

By: Duncan

S.B. No. 1803

A BILL TO BE ENTITLED

AN ACT

relating to licensing food manufacturers, food wholesalers, and warehouse operators under the Texas Food, Drug, and Cosmetic Act.

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

SECTION 1. Section 431.021, Health and Safety Code, is amended to read as follows:

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

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

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

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

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

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

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

5 (e) the introduction or delivery for introduction into
6 commerce of any article in violation of Section 431.084, 431.114,
7 or 431.115;

8 (f) the dissemination of any false advertisement;

9 (g) the refusal to permit entry or inspection, or to permit
10 the taking of a sample or to permit access to or copying of any
11 record as authorized by Sections 431.042-431.044; or the failure to
12 establish or maintain any record or make any report required under
13 Section 512(j), (l), or (m) of the federal Act, or the refusal to
14 permit access to or verification or copying of any such required
15 record;

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

18 (i) the giving of a guaranty or undertaking referred to in
19 Section 431.059, which guaranty or undertaking is false, except by
20 a person who relied on a guaranty or undertaking to the same effect
21 signed by, and containing the name and address of the person
22 residing in this state from whom the person received in good faith
23 the food, drug, device, or cosmetic; or the giving of a guaranty or
24 undertaking referred to in Section 431.059, which guaranty or
25 undertaking is false;

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

1 (k) the alteration, mutilation, destruction, obliteration,
2 or removal of the whole or any part of the labeling of, or the doing
3 of any other act with respect to a food, drug, device, or cosmetic,
4 if such act is done while such article is held for sale after
5 shipment in commerce and results in such article being adulterated
6 or misbranded;

7 (1)(1) forging, counterfeiting, simulating, or falsely
8 representing, or without proper authority using any mark, stamp,
9 tag, label, or other identification device authorized or required
10 by rules adopted under this chapter or the regulations promulgated
11 under the provisions of the federal Act;

12 (2) making, selling, disposing of, or keeping in
13 possession, control, or custody, or concealing any punch, die,
14 plate, stone, or other thing designed to print, imprint, or
15 reproduce the trademark, trade name, or other identifying mark,
16 imprint, or device of another or any likeness of any of the
17 foregoing on any drug or container or labeling thereof so as to
18 render such drug a counterfeit drug;

19 (3) the doing of any act that causes a drug to be a
20 counterfeit drug, or the sale or dispensing, or the holding for sale
21 or dispensing, of a counterfeit drug;

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

1 (n) the using, on the labeling of any drug or device or in
2 any advertising relating to such drug or device, of any
3 representation or suggestion that approval of an application with
4 respect to such drug or device is in effect under Section 431.114 or
5 Section 505, 515, or 520(g) of the federal Act, as the case may be,
6 or that such drug or device complies with the provisions of such
7 sections;

8 (o) the using, in labeling, advertising or other sales
9 promotion of any reference to any report or analysis furnished in
10 compliance with Sections 431.042-431.044 or Section 704 of the
11 federal Act;

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

23 (q)(1) placing or causing to be placed on any drug or device
24 or container of any drug or device, with intent to defraud, the
25 trade name or other identifying mark, or imprint of another or any
26 likeness of any of the foregoing;

27 (2) selling, dispensing, disposing of or causing to be

1 sold, dispensed, or disposed of, or concealing or keeping in
2 possession, control, or custody, with intent to sell, dispense, or
3 dispose of, any drug, device, or any container of any drug or
4 device, with knowledge that the trade name or other identifying
5 mark or imprint of another or any likeness of any of the foregoing
6 has been placed thereon in a manner prohibited by Subdivision (1) of
7 this subsection; or

8 (3) making, selling, disposing of, causing to be made,
9 sold, or disposed of, keeping in possession, control, or custody,
10 or concealing with intent to defraud any punch, die, plate, stone,
11 or other thing designed to print, imprint, or reproduce the
12 trademark, trade name, or other identifying mark, imprint, or
13 device of another or any likeness of any of the foregoing on any
14 drug or container or labeling of any drug or container so as to
15 render such drug a counterfeit drug;

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

19 (s) the failure to register in accordance with Section 510
20 of the federal Act, the failure to provide any information required
21 by Section 510(j) or (k) of the federal Act, or the failure to
22 provide a notice required by Section 510(j)(2) of the federal Act;

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

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

26 (B) furnish any notification or other material or
27 information required by or under Section 519 or 520(g) of the

1 federal Act;

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

5 (u) the movement of a device in violation of an order under
6 Section 304(g) of the federal Act or the removal or alteration of
7 any mark or label required by the order to identify the device as
8 detained;

9 (v) the failure to provide the notice required by Section
10 412(b) or 412(c), the failure to make the reports required by
11 Section 412(d)(1)(B), or the failure to meet the requirements
12 prescribed under Section 412(d)(2) of the federal Act;

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

17 (x) engaging in the wholesale distribution of drugs or
18 operating as a distributor or manufacturer of devices in this state
19 without filing a licensing statement with the commissioner as
20 required by Section 431.202 or having a license as required by
21 Section 431.272, as applicable;

22 (y) engaging in the manufacture of food in this state or
23 operating as a warehouse operator [~~food wholesaler~~] in this state
24 without having a license as required by Section 431.222 or
25 operating as a food wholesaler in this state without having a
26 license under Section 431.222 or being registered under Section
27 431.2211, as appropriate; or

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

SECTION 2. 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 3. 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.

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

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

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

1 (e) A food wholesaler that is not required to obtain a
2 license for a place of business under Subsection (d) shall register
3 that place of business with the department. The department shall
4 adopt rules for the registration of food wholesalers under this
5 section.

6 SECTION 5. Section 431.222, Health and Safety Code, is
7 amended to read as follows:

8 Sec. 431.222. LICENSE REQUIRED; LICENSING FEES. (a)
9 Except as provided by Section 431.2211, a [A] food manufacturer,
10 food wholesaler, or warehouse operator in this state must apply for
11 and obtain from the department each year a license for each place of
12 business that the food manufacturer, food wholesaler, or warehouse
13 operator operates in this state. The food manufacturer, food
14 wholesaler, or warehouse operator must pay a licensing fee for each
15 establishment.

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

20 ~~[(c) For the purposes of collecting licensing fees under~~
21 ~~this section, the]~~ department shall require a food manufacturer
22 that distributes only food manufactured by that firm to obtain only
23 a license as a food manufacturer. A person that does not
24 manufacture food and serves only as a food wholesaler ~~[wholesale~~
25 ~~distributor]~~ must obtain only a food wholesaler's ~~[wholesale~~
26 ~~distributor's]~~ license. A person that distributes both its own
27 manufactured food and food it does not manufacture must obtain only

1 a food manufacturer's license. A warehouse operator who also
2 distributes food is required to obtain only a warehouse operator
3 license.

4 SECTION 6. Section 431.223(a), Health and Safety Code, is
5 amended to read as follows:

6 (a) The person applying for a license under this subchapter
7 must provide, at a minimum, the following information in a license
8 application:

9 (1) the name under which the food manufacturer, ~~or~~
10 wholesale distributor, or warehouse operator conducts business;

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

13 (3) if the food manufacturer, ~~or~~ wholesale
14 distributor, or warehouse operator is an individual, a partnership,
15 or an association, the name or names of:

16 (A) the proprietor, if the business is a sole
17 proprietorship;

18 (B) all partners, if the business is a
19 partnership; or

20 (C) all principals, if the business is an
21 association;

22 (4) if the food manufacturer, ~~or~~ wholesale
23 distributor, or warehouse operator is a corporation, the date and
24 place of incorporation and the name and address of its registered
25 agent in this state;

26 (5) the names and residences of the individuals in an
27 administrative capacity, showing:

1 (A) the managing proprietor, if the business is a
2 sole proprietorship;

3 (B) the managing partner, if the business is a
4 partnership;

5 (C) the officers and directors, if the business
6 is a corporation; or

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

9 (6) the residence address of a person in charge of each
10 place of business.

11 SECTION 7. (a) This Act takes effect September 1, 2003, and
12 applies only to a food manufacturer license, food wholesaler
13 license, or warehouse operator license issued on or after that
14 date. A food manufacturer license, food wholesaler license, or
15 warehouse operator license issued before the effective date of this
16 Act is covered by the law in effect on the date the license was
17 issued, and the former law is continued in effect for that purpose.

18 (b) A food wholesaler that obtains or renews a license
19 before the effective date of this Act is not entitled to a refund
20 for any fee paid to the Texas Department of Health for the license
21 issuance or renewal, regardless of the food wholesaler's
22 eligibility for an exemption under Section 431.2211(d), Health and
23 Safety Code, as added by this Act.