. Non-certified colors:

- List as "artificial color," "artificial coloring," or by their specific common or usual names such as "caramel coloring" and "colored with beet juice."



Ingredient List

Labeling of colors

Spices used as Colors- 21 CFR 101.22(a)(2)

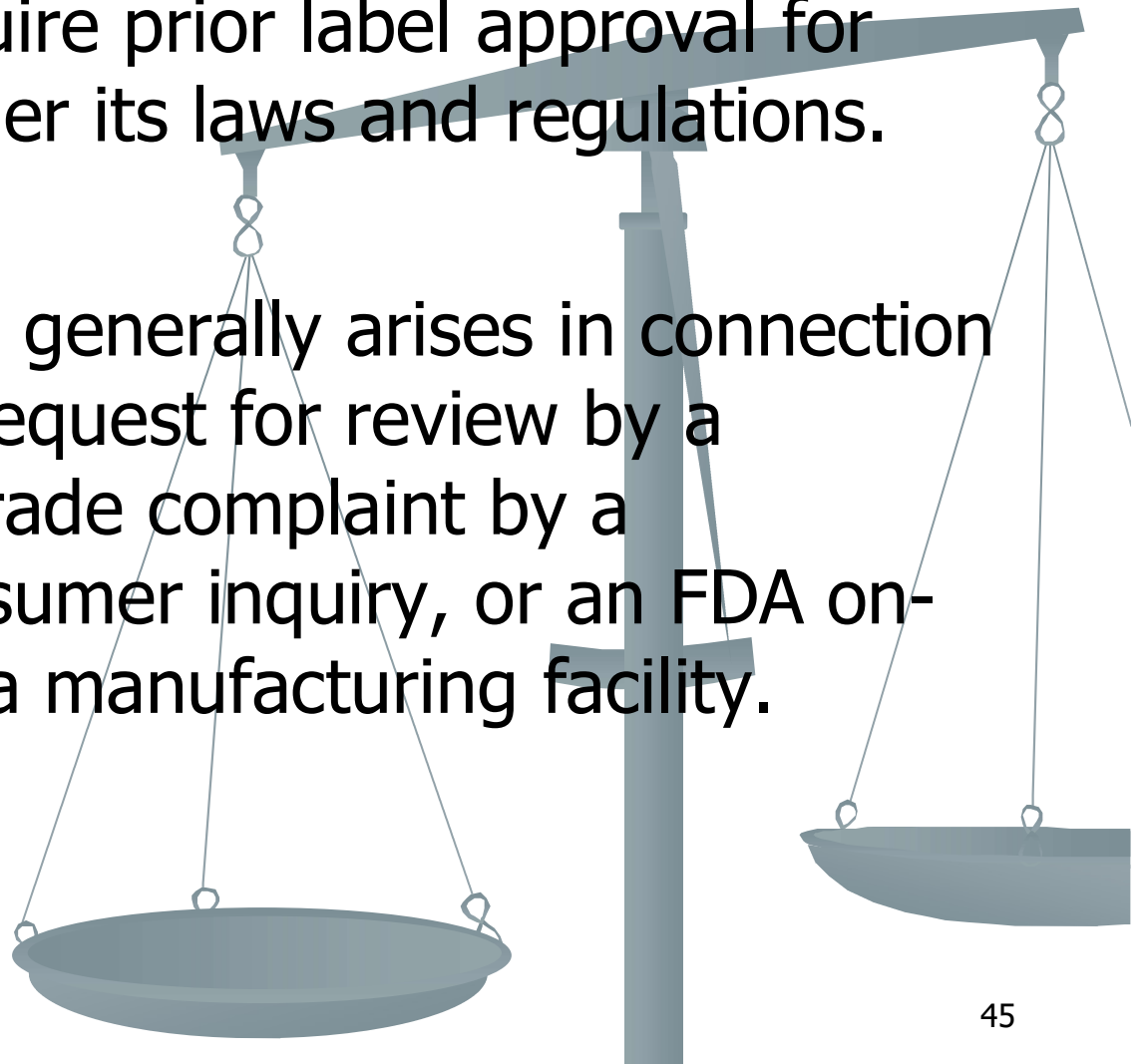
- Spices, such as paprika, turmeric, saffron and others that are also colorings must be declared either by the term "spice and coloring" or by the actual (common or usual) names, such as "paprika."

21 CFR 101.22(k)(3) or 21 CFR 73 or 74

- When a coloring has been added to butter, cheese, or ice cream, it **need not** be declared in the ingredient list unless required by a regulation in part 73 or part 74.
- Voluntary declaration of all colorings added to butter, cheese, and ice cream, however, is recommended.

Labeling Approval

- FDA **does not** require prior label approval for food products under its laws and regulations.
- FDA's label review generally arises in connection with an informal request for review by a manufacturer, a trade complaint by a competitor, a consumer inquiry, or an FDA on-site inspection of a manufacturing facility.

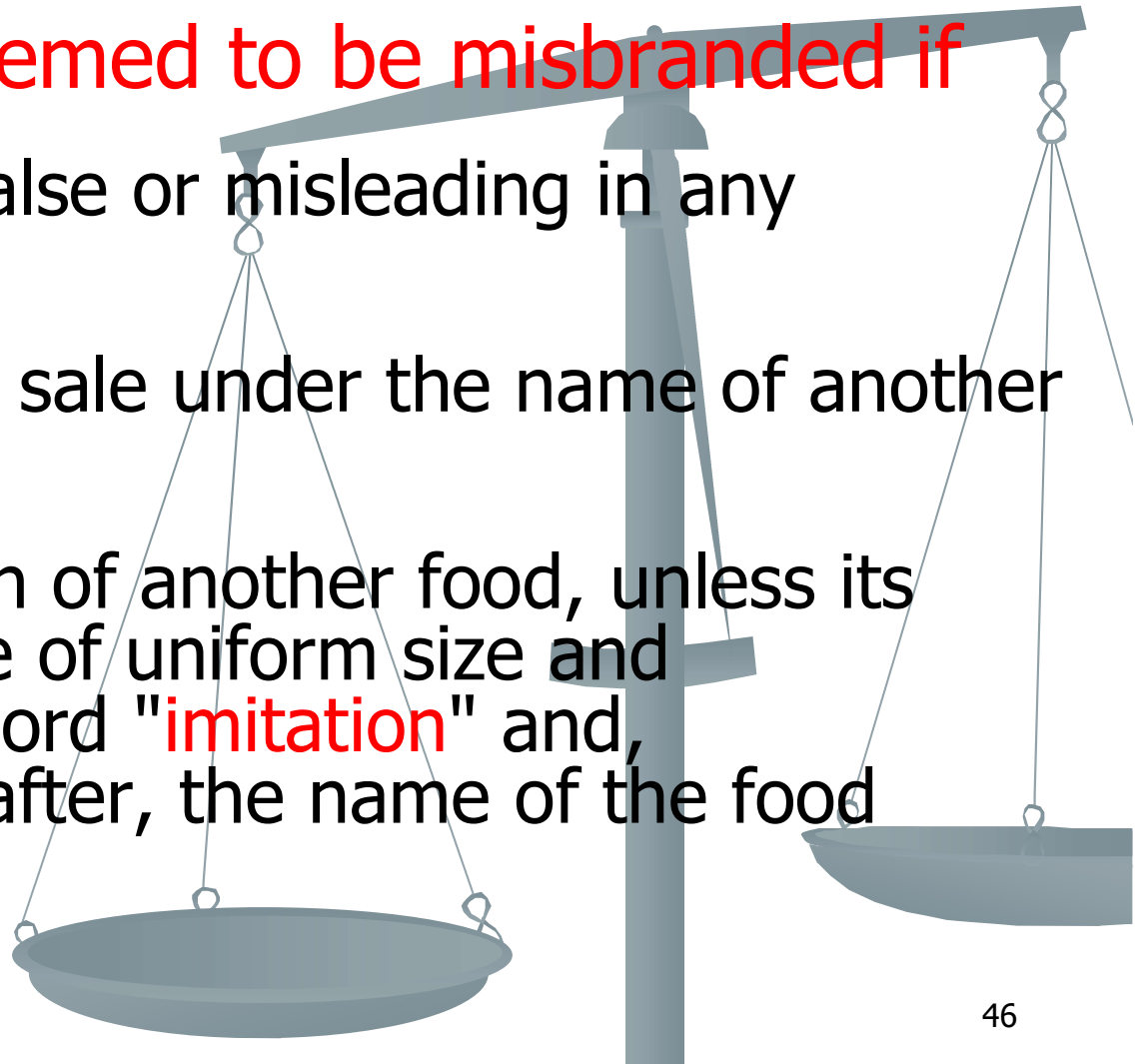


Misbranded Food

FD&C Act Sec. 403. or [21 USC § 343]

A food shall be deemed to be misbranded if

- (1) its labeling is false or misleading in any particular,
- (b) it is offered for sale under the name of another food.
- (c) it is an imitation of another food, unless its label bears, in type of uniform size and prominence, the word "**imitation**" and, immediately thereafter, the name of the food imitated.

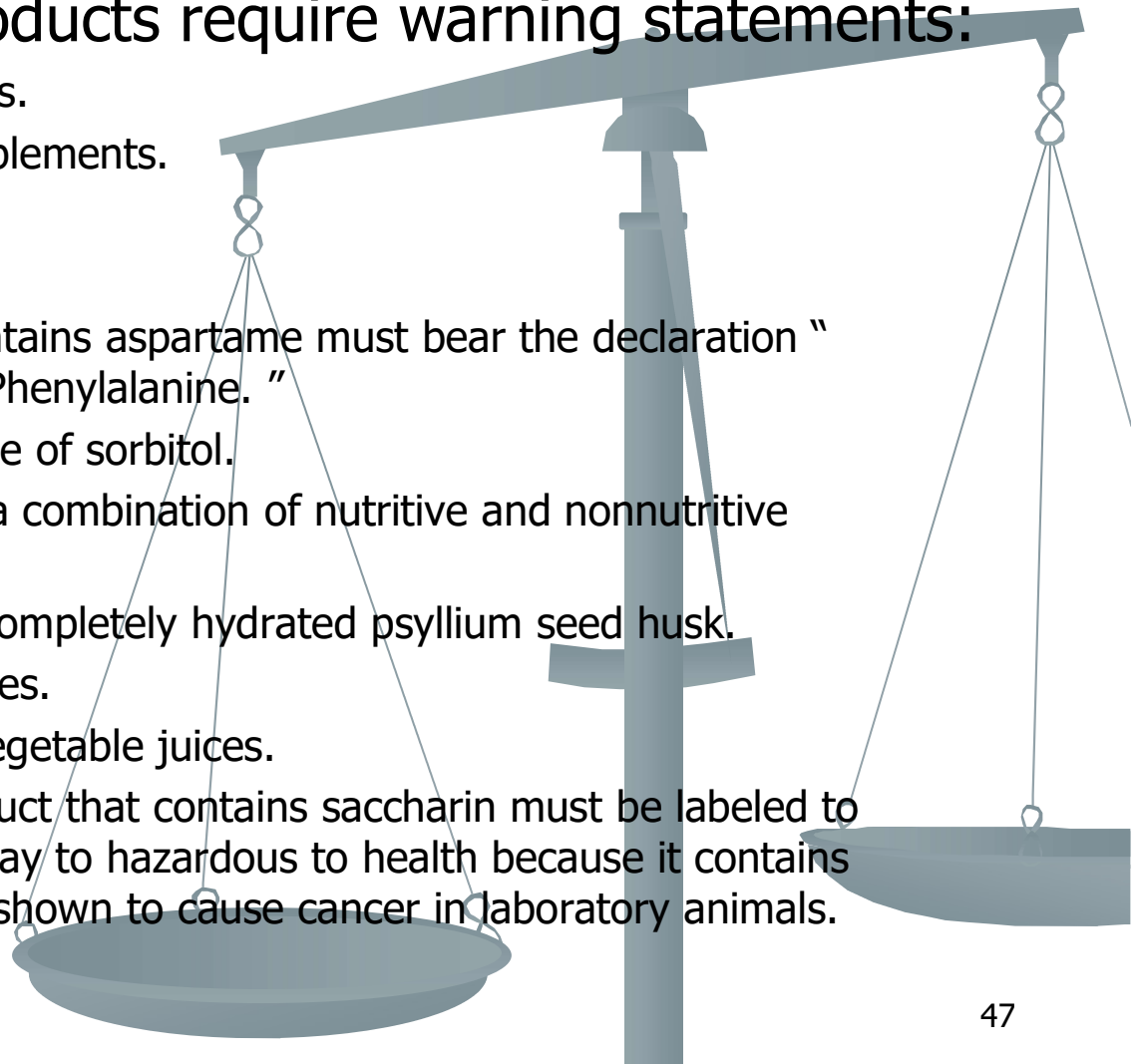


Warning Statements: Products Requiring Warning Labels

21CFR101.17

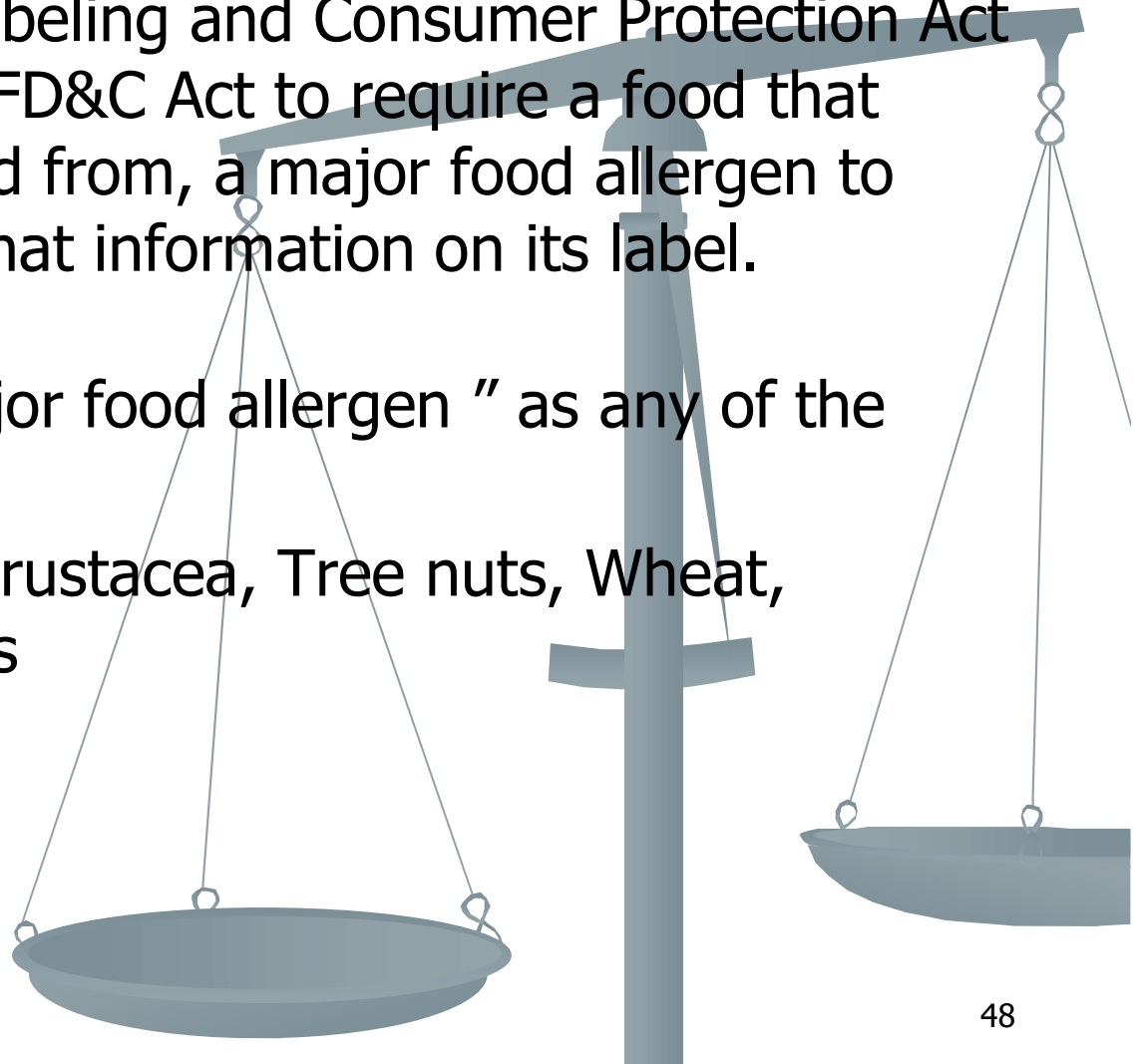
■ A number of food products require warning statements:

- Self - pressurized containers.
- Certain protein dietary supplements.
- Iron dietary supplements.
- Shell eggs.
- Aspartame — food that contains aspartame must bear the declaration "Phenylketonurics: Contains Phenylalanine."
- Food with 50 grams or more of sorbitol.
- Diet beverages containing a combination of nutritive and nonnutritive sweeteners.
- Foods containing dry or incompletely hydrated psyllium seed husk.
- Ozone - depleting substances.
- Nonpasteurized fruit and vegetable juices.
- Saccharin — any food product that contains saccharin must be labeled to indicate that the product may be hazardous to health because it contains saccharin, which has been shown to cause cancer in laboratory animals.



Allergens

- The Food Allergen Labeling and Consumer Protection Act of 2004 amends the FD&C Act to require a food that contains, or is derived from, a major food allergen to specifically indicate that information on its label.
- The act defines “major food allergen” as any of the following:
 - Milk, Eggs, Fish, Crustacea, Tree nuts, Wheat, Peanuts, Soybeans



USDA Food Labeling Requirements for Meats and Poultry

- FSIS has different labeling requirements for meats and poultry than the FDA.
- The Labeling and Program Delivery Division (LPDD) develops labeling policies and inspection methods and administers programs to protect consumers from misbranded and economically adulterated meat, poultry, and egg products.
- **Regulations are codified in 9 CFR Part 317**



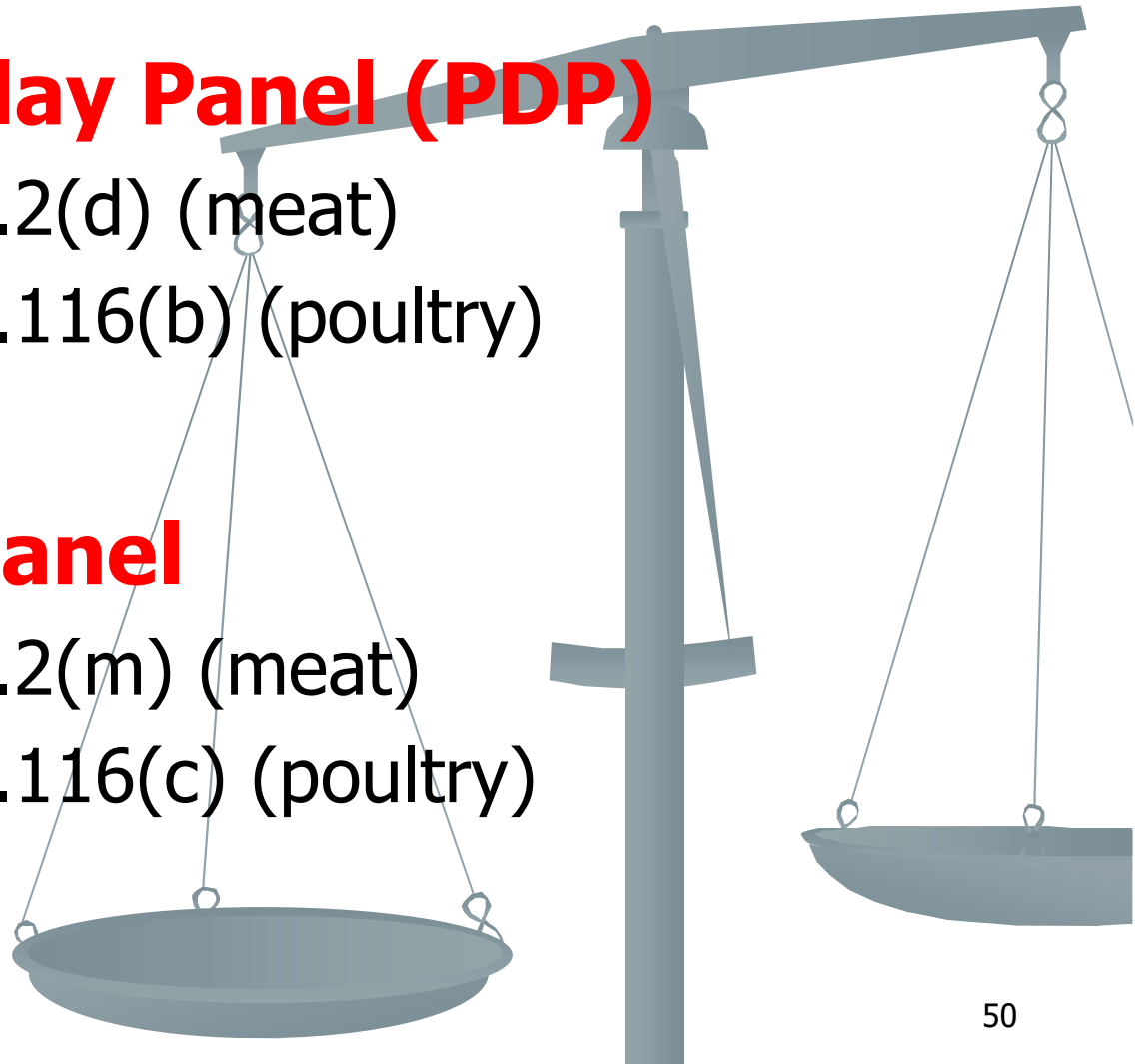
USDA Food Labeling Requirements for Meats and Poultry

■ **Principal Display Panel (PDP)**

- 9 C.F.R. § 317.2(d) (meat)
- 9 C.F.R. § 381.116(b) (poultry)

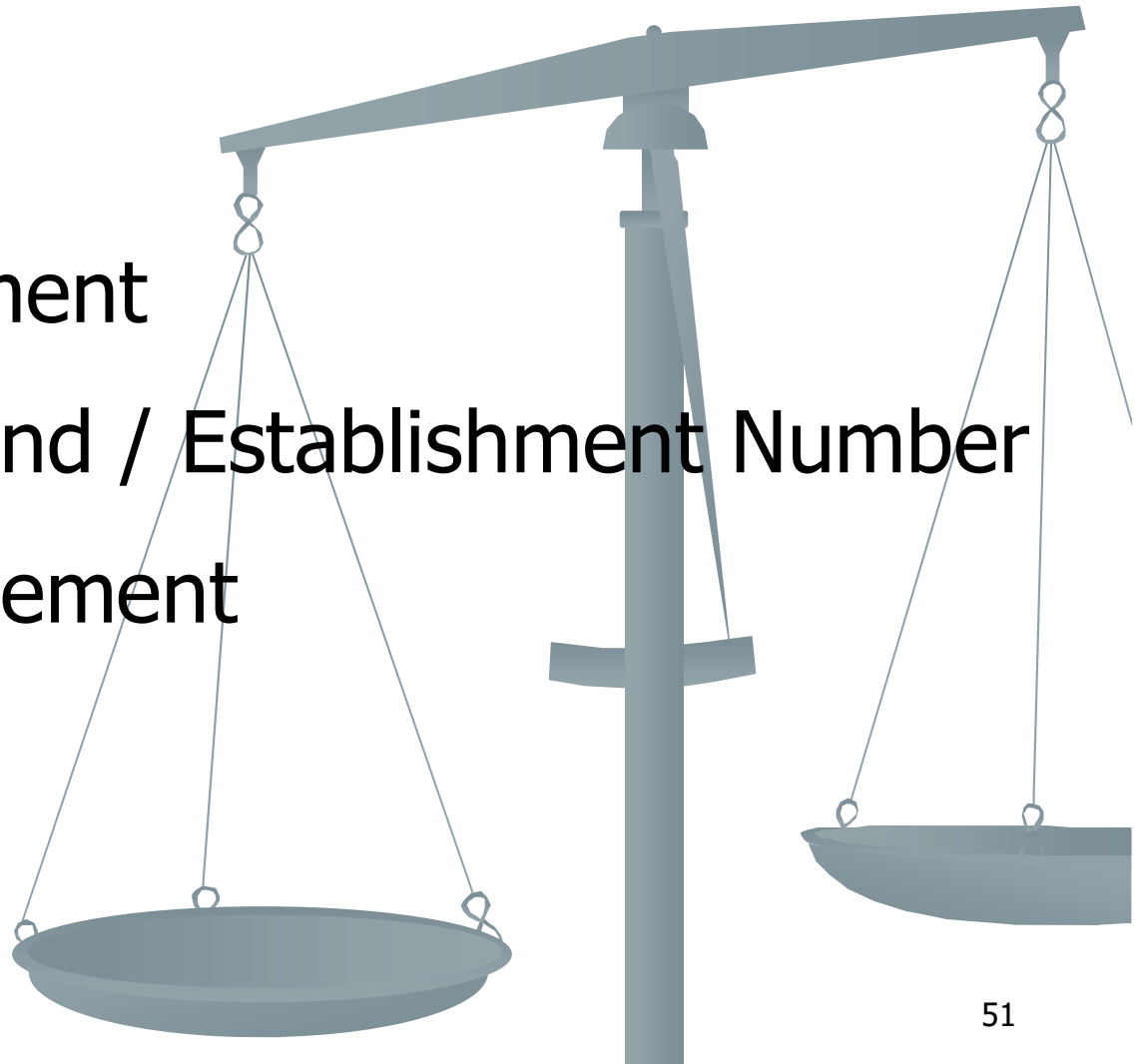
■ **Information Panel**

- 9 C.F.R. § 317.2(m) (meat)
- 9 C.F.R. § 381.116(c) (poultry)



Mandatory Features Located on PDP

- Product Name
- Handling Statement
- Inspection Legend / Establishment Number
- Net Weight Statement



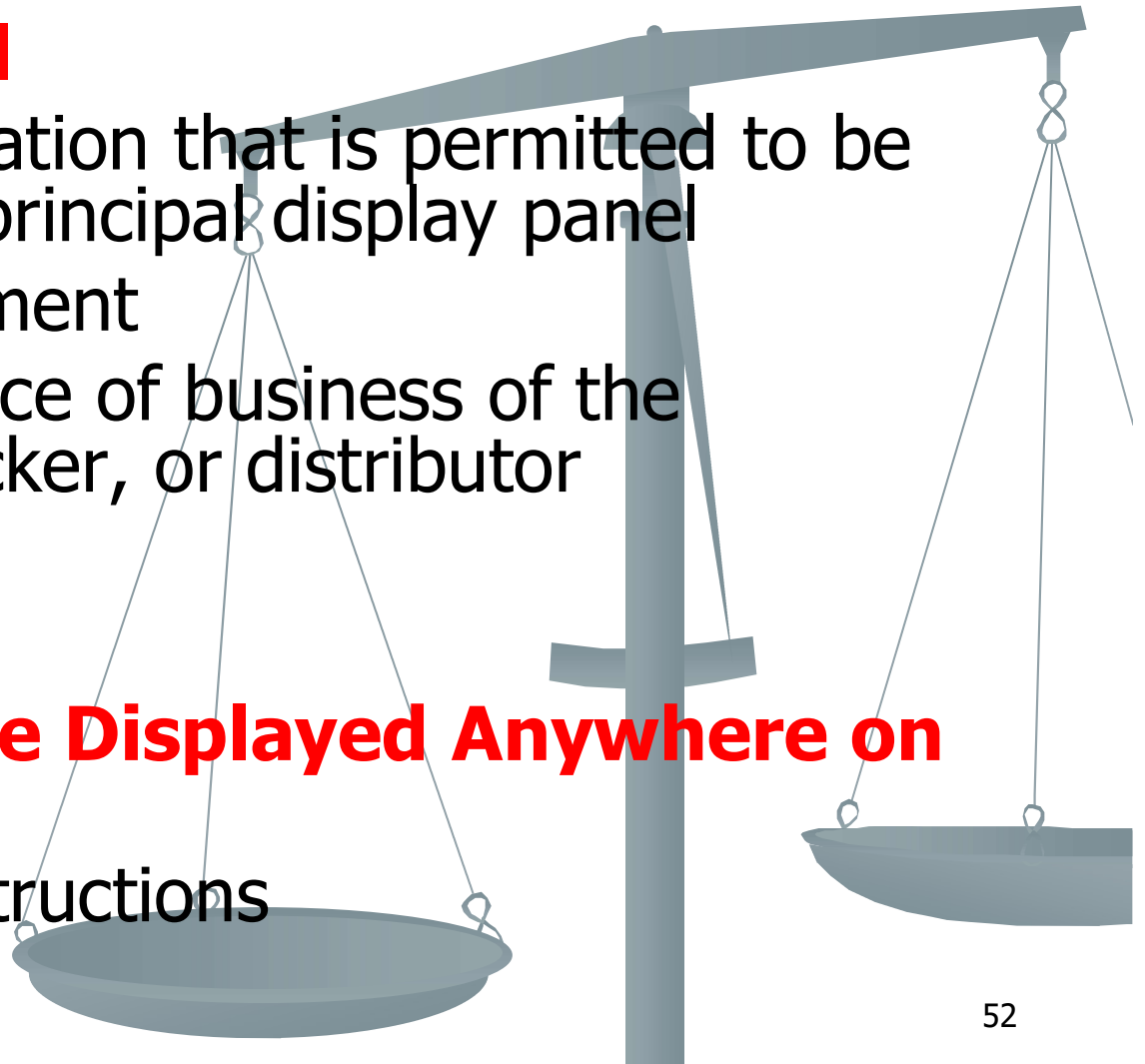
Mandatory Features Located on Information Panel

Information Panel

- Mandatory information that is permitted to be displayed off the principal display panel
- Ingredients Statement
- The name and place of business of the manufacturer, packer, or distributor
- Nutrition Facts

Mandatory Feature Displayed Anywhere on Labeling

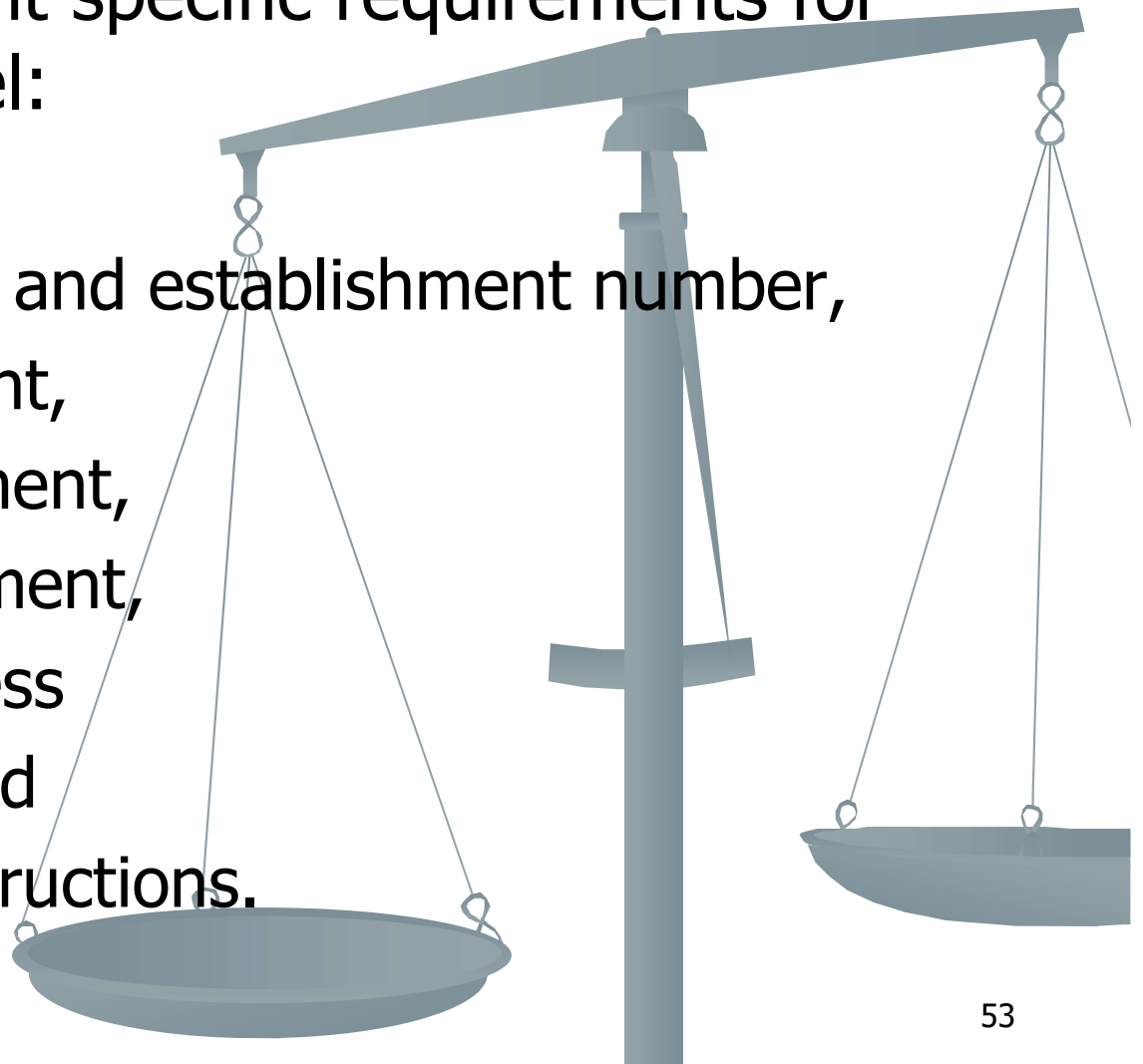
- Safe Handling Instructions



Mandatory Requirements

There are up to eight specific requirements for each product label:

- (1) product name,
- (2) inspection legend and establishment number,
- (3) handling statement,
- (4) net weight statement,
- (5) ingredients statement,
- (6) Address of business
- (7) nutrition facts, and
- (8) safe handling instructions.



Mandatory Requirements

- **PRODUCT NAME**

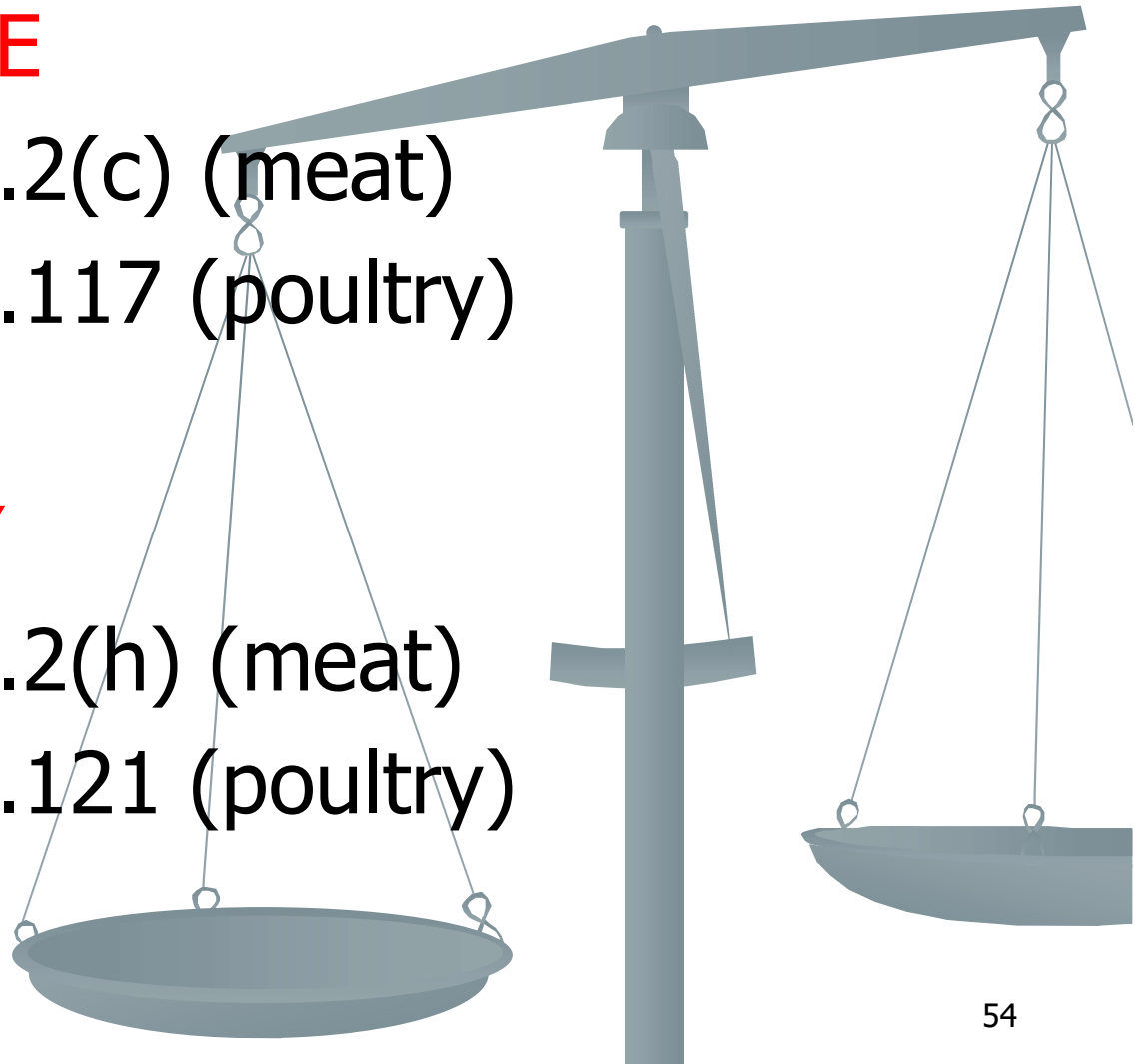
9 C.F.R. § 317.2(c) (meat)

9 C.F.R. § 381.117 (poultry)

- **NET QUANTITY**

9 C.F.R. § 317.2(h) (meat)

9 C.F.R. § 381.121 (poultry)



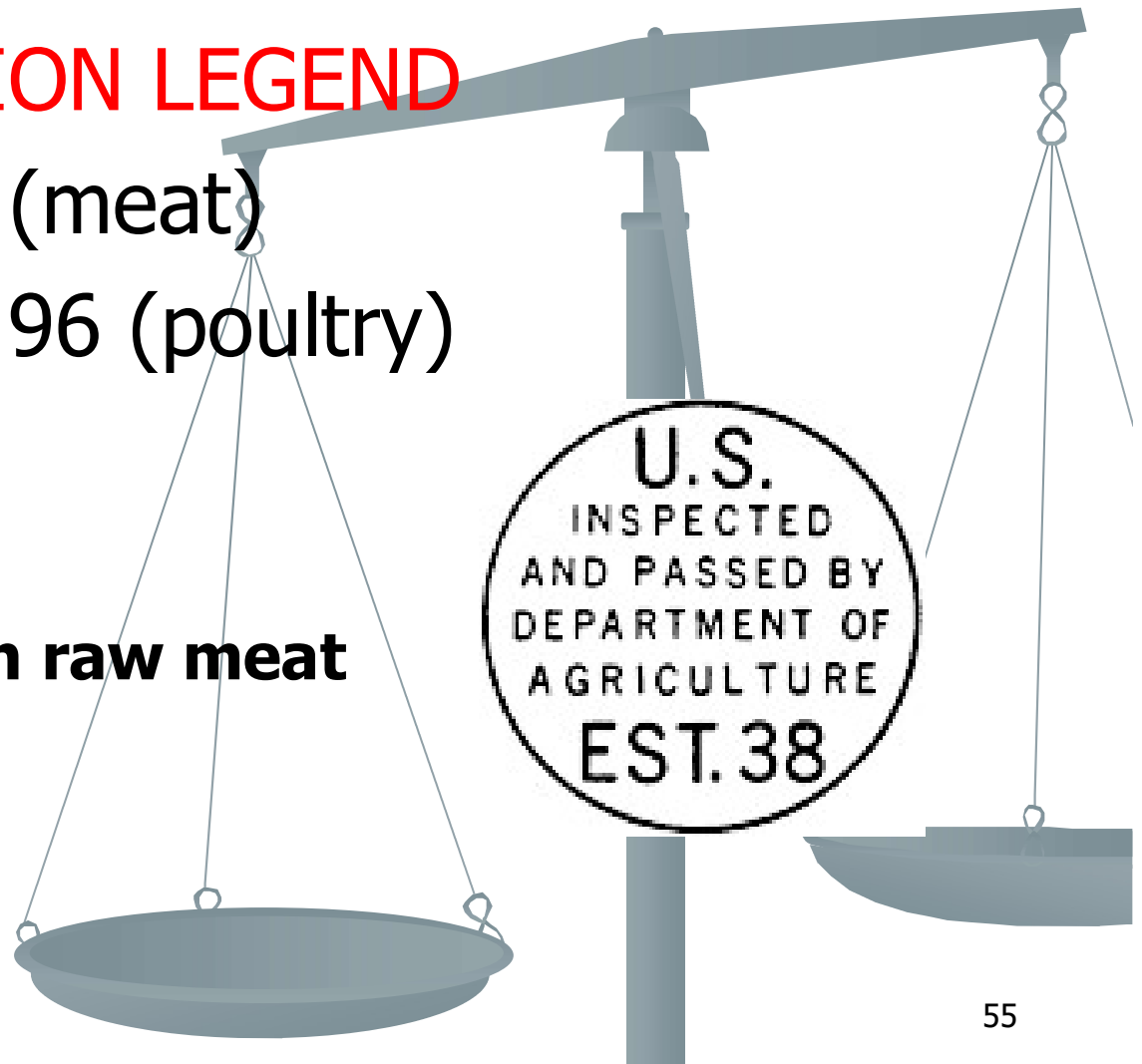
Mandatory Requirements

- **USDA INSPECTION LEGEND**

9 C.F.R. § 312 (meat)

9 C.F.R. § 381.96 (poultry)

Inspection mark on raw meat



Mandatory Requirements

- **INGREDIENTS LABELING**

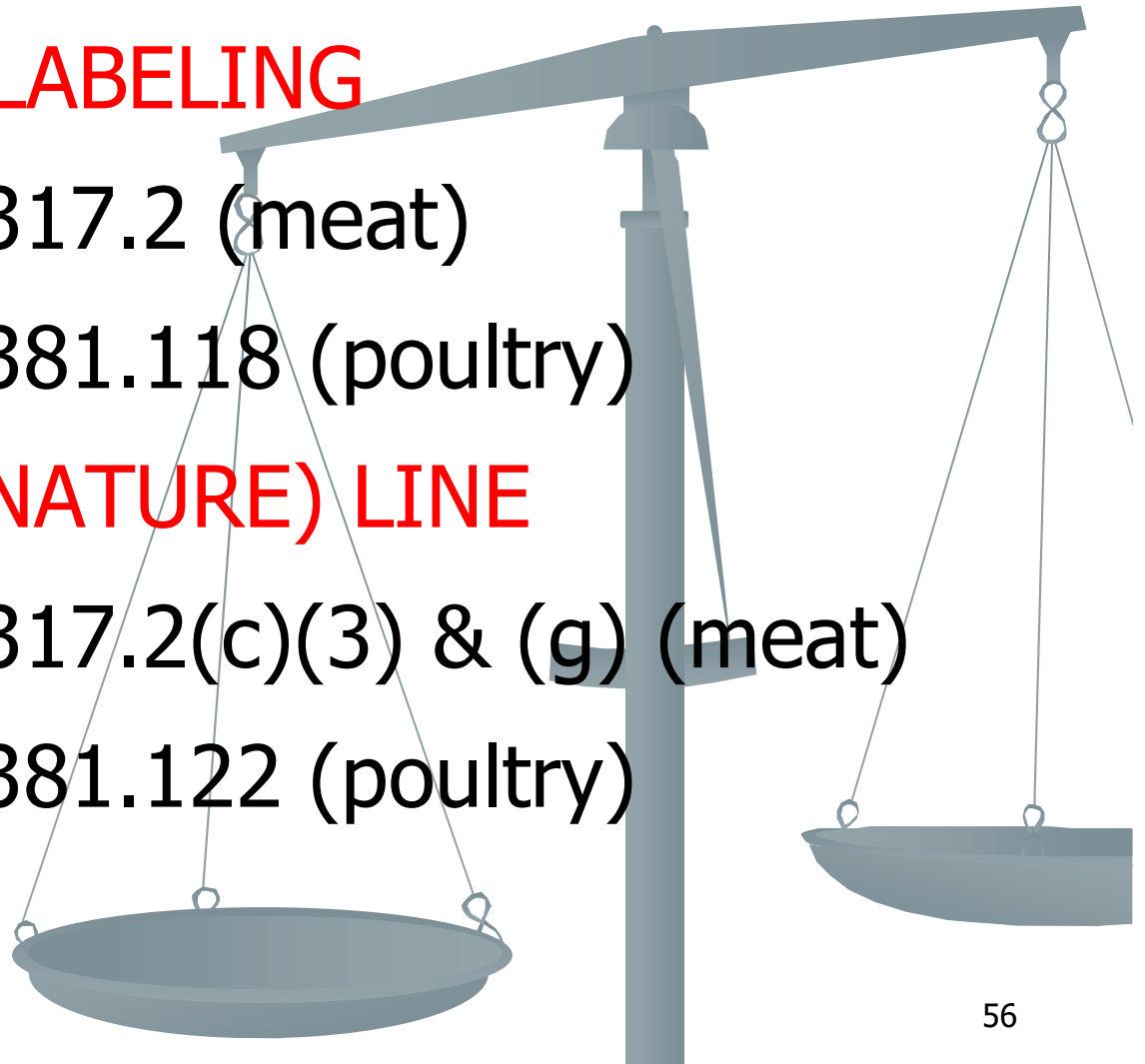
9 C.F.R. § 317.2 (meat)

9 C.F.R. § 381.118 (poultry)

- **ADDRESS (SIGNATURE) LINE**

9 C.F.R. § 317.2(c)(3) & (g) (meat)

9 C.F.R. § 381.122 (poultry)



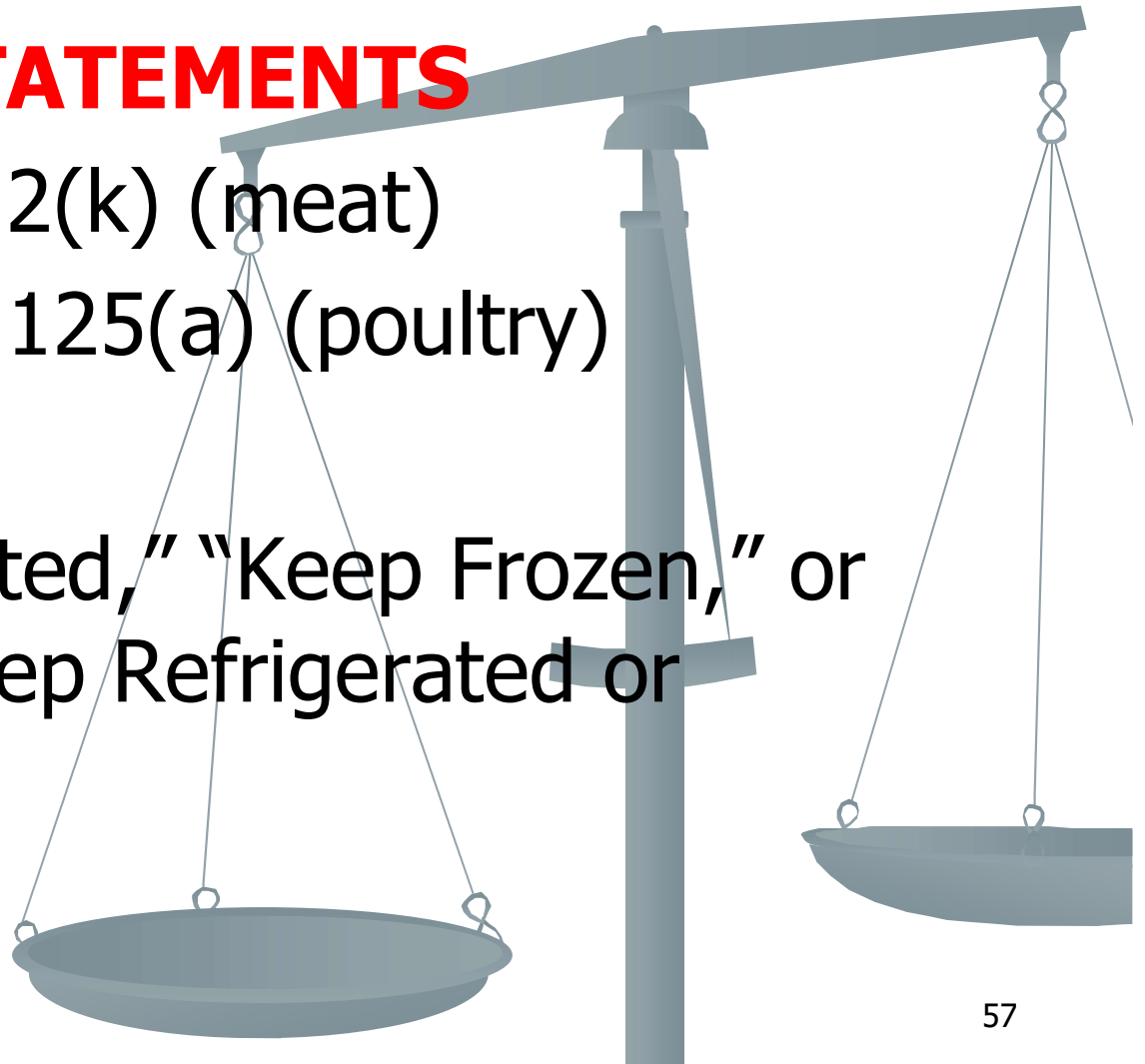
Mandatory Requirements

■ HANDLING STATEMENTS

9 C.F.R. § 317.2(k) (meat)

9 C.F.R. § 381.125(a) (poultry)

"Keep Refrigerated," "Keep Frozen," or
"Perishable—Keep Refrigerated or
Frozen."



Mandatory Requirements

■ SAFE HANDLING INSTRUCTIONS

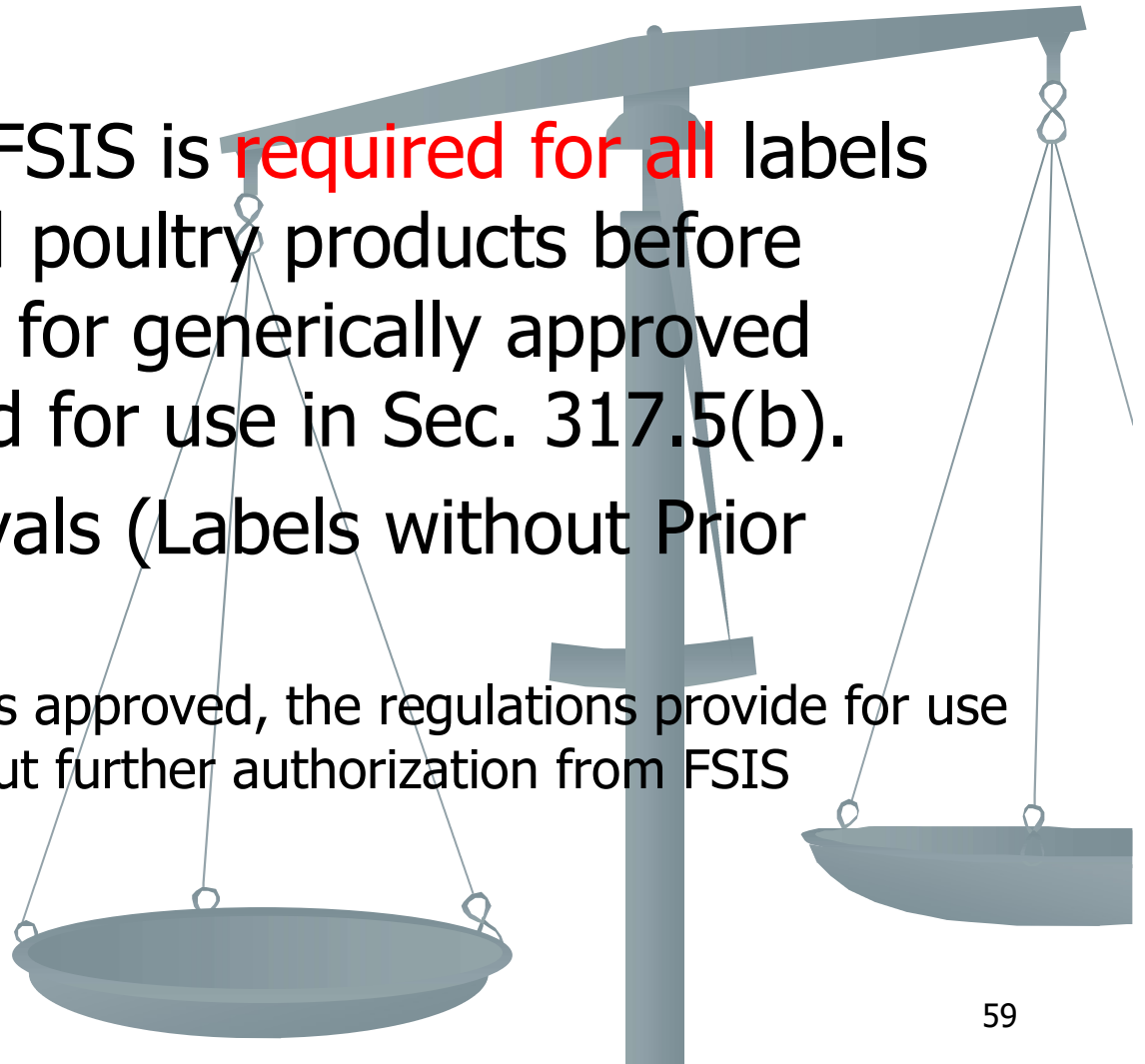
9 C.F.R. § 317.2(l) (meat)

9 C.F.R. § 381.125(b) (poultry)



Labeling Approval

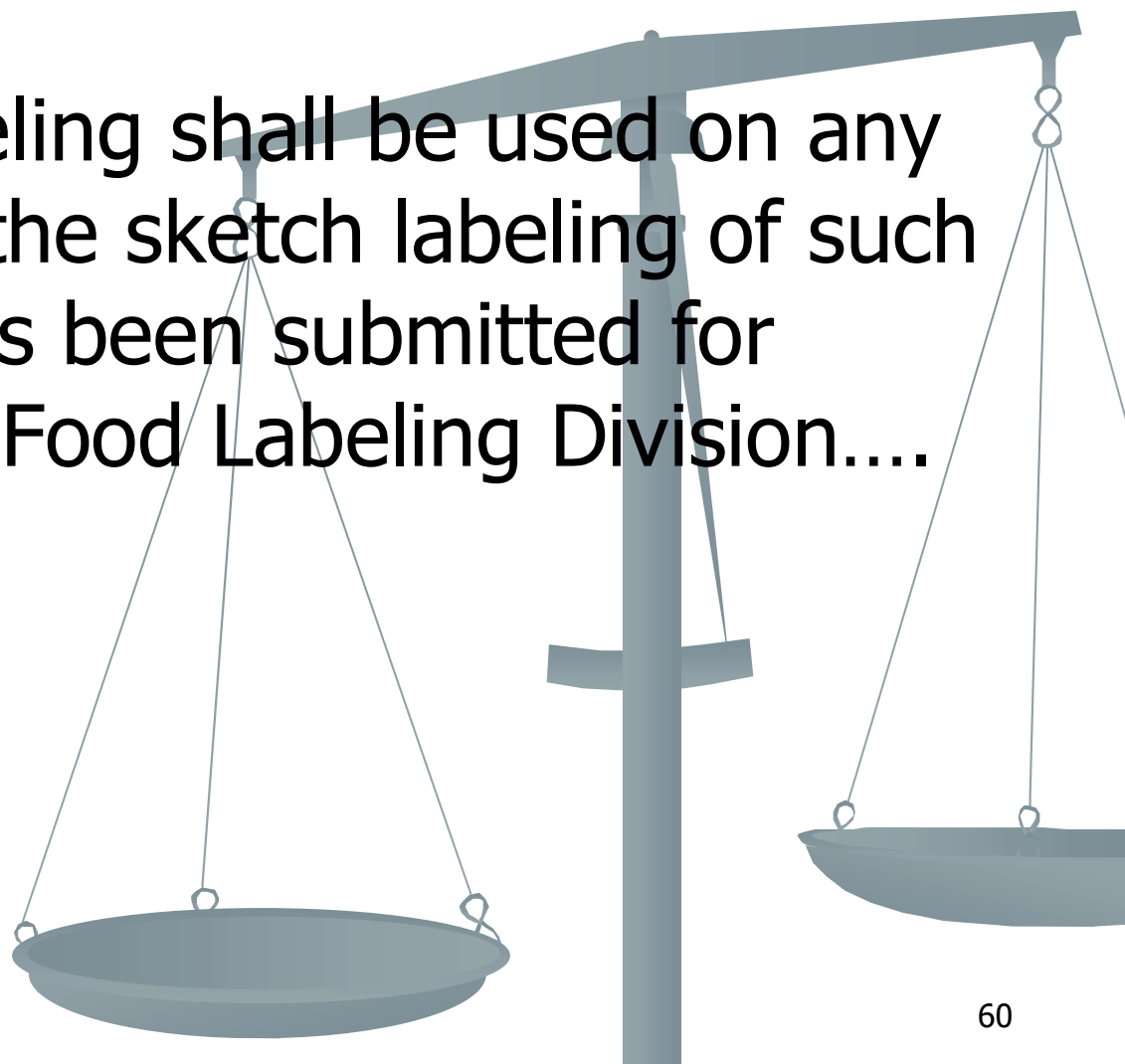
- Prior approval by FSIS is **required for all** labels used for meat and poultry products before marketing, except for generically approved labeling authorized for use in Sec. 317.5(b).
- “Generic” Approvals (Labels without Prior Approval)
 - Once a generic label is approved, the regulations provide for use of final labeling without further authorization from FSIS



Labeling Approval

9 CFR 317.4(a)

- (a) No final labeling shall be used on any product unless the sketch labeling of such final labeling has been submitted for approval to the Food Labeling Division....



Labeling Guidance to Food Companies

FDA Guidance

- Guidance for Industry: A Food Labeling Guide

<https://www.fda.gov/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/LabelingNutrition/ucm2006828.htm>

USDA Guidance

- A Guide to Federal Food Labeling Requirements For Meat and Poultry Products, 2007.

<https://www.fsis.usda.gov/wps/portal/fsis/topics/regulatory-compliance/labeling/labeling-policies/basics-of-labeling/basics-labeling>

