

Assembly Bill No. 764

CHAPTER 516

An act to amend Sections 110165, 110305, 110403, 110405, and 111635 of, and to repeal Section 110408 of, the Health and Safety Code, relating to food and drugs.

[Approved by Governor September 28, 1997. Filed
with Secretary of State September 29, 1997.]

LEGISLATIVE COUNSEL'S DIGEST

AB 764, Davis. Food and drug inspections.

Existing law, the Sherman Food, Drug, and Cosmetic Laws, requires the State Department of Health Services to cause a special investigation of the preparation and sale of drugs and food and their adulteration. Existing law also requires the department to perform duties that are required by law for the detection and prevention of the adulteration of articles used for food and drink, and for the punishment of persons who are found guilty of violating any law that provides against their adulteration.

Existing law provides that it is unlawful for any person to use to his or her own advantage, or to reveal to any person other than to the director, officers, or employees of the department, or to the courts when relevant in any judicial proceeding under the Sherman Food, Drug, and Cosmetic Laws, any information acquired under authority of that law concerning any method or process which as a trade secret is entitled to protection.

This bill would permit an authorized agent of the department to receive the trade secret information. The bill would authorize the department to reveal trade secret information in connection with the responsibilities of the department under the Sherman Food, Drug, and Cosmetic Laws, to any employee of the federal Food and Drug Administration who is authorized in writing by the Chief of the Food and Drug Branch of the department or his or her designee to receive this type of information. The employee receiving this type of information would be subject to certain procedures relating to maintaining the confidentiality of the information.

Existing law provides that it is unlawful for any person to use on the labeling of any drug or device, or any advertisement relating to any drug or device, any representation or suggestion that an application is effective under a prescribed provision of law relating to new drugs and devices or that the drug or device complies with that law.

This bill would revise this provision to no longer apply to an advertisement relating to any drug or device.

Existing law provides that it is unlawful for any person to advertise any drug or device represented to have any effect in enumerated conditions, disorders, or diseases.

This bill would create an exception to that provision if the advertisement is disseminated or distributed as prescribed or, as to certain advertisements, has received approval or clearance for that marketing through designated means.

Under existing law, it is unlawful for any person to disseminate any false advertisement of any food, drug, device, or cosmetic. Existing law provides that an advertisement of a drug or device represented to have an effect in enumerated conditions, disorders, or diseases is not unlawful, under this and other provisions, if it is disseminated only to members of the medical, dental, pharmaceutical, or veterinary professions, or appears only in the scientific periodicals of these professions, or is disseminated only for the purpose of public health education by persons not commercially interested, directly or indirectly, in the sale of drugs or devices.

This bill would provide that an advertisement that a drug or device has a specific curative or therapeutic effect on the enumerated conditions, disorders, or diseases mentioned above is not unlawful under these provisions if the drug or device is approved or cleared for marketing for that specific curative or therapeutic effect through any one of designated means.

Existing law provides that whenever the department determines that an advance in medical science has made any type of self-medication safe and effective as to any of the enumerated conditions, disorders, or diseases mentioned above, the department shall, by regulation, authorize the advertisement of that drug or device as having a curative or therapeutic effect for the disease, subject to conditions and restrictions as the department may consider necessary to the interests of public health.

This bill would repeal this provision.

Existing law requires the department to inspect each place of business for the manufacture of any drug or device prior to issuing a license or renewing a license annually.

This bill would delete the requirement that the department inspect each place of business prior to renewing an annual license. The bill would require the department, in addition to the inspection prior to issuing an initial license, to inspect the place of business once every 2 years. The bill would require the department to use the information contained in the written documentation pertaining to an inspection conducted within the previous 2 years by the United States Food and Drug Administration (USFDA) and would authorize the department to inspect to obtain information not included or not sufficiently clear in the USFDA written documentation. It would also authorize the department to use, in lieu of all or part of any inspection required under these provisions, information from audits conducted



pursuant to various quality system standards or other information identified by the department by regulation.

Existing law prohibits any person from manufacturing any drug or device without a license from the department and exempts from that licensure requirement certain entities.

This bill would also exempt from licensure any person who has registered an establishment and listed all products in compliance with a prescribed federal law and submits a copy of the federal registration and listing to the department in accordance with regulations established by the department.

The people of the State of California do enact as follows:

SECTION 1. The Legislature finds and declares all of the following:

(a) The medical technology industry, encompassing biotechnology and medical device and equipment manufacturing, is a rapidly growing California industry, and is critical to the future health of California's economy.

(b) This industry produces therapeutic drugs, medical devices, equipment, and diagnostic products transforming the practice of medicine and improving the lives of millions of patients around the world.

(c) The majority of the companies comprising this sector are small businesses who must invest heavily in research and development for several years before they market their first product, and who are heavily impacted by federal and state regulation.

(d) The businesses that comprise this industry are subject to rigorous health and safety regulation by both the U.S. Food and Drug Administration (FDA) and the Food and Drug Branch of the State Department of Health Services.

(e) The Legislature should, to the extent possible, seek to reasonably reform state laws and regulations with respect to this industry, with the goal being to eliminate duplicative procedures which add no value to consumers. Additional goals of the Legislature include to harmonize state and federal regulatory requirements, promote federal-state planning and information sharing, and assure that state health protection resources are used in an efficient manner that maximizes public health protection.

SEC. 2. Section 110165 of the Health and Safety Code is amended to read:

110165. It is unlawful for any person to use to his or her own advantage, or to reveal to any person other than to the director, officers, employees, or authorized agents of this department, or to the courts when relevant in any judicial proceeding under this part, any information acquired under authority of this part concerning any method or process which as a trade secret is entitled to protection.



However, the department may reveal trade secret information in connection with the responsibilities of the department under this part, to any employee of the federal Food and Drug Administration who is authorized in writing by the Chief of the Food and Drug Branch of the department or his or her designee to receive this type of information. The employee receiving this type of information shall be informed in writing of the prohibitions under this section, shall be informed in writing that the information provided contains trade secrets, as defined under state and federal law, and shall agree in writing to keep the information confidential.

SEC. 3. Section 110305 of the Health and Safety Code is amended to read:

110305. It is unlawful for any person to use on the label of any drug or device any representation or suggestion that an application with respect to the drug or device is effective under Section 111550 or that the drug or device complies with that section.

SEC. 4. Section 110403 of the Health and Safety Code is amended to read:

110403. Except as otherwise provided in Section 110405, it is unlawful for any person to advertise any drug or device represented to have any effect in any of the following conditions, disorders, or diseases:

- (a) Appendicitis.
- (b) Blood disorders.
- (c) Bone or joint diseases.
- (d) Kidney diseases or disorders.
- (e) Cancer.
- (f) Carbuncles.
- (g) Diseases, disorders, or conditions of the eye.
- (h) Diabetes.
- (i) Diphtheria.
- (j) Gallbladder diseases or disorders.
- (k) Heart and vascular diseases.
- (l) High blood pressure.
- (m) Diseases or disorders of the ear or auditory apparatus, including hearing loss and deafness.
- (n) Measles.
- (o) Meningitis.
- (p) Mental disease or mental retardation.
- (q) Paralysis.
- (r) Pneumonia.
- (s) Poliomyelitis.
- (t) Prostate gland disorders.
- (u) Conditions of the scalp, affecting hair loss, or baldness.
- (v) Alcoholism.
- (w) Periodontal diseases.
- (x) Epilepsy.



- (y) Goiter.
- (z) Endocrine disorders.
- (aa) Sexual impotence.
- (ab) Sinus infections.
- (ac) Encephalitis.
- (ad) Tumors.
- (ae) Venereal diseases.
- (af) Tuberculosis.
- (ag) Ulcers of the stomach.
- (ah) Varicose ulcers.
- (ai) Scarlet fever.
- (aj) Typhoid fever.
- (ak) Whooping cough.
- (al) Acquired immune deficiency syndrome (AIDS).
- (am) AIDS-related complex (ARC).
- (an) Diseases, disorders, or conditions of the immune system.

SEC. 5. Section 110405 of the Health and Safety Code is amended to read:

110405. An advertisement that is not unlawful under Section 110390 is not unlawful under Section 110403 if it is either one of the following:

(a) Disseminated only to members of the medical, dental, pharmaceutical, or veterinary professions, or appears only in the scientific periodicals of these professions, or is disseminated only for the purpose of public health education by persons not commercially interested, directly or indirectly, in the sale of drugs or devices.

(b) An advertisement that a drug or device has a specific curative or therapeutic effect on a condition, disorder, or disease listed in Section 110403 if the drug or device is approved or cleared for marketing for that specific curative or therapeutic effect through any of the following means:

(1) A new drug application approved pursuant to Section 111500 or Section 505 of the federal act (21 U.S.C. Sec. 355).

(2) An abbreviated new drug application approved pursuant to Section 505 of the federal act (21 U.S.C. Sec. 355).

(3) A licensed biological product pursuant to Section 351 of the Public Health Service Act (42 U.S.C. Sec. 262).

(4) An over the counter drug that meets the requirements of Part 330 of Title 21 of the Code of Federal Regulations.

(5) A new animal drug application approved under Section 512 of the federal act (21 U.S.C. Sec. 360b).

(6) An abbreviated new animal drug application approved pursuant to Section 512 of the federal act (21 U.S.C. Sec. 360b).

(7) A new device application approved pursuant to Section 111550.

(8) A device premarket approval application approved under Section 515 of the federal act (21 U.S.C. Sec. 360e).



(9) A determination of substantial equivalence for a device pursuant to Section 513(f)(1) of the federal act (21 U.S.C. Sec. 360c(i)).

SEC. 6. Section 110408 of the Health and Safety Code is repealed.

SEC. 7. Section 111635 of the Health and Safety Code is amended to read:

111635. (a) Prior to issuing a license required by Section 111615, the department shall inspect each place of business.

(b) The department shall subsequently inspect the place of business of each person licensed under Section 111615 once every two years. The department shall conduct these inspections to determine ownership, adequacy of facilities, and personnel qualifications. Where the United States Food and Drug Administration has conducted an inspection of the place of business within the previous two years, the department shall use the information contained in the written documentation pertaining to that inspection rather than conducting its own inspection pursuant to this subdivision. The department may, if necessary, inspect to obtain information not included or not sufficiently clear in the United States Food and Drug Administration written documentation pertaining to the inspection and needed to determine ownership, adequacy of facilities, personnel qualifications, and compliance with this part.

(c) The department may, in lieu of all or part of any inspection required under this section, use information from audits conducted pursuant to the provisions of the International Standards Organization (ISO) 9000 series or European (EN) 46000 series quality system standards, or other information identified by the department by regulation.

