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 6. Drugs and Devices [111225 - 111656.13] *(Chapter 6 added by Stats. 1995, Ch. 415, Sec. 6.)*

ARTICLE 3. Misbranded Drugs or Devices [111330 - 111510] *(Article 3 added by Stats. 1995, Ch. 415, Sec. 6.)*

111330. Any drug or device is misbranded if its labeling is false or misleading in any particular.

(Amended by Stats. 2000, Ch. 796, Sec. 7. Effective January 1, 2001.)

111335. Any drug or device is misbranded if its labeling or packaging does not conform to the requirements of Chapter 4 (commencing with Section 110290).

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

111340. Any drug or device is misbranded unless it bears a label containing all of the following information:

(a) The name and place of business of the manufacturer, packer, or distributor.

(b) An accurate statement of the quantity of the contents in terms of weight, measure, or numerical count.

Reasonable variations from the requirements of subdivision (b) shall be permitted. Requirements for placement and prominence of the information and exemptions as to small packages shall be established in accordance with regulations adopted pursuant to Section 110380.

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

111345. Any drug or device is misbranded if any word, statement, or other information required by or under this part to appear on the label or labeling is not prominently placed on the label or labeling with conspicuousness, as compared with other words, statements, designs, or devices in the labeling, and in terms as to render it likely to be read and understood by the ordinary individual under customary conditions of purchase and use.

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

111355. (a) Any drug is misbranded unless its label bears, to the exclusion of any other nonproprietary name except the applicable, systematic chemical name or the chemical formula, all of the following information:

(1) The established name of the drug, if any.

(2) If it is fabricated from two or more ingredients, the established name and quantity of each active ingredient, including the kind and quantity or proportion of any alcohol, and also including, whether active or not, the established name and quantity or proportion of any bromides, ether, chloroform, acetanilide, acetophenetidin, antipyrine, atropine, hyoscine, hyoscyamine, codeine, arsenic, digitalis, digitalis glycosides, mercury, ouabain, strophanthin, strychnine, barbituric acid, or any derivative or preparation of any substances contained therein.

(3) For nonprescription drugs, the quantity or proportion of each active ingredient and the established name of each inactive ingredient in accordance with Sections 502(e)(1)(A)(ii) and (iii) of the federal act (21 U.S.C. 352(e)(1)(A)(ii) and (iii)).

(b) The requirement for stating the quantity of the active ingredients of any drug, including the quantity or proportion of any alcohol, and also including, whether active or not, the quantity or proportion of any bromides, ether, chloroform, acetanilide, acetophenetidin, antipyrine, atropine, hyoscine, hyoscyamine, codeine, arsenic, digitalis, digitalis glycosides, mercury, ouabain, strophanthin,

strychnine, barbituric acid, or any derivative or preparation of any substances contained therein, shall apply to all drugs, including prescription drugs and nonprescription drugs. However, the requirement for declaration of quantity shall not apply to nonprescription drugs that are also cosmetics, as defined in Section 201(i) of the federal Food, Drug, and Cosmetic Act (21 U.S.C. Sec. 321(i)) and that are labeled in compliance with federal labeling requirements concerning declaration of ingredients including active ingredients and also the quantity and proportion of any alcohol, except that the quantity or proportion of the following ingredients, whether active or not, shall be declared: bromides, ether, chloroform, acetanilide, acetophenetidin, antipyrine, atropine, hyoscine, hyoscyamine, codeine, arsenic, digitalis, digitalis glycosides, mercury, ouabain, strophanthin, strychnine, barbituric acid, or any derivative or preparation of any substances contained therein. The department may exempt any nonprescription drug from the requirement of stating the quantity of the active ingredients, other than those specifically named in this subdivision, upon a showing by the applicant through evidence satisfactory to the department that the granting of the exemption will not endanger the public health. For any prescription drug the established name of the drug or ingredient, as the case may be, on the label and on any labeling on which a name for the drug or ingredient is used shall be printed prominently and in type at least half as large as that used thereon for any proprietary name or designation for the drug or ingredient.

The changes made in this section by Chapter 943 of the Statutes of 1978 shall not apply to any drug shipped by a manufacturer or packer to a retailer or wholesaler before January 1, 1980. Any such drugs so shipped shall comply with this section on and after January 1, 1981.

(Amended by Stats. 2000, Ch. 796, Sec. 9. Effective January 1, 2001.)

111360. Any drug subject to Section 111470 is misbranded unless the manufacturer, packer, or distributor of the drug includes, in all advertisements and other descriptive matter issued or caused to be issued by the manufacturer, packer, or distributor with respect to that drug, a true statement of all of the following:

(a) The established name, printed prominently and in a type at least half as large as that used for any proprietary name of the drug.

(b) The formula showing quantitatively each ingredient of the drug to the extent required for labels under Section 111355.

(c) The name and place of business of the manufacturer that produced the finished dosage form of the drug, as prescribed by regulations issued by the department. This subdivision applies only to advertisements or descriptive matter issued for drugs manufactured in finished dosage form on or after April 1, 1973.

(d) Such other information, in brief summary relating to side effects, contraindications, and effectiveness as shall be required by regulations promulgated by the department.

Regulations relating to side effects, contraindications, and effectiveness issued pursuant to Section 502(n) of the federal act (21 U.S.C. Sec. 352(n)) are the regulations establishing information requirements relating to side effects, contraindications and effectiveness in this state. The department may, by regulation, make other requirements relating to side effects, contraindications, and effectiveness whether or not in accordance with the regulations adopted under the federal act.

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

111365. Any drug subject to Section 111470 is misbranded unless the established name of the prescription drug or prescription drug ingredient is printed on the label prominently and in type at least half as large as that used for the proprietary name or designation on the label, labeling, or advertising.

The department may, by regulation, establish exemptions from the requirements of this section when compliance with this section is not considered necessary for the protection of health and safety.

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

111375. Any drug or device is misbranded unless its labeling bears all of the following information:

(a) Adequate directions for use.

(b) Such adequate warnings against use in pathological conditions or by children where its use may be dangerous to health.

(c) Adequate warning against unsafe dosage or methods or duration of administration or application.

Warnings shall be in a manner and form as are necessary for the protection of users.

If the department determines that any requirement of subdivision (a), as applied to any drug or device, is not necessary for the protection of the public health, the department may adopt regulations exempting the drug or device from these requirements.

Any drug or device exempted under Section 502(f) of the federal act (21 U.S.C. Sec. 352(f)) is exempt from the requirement of this section. The department, however, may adopt any regulation including a drug or device within, or excluding a drug or device from the requirements of this section, whether or not the inclusion or exclusion of the drug or device is in accord with the federal act.

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

111380. Any drug is misbranded if it purports to be a drug that is recognized in an official compendium and it is not packaged and labeled as prescribed in the official compendium. The method of packaging, however, may be modified with the consent of the department.

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

111385. Any drug or device is misbranded if the department determines that the drug or device is liable to deterioration, unless it is packaged in that form and manner and its label bears a statement of the precautions, as the department, by regulation, may require as necessary for the protection of public health. Such regulations shall not be established for any drug or device recognized in an official compendium, unless the department has informed the appropriate body, charged with the revision of the official compendium, of the need for that packaging or labeling requirements and that body has not prescribed the requirements in a reasonable length of time.

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

111390. Any drug or device is misbranded if its container is so made, formed, or filled as to be misleading.

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

111395. Any drug is misbranded in any of the following cases:

(a) It is an imitation of another drug.

(b) It is offered for sale under the name of another drug.

(c) The contents of the original package have been, wholly or partly, removed and replaced with other material in the package.

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

111397. (a) Any foreign dangerous drug that is not approved by the United States Food and Drug Administration or that is obtained outside of the licensed supply chain regulated by the United States Food and Drug Administration, California State Board of Pharmacy, or State Department of Public Health is misbranded.

(b) Any foreign dangerous drug that is imported lawfully under the Federal Food, Drug, and Cosmetic Act (21 U.S.C. Sec. 301 et seq.) or pursuant to an announcement by the United States Food and Drug Administration of the exercise of enforcement discretion for instances including, but not limited to, clinical research purposes, drug shortages, development of countermeasures against chemical, biological, radiological, and nuclear terrorism agents, or pandemic influenza preparedness and response is not misbranded.

(Added by Stats. 2014, Ch. 492, Sec. 13. (SB 600) Effective January 1, 2015.)

111400. Any drug or device is misbranded if it is dangerous to health when used in the dosage, or with the frequency or duration prescribed, recommended, or suggested in its labeling.

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

111415. Any drug is misbranded if it is a color additive, intended for use in or on drugs for the purpose of coloring only and its packaging and labeling fail to conform to the packaging and labeling requirements adopted pursuant to Section 110090.

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

111420. A drug or device is misbranded if a trademark, trade name, or other identifying mark, imprint, or device of another person, or any likeness of the trademark, trade name, or other identifying mark, imprint, or device of another person, has been placed on the drug or device, or upon its container.

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

111425. A drug or device is misbranded if it was manufactured in this state in an establishment not duly licensed as provided in this part.

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

111430. A drug or device is misbranded if it was manufactured in an establishment not duly registered with the Secretary of Health, Education, and Welfare of the United States.

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

111435. Any drug is misbranded if its packaging or labeling is in violation of an applicable regulation issued pursuant to Section 108685 or 108700.

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

111440. It is unlawful for any person to manufacture, sell, deliver, hold, or offer for sale any drug or device that is misbranded.

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

111445. It is unlawful for any person to misbrand any drug or device.

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

111450. It is unlawful for any person to receive in commerce any drug or device that is misbranded or to deliver or proffer for delivery any drug or device.

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

111455. It is unlawful for any person to alter, mutilate, destroy, obliterate, or remove the label or any part of the labeling of any drug or device if the act results in the drug or device being misbranded.

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

111460. Any drug or device intended for export shall not be deemed to be misbranded under this part if it satisfies all of the following requirements:

(a) It accords to the specifications of the foreign purchaser.

(b) It is not in conflict with the laws of the importing country.

(c) It is labeled on the outside of the shipping package to show that it is intended for export.

If the article is sold or offered for sale in domestic commerce, this section shall not exempt it from any of the provisions of this part.

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

111465. A drug or device is deemed misbranded under the laws of this state if it is subject to regulations issued by the United States Food and Drug Administration relating to tamper-resistant packaging, as set forth in Parts 200, 211, 314, and 800 of Volume 21 of the Code of Federal Regulations, as amended, but is not in compliance therewith.

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

111470. The following drugs or devices, that are intended for use by man, shall be sold only upon a written prescription of a practitioner licensed by law to prescribe the drug or device, or upon an oral prescription of the licensee that is reduced promptly to writing and filed by the pharmacist, or by refilling the written or oral prescription if the refilling is authorized by the prescriber either in the original prescription or by oral order that is reduced promptly to writing and filed by the pharmacist:

(a) A habit forming drug to which Section 111350 applies.

(b) A drug or device that, because of its toxicity or other potentiality for harmful effect, or the method of its use, or the collateral measures necessary to its use, is not safe for use except under the supervision of a practitioner licensed by law to administer the drug or device.

(c) A drug or device for which adequate directions cannot be written for persons, who are not practitioners licensed by law to prescribe the drug or device, for safe and effective self-medication or treatment by those persons, who are not practitioners licensed by law to prescribe the drug or device.

(d) A drug or device that is limited by an effective application under Section 505 of the federal act (21 U.S.C. Sec. 355) or Section 111550 to use under the professional supervision of a practitioner licensed by law to administer the drug or device.

If any prescription for the drug does not indicate the number of times it may be refilled, if any, the prescription may not be refilled unless the pharmacist obtains a new order from the practitioner.

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

111475. The act of selling a drug or device contrary to Section 111470 shall be deemed to be an act that results in the drug or device being misbranded while held for sale.

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

111480. Any drug or device sold by filling or refilling a written or oral prescription of a practitioner licensed to prescribe the drug or device shall be exempt from the labeling requirements of Sections 111335, 111340, 111350, 111355, 111360, 111365, 111375, 111380, 111385, 111395, 111415, and 111420, if the drug or device bears a label displaying all the following:

(a) Except where the prescriber orders otherwise, either the manufacturer's trade name of the drug, or the generic name and the name of the manufacturer. Commonly used abbreviations may be used. Preparations containing two or more active ingredients may be identified by the manufacturer's trade name or the commonly used name or the principal active ingredients.

(b) The directions for the use of the drug or device.

(c) The name of the patient(s).

(d) The name of the prescriber.

(e) The date of issue.

(f) The name, address of the furnisher, and prescription number or other means of identifying the prescription.

(g) The strength of the drug or drugs dispensed.

(h) The quantity of the drug or drugs dispensed.

(i) The expiration date of the effectiveness of the drug or device if the information is included on the original label of the manufacturer of the drug or device.

If a pharmacist dispenses a prescribed drug by means of a unit dose medication system, as defined by administrative regulation, for a patient in a skilled nursing, intermediate care or other health care facility, the requirements of this section will be satisfied if the unit dose medication system contains the aforementioned information or the information is otherwise readily available at the time of drug administration.

The exemption shall not apply to any drug or device dispensed in the course of the conduct of a business of dispensing drugs or devices pursuant to diagnosis by mail, or to a drug or device dispensed in violation of Section 111470.

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

111485. The department may, by regulation, remove any drug or device subject to Sections 111350 and 111550 from the requirements of Section 111470, when the requirements are not necessary for the protection of the public health. Any drug removed from the prescription requirements of the federal act by regulations adopted pursuant to the federal act is removed from the requirements of Section 111470. The department may, however, by regulation, continue the applicability of Section 111470 for any drug or device, or make these sections inapplicable to any drug or device, whether or not the inclusion or exclusion of the drug or device is in accordance with the regulations adopted pursuant to the federal act.

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

111490. (a) A drug or device that is subject to Section 111470 is misbranded if at any time prior to dispensing, its label fails to bear the statement "Caution: federal law prohibits dispensing without prescription," or "Caution: state law prohibits dispensing without prescription," or "R x only." A drug or device to which Section 111470 does not apply is misbranded if at any time prior to dispensing its label bears the caution statement or "R x only" quoted in the preceding sentence.

(b) A device that is subject to Section 111470 is misbranded if, at any time prior to dispensing, its label fails to bear the statement "Caution: federal law restricts this device to sale by or on the order of a ____ ," the blank to be filled in with the designation of the practitioner licensed to use or order use of the device. A device to which Section 111470 does not apply is misbranded if, at any time prior to dispensing, its label bears the caution statement quoted in the preceding sentence.

(Amended by Stats. 2000, Ch. 796, Sec. 12. Effective January 1, 2001.)

111495. Nothing in this article shall be construed to relieve any person from any requirement prescribed by or under authority of law with respect to drugs now included or that may hereafter be included within the classification stated in Division 10 (commencing with Section 11000) or in the applicable federal law relating to controlled substances.

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

111500. A physician, dentist, podiatrist, or veterinarian may personally furnish his or her own patient with drugs as are necessary in the treatment of the condition for which he or she attends the patient provided that the drug is properly labeled to show all the information required in Section 111480 except the prescription number.

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

111505. For purposes of Section 111510, the following definitions shall apply:

(a) “Distributor” means any corporation, person, or other entity, not engaged in the manufacture of a legend drug product, who distributes for resale and distribution a legend drug product under the label of the corporation, person, or entity.

(b) “Legend drug” means any controlled substance subject to the Federal Controlled Substances Act (Title II, P.L. 91-513) or subject to the Uniform Controlled Substances Act, Division 10 (commencing with Section 11000), and any drug described in Section 4211 of the Business and Professions Code or Section 111470.

(c) “Solid dosage forms” means capsules or tablets intended for oral administration.

(d) “Code imprint” means a series of letters or numbers assigned by the manufacturer or distributor to a specific drug, or marks or monograms unique to the manufacturer, distributor, or both. The National Drug Code may be used as a code imprint.

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

111510. (a) No legend drug in solid dosage form may be manufactured or distributed for sale in this state unless it is clearly marked or imprinted with a code imprint identifying the drug and the manufacturer or distributor of the drug. Manufacturers or distributors who only repack an already finished dosage form of a legend drug shall not have the responsibility to do the imprint.

(b) On or before July 1, 1982, manufacturers or distributors of legend drugs, depending on whether the manufacturer’s or distributor’s code imprint will appear on the surface of the solid dosage form, shall provide to the department a list of their legend drugs and the intended code imprints. The department shall provide for the distribution of the information required to be submitted under this subdivision to all poison control centers in the state. Manufacturers, distributors, and the department shall provide to any licensed health care provider, upon request, lists of legend drugs and code imprints provided to the department under this section, but may charge a reasonable fee to cover copying and postage costs. Updated lists shall be provided to the department annually or as changes or revisions occur.

(c) The department may grant exemptions from the requirements of this section upon application of a manufacturer or distributor indicating size or other characteristics that render the product impractical for the imprinting required by this section.

(d) A legend drug that does not meet the requirements is misbranded.

(e) It is the intent of the Legislature that all legend drugs having solid dosage forms be imprinted regardless of by whom they are distributed.

(f) This section shall apply to all legend drugs sold in California on or after January 1, 1983.

(g) Pharmacists, pharmacies, and licensed wholesalers shall only be liable for knowing and willful violations of this section, except that no liability shall accrue if the pharmacist acts pursuant to Section 4229.5 of the Business and Professions Code.

(h) The provisions of subdivisions (a) to (g), inclusive, shall not apply to any of the following:

(1) Drugs purchased by a pharmacy, pharmacist, or licensed wholesaler prior to January 1, 1983, and held in stock for resale.

(2) Drugs that are the subject of an investigation pursuant to Section 111590 or 111595.

(3) Drugs that are manufactured by or upon the order of a practitioner licensed by law to prescribe or administer drugs and that are to be used solely by the patient for whom prescribed.

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