

**ASSEMBLY BILL**

**No. 556**

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**Introduced by Assembly Member Davis**

February 19, 1999

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An act to amend Sections 109925, 110025, 110110, 110405, 111330, 111355, 111490, and 111610 of, and to repeal Sections 109890, 110305, 111350, 111405, and 111410 of, the Health and Safety Code, relating to food and drugs.

LEGISLATIVE COUNSEL'S DIGEST

AB 556, as introduced, Davis. Food and drug inspections.

Existing law, the Sherman Food, Drug, and Cosmetic Law, 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 the law that provides against their adulteration.

This bill would conform these provisions to the federal Food and Drug Administration Modernization Act of 1997 with regard to the regulation of products subject to the federal Food and Drug Administration jurisdiction.

Vote: majority. Appropriation: no. Fiscal committee: yes. State-mandated local program: no.

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

1 SECTION 1. Section 109890 of the Health and Safety  
2 Code is repealed.

3 ~~109890. “Antibiotic drug” means any drug intended~~  
4 ~~for use by man or other animal and that contains any~~  
5 ~~quantity of any chemical substance produced by a~~  
6 ~~micro-organism or the chemically synthesized equivalent~~  
7 ~~and that, in dilute solutions, has the capacity to inhibit or~~  
8 ~~destroy micro-organisms.~~

9 SEC. 2. Section 109925 of the Health and Safety Code  
10 is amended to read:

11 109925. “Drug” means any of the following:

12 (a) Any article recognized in an official compendium.

13 (b) Any article used or intended for use in the  
14 diagnosis, cure, mitigation, treatment, or prevention of  
15 disease in human beings or any other animal.

16 (c) Any article other than food, that is used or  
17 intended to affect the structure or any function of the  
18 body of human beings or any other animal.

19 (d) Any article used or intended for use as a  
20 component of any article designated in subdivision (a),  
21 (b), or (c) of this section.

22 The term “drug” does not include any device.

23 Any food for which a claim, (as described in Sections  
24 403(r)(1)(B) (21 U.S.C. Sec. 343(r)(1)(B)) and  
25 403(r)(3) (21 U.S.C. Sec. 343(r)(3)) or Sections  
26 403(r)(1)(B) (21 U.S.C. Sec. 343(r)(1)(B)) and  
27 403(r)(5)(D) (21 U.S.C. Sec. 343(r)(5)(D)) of the  
28 federal act), is made in accordance with the  
29 requirements set forth in Section 403(r) (21 U.S.C. Sec.  
30 343(r)) of the federal act, is not a drug under subdivision  
31 (b) solely because the label or labeling contains such a  
32 claim.

33 (e) *Any requirement for a nonprescription drug shall*  
34 *comply with the provisions of Section 751 of the federal*  
35 *act (21 U.S.C. Sec. 379r).*

36 SEC. 3. Section 110025 of the Health and Safety Code  
37 is amended to read:



1 110025. (a) “Substantial evidence” means evidence  
2 consisting of adequate and well-controlled investigations,  
3 including clinical investigations, by experts qualified by  
4 scientific training and experience to evaluate the  
5 effectiveness of the drug or device involved, on the basis  
6 of that it could be fairly and responsibly concluded by the  
7 experts that the drug or device will have the effect it  
8 purports or is represented to have under the conditions  
9 of use prescribed, recommended, or suggested in the  
10 labeling, proposed labeling, or advertising of any drug or  
11 device.

12 (b) *“Substantial evidence” shall have the meaning*  
13 *established in Section 505(d) of the federal act (21 U.S.C.*  
14 *Sec. 355(d)).*

15 SEC. 4. Section 110110 of the Health and Safety Code  
16 is amended to read:

17 110110. (a) All regulations relating to (1) new drug  
18 applications, except for abbreviated new drug  
19 applications, adopted pursuant to ~~Section 505 of the~~  
20 ~~federal act (21 U.S.C. Sec. 355)~~ *Sections 505, 506, 506A,*  
21 *551-557, 561, 746, and 756 of the federal act (21 U.S.C. Secs.*  
22 *355, 356, 356a, 360aaa-360bbb, 379, and 379v), (2)*  
23 *applications for premarket approval of new devices,*  
24 *adopted pursuant to Section 515 of the federal act (21*  
25 *U.S.C. Sec. 360e), and (3) postmarketing reports,*  
26 *recordkeeping, and other postapproval requirements for*  
27 *approved new drug applications or approved new device*  
28 *premarket approval applications, adopted pursuant to*  
29 *the federal act, that are in effect on January 1, 1993, or that*  
30 *are adopted on or after that date, shall be the new drug*  
31 *and new device application regulations of this state, and*  
32 *(4) drug compounding, adopted pursuant to Section*  
33 *503A of the federal act (21 U.S.C. Sec. 353a).*

34 (b) The department may, by regulation, adopt any  
35 new drug or new device application regulation that it  
36 determines is necessary for the administration and  
37 enforcement of this part, whether or not the regulation  
38 is in accordance with the regulations adopted pursuant to  
39 the federal act.



1 SEC. 5. Section 110305 of the Health and Safety Code  
2 is repealed.

3 ~~110305. It is unlawful for any person to use on the label  
4 of any drug or device any representation or suggestion  
5 that an application with respect to the drug or device is  
6 effective under Section 111550 or that the drug or device  
7 complies with that section.~~

8 SEC. 6. Section 110405 of the Health and Safety Code  
9 is amended to read:

10 110405. An advertisement that is not unlawful under  
11 Section 110390 is not unlawful under Section 110403 if it  
12 is either one of the following:

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

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

26 (1) A new drug application approved pursuant to  
27 Section 111500 or ~~Section~~ *Sections 505 or 506* of the federal  
28 act (21 U.S.C. ~~Secs~~ *Secs 355 or 356*).

29 (2) An abbreviated new drug application approved  
30 pursuant to Section 505 of the federal act (21 U.S.C. Sec.  
31 355).

32 (3) A licensed biological product pursuant to Section  
33 351 of the Public Health Service Act (42 U.S.C. Sec. 262).

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

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



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

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

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

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

12 SEC. 7. Section 111330 of the Health and Safety Code  
13 is amended to read:

14 111330. (a) Any drug or device is misbranded if its  
15 labeling is false or misleading in any particular.

16 (b) *Health care economic information may be*  
17 *provided as set forth in Section 502(a) of the federal act*  
18 *(21 U.S.C. Sec. 352(a)).*

19 SEC. 8. Section 111350 of the Health and Safety Code  
20 is repealed.

21 ~~111350. Any drug is misbranded if it is for use by man~~  
22 ~~and contains any quantity of the narcotic or hypnotic~~  
23 ~~substances alpha-eucaine, barbituric acid, beta-eucaine,~~  
24 ~~bromal, cannabis, carbromal, chloral, coea, cocaine,~~  
25 ~~codeine, heroin, marijuana, morphine, opium,~~  
26 ~~paraldehyde, peyote, or sulfonmethane; or any chemical~~  
27 ~~derivative of those substances, that derivative, after~~  
28 ~~investigation, has been found to be and designated as~~  
29 ~~habit forming, by regulations adopted by the~~  
30 ~~department, unless its label bears the name and quantity~~  
31 ~~or proportion of the substance or derivative and in~~  
32 ~~juxtaposition therewith the statement, "Warning may~~  
33 ~~be habit forming."~~

34 ~~Regulations designating habit-forming drugs issued~~  
35 ~~pursuant to Section 502(d) of the federal act (21 U.S.C.~~  
36 ~~Sec. 352(d)) are the regulations designating~~  
37 ~~habit-forming drugs in this state. However, the~~  
38 ~~department may, by regulation, designate habit-forming~~  
39 ~~drugs whether or not these habit-forming drugs are in~~



1 ~~accordance with the regulations adopted under the~~  
2 ~~federal act.~~

3 SEC. 9. Section 111355 of the Health and Safety Code  
4 is amended to read:

5 111355. (a) Any drug is misbranded unless its label  
6 bears, to the exclusion of any other nonproprietary name  
7 except the applicable, systematic chemical name or the  
8 chemical formula, all of the following information:

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

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

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

26 (b) The requirement for stating the quantity of the  
27 active ingredients of any drug, including the quantity or  
28 proportion of any alcohol, and also including, whether  
29 active or not, the quantity or proportion of any bromides,  
30 ether, chloroform, acetanilide, acetophenetidin,  
31 antipyrine, atropine, hyoscine, hyoscyamine, codeine,  
32 arsenic, digitalis, digitalis glycosides, mercury, ouabain,  
33 strophanthin, strychnine, barbituric acid, or any  
34 derivative or preparation of any substances contained  
35 therein, shall apply to all drugs, including prescription  
36 drugs and nonprescription drugs. However, the  
37 requirement for declaration of quantity shall not apply to  
38 nonprescription drugs that are also cosmetics, as defined  
39 in Section 201(i) of the federal Food, Drug, and Cosmetic  
40 Act (21 U.S.C. Sec. 321(i)) and that are labeled in



1 compliance with federal labeling requirements  
2 concerning declaration of ingredients including active  
3 ingredients and also the quantity and proportion of any  
4 alcohol, except that the quantity or proportion of the  
5 following ingredients, whether active or not, shall be  
6 declared: bromides, ether, chloroform, acetanilide,  
7 acetophenetidin, antipyrine, atropine, hyoscine,  
8 hyoscyamine, codeine, arsenic, digitalis, digitalis  
9 glycosides, mercury, ouabain, strophanthin, strychnine,  
10 barbituric acid, or any derivative or preparation of any  
11 substances contained therein. The department may  
12 exempt any nonprescription drug from the requirement  
13 of stating the quantity of the active ingredients, other  
14 than those specifically named in this subdivision, upon a  
15 showing by the applicant through evidence satisfactory to  
16 the department that the granting of the exemption will  
17 not endanger the public health. For any prescription  
18 drug the established name of the drug or ingredient, as  
19 the case may be, on the label and on any labeling on which  
20 a name for the drug or ingredient is used shall be printed  
21 prominently and in type at least half as large as that used  
22 thereon for any proprietary name or designation for the  
23 drug or ingredient.

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

29 SEC. 10. Section 111405 of the Health and Safety Code  
30 is repealed.

31 ~~111405. Any drug is misbranded if it is, or purports to~~  
32 ~~be, or is represented as, a drug composed wholly or partly~~  
33 ~~of insulin, unless both of the following requirements are~~  
34 ~~satisfied:~~

35 ~~(a) It is from a batch to which a certificate or release~~  
36 ~~has been issued pursuant to Section 506 (21 U.S.C. Sec.~~  
37 ~~356) of the federal act.~~

38 ~~(b) The certificate or release is in effect with respect~~  
39 ~~to the drug.~~



1 SEC. 11. Section 111410 of the Health and Safety Code  
2 is repealed.

3 ~~111410. Any drug is misbranded if it is, purports to be,  
4 or is represented as a drug composed, wholly or partly, of  
5 any antibiotic drug, or any derivative thereof, unless both  
6 of the following requirements are satisfied:~~

7 ~~(a) It is from a batch to which a certificate or release  
8 has been issued pursuant to Section 507 of the federal act  
9 (21 U.S.C. Sec. 357).~~

10 ~~(b) The certificate or release is in effect with respect  
11 to that drug. This section shall not, however, apply to any  
12 drug or class of drugs exempted by regulations adopted  
13 pursuant to Section 507(c) or 507(d) of the federal act (21  
14 U.S.C. Sec. 357(e) or 357(d)).~~

15 SEC. 12. Section 111490 of the Health and Safety Code  
16 is amended to read:

17 111490. A drug or device that is subject to Section  
18 111470 is misbranded if at any time prior to dispensing, its  
19 label fails to bear the statement “Caution: federal law  
20 prohibits dispensing without prescription,” or “Caution:  
21 state law prohibits dispensing without prescription,” or  
22 “Caution: federal law restricts this device to sale by or on  
23 the order of a \_\_\_\_\_,” the blank to be filled in with the  
24 designation of the practitioner licensed to use or order  
25 use of the device; *or* “*R<sub>x</sub> only.*” A drug or device to which  
26 Section 111470 does not apply is misbranded if at any time  
27 prior to dispensing its label bears the caution statement  
28 quoted in the preceding sentence.

29 SEC. 13. Section 111610 of the Health and Safety Code  
30 is amended to read:

31 111610. Section 111550 does not apply to any of the  
32 following:

33 (a) A drug or device that is sold in this state, or  
34 introduced into interstate commerce, at any time prior to  
35 the enactment of the federal act, if its labeling and  
36 advertising contained the same representations  
37 concerning the conditions of its use.

38 (b) Any drug that is licensed under the Public Health  
39 Service Act of July 1, 1944 (58 Stats. 682, as amended; 42  
40 U.S.C. Sec. 201 et seq.) or under the eighth paragraph of



1 the heading of Bureau of Animal Industry of the act of  
2 March 4, 1913 (37 Stat. 832–833; 21 U.S.C. Sec. 151 et seq.),  
3 commonly known as the “Virus-Serum-Toxin Act.”  
4 ~~(e) Any antibiotic drug that is subject to Section~~  
5 ~~111445.~~

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