Food Labeling – Applicable Legal Principles

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Certified Color Additives in Food & Hyperactivity in Children
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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
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.