Drug Misbranding Laws

California Business and Professions Code

4022 – Defines "Dangerous drug" or "dangerous device" means any drug or device unsafe for self-use in humans or animals.

4169(a)(3) – A prescriber shall not dispense drugs or dangerous devices to patients in the prescriber's office or place of practice unless all of the following conditions are met: The Medical Board of California, the California State Board of Optometry, the California Board of Naturopathic Medicine, the Dental Board of California, the Podiatric Medical Board of California, the Osteopathic Medical Board of California, the Board of Registered Nursing, the Veterinary Medical Board, and the Physician Assistant Board shall have authority with the California State Board of Pharmacy to ensure compliance with this section, and those boards are specifically charged with the enforcement of this chapter with respect to their respective licensees.

4170(c) – Provides exceptions for certain entities (such as clinics or licensed professionals) from wholesaler licensure requirements under limited circumstances.

4342(a) – The board may institute any action or actions as may be provided by law and that, in its discretion, are necessary, to prevent the sale of pharmaceutical preparations and drugs that do not conform to the standard and tests as to quality and strength, provided in the latest edition of the United States Pharmacopoeia or the National Formulary, or that violate any provision of the Sherman Food, Drug, and Cosmetic Law

4883(g)(3) – The board may deny, revoke, or suspend a license or registration or assess a fine as provided in Section 4875 for any of the following: A violation of any federal statute, rule, or regulation or any of the statutes, rules, or regulations of this state regulating dangerous drugs or controlled substances.

California Code of Regulations, Title 16

2030(f)(6) – Requires veterinarians to ensure all drugs and biologicals shall be maintained, administered, dispensed and prescribed in compliance with state and federal laws.

California Health and Safety Code

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

111335 – Defines misbranding and lists criteria that make a drug misbranded, such as false or misleading labeling. Any drug or device is misbranded if its labeling or packaging does not conform to the requirements of Chapter 4

111430 – States that 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.

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

111450 – Makes 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.

United States Code of Federal Regulations

21 USC 331(a),(c) – The following acts and the causing thereof are prohibited: The introduction or delivery for introduction into interstate commerce of any food, drug, device, tobacco product, or cosmetic that is adulterated or misbranded. (a) The receipt in interstate commerce of any food, drug, device, tobacco product, or cosmetic that is adulterated or misbranded, and the delivery or proffered delivery thereof for pay or otherwise. (c)

21 USC 333(b)(1) – Provides for criminal penalties (including fines and imprisonment) for intentional violations related to misbranding and adulteration.

21 USC 351(a)(5) – A drug or device shall be deemed to be adulterated—if it is a new animal drug which is unsafe within the meaning of section 360b of this title

21 USC 352(a)(1) – A drug or device shall be deemed to be misbranded—If its labeling is false or misleading in any particular.

21 USC 352(o),(w) – Addresses misbranding for animal drugs, including failure to register facilities (o) and possession/use of unapproved new animal drugs (w).