

AMENDED IN SENATE JUNE 20, 2012

AMENDED IN SENATE JANUARY 4, 2012

AMENDED IN SENATE JUNE 29, 2011

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AMENDED IN ASSEMBLY MARCH 31, 2011

CALIFORNIA LEGISLATURE—2011–12 REGULAR SESSION

ASSEMBLY BILL

No. 1277

Introduced by Assembly Members Hill and Perea
(Coauthors: Assembly Members Alejo, Fletcher, Pan, and Smyth)
(Coauthors: Senators Blakeslee and Padilla)

February 18, 2011

An act to amend Sections 111550, 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department has approved a new drug or device application for that new drug or new device and that approval has not been withdrawn, terminated, or suspended or a new drug application has been approved for it and that approval has not been withdrawn, terminated, or suspended under specified provisions of the Federal Food, Drug, and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Act, or it is a new device for which a premarket approval application has been approved, and that approval has not been withdrawn, terminated, or suspended under the federal act.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~~ *exempt* 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~~ *manufacturer of a drug or device in the state* prior to issuance of the license and, thereafter, 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 each place of business to submit to the department documentation that evidences *ownership and* that the place of business is operating pursuant to a valid *biologics license, establishment registration, or approved investigational new drug or investigational device exemption* issued by the United States Food and Drug Administration, as prescribed, or is in compliance with audits conducted pursuant to specified standards, prior to the department issuing the place of business a license. *If the business does not provide this documentation, the bill would require the department to inspect the place of business prior to licensure.* This bill would authorize the business to request ~~specified written verification from the department that its place of business was approved by the department based upon specified information and require the department to provide a prescribed written response~~ *an official copy of the valid license.*

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, instead, require the department to make these investigations or inspections only under specified circumstances, including when the department makes a determination that the health and safety of the public is at *serious* risk, notification has been sent by the United States Food and Drug Administration ~~of to the department requesting assistance regarding a specified~~ *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).
10 (2) A new biologic product for which a license has been issued
11 as required by the federal Public Health Service Act (42 U.S.C.
12 Sec. 262).
13 (3) A new device that is reported under Section 510(k) of the
14 federal act (21 U.S.C. Sec. 360(k)), or exempted therefrom pursuant
15 to 21 U.S.C. Sec. 360(m), or for which a premarket approval
16 application has been approved, and that approval has not been
17 withdrawn, terminated, or suspended under Section 515 of the
18 federal act (21 U.S.C. Sec. 360e).
19 (b) The department has approved a new drug or device
20 application for that new drug or new device and that approval has
21 not been withdrawn, terminated, or suspended. Any person who
22 files a new drug or device application with the department shall
23 submit, as part of the application, all of the following information:
24 (1) Full reports of investigations that have been made to show
25 whether or not the new drug or device is safe for use and whether
26 the new drug or device is effective in use under the conditions
27 prescribed, recommended, or suggested in the labeling or
28 advertising of the new drug or device.
29 (2) A full list of the articles used as components of the new drug
30 or device.
31 (3) A full statement of the composition of the new drug or
32 device.
33 (4) A full description of the methods used in, and the facilities
34 and controls used for, the manufacture, processing, and packing
35 of the new drug, or in the case of a new device, a full statement of

1 its composition, properties, and construction, and the principles
2 of its operation.

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

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

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

9 111635. (a) Prior to issuing a license required by Section
10 111615 to any place of business *where a drug or device is*
11 *manufactured*, the department shall receive from each place of
12 business documentation that evidences ~~that the ownership and any~~
13 *of the following:*

14 (1) *The place of business is operating pursuant to a valid*
15 ~~establishment registration~~ *biologics license* issued by the United
16 States Food and Drug Administration in compliance with Section
17 351 of the federal Public Health Service Act (42 U.S.C. Sec. 262)
18 ~~and Section 704 of the Federal Food, Drug, and Cosmetic Act (21~~
19 ~~U.S.C. Sec. 374), or is. This documentation shall include an~~
20 *attestation from the place of business that a federal inspection was*
21 *completed within the past two years from the date of the attestation.*

22 (2) *The place of business is operating with a valid establishment*
23 *registration pursuant to Section 510 of the federal act (21 U.S.C.*
24 *Sec. 360).*

25 (3) *The place of business is operating in compliance with audits*
26 *conducted pursuant to the International Standards Organization*
27 *(ISO) 9000:2005, ISO 13485:2003 quality management systems*
28 *standards, ISO 15378:2006 quality management systems standards,*
29 ~~or similar standards identified by the department by regulation~~
30 *pursuant to Parts 210 and 211 of Title 21 of the Code of Federal*
31 *Regulations, or pursuant to Part 820 of Title 21 of the Code of*
32 *Federal Regulations.*

33 (4) *The place of business is operating pursuant to an approved*
34 *investigational new drug issued by the federal Food and Drug*
35 *Administration pursuant to Sections 312.22 and 312.23 of Title*
36 *21 of the Code of Federal Regulations or pursuant to an approved*
37 *investigational device exemption issued by the federal Food and*
38 *Drug Administration pursuant to Part 812 of Title 21 of the Code*
39 *of Federal Regulations.*

1 (b) If the department receives documentation that satisfies the
2 requirements of subdivision (a), the department shall not inspect
3 the place of business prior to issuing a license required by Section
4 111615. If the department does not receive the documentation
5 required, the department shall inspect the place of business prior
6 to issuing a license required by Section 111615.

7 (b)

8 (c) Upon request by a place of business licensed under Section
9 111615, the department shall provide written verification that the
10 department issued the license based on documentation that
11 evidences that the place of business is operating pursuant to a valid
12 establishment registration issued by the United States Food and
13 Drug Administration in compliance with Section 351 of the federal
14 Public Health Service Act (42 U.S.C. Sec. 262) and Section 704
15 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. Sec. 374),
16 or is operating in compliance with audits conducted pursuant to
17 the International Standards Organization (ISO) 9000:2005, ISO
18 13485:2003 quality management systems standards, ISO
19 15378:2006 quality management systems standards, or similar
20 standards identified by the department by regulation *an official*
21 *copy of the valid license to the place of business in accordance*
22 *with Sections 110230 and 110235.*

23 SEC. 3. Section 111640 of the Health and Safety Code is
24 amended to read:

25 111640. With respect to drugs and devices, the department
26 shall make investigations or inspections authorized by Article 2
27 (commencing with Section 110140) of Chapter 2 only when any
28 of the following occur:

29 (a) The department makes a determination that the health and
30 safety of the public is at *serious* risk.

31 (b) A complaint has been registered with the department and
32 the department makes a determination that the public health and
33 safety is at *serious* risk.

34 (c) A notification has been sent by the United States Food and
35 Drug Administration ~~of to the department that requests assistance~~
36 *regarding any Class I or II recall action memorandum.*

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

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