HEALTH AND SAFETY CODE - HSC

DIVISION 104. ENVIRONMENTAL HEALTH [106500 - 119406] *(Division 104 added by Stats. 1995, Ch. 415, Sec. 6.)*

PART 5. SHERMAN FOOD, DRUG, AND COSMETIC LAWS [109875 - 111929.4] *(Part 5 added by Stats. 1995, Ch. 415, Sec. 6.)*

CHAPTER 1. General Provisions and Definitions [109875 - 110040] *(Chapter 1 added by Stats. 1995, Ch. 415, Sec. 6.)*

109875. This part shall be known as the Sherman Food, Drug, and Cosmetic Law.

(Added by Stats. 1995, Ch. 415, Sec. 6. Effective January 1, 1996.)

109880. Unless the context otherwise requires, the definitions set forth in this article govern the construction of this part.

(Added by Stats. 1995, Ch. 415, Sec. 6. Effective January 1, 1996.)

109885. "Advertisement" means any representations, including, but not limited to, statements upon the products, its packages, cartons, and any other container, disseminated in any manner or by any means, for the purpose of inducing, or that is likely to induce, directly or indirectly, the purchase or use of any food, drug, device, or cosmetic.

(Added by Stats. 1995, Ch. 415, Sec. 6. Effective January 1, 1996.)

109890. "Antibiotic drug" means any drug , except drugs for use in animals other than humans, composed in whole or in part of any form of penicillin, streptomycin, chlortetracycline chloramphenicol, bacitracin, or any other drug intended for human use containing any quantity of any chemical substance that is produced by micro-organisms, and that has the capacity to inhibit or destroy micro-organisms in dilute solution, including a chemically synthesized equivalent, or any derivative thereof.

(Amended by Stats. 2000, Ch. 796, Sec. 1. Effective January 1, 2001.)

109895. "Color additive" means a substance that satisfies both of the following requirements:

(a) It is a dye, pigment, or other substance made by a process of synthesis or similar artifice, or extracted, isolated, or otherwise derived, with or without intermediate or final change of identity, from a vegetable, animal, mineral, or other source.

(b) When added or applied to a food, drug, device, or cosmetic, or to the human body or any part of the body, it is capable, alone or through reaction with any other substance, of imparting color to the food, drug, device, or cosmetic, or to the human body or the part of the human body, to which it is added or applied.

The term "color additive" does not include any material that the department, by regulation, determines is used, or intended to be used, solely for a purpose or purposes other than coloring.

The term "color," as used in this section, includes black, white, and intermediate grays.

This section does not apply to any pesticide chemical, soil, or plant nutrient, or other agricultural chemical, solely because of its effect in aiding, retarding, or otherwise affecting, directly or indirectly, the growth or other natural physiological process of produce of the soil and thereby affecting its color, whether before or after harvest.

(Added by Stats. 1995, Ch. 415, Sec. 6. Effective January 1, 1996.)

109900. "Cosmetic" means any article, or its components, intended to be rubbed, poured, sprinkled, or sprayed on, introduced into, or otherwise applied to, the human body, or any part of the human body, for cleansing, beautifying, promoting attractiveness, or altering the appearance.

The term "cosmetic" does not include soap.

(Added by Stats. 1995, Ch. 415, Sec. 6. Effective January 1, 1996.)

109905. “Counterfeit”, as used in respect to any food, drug, device, or cosmetic, means a food, drug, device, or cosmetic that bears or whose package or labeling bears, without authorization, the trademark, trade name, or other identifying mark, imprint, or device, or any likeness or trademark, trade name, or other identifying mark, imprint, or device of a manufacturer, processor, packer, or distributor, other than the actual manufacturer, processor, packer, or distributor, or that falsely purports or is represented to be the product of, or to have been packed or distributed by, the other manufacturer, processor, packer, or distributor.

(Added by Stats. 1995, Ch. 415, Sec. 6. Effective January 1, 1996.)

109910. “Department” means the State Department of Health Services.

(Added by Stats. 1995, Ch. 415, Sec. 6. Effective January 1, 1996.)

109915. “Director” means the State Director of Health Services.

(Added by Stats. 1995, Ch. 415, Sec. 6. Effective January 1, 1996.)

109920. “Device” means any instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related article, including any component, part, or accessory, that is any of the following:

(a) Recognized in the official National Formulary or the United States Pharmacopoeia, or any supplement to them.

(b) Intended for use in the diagnosis of disease or other condition, or in the cure, mitigation, treatment, or prevention of disease in humans or any other animal.

(c) Intended to affect the structure or any function of the body of humans or any other animal and that does not achieve any of its principal intended purposes through chemical action within or on the body of humans or other animals and that is not dependent upon being metabolized for the achievement of any of its principal intended purposes.

(Added by Stats. 1995, Ch. 415, Sec. 6. Effective January 1, 1996.)

109925. (a) “Drug” means any of the following:

(1) An article recognized in an official compendium.

(2) An article used or intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in human beings or any other animal.

(3) An article other than food, that is used or intended to affect the structure or any function of the body of human beings or any other animal.

(4) An article used or intended for use as a component of an article designated in paragraphs (1) to (3), inclusive.

(b) The term “drug” does not include any device.

(c) Any food for which a claim (as described in Sections 403(r)(1)(B) (21 U.S.C. Sec. 343(r)(1)(B)) and 403(r)(3) (21 U.S.C. Sec. 343(r)(3)) or Sections 403(r)(1)(B) (21 U.S.C. Sec. 343(r)(1)(B)) and 403(r)(5)(D) (21 U.S.C. Sec. 343(r)(5)(D)) of the federal act), is made in accordance with the requirements set forth in Section 403(r) (21 U.S.C. Sec. 343(r)) of the federal act, is not a drug under subdivision (b) solely because the label or labeling contains such a claim.

(d) Cannabis product, including any cannabis product intended for external use, is not a drug.

(Amended by Stats. 2017, Ch. 27, Sec. 160. (SB 94) Effective June 27, 2017.)

109930. “Federal act” means the federal Food, Drug, and Cosmetic Act, as amended (21 U.S.C. Sec. 301 et seq.).

(Added by Stats. 1995, Ch. 415, Sec. 6. Effective January 1, 1996.)

109935. “Food” means either of the following:

(a) Any article used or intended for use for food, drink, confection, condiment, or chewing gum by man or other animal.

(b) Any article used or intended for use as a component of any article designated in subdivision (a).

(Amended by Stats. 2001, Ch. 641, Sec. 1. Effective January 1, 2002.)

109940. “Food additive” means any substance, the intended use of which results or may reasonably be expected to result, directly or indirectly, in the substance becoming a component of the food or otherwise affecting characteristics of the food. This includes any

substance or radiation source intended for use in producing, manufacturing, packing, treating, packaging, transporting, or holding any food.

The term “food additive” does not include any of the following:

(a) A pesticide chemical in or on a raw agricultural commodity.

(b) A pesticide chemical that is used, or intended for use, in the production, storage, or transportation of any raw agricultural commodity.

(c) A color additive.

(d) Any substance used in accordance with a sanction or approval granted prior to the enactment of the Food Additives Amendment of 1958 (72 Stat. 1784), pursuant to the federal act; the Poultry Products Inspection Act (71 Stat. 441; 21 U.S.C. Sec. 451 et seq.); the Meat Inspection Act of March 4, 1907 (34 Stat. 1260), as amended and extended (21 U.S.C. Sec. 71 et seq.); or the Food and Agricultural Code of this state.

(Added by Stats. 1995, Ch. 415, Sec. 6. Effective January 1, 1996.)

109945. “Food and drug inspector” means any authorized agent of the Bureau of Food and Drug of the department, who shall have the powers set forth in Section 106500.

(Added by Stats. 1995, Ch. 415, Sec. 6. Effective January 1, 1996.)

109947. “Food processing facility” means any facility operated for the purposes of manufacturing, packing, or holding processed food. Food processing facility does not include a food facility as defined in Section 113785, a cottage food operation that is registered or has a permit pursuant to Section 114365, or any facility exclusively storing, handling, or processing dried beans.

(Amended by Stats. 2012, Ch. 415, Sec. 3. (AB 1616) Effective January 1, 2013.)

109948. (a) “Home medical device retail facility” is an area, place, or premises, other than a licensed pharmacy, in and from which prescription devices, home medical devices, or home medical device services are sold, fitted, or dispensed pursuant to prescription. “Home medical device retail facility” includes, but is not limited to, any area or place in which prescription devices, home medical devices, or home medical device services are stored, possessed, prepared, manufactured, or repackaged, and from which the prescription devices, home medical devices, and home medical device services are furnished, sold, or dispensed at retail.

(b) “Home medical device retail facility” shall not include any area in a facility licensed by the department where floor supplies, ward supplies, operating room supplies, or emergency room supplies of prescription devices are stored or possessed solely for treatment of patients registered for treatment in the facility or for treatment of patients receiving emergency care in the facility.

(c) “Home medical device retail facility” shall not include any area of a home health agency licensed under Chapter 8 (commencing with Section 1725) of, or a hospice licensed under Chapter 8.5 (commencing with Section 1745) of Division 2 where the supplies specified in subdivision (c) of Section 4057 of the Business and Professions Code are stored or possessed solely for treatment of patients by a licensed home health agency or licensed hospice, as long as all prescription devices are furnished to these patients only upon the prescription or order of health care practitioners authorized to prescribe or order home medical devices or who use home medical devices or who use home medical devices to treat their patients.

(Added by Stats. 2000, Ch. 837, Sec. 28. Effective January 1, 2001.)

109948.1. (a) “Home medical device services” means the delivery, installation, maintenance, replacement of, or instruction in the use of, home medical devices used by a sick or disabled individual to allow the individual to be maintained in a residence.

(b) “Home medical device” means a device intended for use in a home care setting including, but not limited to, all of the following:

(1) Oxygen delivery systems and prefilled cylinders.

(2) Ventilators.

(3) Continuous Positive Airway Pressure devices (CPAP).

(4) Respiratory disease management devices.

(5) Hospital beds and commodes.

(6) Electronic and computer driven wheelchairs and seating systems.

(7) Apnea monitors.

(8) Low air loss continuous pressure management devices.

(9) Transcutaneous Electrical Nerve Stimulator (TENS) units.

(10) Prescription devices.

(11) Disposable medical supplies including, but not limited to, incontinence supplies as defined in Section 14125.1 of the Welfare and Institutions Code.

(12) In vitro diagnostic tests.

(13) Any other similar device as defined in regulations adopted by the department.

(c) The term “home medical device” does not include any of the following:

(1) Devices used or dispensed in the normal course of treating patients by hospitals and nursing facilities, other than devices delivered or dispensed by a separate unit or subsidiary corporation of a hospital or nursing facility or agency that is in the business of delivering home medical devices to an individual’s residence.

(2) Prosthetics and orthotics.

(3) Automated external defibrillators (AEDs).

(4) Devices provided through a physician’s office incident to a physician’s service.

(5) Devices provided by a licensed pharmacist that are used to administer drugs that can be dispensed only by a licensed pharmacist.

(6) Enteral and parenteral devices provided by a licensed pharmacist.

(Amended by Stats. 2001, Ch. 728, Sec. 70. Effective January 1, 2002.)

109950. “Immediate container” does not include any package liner.

(Added by Stats. 1995, Ch. 415, Sec. 6. Effective January 1, 1996.)

109951. “Infant formula” shall have the same definition as that term is used in the Federal Food, Drug, and Cosmetic Act (21 U.S.C. Sec. 321(z)). The department shall review all changes to the federal definition of “infant formula” before those changes are incorporated by reference pursuant to this section. Within six months after the effective date of any changes to the federal definition, the department shall complete its review of the changes, and post a report on its Internet Web site that describes the changes and makes a recommendation as to whether it is appropriate to incorporate the changes by reference pursuant to this section. Any change to the federal definition shall take effect pursuant to this section one year after the effective date of the federal change, unless a law that specifically prohibits the change from taking effect is enacted and becomes effective.

(Amended by Stats. 2012, Ch. 728, Sec. 101. (SB 71) Effective January 1, 2013.)

109955. “Label” means a display of written, printed, or graphic matter upon a food, drug, device, or cosmetic or upon its immediate container.

(Added by Stats. 1995, Ch. 415, Sec. 6. Effective January 1, 1996.)

109960. “Labeling” means any label or other written, printed, or graphic matter upon a food, drug, device, or cosmetic or upon its container or wrapper, or that accompanies any food, drug, device, or cosmetic.

(Added by Stats. 1995, Ch. 415, Sec. 6. Effective January 1, 1996.)

109965. “Local health department” means the health department of a city, county, city and county, or local health district that qualifies for state assistance pursuant to Chapter 3 (commencing with Section 101175) of Part 3 of Division 101, or any city health department of a city that has had its own health department for 12 years or more.

(Added by Stats. 1995, Ch. 415, Sec. 6. Effective January 1, 1996.)

109970. “Manufacture” means the preparation, compounding, propagation, processing, or fabrication of any food, drug, device, or cosmetic. The term “manufacture” includes repackaging or otherwise changing the container, wrapper, or labeling of any food, drug, device, or cosmetic in furtherance of the distribution of the food, drug, device, or cosmetic. The term “manufacture” does not include repackaging from a bulk container by a retailer at the time of sale to its ultimate consumer.

(Added by Stats. 1995, Ch. 415, Sec. 6. Effective January 1, 1996.)

109971. “Medical food” means any product that meets the definition of medical food in the Federal Food, Drug, and Cosmetic Act (21 U.S.C. Sec. 360ee(b)(3)). The department shall review all changes to the federal definition of “medical food” before those changes are incorporated by reference pursuant to this section. Within six months after the effective date of any changes to the federal definition, the department shall complete its review of the changes, and submit a report to the Senate Health and Human Services Committee and the Assembly Health Committee that describes the changes and makes a recommendation as to whether it is appropriate to incorporate the changes by reference pursuant to this section. Any change to the federal definition shall take effect pursuant to this section one year after the effective date of the federal change, unless a law that specifically prohibits the change from taking effect is enacted and becomes effective.

(Amended by Stats. 2001, Ch. 641, Sec. 3. Effective January 1, 2002.)

109975. “New device” means any of the following:

(a) Any device the composition, construction, or properties of which are such that the device is not generally recognized, among experts qualified by scientific training and experience to evaluate the safety and effectiveness of devices, as having been adequately shown, through scientific investigations to be safe and effective for use under the conditions prescribed, recommended, or suggested in the labeling or advertising thereof.

(b) Any device the composition, construction, or properties of which are such that the device, as a result of such investigation to determine its safety and effectiveness for use under these conditions, has become so recognized, but which has not, otherwise than in the investigations, been used to a material extent or for a material time under the conditions.

(Added by Stats. 1995, Ch. 415, Sec. 6. Effective January 1, 1996.)

109980. “New drug” means either of the following:

(a) Any drug the composition of which is such that the drug is not generally recognized, among experts qualified by scientific training and experience to evaluate the safety and effectiveness of drugs, as safe and effective for use under the conditions prescribed, recommended, or suggested in the labeling or advertising thereof.

(b) Any drug the composition of which is such that the drug, as a result of investigations to determine its safety and effectiveness for use under these conditions, has become so recognized, but that has not, otherwise than in the investigations, been used to a material extent or for a material time under the conditions.

(Added by Stats. 1995, Ch. 415, Sec. 6. Effective January 1, 1996.)

109985. “Official compendium” means the latest edition of the United States Pharmacopoeia, the latest edition of the Homeopathic Pharmacopoeia of the United States, or the latest edition of the National Formulary, or any supplement to any of these.

(Added by Stats. 1995, Ch. 415, Sec. 6. Effective January 1, 1996.)

109990. “Package” means any container or wrapper that may be used by a manufacturer, producer, jobber, packer, or dealer for enclosing or containing any food, drug, device, or cosmetic.

The term “package” does not include any of the following:

(a) Any shipping container or outer wrapping used solely for the transportation of a food, drug, device, or cosmetic in bulk quantity to any manufacturer, packer, processor, or wholesale or retail distributor.

(b) Any shipping container or outer wrapping used by any retailer to ship or deliver any food, drug, device, or cosmetic to any retail consumer if the container or wrapping bears no printed matter pertaining to any food, drug, device, or cosmetic.

(Added by Stats. 1995, Ch. 415, Sec. 6. Effective January 1, 1996.)

109992. “Pasteurized in-shell eggs” means shell eggs that have been pasteurized by any method approved by the federal Food and Drug Administration, the Department of Food and Agriculture, or the department.

(Added by Stats. 2014, Ch. 11, Sec. 6. (AB 1414) Effective April 17, 2014.)

109995. “Person” means any individual, firm, partnership, trust, corporation, limited liability company, company, estate, public or private institution, association, organization, group, city, county, city and county, political subdivision of this state, other governmental agency within the state, and any representative, agent, or agency of any of the foregoing.

(Added by Stats. 1995, Ch. 415, Sec. 6. Effective January 1, 1996.)

110000. “Pesticide chemical” means any substance that alone, in chemical combination, or in formulation with one or more substances, is an “economic poison” within the meaning of Section 12753 of the Food and Agricultural Code of this state or the

Federal Insecticide, Fungicide, and Rodenticide Act (61 Stat. 163; 7 U.S.C. Sec. 135 et seq.), and that is used in the production, storage, or transportation of any raw agricultural commodity.

(Added by Stats. 1995, Ch. 415, Sec. 6. Effective January 1, 1996.)

110005. "Potentially hazardous food" means any food capable of supporting growth of infectious or toxigenic micro-organisms when held at temperatures above 45 degrees Fahrenheit.

(Amended by Stats. 1999, Ch. 915, Sec. 2. Effective January 1, 2000.)

110010. "Prescription" means an oral order given individually for the patient for whom prescribed directly from the prescriber to the furnisher or indirectly by means of a written order signed by the prescriber that bears the name and address of the prescriber, the license classification of the prescriber, the name and address of the patient, the name and quantity of drug or device prescribed, the directions for use, and the date of issue.

(Added by Stats. 1995, Ch. 415, Sec. 6. Effective January 1, 1996.)

110010.1. "Prescription device" means any device limited to prescription use under Section 111470.

(Added by Stats. 2000, Ch. 837, Sec. 30. Effective January 1, 2001.)

110010.2. "Prescription drug" means any drug limited to prescription use under Section 111470.

(Added by Stats. 2000, Ch. 837, Sec. 31. Effective January 1, 2001.)

110015. "Principal display panel" means that part of a label most likely to be displayed, presented, shown, or examined under normal and customary conditions of display for retail sale.

(Added by Stats. 1995, Ch. 415, Sec. 6. Effective January 1, 1996.)

110020. "Raw agricultural commodity" means any food in its raw or natural state. It includes, but is not limited to, any fruit that is washed, colored, or otherwise treated in its unpeeled natural form prior to marketing.

(Added by Stats. 1995, Ch. 415, Sec. 6. Effective January 1, 1996.)

110025. (a) "Substantial evidence" means evidence consisting of adequate and well-controlled investigations, including clinical investigations, by experts qualified by scientific training and experience to evaluate the effectiveness of the drug or device involved, on the basis that it could be fairly and responsibly concluded by the experts that the drug or device will have the effect it purports or is represented to have under the conditions of use prescribed, recommended, or suggested in the labeling, proposed labeling, or advertising of any drug or device.

(b) If the department determines, based on relevant science, that data from one adequate and well-controlled clinical investigation, and confirming evidence, obtained prior to or after the investigation, sufficiently establish effectiveness, then the department may consider that data and evidence, to constitute substantial evidence for purposes of the preceding sentence.

(Amended by Stats. 2000, Ch. 796, Sec. 3. Effective January 1, 2001.)

110030. The provisions of this part regarding the selling of any food, drug, device, or cosmetic include, but are not limited to, all of the following:

(a) The manufacture, production, processing, and packing of any food, drug, device, or cosmetic.

(b) The exhibition, offer, possession, or holding of any food, drug, device, or cosmetic for sale, dispensing, giving, supplying, or applying in the conduct of any establishment.

(c) The sale, dispensing, giving, supplying, or applying of any food, drug, device, or cosmetic in the conduct of any establishment.

(Added by Stats. 1995, Ch. 415, Sec. 6. Effective January 1, 1996.)

110035. All regulations pertaining to any food, drug, device, or cosmetic adopted by the department that are in effect on the effective date of this part shall remain in effect until the department adopts regulations pursuant to this part which repeal the regulations.

(Added by Stats. 1995, Ch. 415, Sec. 6. Effective January 1, 1996.)

110036. All laws and regulations pertaining to industrial hemp products shall remain in effect until the adoption of regulations pursuant to the federal law that authorizes industrial hemp products. At that time, the department shall adopt new regulations either as necessary pursuant to the federal law or deemed necessary to protect consumers.

(Added by Stats. 2021, Ch. 576, Sec. 4. (AB 45) Effective October 6, 2021.)

110040. This part shall be so construed as to not be in conflict with the Food and Agricultural Code, or with the Alcoholic Beverage Control Act, Division 9 (commencing with Section 23000) of the Business and Professions Code, and the regulations adopted pursuant thereto.

(Added by Stats. 1995, Ch. 415, Sec. 6. Effective January 1, 1996.)