

# What is a Food?

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# Introduction to FD&C Act of 1938

- Most foods are regulated under the Federal Food, Drug, and Cosmetic Act (FD&C Act) of 1938.
- The Act is codified under Title 21 in the United States Code (U.S.C.).

<http://www.gpo.gov/fdsys/browse/collectionUSCode.action?collectionCode=USCODE>

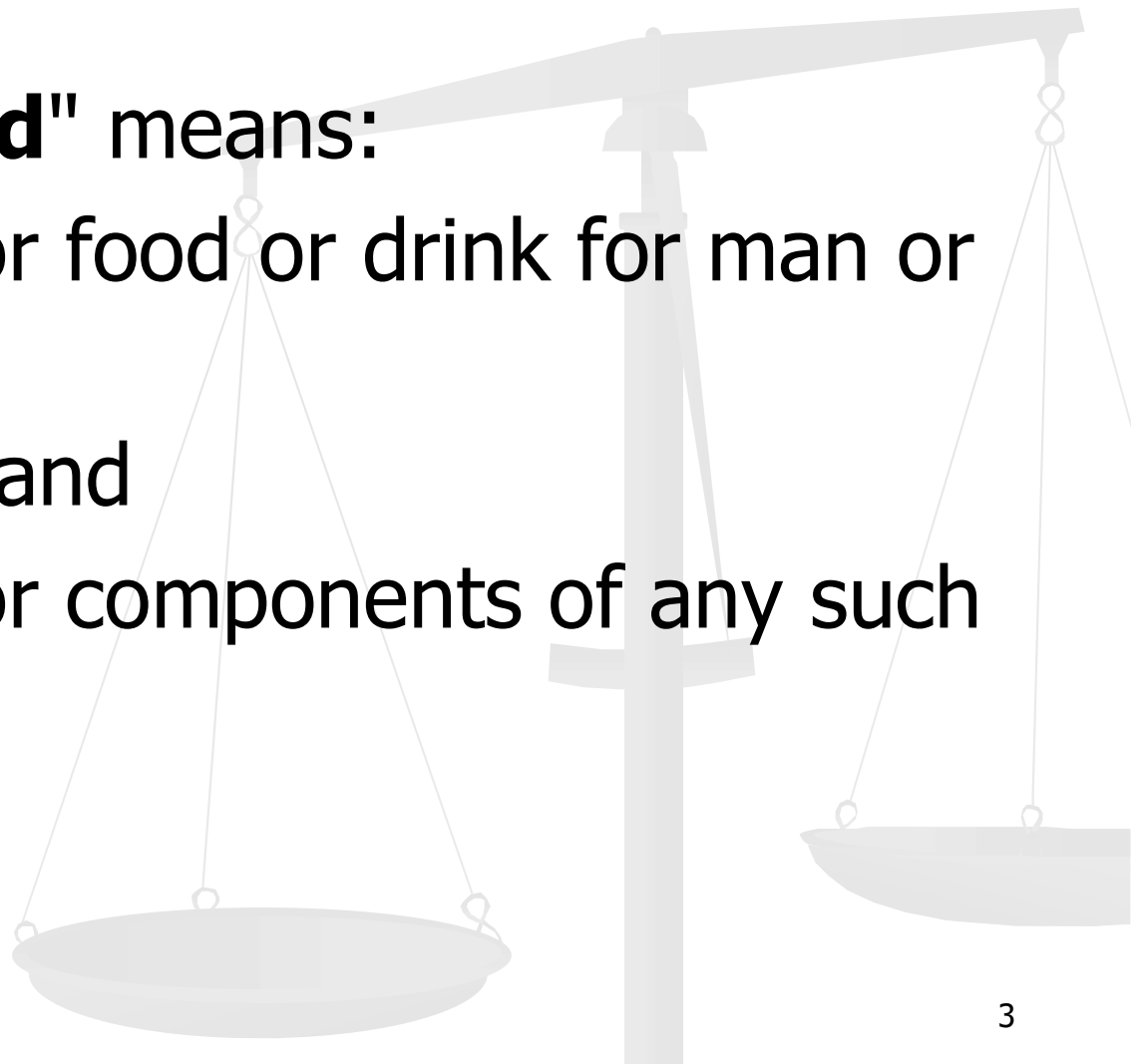
Legislation
► Federal Food, Drug, and Cosmetic Act (FD&C Act)
Section Number Reference: Federal Food, Drug, and Cosmetic Act
FD&C Act Chapters I and II: Short Title and Definitions
FD&C Act Chapter III: Prohibited Acts and Penalties
FD&C Act Chapter IV: Food
FD&C Act Chapter V: Drugs and Devices
FD&C Act Chapter VI: Cosmetics
FD&C Act Chapter VII: General Authority
FD&C Act Chapter VIII: Imports and Exports
FD&C Act Chapter IX: Miscellaneous
Significant Amendments to the FD&C Act

# DEFINITIONS

## SEC. 201 [21 U.S.C. § 321]

(f) The term "**food**" means:

- (1) articles used for food or drink for man or other animals,
- (2) chewing gum, and
- (3) articles used for components of any such article.



# 21 U.S.C. § 321

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# DEFINITIONS

## SEC. 201 [21 U.S.C. § 321]

g)(1) The term "**drug**" means:

- (A) articles recognized in the official U.S. Pharmacopoeia, official Homoeopathic Pharmacopoeia of the U.S., or official National Formulary, or any supplement to any of them; and
- (B) articles intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in man or other animals; and

# DEFINITIONS

## SEC. 201 [21 U.S.C. § 321]

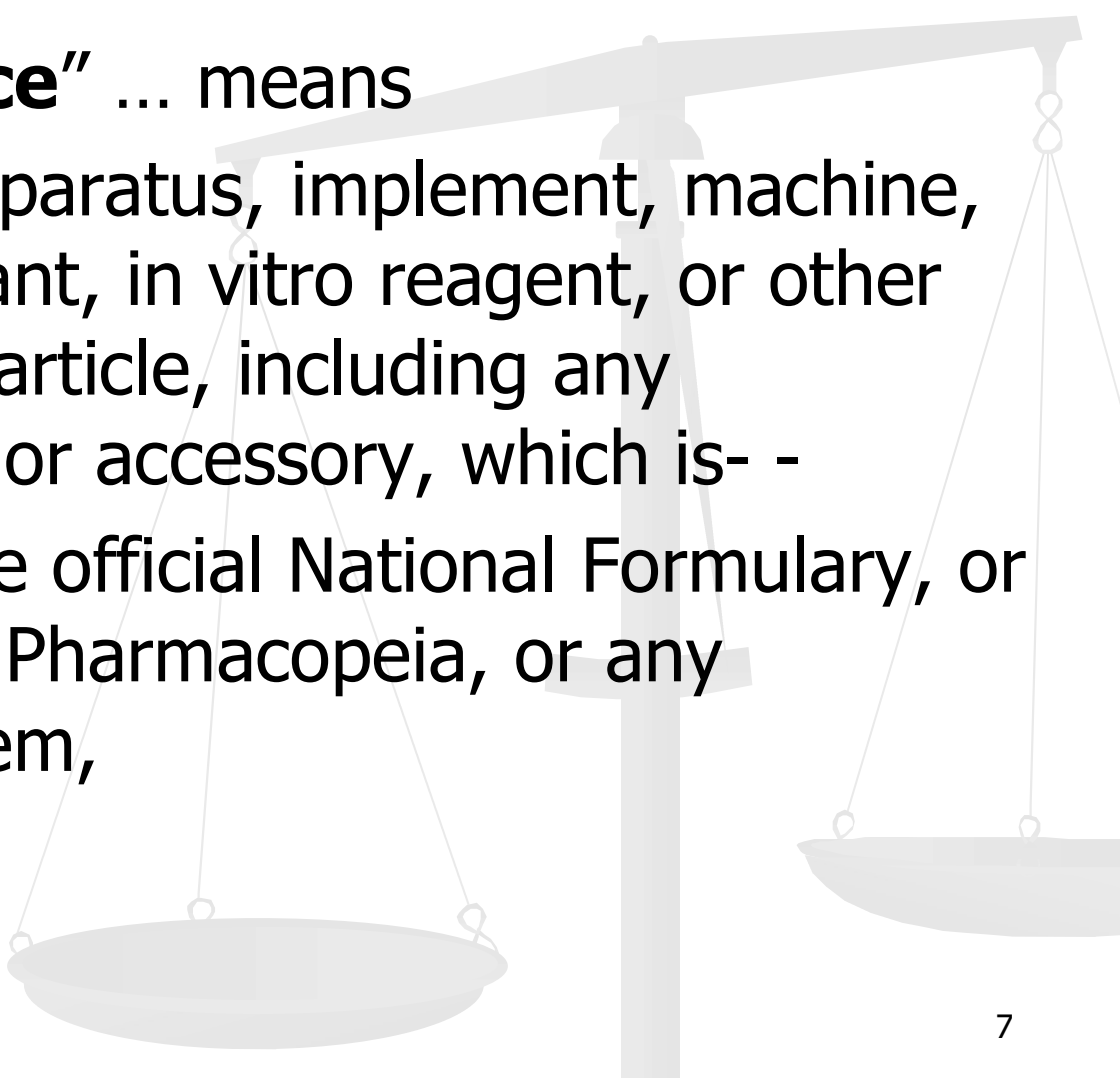
(C) articles (other than food) intended to affect the structure or any function of the body of man or other animals; and

(D) articles intended for use as a component of any article specified in clause (A), (B), or (C)...

A food, dietary ingredient, or dietary supplement for which a truthful and not misleading statement is made in accordance with section 403(r)(6) is not a drug under clause (C) solely because the label or the labeling contains such a statement.

# DEFINITIONS

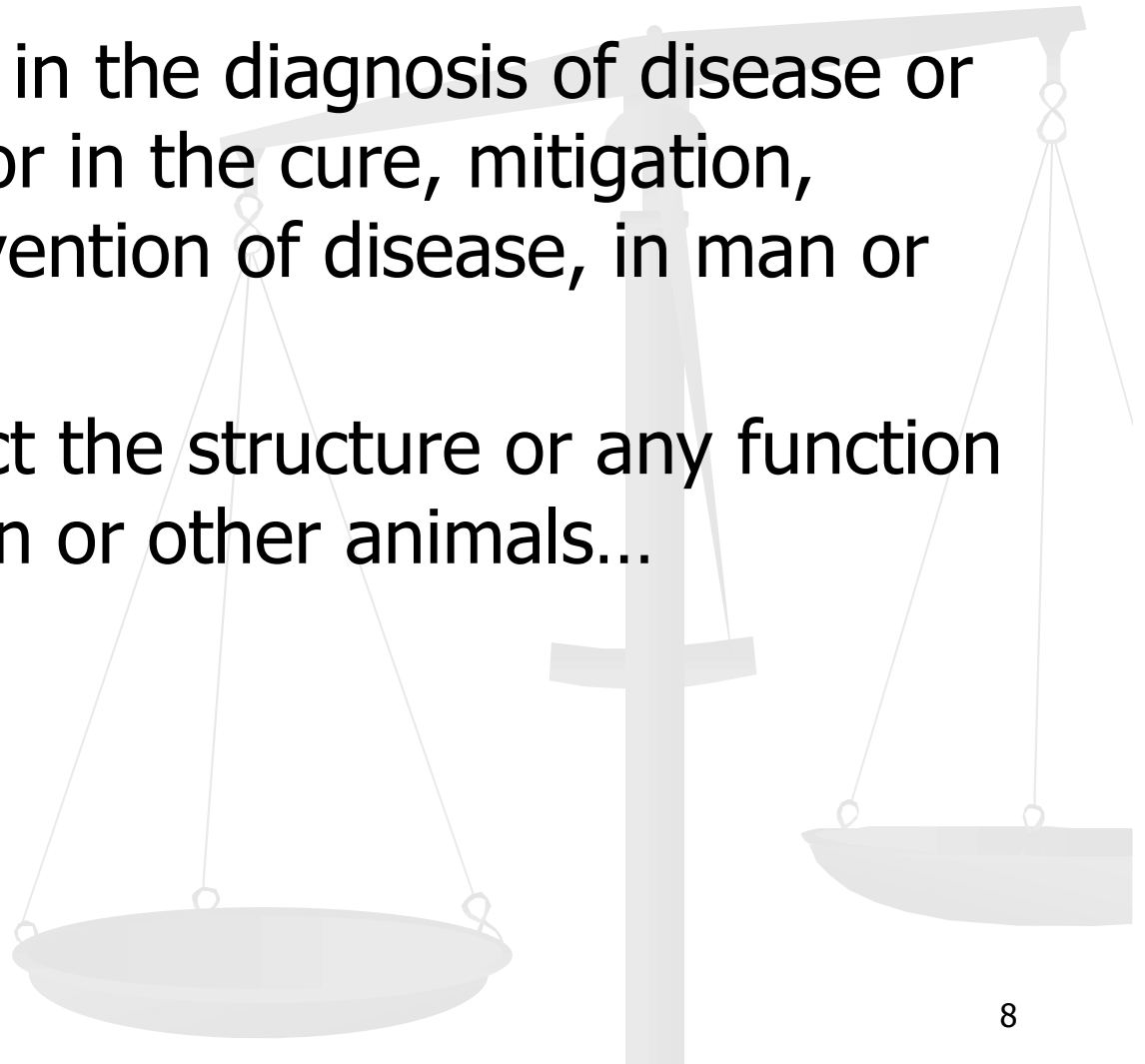
## SEC. 201. [21 U.S.C. § 321]

- (h) The term "**device**" ... means
- an instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related article, including any component, part, or accessory, which is- -
- (1) recognized in the official National Formulary, or the United States Pharmacopeia, or any supplement to them,
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# DEFINITIONS

## SEC. 201. [21 U.S.C. § 321]

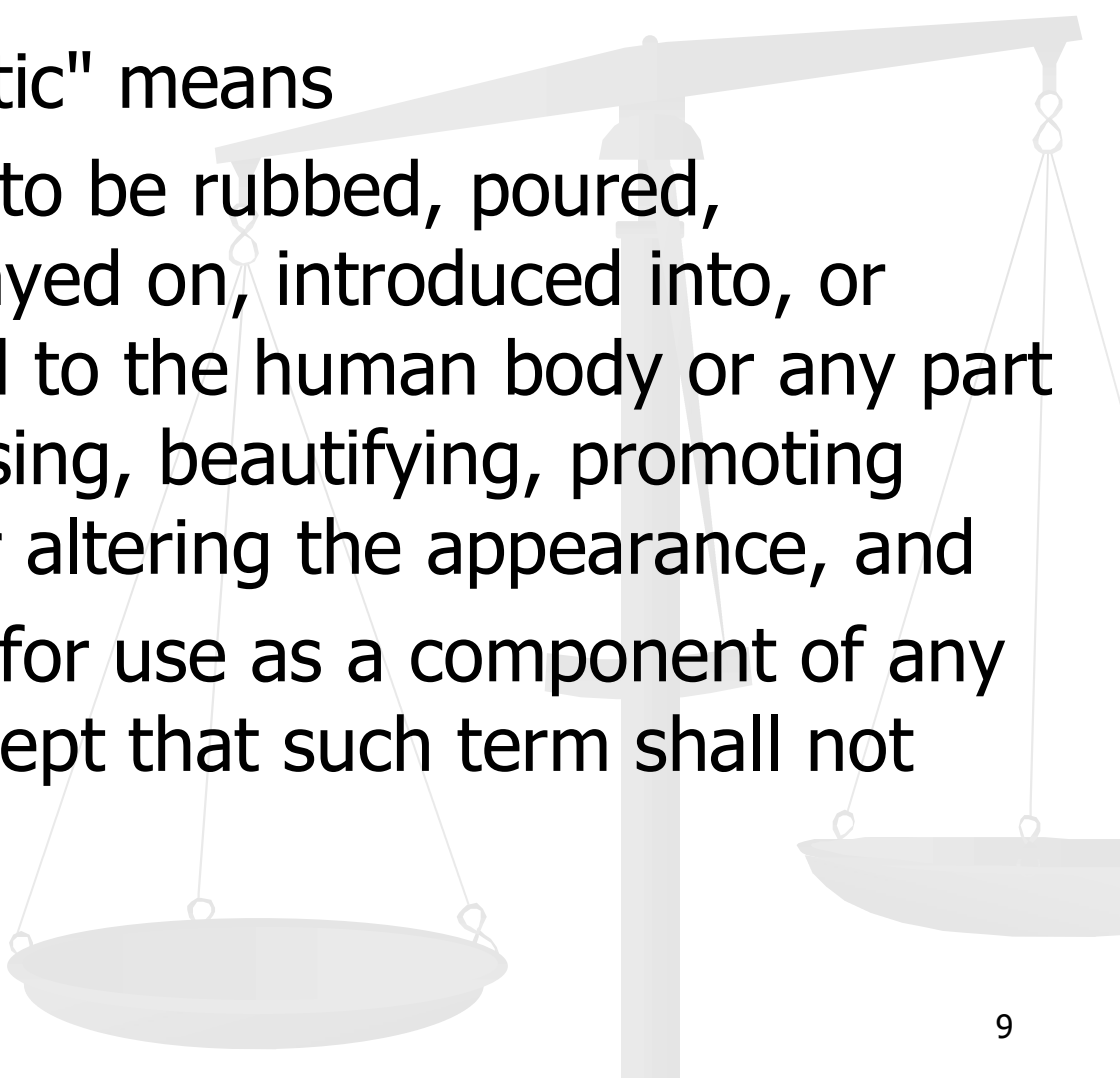
- (2) intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease, in man or other animals, or
- (3) intended to affect the structure or any function of the body of man or other animals...





# DEFINITIONS

## SEC. 201. [21 U.S.C. § 321]

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- (i) The term "cosmetic" means
- (1) articles intended to be rubbed, poured, sprinkled, or sprayed on, introduced into, or otherwise applied to the human body or any part thereof for cleansing, beautifying, promoting attractiveness, or altering the appearance, and
  - (2) articles intended for use as a component of any such articles; except that such term shall not include soap.

# DEFINITIONS

## SEC. 201. [21 U.S.C. § 321]

(s) The term "**food additive**" means:

any substance the intended use of which results or may reasonably be expected to result, directly or indirectly, in its becoming a component or otherwise affecting the characteristics of any food (including any substance intended for use in producing, manufacturing, packing, processing, preparing, treating, packaging, transporting, or holding food; and including any source of radiation intended for any such use),

# DEFINITIONS

## SEC. 201. [21 U.S.C. § 321]

- ...such term does not include—
  - (1) a pesticide chemical residue in or on a raw agricultural commodity or processed food; or
  - (2) a pesticide chemical; or
  - (3) a color additive; or
  - (4) any substance used in accordance with a sanction or approval granted prior to the enactment of this paragraph pursuant to this Act ...
  - (5) a new animal drug; or
  - (6) an ingredient described in paragraph (ff) in, or intended for use in, a dietary supplement.

# DEFINITIONS

## SEC. 201. [21 U.S.C. § 321]

(ff) The term "**dietary supplement**"—

(1) means a product (other than tobacco) intended to supplement the diet that bears or contains one or more of the following dietary ingredients:

- (A) a vitamin;
- (B) a mineral;
- (C) an herb or other botanical;
- (D) an amino acid;
- (E) a dietary substance for use by man to supplement the diet by increasing the total dietary intake; or
- (F) (F) a concentrate, metabolite, constituent, extract, or combination of any ingredient described in clause (A), (B), (C), (D), or (E);

# DEFINITIONS

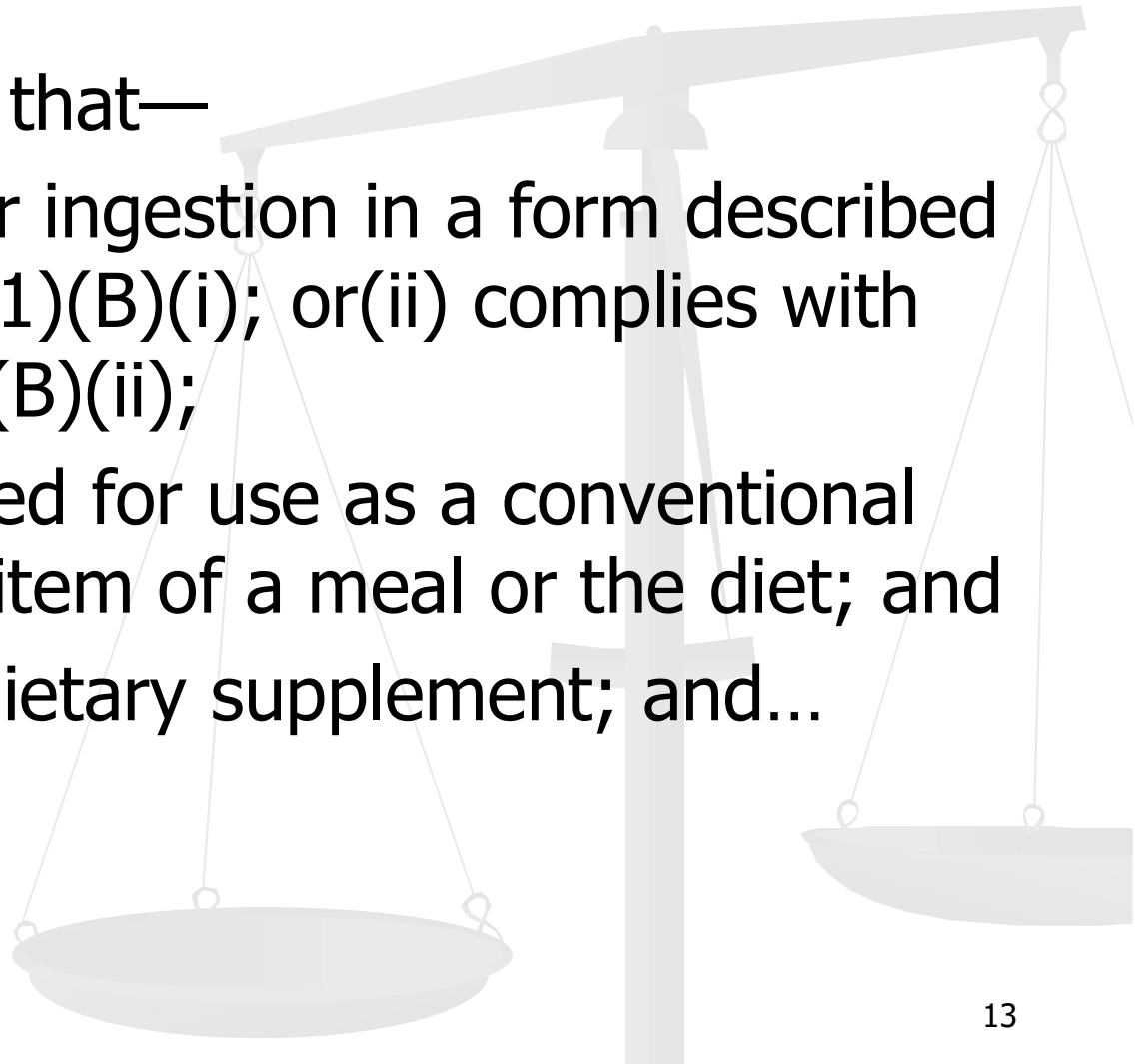
## SEC. 201. [21 U.S.C. § 321]

2) means a product that—

(A)(i) is intended for ingestion in a form described in section 411(c)(1)(B)(i); or(ii) complies with section 411(c)(1)(B)(ii);

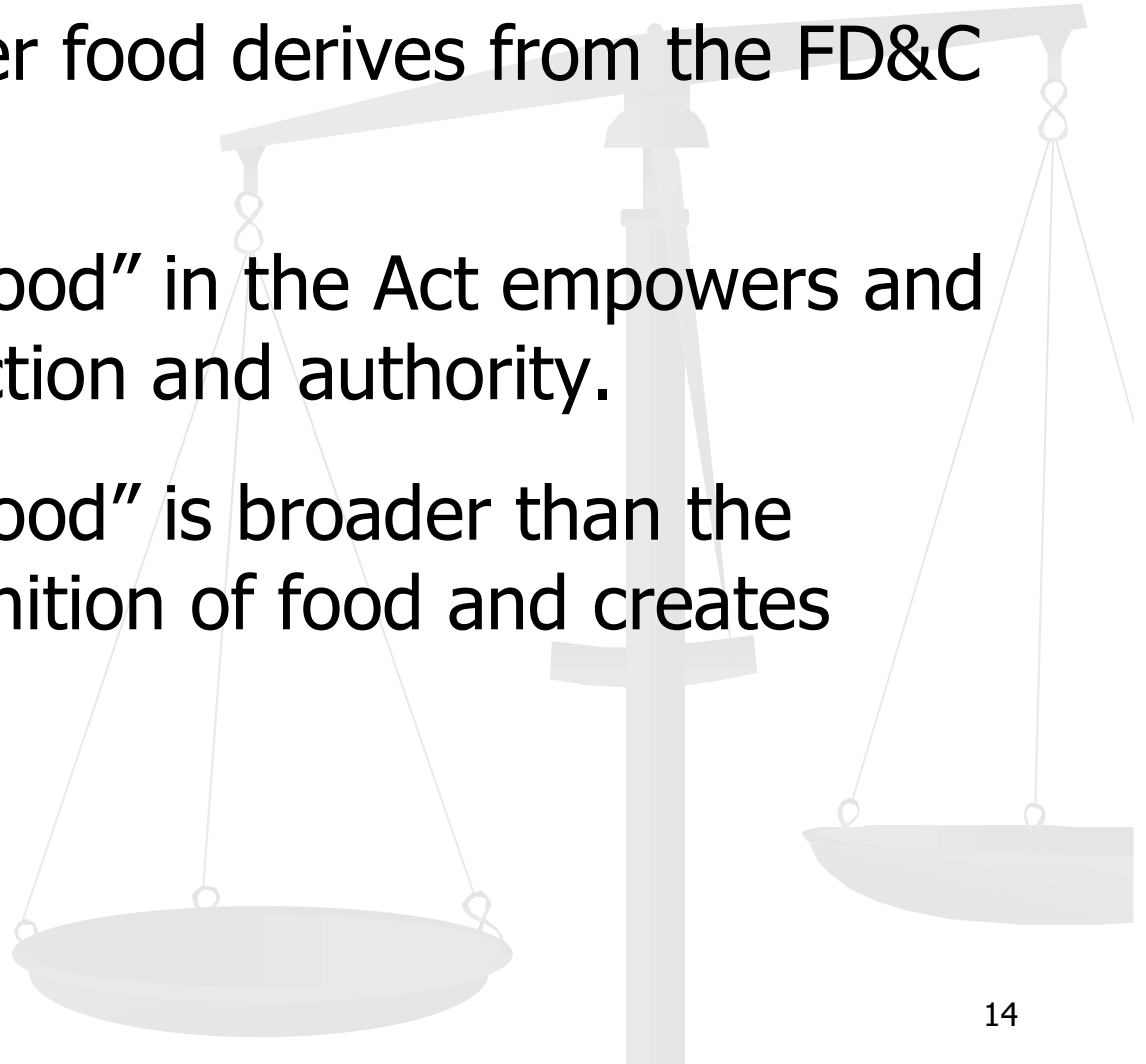
(B) is not represented for use as a conventional food or as a sole item of a meal or the diet; and

(C) is labeled as a dietary supplement; and...



# FDA's Jurisdiction and the Definition of Food

- FDA's authority over food derives from the FD&C Act.
- The definition of "food" in the Act empowers and limits FDA's jurisdiction and authority.
- The definition of "food" is broader than the commonsense definition of food and creates numerous pitfalls.



# Specific Food Classifications

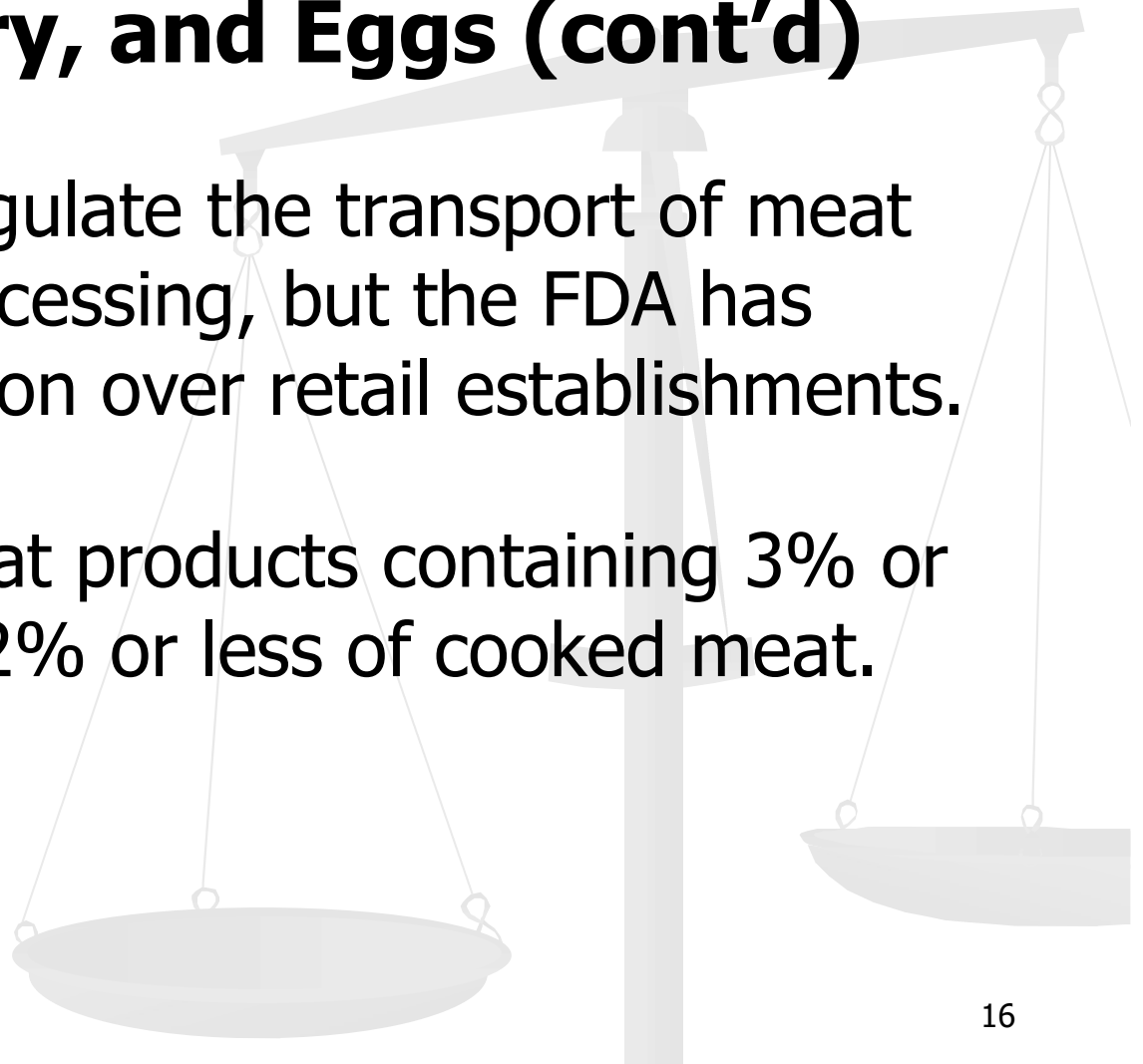
## Meat, Poultry, and Eggs

- USDA regulates meats, poultry, and processed eggs.
- All foods are subject to the FD&C Act- meats are exempted, but only to the extent that Federal Meat Inspection Act (FMIA) applies.
- FDA regulates live meat animals, while USDA regulates slaughter and processing of meat animals.
- USDA and FDA have a joint jurisdiction for food additives in meat and poultry.

# Specific Food Classifications

## Meat, Poultry, and Eggs (cont'd)

- FDA and USDA regulate the transport of meat products after processing, but the FDA has exclusive jurisdiction over retail establishments.
- FDA regulates meat products containing 3% or less raw meat or 2% or less of cooked meat.





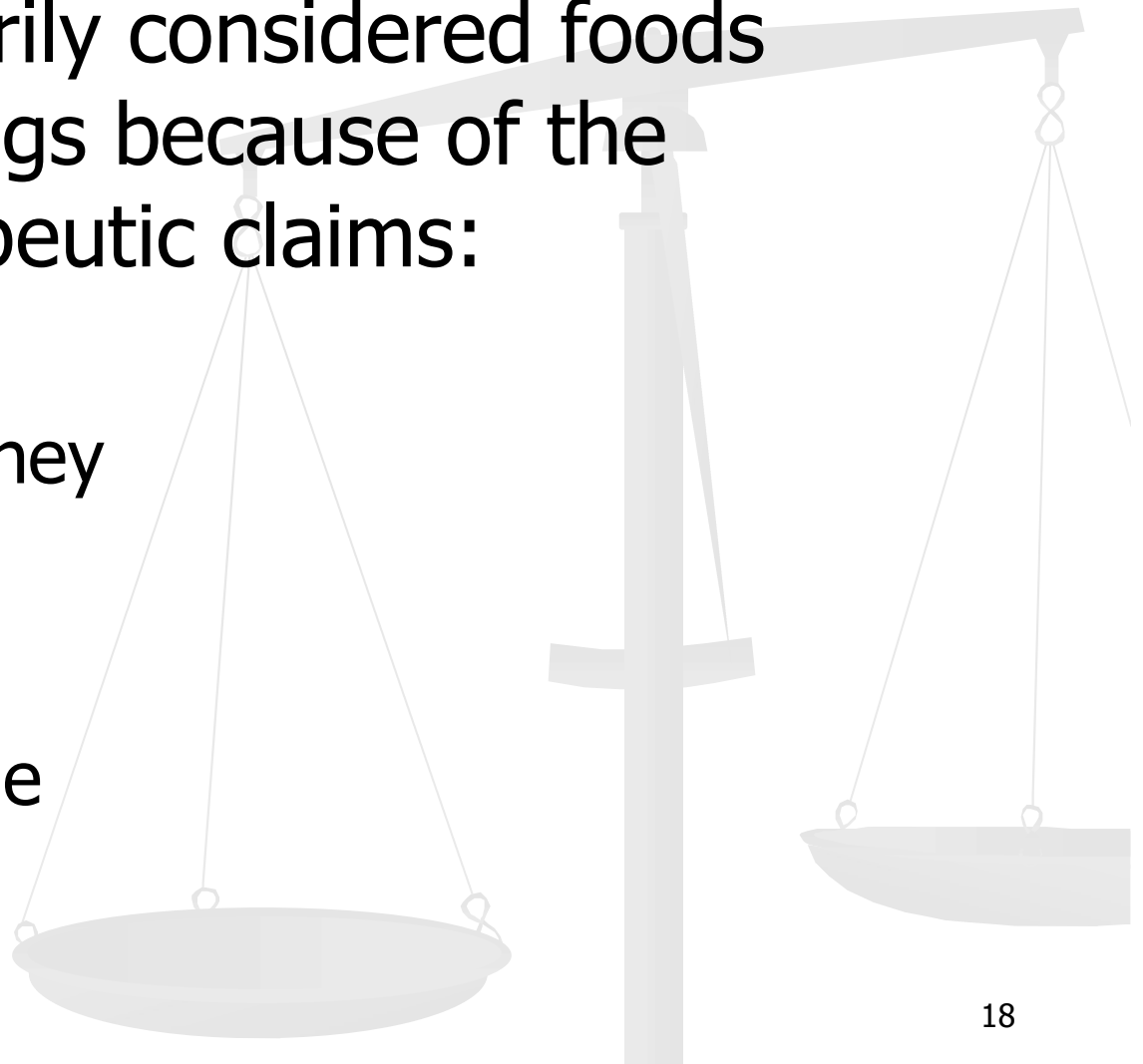
# Specific Food Classifications

## Water

- The EPA is responsible for the safety and purity of drinking water.
- The FDA regulates bottled drinking water.
- This creates consternation for the agencies, bottled water industry, and municipal agencies.
- Water and ice, when used as a food ingredients, are food, and thus regulated by the FDA.

# Products Ordinarily Considered Foods

- Products ordinarily considered foods classified as drugs because of the product's therapeutic claims:
  - Honey
  - Vinegar and honey
  - Tea
  - Water
  - Blue-green algae
  - Mussels



# Products Intended to Be Processed into Food

Some Products have been deemed to be a “food” within the FD&C Act definition because they are intended to be processed into a food or a component of food.

- **Green coffee beans**

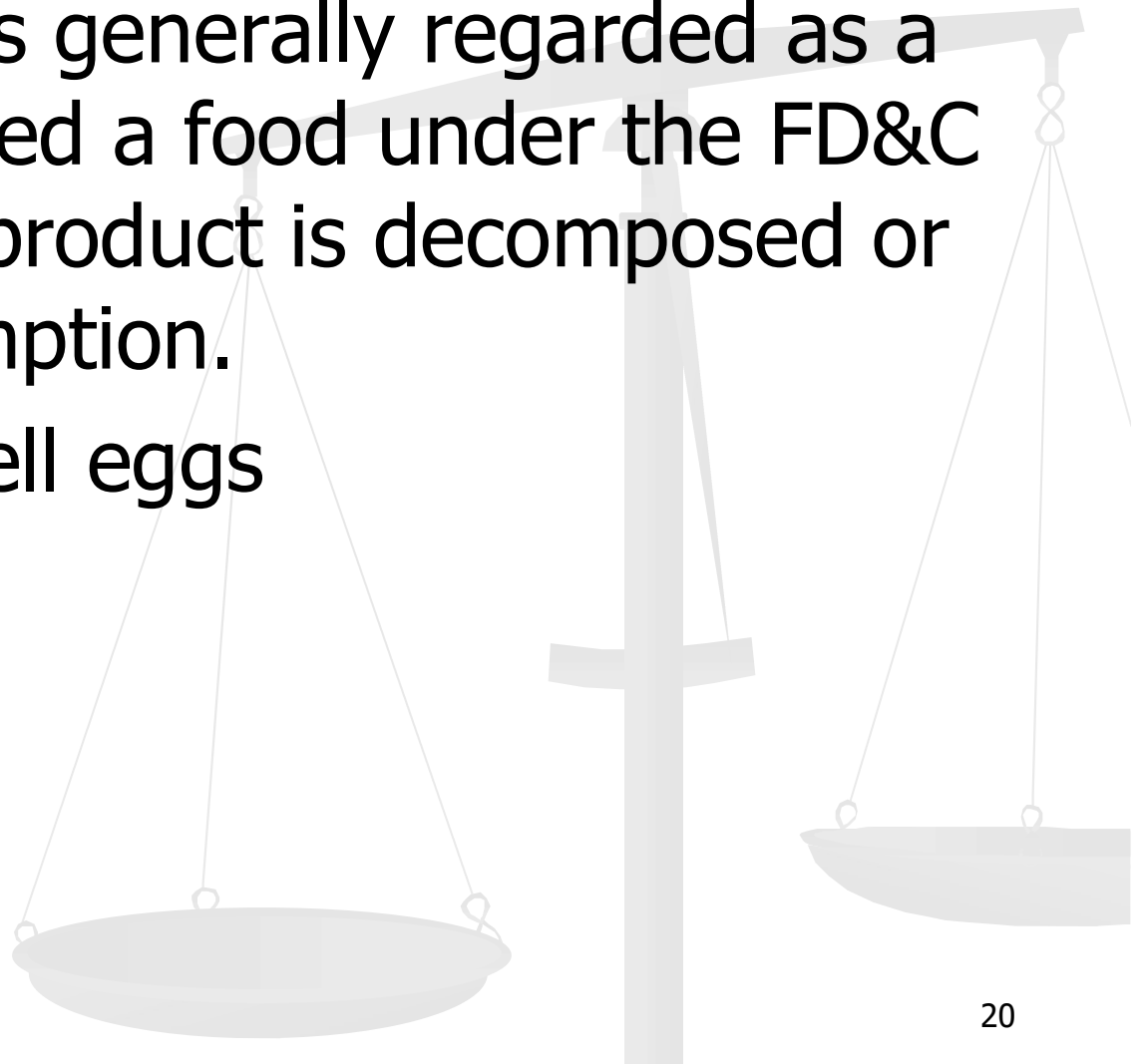
- it doesn't matter if the beans require further processing and not ready for consumption

- **Live beef cattle**

- the edible tissues of live cattle constitute “food” as defined by the Act and thus subject to the adulteration provisions.

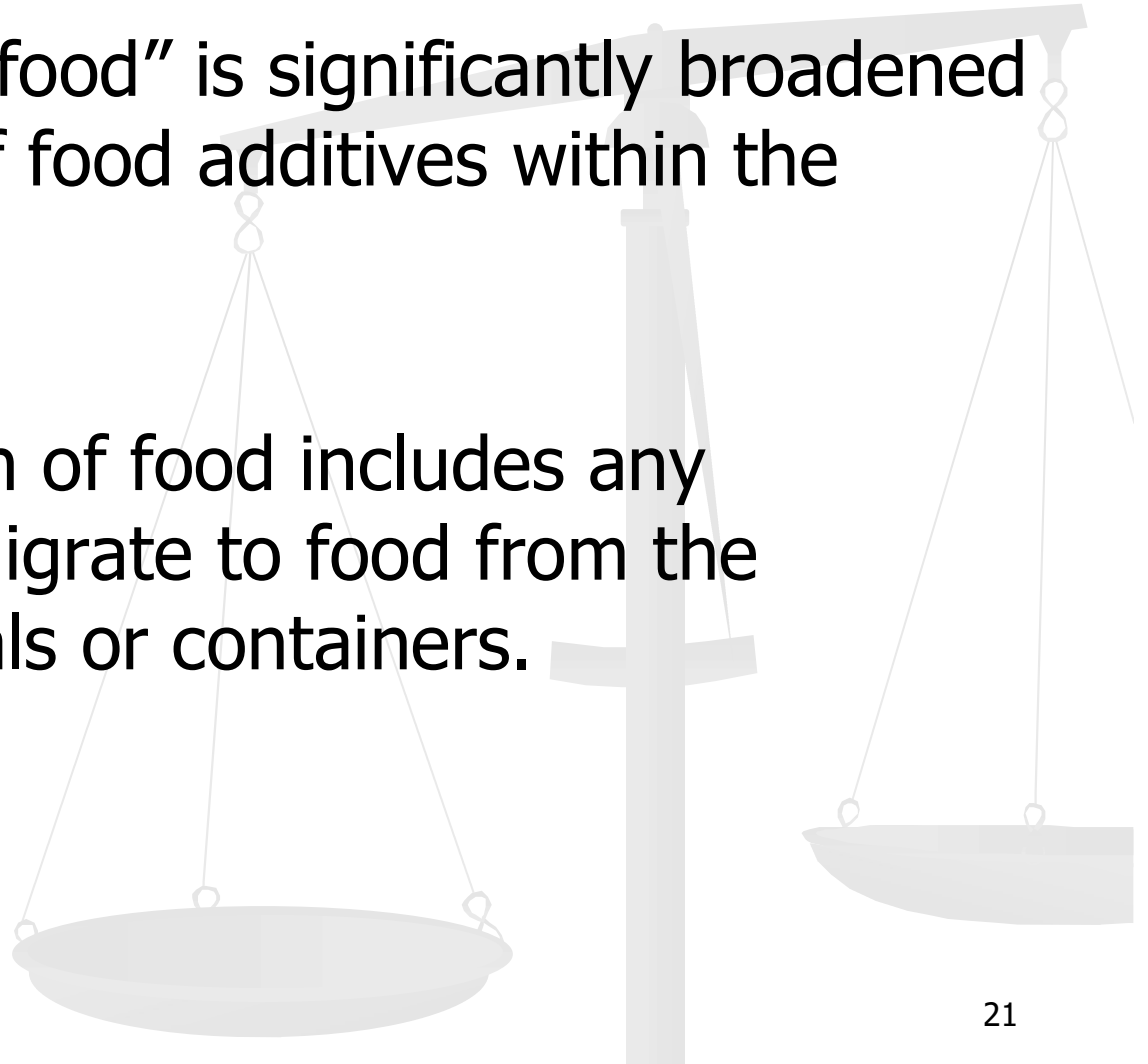
# Products No Longer Fit for Food

- A product that is generally regarded as a food is considered a food under the FD&C Act even if the product is decomposed or unfit for consumption.
- e.g. inedible shell eggs



# Packaging Materials

- The definition of “food” is significantly broadened by the inclusion of food additives within the definition of food.
- Thus the definition of food includes any substances that migrate to food from the packaging materials or containers.



# Evidence of Intended Use

- In determining whether a product is a “drug” because of intended therapeutic use, FDA is not bound by a manufacturer's subjective claims of intent.
- The FD&C Act definition of “food” lacks any reference to intent.
- However, a court may consider the intended use of the product in considering whether it is a food.

