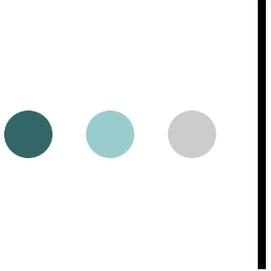


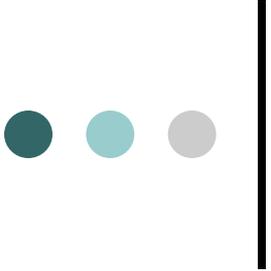
# Food Labeling – Applicable Legal Principles

Food Advisory Committee Meeting  
Certified Color Additives in Food & Hyperactivity in Children  
March 30, 2011



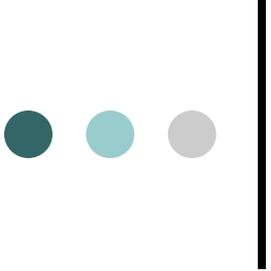
# Terminology: Labels and Labeling

- “Label” means a display of written, printed, or graphic matter upon the immediate container of a product [21 U.S.C. § 321(k)]
- “Labeling” means all labels and other written, printed, or graphic matter on a food or any of its containers or wrappers, or accompanying the food [21 U.S.C. § 321(m)]



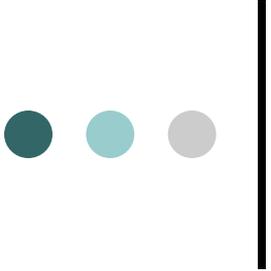
# Elements of Food Labeling

- Mandatory – e.g., list of ingredients, nutrition information, any other material facts about the food
- Optional – e.g., nutrient content claims, quantity of optional nutrients
- Prohibited – e.g., false or misleading information



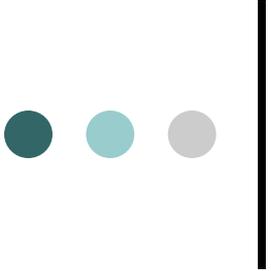
# Key Principles

- Food labeling cannot be false
- Food labeling cannot be misleading
- Absent statutory requirements, FDA cannot require additional information (such as a warning statement) in food labeling unless it is necessary to ensure that the labeling is not false or misleading
- A manufacturer may, on its own initiative, include additional information in the labeling of its products if that information is truthful and not misleading



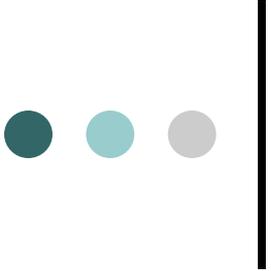
# Food labeling cannot be false

- A food is misbranded if its labeling is false  
[21 U.S.C. § 343(a)(1)]
- Examples
  - A label must declare the presence of all ingredients in the product
  - A label cannot claim that a food contains “no preservatives” if the food does contain a preservative



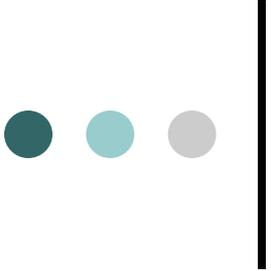
# Food labeling cannot be misleading

- A food is misbranded if its labeling is misleading [21 U.S.C. § 343(a)(1)]
- In determining whether labeling is misleading ‘there shall be taken into account . . . *not only representations made . . . but also the extent to which the labeling . . . fails to reveal facts material* in light of such representations or material with respect to consequences which may result from the use of the article . . .” [21 U.S.C. § 201(n); 21 CFR 1.21(a)]
- Thus, the omission of certain material facts from a product’s labeling may cause the product to be misbranded



# What information can be material?

- Information about the characteristics of the food itself
- Information that would prevent a consumer from assuming that a food, because of its similarity to another food, has nutritional, organoleptic, or functional properties of the food it resembles, when in fact it does not
- Information about the consequences that may result from the consumption of a given food



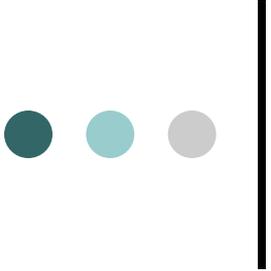
# Examples

- Disclosure Statements to provide information relevant in light of other label statements
  - Nutrient disclosure statements required for foods bearing nutrient content claims (21 CFR 101.13(h))
- Warning Statements conveying material facts about consequences of use
  - Protein products used in very low calorie diets (21 CFR 101.17(d))
  - Foods containing psyllium husk (21 CFR 101.17(f))
  - Unpasteurized juice (21 CFR 101.17(g))



# What information is not material?

- Consumer interest, alone
  - FDA does not require additional labeling of milk from cows treated with rBST, even though widespread consumer demand for information
- Information about potential effects of consumption that are widely known or are not significant
  - FDA concluded that previously required warning statement about potential effects of olestra no longer necessary because effects were insignificant and consumers were aware of them



# Summary

- A product is misbranded if its labeling is false or misleading
- Labeling can be misleading if it fails to reveal facts that are material with respect to consequences that could result from the use of the article
- FDA has the authority to require additional information (e.g., a warning statement) in food labeling to ensure that the labeling is not false or misleading