

# State of California

## DIETARY SUPPLEMENTS

California Code of Regulations, Title 17

§10200.

(a) "Dietary supplement"

- (1) Means an article (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 humans 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);
- (2) Means a product that
  - (A) Is labeled as a dietary supplement and
  - (B) Is intended for ingestion in tablet, capsule, powder, softgel, gelcap, or liquid form, or if not intended for ingestion in such a form
  - (C) Is not represented for use as a conventional food, or as a sole item of a meal or the diet; and
- (3) Does
  - (A) Include an article that is approved as a new drug in compliance with Health and Safety Code section 111550, subdivision (a) or (b), certified as an antibiotic under the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. section 357, and/or licensed as a biologic under the Public Health and Safety Act, 42 U.S.C. section 262 and was, prior to such approval, certification, or license, marketed as a dietary supplement or as a food, unless the article, when used as or in a dietary supplement under the conditions of use set forth in the labeling for such dietary supplement is adulterated under California Health and Safety Code section 110545, and
  - (B) Not include
    1. An article that is approved as a new drug in compliance with Health and Safety Code section 111550, subdivision (a) or (b), certified as an antibiotic under the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. section 357, and/or licensed as a biologic under the Public Health and Safety Act, 42 U.S.C., section 262, or
    2. An article authorized for investigation as a new drug, antibiotic, or biologic for which substantial clinical investigations have been instituted and for which the existence of such investigations has been made public, and which was not, before its approval, certification, licensing, or authorization, marketed as a dietary supplement.

(b) A dietary supplement may be a food or a drug, or both a food and a drug, as these terms are defined in Health and Safety code sections 109935 and 109925.

#### NOTE

Authority cited: Sections 100275, 110065 and 110100, Health and Safety Code. Reference: Sections 110175, 110290, 110545, 110620, 110625, 110630, 110660, 110705, 110760, 110765 and 110770, Health and Safety Code.

#### HISTORY

1. New article 1 (section 10200) and section filed 10-15-96; operative 1-1-97 (Register 96, No. 42). A Certificate of Compliance must be transmitted to OAL by 5-1-97 or emergency language will be repealed by operation of law on the following day.
2. New article 1 (section 10200) and section refiled 4-29-97 as an emergency; operative 5-2-97 (Register 97, No. 18). A Certificate of Compliance must be transmitted to OAL by 9-2-97 or emergency language will be repealed by operation of law on the following day.
3. Certificate of Compliance as to 4-29-97 order transmitted to OAL 8-28-97 and filed 10-9-97 (Register 97, No. 41).