

By: Duncan, et al.

S.B. No. 1803

Substitute the following for S.B. No. 1803:

By: Truitt

C.S.S.B. No. 1803

A BILL TO BE ENTITLED

AN ACT

relating to certain licensing requirements and violations under the Texas Food, Drug, and Cosmetic Act; providing penalties.

BE IT ENACTED BY THE LEGISLATURE OF THE STATE OF TEXAS:

SECTION 1. Subdivision (23), Section 431.002, Health and Safety Code, is amended to read as follows:

(23) "Manufacture" means:

(A) the process of combining or purifying food or packaging food for sale to a person at wholesale or retail, and includes repackaging, ~~or~~ labeling, or relabeling of any food;

(B) the process of preparing, propagating, compounding, processing, packaging, repackaging, labeling, testing, or quality control of a drug or drug product, but does not include compounding that is done within the practice of pharmacy and pursuant to a prescription from a practitioner for a patient;

(C) the process of preparing, fabricating, assembling, processing, packing, repacking, labeling, or relabeling a device; or

(D) the making of any cosmetic product by chemical, physical, biological, or other procedures, including manipulation, sampling, testing, or control procedures applied to the product.

SECTION 2. Section 431.021, Health and Safety Code, is amended to read as follows:

1 Sec. 431.021. PROHIBITED ACTS. The following acts and the
2 causing of the following acts within this state are unlawful and
3 prohibited:

4 (a) the introduction or delivery for introduction into
5 commerce of any food, drug, device, or cosmetic that is adulterated
6 or misbranded;

7 (b) the adulteration or misbranding of any food, drug,
8 device, or cosmetic in commerce;

9 (c) the receipt in commerce of any food, drug, device, or
10 cosmetic that is adulterated or misbranded, and the delivery or
11 proffered delivery thereof for pay or otherwise;

12 (d) the distribution in commerce of a consumer commodity, if
13 such commodity is contained in a package, or if there is affixed to
14 that commodity a label that does not conform to the provisions of
15 this chapter and of rules adopted under the authority of this
16 chapter; provided, however, that this prohibition shall not apply
17 to persons engaged in business as wholesale or retail distributors
18 of consumer commodities except to the extent that such persons:

19 (1) are engaged in the packaging or labeling of such
20 commodities; or

21 (2) prescribe or specify by any means the manner in
22 which such commodities are packaged or labeled;

23 (e) the introduction or delivery for introduction into
24 commerce of any article in violation of Section 431.084, 431.114,
25 or 431.115;

26 (f) the dissemination of any false advertisement;

27 (g) the refusal to permit entry or inspection, or to permit

1 the taking of a sample or to permit access to or copying of any
2 record as authorized by Sections 431.042-431.044; or the failure to
3 establish or maintain any record or make any report required under
4 Section 512(j), (l), or (m) of the federal Act, or the refusal to
5 permit access to or verification or copying of any such required
6 record;

7 (h) the manufacture within this state of any food, drug,
8 device, or cosmetic that is adulterated or misbranded;

9 (i) the giving of a guaranty or undertaking referred to in
10 Section 431.059, which guaranty or undertaking is false, except by
11 a person who relied on a guaranty or undertaking to the same effect
12 signed by, and containing the name and address of the person
13 residing in this state from whom the person received in good faith
14 the food, drug, device, or cosmetic; or the giving of a guaranty or
15 undertaking referred to in Section 431.059, which guaranty or
16 undertaking is false;

17 (j) the use, removal, or disposal of a detained or embargoed
18 article in violation of Section 431.048;

19 (k) the alteration, mutilation, destruction, obliteration,
20 or removal of the whole or any part of the labeling of, or the doing
21 of any other act with respect to a food, drug, device, or cosmetic,
22 if such act is done while such article is held for sale after
23 shipment in commerce and results in such article being adulterated
24 or misbranded;

25 (l)(1) forging, counterfeiting, simulating, or falsely
26 representing, or without proper authority using any mark, stamp,
27 tag, label, or other identification device authorized or required

1 by rules adopted under this chapter or the regulations promulgated
2 under the provisions of the federal Act;

3 (2) making, selling, disposing of, or keeping in
4 possession, control, or custody, or concealing any punch, die,
5 plate, stone, or other thing designed to print, imprint, or
6 reproduce the trademark, trade name, or other identifying mark,
7 imprint, or device of another or any likeness of any of the
8 foregoing on any drug or container or labeling thereof so as to
9 render such drug a counterfeit drug;

10 (3) the doing of any act that causes a drug to be a
11 counterfeit drug, or the sale or dispensing, or the holding for sale
12 or dispensing, of a counterfeit drug;

13 (m) the using by any person to the person's own advantage,
14 or revealing, other than to the commissioner, an authorized agent,
15 a health authority or to the courts when relevant in any judicial
16 proceeding under this chapter, of any information acquired under
17 the authority of this chapter concerning any method or process that
18 as a trade secret is entitled to protection;

19 (n) the using, on the labeling of any drug or device or in
20 any advertising relating to such drug or device, of any
21 representation or suggestion that approval of an application with
22 respect to such drug or device is in effect under Section 431.114 or
23 Section 505, 515, or 520(g) of the federal Act, as the case may be,
24 or that such drug or device complies with the provisions of such
25 sections;

26 (o) the using, in labeling, advertising or other sales
27 promotion of any reference to any report or analysis furnished in

1 compliance with Sections 431.042-431.044 or Section 704 of the
2 federal Act;

3 (p) in the case of a prescription drug distributed or
4 offered for sale in this state, the failure of the manufacturer,
5 packer, or distributor of the drug to maintain for transmittal, or
6 to transmit, to any practitioner licensed by applicable law to
7 administer such drug who makes written request for information as
8 to such drug, true and correct copies of all printed matter that is
9 required to be included in any package in which that drug is
10 distributed or sold, or such other printed matter as is approved
11 under the federal Act. Nothing in this subsection shall be
12 construed to exempt any person from any labeling requirement
13 imposed by or under other provisions of this chapter;

14 (q)(1) placing or causing to be placed on any drug or device
15 or container of any drug or device, with intent to defraud, the
16 trade name or other identifying mark, or imprint of another or any
17 likeness of any of the foregoing;

18 (2) selling, dispensing, disposing of or causing to be
19 sold, dispensed, or disposed of, or concealing or keeping in
20 possession, control, or custody, with intent to sell, dispense, or
21 dispose of, any drug, device, or any container of any drug or
22 device, with knowledge that the trade name or other identifying
23 mark or imprint of another or any likeness of any of the foregoing
24 has been placed thereon in a manner prohibited by Subdivision (1) of
25 this subsection; or

26 (3) making, selling, disposing of, causing to be made,
27 sold, or disposed of, keeping in possession, control, or custody,

1 or concealing with intent to defraud any punch, die, plate, stone,
2 or other thing designed to print, imprint, or reproduce the
3 trademark, trade name, or other identifying mark, imprint, or
4 device of another or any likeness of any of the foregoing on any
5 drug or container or labeling of any drug or container so as to
6 render such drug a counterfeit drug;

7 (r) dispensing or causing to be dispensed a different drug
8 in place of the drug ordered or prescribed without the express
9 permission in each case of the person ordering or prescribing;

10 (s) the failure to register in accordance with Section 510
11 of the federal Act, the failure to provide any information required
12 by Section 510(j) or (k) of the federal Act, or the failure to
13 provide a notice required by Section 510(j)(2) of the federal Act;

14 (t)(1) the failure or refusal to:

15 (A) comply with any requirement prescribed under
16 Section 518 or 520(g) of the federal Act; or

17 (B) furnish any notification or other material or
18 information required by or under Section 519 or 520(g) of the
19 federal Act;

20 (2) with respect to any device, the submission of any
21 report that is required by or under this chapter that is false or
22 misleading in any material respect;

23 (u) the movement of a device in violation of an order under
24 Section 304(g) of the federal Act or the removal or alteration of
25 any mark or label required by the order to identify the device as
26 detained;

27 (v) the failure to provide the notice required by Section

1 412(b) or 412(c), the failure to make the reports required by
2 Section 412(d)(1)(B), or the failure to meet the requirements
3 prescribed under Section 412(d)(2) of the federal Act;

4 (w) except as provided under Subchapter M, the acceptance by
5 a person of an unused prescription or drug, in whole or in part, for
6 the purpose of resale, after the prescription or drug has been
7 originally dispensed, or sold;

8 (x) engaging in the wholesale distribution of drugs or
9 operating as a distributor or manufacturer of devices in this state
10 without filing a licensing statement with the commissioner as
11 required by Section 431.202 or having a license as required by
12 Section 431.272, as applicable;

13 (y) engaging in the manufacture of food in this state or
14 operating as a warehouse operator [~~food wholesaler~~] in this state
15 without having a license as required by Section 431.222 or
16 operating as a food wholesaler in this state without having a
17 license under Section 431.222 or being registered under Section
18 431.2211, as appropriate; [or]

19 (z) unless approved by the United States Food and Drug
20 Administration pursuant to the federal Act, the sale, delivery,
21 holding, or offering for sale of a self-testing kit designed to
22 indicate whether a person has a human immunodeficiency virus
23 infection, acquired immune deficiency syndrome, or a related
24 disorder or condition; or

25 (aa) making a false statement or false representation in an
26 application for a license or in a statement, report, or other
27 instrument to be filed with the board, the commissioner, or the

department under this chapter.

SECTION 3. Subsection (a), Section 431.059, Health and Safety Code, is amended to read as follows:

(a) A person commits an offense if the person violates any of the provisions of Section 431.021 relating to unlawful or prohibited acts. A first [An] offense under this subsection is a Class A misdemeanor unless it is shown on the trial of an offense under this subsection that the defendant was previously convicted of an offense under this subsection, in which event the offense is a state jail felony. In a criminal proceeding under this section, it is not necessary to prove intent, knowledge, recklessness, or criminal negligence of the defendant beyond the degree of culpability, if any, stated in Section 431.021 to establish criminal responsibility for the violation.

SECTION 4. The heading to Subchapter J, Chapter 431, Health and Safety Code, is amended to read as follows:

SUBCHAPTER J. FOOD MANUFACTURERS, ~~[AND]~~ FOOD WHOLESALERS, AND
WAREHOUSE OPERATORS

SECTION 5. Section 431.221, Health and Safety Code, is amended by amending Subdivision (1) and adding Subdivision (6) to read as follows:

(1) "Place of business" means:

(A) each location where:

(i) a person manufactures food; or

(ii) [where] food for wholesale is distributed; or

(B) a warehouse where food is stored.

1 (6) "Warehouse operator" means a person that operates
2 a warehouse where food is stored.

3 SECTION 6. Section 431.2211, Health and Safety Code, is
4 amended by adding Subsections (d) and (e) to read as follows:

5 (d) A food wholesaler is not required to obtain a license
6 under this subchapter for a place of business if all of the food
7 distributed from that place of business will be stored in a
8 warehouse licensed under this subchapter.

9 (e) A food wholesaler that is not required to obtain a
10 license for a place of business under Subsection (d) shall register
11 that place of business with the department. The department shall
12 adopt rules for the registration of food wholesalers under this
13 section.

14 SECTION 7. Section 431.222, Health and Safety Code, is
15 amended to read as follows:

16 Sec. 431.222. LICENSE REQUIRED; LICENSING FEES. (a)
17 Except as provided by Section 431.2211, a [A] food manufacturer,
18 food wholesaler, or warehouse operator in this state must apply for
19 and obtain from the department each year a license for each place of
20 business that the food manufacturer, food wholesaler, or warehouse
21 operator operates in this state. The food manufacturer, food
22 wholesaler, or warehouse operator must pay a licensing fee for each
23 establishment.

24 (b) ~~The [A food wholesaler in this state must apply for and~~
25 ~~obtain from the department each year a license for each place of~~
26 ~~business that the wholesaler operates in this state. The food~~
27 ~~wholesaler must pay a licensing fee for each place of business.~~

1 ~~[(c) For the purpose of collecting licensing fees under this~~
2 ~~section, the]~~ department shall require a food manufacturer that
3 distributes only food manufactured by that firm to obtain only a
4 license as a food manufacturer. A person that does not manufacture
5 food and serves only as a food wholesaler ~~[wholesale distributor]~~
6 must obtain only a food wholesaler's ~~[wholesale distributor's]~~
7 license. A person that distributes both its own manufactured food
8 and food it does not manufacture must obtain only a food
9 manufacturer's license. A warehouse operator who also distributes
10 food is required to obtain only a warehouse operator license.

11 SECTION 8. Subsection (a), Section 431.223, Health and
12 Safety Code, is amended to read as follows:

13 (a) The person applying for a license under this subchapter
14 must provide, at a minimum, the following information in a license
15 application:

16 (1) the name under which the food manufacturer, [or]
17 wholesale distributor, or warehouse operator conducts business;

18 (2) the address of each place of business in this state
19 that is licensed;

20 (3) if the food manufacturer, [or] wholesale
21 distributor, or warehouse operator is an individual, a partnership,
22 or an association, the name or names of:

23 (A) the proprietor, if the business is a sole
24 proprietorship;

25 (B) all partners, if the business is a
26 partnership; or

27 (C) all principals, if the business is an

1 association;

2 (4) if the food manufacturer, ~~[or]~~ wholesale
3 distributor, or wholesale operator is a corporation, the date and
4 place of incorporation and the name and address of its registered
5 agent in this state;

6 (5) the name and residences of the individuals in an
7 administrative capacity, showing:

8 (A) the managing proprietor, if the business is a
9 sole proprietorship;

10 (B) the managing partner, if the business is a
11 partnership;

12 (C) the officers and directors, if the business
13 is a corporation; or

14 (D) the persons in a managerial capacity, if the
15 business is an association; and

16 (6) the residence address of a person in charge of each
17 place of business.

18 SECTION 9. (a) This Act applies only to a food manufacturer
19 license, food wholesaler license, or warehouse operator license
20 issued on or after that date. A food manufacturer license, food
21 wholesaler license, or warehouse operator license issued before the
22 effective date of this Act is covered by the law in effect on the
23 date the license was issued, and the former law is continued in
24 effect for that purpose.

25 (b) A food wholesaler that obtains or renews a license
26 before the effective date of this Act is not entitled to a refund
27 for any fee paid to the Texas Department of Health for the license

1 issuance or renewal, regardless of the food wholesaler's
2 eligibility for an exemption under Subsection (d), Section
3 431.2211, Health and Safety Code, as added by this Act.

4 SECTION 10. (a) The change in law made by this Act to
5 Sections 431.002, 431.021, and 431.059, Health and Safety Code,
6 applies only to an offense committed on or after the effective date
7 of this Act. For purposes of this section, an offense is committed
8 before the effective date of this Act if any element of the offense
9 occurs before that date.

10 (b) An offense committed before the effective date of this
11 Act is covered by the law in effect when the offense was committed,
12 and the former law is continued in effect for that purpose.

13 SECTION 11. This Act takes effect September 1, 2003.