Assembly Bill No. 1277

CHAPTER 688

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

[Approved by Governor September 28, 2012. Filed with Secretary of State September 28, 2012.]

LEGISLATIVE COUNSEL'S DIGEST

AB 1277, 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department has approved a new drug or device application for that new drug or new device and that approval has not been withdrawn, terminated, or suspended or a new drug application has been approved for it and that approval has not been withdrawn, terminated, or suspended under specified provisions of the Federal Food, Drug, and Cosmetic Act, or it is a new device for which a premarket approval application has been approved, and that approval has not been withdrawn, terminated, or suspended under the federal act.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 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 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 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 require, for any place of business where a drug or device is manufactured and its manufacturer has received a license, the department to make investigations or inspections only under specified circumstances, including when the department makes a determination that the health and safety of the public is at risk, notification has been sent by the United States Food and Drug Administration 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.

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

SECTION 1. Section 111550 of the Health and Safety Code is amended to read:

111550. No person shall sell, deliver, or give away any new drug or new device unless it satisfies either of the following:

(a) It is one of the following:

(1) A new drug, and a new drug application has been approved for it and that approval has not been withdrawn, terminated, or suspended under Section 505 of the federal act (21 U.S.C. Sec. 355).

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

(3) A device that is reported under Section 510(k) of the federal act (21 U.S.C. Sec. 360(k)), or is a device exempted pursuant to subsection (*l*) or (m) of Section 360 of Title 21 of the United States Code, 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 Section 515 of the federal act (21 U.S.C. Sec. 360e).

(b) 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. Any person who files a new drug or device application with the department shall submit, as part of the application, all of the following information:

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

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

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

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

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

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

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

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

(1) The place of business is operating pursuant to a valid biologics license issued by the United States Food and Drug Administration in compliance with Section 351 of the federal Public Health Service Act (42 U.S.C. Sec. 262).

(2) The place of business is operating with a valid establishment registration pursuant to Section 510 of the federal act (21 U.S.C. Sec. 360). This documentation shall include an attestation from an officer of the place of business that a federal inspection was completed within the two years prior to the date of the attestation.

(3) The place of business is operating in compliance with audits conducted pursuant to the International Standards Organization (ISO) 9000 series, ISO 13485:2003 quality management systems standards, ISO 15378:2006 quality management systems standards, pursuant to Parts 210 and 211 of Title 21 of the Code of Federal Regulations, or pursuant to Part 820 of Title 21 of the Code of Federal Regulations.

(4) The place of business is operating pursuant to an approved investigational new drug issued by the federal Food and Drug Administration pursuant to Section 312.20 of Title 21 of the Code of Federal Regulations or pursuant to an approved investigational device exemption issued by the federal Food and Drug Administration pursuant to Section 812.20 of Title 21 of the Code of Federal Regulations.

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

(c) Upon request by a place of business licensed under Section 111615, the department shall provide an official copy of the valid license to the place of business in accordance with Sections 110230 and 110235.

(d) Notwithstanding Section 111640, for any place of business where a drug or device is manufactured and the manufacturer has received a license pursuant to this section, the department shall make investigations or inspections authorized by Article 2 (commencing with Section 110140) of Chapter 2 only when any of the following occur:

(1) The department becomes aware of an issue and makes a determination that the health and safety of the public is at risk.

(2) A complaint has been registered with the department and the department makes a determination that the health and safety of the public is at risk.

(3) A notification has been sent by the United States Food and Drug Administration to the department that requests assistance regarding any Class I or II recall action memorandum.

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

(e) Inspections made pursuant to subdivision (d) shall be limited to inspections for compliance with, or violations of, Chapter 4 (commencing with Section 110290) or this chapter.

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