

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

1 department under this chapter.

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

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

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

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

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

22 (1) "Place of business" means:

23 (A) each location where:

24 (i) a person manufactures food; or

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

27 (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.  
17 (a) Except as provided by Section 431.2211, a [A] food  
18 manufacturer, food wholesaler, or warehouse operator in this state  
19 must apply for and obtain from the department each year a license  
20 for each place of business that the food manufacturer, food  
21 wholesaler, or warehouse operator operates in this state. The food  
22 manufacturer, food wholesaler, or warehouse operator must pay a  
23 licensing fee for each 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 purposes of collecting licensing fees under~~  
 2 ~~this section, the]~~ department shall require a food manufacturer  
 3 that distributes only food manufactured by that firm to obtain only  
 4 a license as a food manufacturer. A person that does not  
 5 manufacture food and serves only as a food wholesaler ~~[wholesale~~  
 6 ~~distributor]~~ must obtain only a food wholesaler's ~~[wholesale~~  
 7 ~~distributor's]~~ license. A person that distributes both its own  
 8 manufactured food and food it does not manufacture must obtain only  
 9 a food manufacturer's license. A warehouse operator who also  
 10 distributes food is required to obtain only a warehouse operator  
 11 license.

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

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

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

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

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

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

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

1 (C) all principals, if the business is an  
2 association;

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

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

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

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

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

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

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

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

26 (b) A food wholesaler that obtains or renews a license  
27 before the effective date of this Act is not entitled to a refund

1 for any fee paid to the Texas Department of Health for the license  
2 issuance or renewal, regardless of the food wholesaler's  
3 eligibility for an exemption under Subsection (d), Section  
4 431.2211, Health and Safety Code, as added by this Act.

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

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

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

\_\_\_\_\_  
President of the Senate

\_\_\_\_\_  
Speaker of the House

I hereby certify that S.B. No. 1803 passed the Senate on April 25, 2003, by the following vote: Yeas 31, Nays 0; and that the Senate concurred in House amendment on May 30, 2003, by a viva-voce vote.

\_\_\_\_\_  
Secretary of the Senate

I hereby certify that S.B. No. 1803 passed the House, with amendment, on May 28, 2003, by a non-record vote.

\_\_\_\_\_  
Chief Clerk of the House

Approved:

\_\_\_\_\_  
Date

\_\_\_\_\_  
Governor