

What is a Food?

Introduction to the Food, Drug and Cosmetic Act

- Most foods are regulated under the FD&C act
- Classification of a product as a food or drug determines how rigorously the product is regulated
- Definitions (please note that these have been paraphrased for simplicity):

Food: 1) articles used for food or drink for man or other animals, 2) chewing gum, 3) articles used for components of any other such articles

Drug: 1) articles intended for use in the diagnosis, cure, mitigation, treatment or prevention of disease in man or other animals; 2) articles (other than food) intended to affect the structure or any function of the body of man or other animals

Device: an instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent or other similar related article or component, part or accessory that 1) is used in the diagnosis or treatment of a condition, 2) affects the structure or function of the body- not primarily via chemical action.

Cosmetic: articles intended to be rubbed, poured, sprinkled, or sprayed on, introduced into, or otherwise applied to the human body- for cleansing, beautifying, promoting attractiveness, or altering the appearance. E.g. skin moisturizers, perfumes and lipsticks. Also includes any substance intended for use as a component of a cosmetic product.

Food Additive: In its broadest sense, a food additive is any substance added to food. Legally: 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.

Dietary supplement: A dietary supplement is a product taken by mouth that is intended to supplement the diet and that contains one or more "dietary ingredients." The "dietary ingredients" in these products may include: vitamins, minerals, herbs or other botanicals, amino acids, other substances found in the human diet, such as enzymes. Dietary supplements must be labeled as such and must not be represented for use as a conventional food or as the sole item of a meal or the diet.

- One way to distinguish dietary supplements from conventional foods is by looking at the nutrition information on the label of the product. Conventional foods must have a "Nutrition Facts" panel on their labels, but dietary supplements must have a "Supplement Facts" panel.

FDA's Jurisdiction and the Definition of Food

- The definition of 'food' in the act has importance in determining the reach and limits of FDA's jurisdiction and authority.