

1-1 By: Duncan, West S.B. No. 1803  
1-2 (In the Senate - Filed March 14, 2003; March 24, 2003, read  
1-3 first time and referred to Committee on Business and Commerce;  
1-4 April 14, 2003, reported favorably by the following vote: Yeas 8,  
1-5 Nays 0; April 14, 2003, sent to printer.)

1-6 A BILL TO BE ENTITLED  
1-7 AN ACT

1-8 relating to licensing food manufacturers, food wholesalers, and  
1-9 warehouse operators under the Texas Food, Drug, and Cosmetic Act.

1-10 BE IT ENACTED BY THE LEGISLATURE OF THE STATE OF TEXAS:

1-11 SECTION 1. Section 431.021, Health and Safety Code, is  
1-12 amended to read as follows:

1-13 Sec. 431.021. PROHIBITED ACTS. The following acts and the  
1-14 causing of the following acts within this state are unlawful and  
1-15 prohibited:

1-16 (a) the introduction or delivery for introduction into  
1-17 commerce of any food, drug, device, or cosmetic that is adulterated  
1-18 or misbranded;

1-19 (b) the adulteration or misbranding of any food, drug,  
1-20 device, or cosmetic in commerce;

1-21 (c) the receipt in commerce of any food, drug, device, or  
1-22 cosmetic that is adulterated or misbranded, and the delivery or  
1-23 proffered delivery thereof for pay or otherwise;

1-24 (d) the distribution in commerce of a consumer commodity, if  
1-25 such commodity is contained in a package, or if there is affixed to  
1-26 that commodity a label that does not conform to the provisions of  
1-27 this chapter and of rules adopted under the authority of this  
1-28 chapter; provided, however, that this prohibition shall not apply  
1-29 to persons engaged in business as wholesale or retail distributors  
1-30 of consumer commodities except to the extent that such persons:

1-31 (1) are engaged in the packaging or labeling of such  
1-32 commodities; or

1-33 (2) prescribe or specify by any means the manner in  
1-34 which such commodities are packaged or labeled;

1-35 (e) the introduction or delivery for introduction into  
1-36 commerce of any article in violation of Section 431.084, 431.114,  
1-37 or 431.115;

1-38 (f) the dissemination of any false advertisement;

1-39 (g) the refusal to permit entry or inspection, or to permit  
1-40 the taking of a sample or to permit access to or copying of any  
1-41 record as authorized by Sections 431.042-431.044; or the failure to  
1-42 establish or maintain any record or make any report required under  
1-43 Section 512(j), (l), or (m) of the federal Act, or the refusal to  
1-44 permit access to or verification or copying of any such required  
1-45 record;

1-46 (h) the manufacture within this state of any food, drug,  
1-47 device, or cosmetic that is adulterated or misbranded;

1-48 (i) the giving of a guaranty or undertaking referred to in  
1-49 Section 431.059, which guaranty or undertaking is false, except by  
1-50 a person who relied on a guaranty or undertaking to the same effect  
1-51 signed by, and containing the name and address of the person  
1-52 residing in this state from whom the person received in good faith  
1-53 the food, drug, device, or cosmetic; or the giving of a guaranty or  
1-54 undertaking referred to in Section 431.059, which guaranty or  
1-55 undertaking is false;

1-56 (j) the use, removal, or disposal of a detained or embargoed  
1-57 article in violation of Section 431.048;

1-58 (k) the alteration, mutilation, destruction, obliteration,  
1-59 or removal of the whole or any part of the labeling of, or the doing  
1-60 of any other act with respect to a food, drug, device, or cosmetic,  
1-61 if such act is done while such article is held for sale after  
1-62 shipment in commerce and results in such article being adulterated  
1-63 or misbranded;

1-64 (1)(1) forging, counterfeiting, simulating, or falsely

representing, or without proper authority using any mark, stamp, tag, label, or other identification device authorized or required by rules adopted under this chapter or the regulations promulgated under the provisions of the federal Act;

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

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

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

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

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

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

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

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

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

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

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

(t)(1) the failure or refusal to:  
 (A) comply with any requirement prescribed under Section 518 or 520(g) of the federal Act; or

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

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

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

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

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

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

(y) engaging in the manufacture of food in this state or operating as a warehouse operator [~~food wholesaler~~] in this state without having a license as required by Section 431.222 or operating as a food wholesaler in this state without having a license under Section 431.222 or being registered under Section 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] ~~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.

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

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

Sec. 431.222. LICENSE REQUIRED; LICENSING FEES.  
 (a) Except as provided by Section 431.2211, a [A] food manufacturer, food wholesaler, or warehouse operator in this state

must apply for and obtain from the department each year a license for each place of business that the food manufacturer, food wholesaler, or warehouse operator operates in this state. The food manufacturer, food wholesaler, or warehouse operator must pay a licensing fee for each establishment.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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