

AMENDED IN SENATE JUNE 29, 2011

AMENDED IN ASSEMBLY APRIL 13, 2011

AMENDED IN ASSEMBLY MARCH 31, 2011

CALIFORNIA LEGISLATURE—2011–12 REGULAR SESSION

**ASSEMBLY BILL**

**No. 1277**

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**Introduced by Assembly Members Hill and Perea**

February 18, 2011

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An act to amend Sections 111550 and ~~111635~~, *111635*, and *111640* of the Health and Safety Code, relating to public health.

LEGISLATIVE COUNSEL'S DIGEST

AB 1277, as amended, Hill. Sherman Food, Drug, and Cosmetic Law.

The Sherman Food, Drug, and Cosmetic Law regulates the packaging, labeling, and advertising of drugs and devices, and is administered by the State Department of Public Health. The law prohibits the sale, delivery, or giving away of any new drug or new device unless either the department has approved a new drug or device application for that new drug or new device and that approval has not been withdrawn, terminated, or suspended or a new drug application has been approved for it and that approval has not been withdrawn, terminated, or suspended under specified provisions of the federal Food, Drug, and Cosmetic Act, or it is a new device for which a premarket approval application has been approved, and that approval has not been withdrawn, terminated, or suspended under the federal act.

The Sherman Food, Drug, and Cosmetic Law requires the department to adopt regulations to establish the application form and set the fee for licensure and renewal of a drug or device license.

This bill would revise the above-described prohibition to also apply to a new biologic product for which a license has been issued under federal law.

Existing law also requires the department to inspect the place of business of each licensed person once every 2 years, unless the United States Food and Drug Administration inspected the place of business within the previous 2 years.

This bill would, *instead*, require ~~inspections once every 4 years, unless each place of business to submit to the department written documentation pertaining to an inspection of the place of business by the United States Food and Drug Administration inspected the place of business within the previous 4 years prior to the department issuing the place of business a license.~~ This bill would authorize the business to request specified written verification from the department that its place of business was approved by the department and require the department to provide a prescribed written response.

Existing law authorizes any authorized agent of the department to enter and inspect specified locations, as prescribed, for purposes of enforcement of the Sherman Food, Drug, and Cosmetic Law.

This bill would require the department to make these investigations or inspections when notification has been sent by the United States Food and Drug Administration of a recall action or when the United States Food and Drug Administration has requested assistance for enforcement activities.

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 111550 of the Health and Safety Code
- 2 is amended to read:
- 3 111550. No person shall sell, deliver, or give away any new
- 4 drug or new device unless it satisfies either of the following:
- 5 (a) It is one of the following:
- 6 (1) A new drug, and a new drug application has been approved
- 7 for it and that approval has not been withdrawn, terminated, or
- 8 suspended under Section 505 of the federal act (21 U.S.C. Sec.
- 9 355).

1 (2) A new biologic product for which a license has been issued  
2 as required by the federal Public Health Service Act (42 U.S.C.  
3 Sec. 262).

4 (3) A new device that is reported under Section 510(k) of the  
5 federal act (21 U.S.C. Sec. 360) or for which a premarket approval  
6 application has been approved, and that approval has not been  
7 withdrawn, terminated, or suspended under Section 515 of the  
8 federal act (21 U.S.C. Sec. 360e).

9 (b) The department has approved a new drug or device  
10 application for that new drug or new device and that approval has  
11 not been withdrawn, terminated, or suspended. Any person who  
12 files a new drug or device application with the department shall  
13 submit, as part of the application, all of the following information:

14 (1) Full reports of investigations that have been made to show  
15 whether or not the new drug or device is safe for use and whether  
16 the new drug or device is effective in use under the conditions  
17 prescribed, recommended, or suggested in the labeling or  
18 advertising of the new drug or device.

19 (2) A full list of the articles used as components of the new drug  
20 or device.

21 (3) A full statement of the composition of the new drug or  
22 device.

23 (4) A full description of the methods used in, and the facilities  
24 and controls used for, the manufacture, processing, and packing  
25 of the new drug or in the case of a new device, a full statement of  
26 its composition, properties, and construction and the principles of  
27 its operation.

28 (5) Samples of the new drug or device and of the articles used  
29 as components of the drug or device as the department may require.

30 (6) Specimens of the labeling and advertisements proposed to  
31 be used for the new drug or device.

32 (c) It is the intent of the Legislature to preclude the department  
33 from requiring a person who intends to sell, deliver, or give away  
34 any new drug or device that meets the federal requirements  
35 described in subdivision (a) to also obtain an approval pursuant to  
36 subdivision (b), except to the extent that the department requires  
37 documentation that the federal requirements are met.

38 SEC. 2. Section 111635 of the Health and Safety Code is  
39 amended to read:

1 111635. (a) Prior to issuing a license required by Section  
2 ~~111615~~, the department shall inspect each place of business.

3 ~~(b) The department shall subsequently inspect the place of~~  
4 ~~business of each person licensed under Section 111615 once every~~  
5 ~~four years. The department shall conduct these inspections to~~  
6 ~~determine ownership, adequacy of facilities, and personnel~~  
7 ~~qualifications. Where the United States Food and Drug~~  
8 ~~Administration has conducted an inspection of the place of business~~  
9 ~~within the previous four years, the department shall use the~~  
10 ~~information contained in the written documentation pertaining to~~  
11 ~~that inspection rather than conducting its own inspection pursuant~~  
12 ~~to this subdivision. The department may, if necessary, inspect to~~  
13 ~~obtain information not included or not sufficiently clear in the~~  
14 ~~United States Food and Drug Administration written documentation~~  
15 ~~pertaining to the inspection and needed to protect the health and~~  
16 ~~safety of the public.~~

17 ~~(c) The department may, in lieu of all or part of any inspection~~  
18 ~~required under this section, use information from audits conducted~~  
19 ~~pursuant to the provisions of the International Standards~~  
20 ~~Organization (ISO) 9000 series or European (EN) 46000 series~~  
21 ~~quality system standards, or other information identified by the~~  
22 ~~department by regulation. *111615, the department shall receive*~~  
23 ~~*from each place of business written documentation pertaining to*~~  
24 ~~*an inspection of the place of business by the United States Food*~~  
25 ~~*and Drug Administration.*~~

26 ~~(b) A business licensed under Section 111615 may request~~  
27 ~~written verification from the department that its place of business~~  
28 ~~was approved by the department where the United States Food~~  
29 ~~and Drug Administration's inspection was utilized as the basis for~~  
30 ~~license approval. The department shall provide the business with~~  
31 ~~a written response that its place of business has been approved~~  
32 ~~for a license under state law based on its passage of a federal~~  
33 ~~inspection.~~

34 ~~SEC. 3. Section 111640 of the Health and Safety Code is~~  
35 ~~amended to read:~~

36 111640. The department shall make investigations or  
37 inspections authorized by Article 2 (commencing with Section  
38 ~~110410~~ 110140) of Chapter 2 ~~as it deems necessary to carry out~~  
39 ~~this chapter when notification has been sent by the United States~~  
40 ~~Food and Drug Administration of a recall action or when the~~

- 1 *United States Food and Drug Administration has requested*
- 2 *assistance for enforcement activities including, but not limited to,*
- 3 *embargoes, seizures, or injunctions.*

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