



California Department of Public Health Food and Drug Branch



DIETARY SUPPLEMENT PROCESSORS

A dietary supplement is a product that contains an "ingredient" intended to help the diet. Dietary supplements are taken by mouth and usually marketed as vitamin or mineral supplements. The "dietary ingredients" in these products may include: vitamins, minerals, herbs or other botanicals, amino acids, and substances such as enzymes, organ tissues, and metabolites. Dietary supplements can also be extracts or concentrates.

Dietary supplements may be sold as tablets, capsules, softgels, gencaps, liquids, or powders. Because of their unique qualities, dietary supplements are regulated differently than conventional foods or drugs. Dietary supplements must be labeled according to the Dietary Supplement Health and Education Act (DSHEA) of 1994. DSHEA prohibits dietary supplements from being sold for the treatment, prevention or cure for a disease or health condition. Dietary supplements with these claims are considered an unapproved drug. Under California law, it is illegal to manufacture and sell unapproved drugs.

DSHEA, requires manufacturers to provide a "disclaimer" statement when there is a claim that the supplement affects the structure or function of the body. The manufacturer is responsible for accuracy and truthfulness of these claims; since they are not approved by FDA.

In addition, **California has regulations** (Title 17, California Code of Regulations, Sections 10200 and 10750) that requires a specific statement on the labels of dietary supplements and other foods that contain aloe latex, buckthorn, cascara, frangula, rhubarb root, or senna.

Dietary supplement manufacturers are required to obtain a registration under the Processed Food Registration (PFR) program.

Links: [Processed Food Registration \(PFR\)](#) program

[Processed Food Registration Application request](#)

California Health and Safety Code (general food laws): [Section 109875 - 111915](#)

California Law [H&SC 110422 - 110424](#)

California Regulation [Title 17, Sections 10200](#)

Federal, the "[Dietary Supplement Health and Education Act](#) (DSHEA)".

Federal Regulations, Good Manufacturing Practice [GMP] [21 CFR, Part 110](#)

Federal Regulations, Labeling Requirements [21 CFR Parts 101 through 105](#)

[Federal Labeling Requirements for Dietary Supplements](#)