

The scope of dietary ingredients under DSHEA

Dietary Ingredients

FD&C Act Sec 201(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) a concentrate, metabolite, constituent, extract, or combination of any ingredient described in clause (A), (B), (C), (D), or (E);

Working Definitions

- Dietary Substance
 - “Dietary substance for use by man...”
 - A substance that is commonly used as human food or drink
 - “...to supplement the diet by increasing the total dietary intake”
 - further evidence it is intended to mean foods and food components that humans eat as part of their usual diet
 - Use as a dietary supplement doesn’t make something a dietary substance

Working Definitions

- Herb/other Botanical
 - A plant, alga, or fungus; a part of a plant, alga, or fungus (e.g., bark, leaves, stems, roots, flowers, fruits, seeds, berries, or parts thereof); or an exudate (secretion) of a plant, alga, or fungus.
- Constituent
 - An article that is a physical part of the whole and can be isolated from the whole.