Amend **CSHB 164** by adding the following appropriately numbered sections to the bill and renumbering existing sections accordingly:

SECTION _____. (a) The heading to Subchapter I, Chapter 431, Health and Safety Code, is amended to read as follows:

SUBCHAPTER I. WHOLESALE [~~DRUG~~] DISTRIBUTORS OF NONPRESCRIPTION DRUGS

(b) Section 431.201, Health and Safety Code, is amended to read as follows:

Sec. 431.201. DEFINITIONS. In this subchapter:

(1) "Nonprescription drug" means any drug that is not a prescription drug as defined by Section 431.401.

(2) "Place of business" means each location at which a drug for wholesale distribution is located.

(3) "Wholesale distribution" means distribution to a person other than a consumer or patient, and includes distribution by a manufacturer, repackager [~~repacker~~], own label distributor, broker, jobber, warehouse, or wholesaler.

[~~(2) "Place of business" means each location at which a drug for wholesale distribution is located.~~]

(c) Subchapter I, Chapter 431, Health and Safety Code, is amended by adding Section 431.2011 to read as follows:

Sec. 431.2011. APPLICABILITY OF SUBCHAPTER. This subchapter applies only to the wholesale distribution of nonprescription drugs.

(d) Section 431.202, Health and Safety Code, is amended to read as follows:

Sec. 431.202. LICENSE [~~STATEMENT~~] REQUIRED. (a) A person may not engage in wholesale distribution of nonprescription drugs in this state unless the person holds a wholesale drug distribution license issued by the department under this subchapter or Subchapter N [~~has filed with the commissioner a signed and verified license statement on a form furnished by the commissioner~~].

(b) An applicant for a license under this subchapter must submit an application to the department on the form prescribed by the department or electronically on the TexasOnline Internet website [~~The license statement must be filed annually~~].

(c) A license issued under this subchapter expires on the

second anniversary of the date of issuance.

(e) Section 431.204, Health and Safety Code, is amended to read as follows:

Sec. 431.204. FEES. (a) The department [~~board~~] shall collect fees for:

(1) a license that is filed or renewed;

(2) a license that is amended, including a notification of a change in the location of a licensed place of business required under Section 431.206; and

(3) an inspection performed in enforcing this subchapter and rules adopted under this subchapter.

(b) The executive commissioner of the Health and Human Services Commission [~~board may charge annual fees.~~

[~~(c) The board~~] by rule shall set the fees in amounts that allow the department to recover [~~at least 50 percent of~~] the biennial [~~annual~~] expenditures of state funds by the department in:

(1) reviewing and acting on a license;

(2) amending and renewing a license;

(3) inspecting a licensed facility; and

(4) implementing and enforcing this subchapter, including a rule or order adopted or a license issued under this subchapter.

(c) [~~(d)~~] Fees collected under this section shall be deposited to the credit of the food and drug registration fee account of the general revenue fund and [~~may be~~] appropriated to the department [~~only~~] to carry out the administration and enforcement of this chapter.

(f) Sections 431.206 and 431.207, Health and Safety Code, are amended to read as follows:

Sec. 431.206. CHANGE OF LOCATION OF PLACE OF BUSINESS. (a) Not fewer than 30 days in advance of the change, the licensee shall notify the department [~~commissioner or the commissioner's designee~~] in writing of the licensee's intent to change the location of a licensed place of business.

(b) The notice shall include the address of the new location, and the name and residence address of the individual in charge of the business at the new location.

(c) Not more than 10 days after the completion of the change of location, the licensee shall notify the department [~~commissioner or the commissioner's designee~~] in writing to confirm the completion of [~~verify~~] the change of location and provide verification of the information previously provided or correct and confirm any information that has changed since providing the notice of intent[~~, the address of the new location, and the name and residence address of the individual in charge of the business at the new address~~].

(d) The notice and confirmation required by this section are [~~Notice will be~~] deemed adequate if the licensee sends [~~provides~~] the [~~intent and verification~~] notices [~~to the commissioner or the commissioner's designee~~] by certified mail, return receipt requested, [~~mailed~~] to the central office of the department or submits them electronically through the TexasOnline Internet website.

Sec. 431.207. REFUSAL TO LICENSE; SUSPENSION OR REVOCATION OF LICENSE. (a) The commissioner of state health services may refuse an application for a license or may suspend or revoke a license if the applicant or licensee:

(1) has been convicted of a felony or misdemeanor that involves moral turpitude;

(2) is an association, partnership, or corporation and the managing officer has been convicted of a felony or misdemeanor that involves moral turpitude;

(3) has been convicted in a state or federal court of the illegal use, sale, or transportation of intoxicating liquors, narcotic drugs, barbiturates, amphetamines, desoxyephedrine, their compounds or derivatives, or any other dangerous or habit-forming drugs;

(4) is an association, partnership, or corporation and the managing officer has been convicted in a state or federal court of the illegal use, sale, or transportation of intoxicating liquors, narcotic drugs, barbiturates, amphetamines, desoxyephedrine, their compounds or derivatives, or any other dangerous or habit-forming drugs; [~~or~~]

(5) has not complied with this chapter or the [~~board's~~]

rules implementing this chapter;

(6) has violated Section 431.021(l)(3), relating to the counterfeiting of a drug or the sale or holding for sale of a counterfeit drug;

(7) has violated Chapter 481 or 483;

(8) has violated the rules of the director of the Department of Public Safety, including being responsible for a significant discrepancy in the records that state law requires the applicant or licensee to maintain; or

(9) fails to complete a license application or submits an application that contains false, misleading, or incorrect information or contains information that cannot be verified by the department.

(b) The executive commissioner of the Health and Human Services Commission by rule shall establish minimum standards required for the issuance or renewal of a license under this subchapter [~~may refuse an application for a license or may suspend or revoke a license if the commissioner determines from evidence presented during a hearing that the applicant or licensee:~~

[~~(1) has violated Section 431.021(l)(3), relating to the counterfeiting of a drug or the sale or holding for sale of a counterfeit drug;~~

[~~(2) has violated Chapter 481 (Texas Controlled Substances Act) or 483 (Dangerous Drugs); or~~

[~~(3) has violated the rules of the director of the Department of Public Safety, including being responsible for a significant discrepancy in the records that state law requires the applicant or licensee to maintain~~].

(c) The refusal to license an applicant or the suspension or revocation of a license by the department [~~commissioner~~] and the appeal from that action are governed by [~~the board's formal hearing procedures and~~] the procedures for a contested case hearing under Chapter 2001, Government Code.

(g) Chapter 431, Health and Safety Code, is amended by adding Subchapter N to read as follows:

SUBCHAPTER N. WHOLESALE DISTRIBUTORS OF PRESCRIPTION DRUGS

Sec. 431.401. DEFINITIONS. In this subchapter:

(1) "Authentication" means to affirmatively verify before any wholesale distribution of a prescription drug occurs that each transaction listed on the pedigree for the drug has occurred.

(2) "Authorized distributor of record" means a distributor with whom a manufacturer has established an ongoing relationship to distribute the manufacturer's products in accordance with Section 431.4011.

(3) "Chain pharmacy warehouse" means a location for which a person holds a wholesale drug distribution license under this subchapter, that serves primarily as a central warehouse for drugs or devices, and from which intracompany sales or transfers of drugs or devices are made to a group of pharmacies under common ownership and control.

(4) "Logistics provider" means a person that receives prescription drugs only from the original manufacturer, delivers the prescription drugs at the direction of that manufacturer, and does not purchase, sell, trade, or take title to any prescription drug.

(5) "Normal distribution chain" means a chain of custody for a drug from:

(A) a manufacturer to an authorized distributor of record or to a wholesale distributor licensed under this subchapter to a pharmacy or practitioner to a patient;

(B) a manufacturer to an authorized distributor of record to one other authorized distributor of record to a pharmacy or practitioner to a patient; or

(C) a manufacturer to an authorized distributor of record to a chain pharmacy warehouse to a pharmacy or practitioner to a patient.

(6) "Pedigree" means a document or electronic file containing information that records each wholesale distribution of a prescription drug, from sale by a manufacturer, through acquisition and sale by any wholesale distributor or repackager,

until final sale to a pharmacy or other person dispensing or administering the prescription drug.

(7) "Place of business" means each location at which a drug for wholesale distribution is located.

(8) "Prescription drug" has the meaning assigned by 21 C.F.R. Section 203.3.

(9) "Repackage" means repackaging or otherwise changing the container, wrapper, or labeling of a drug to further the distribution of a prescription drug. The term does not include repackaging by a pharmacist to dispense a drug to a patient.

(10) "Repackager" means a person who engages in repackaging.

(11) "Wholesale distribution" means distribution to a person other than a consumer or patient, and includes distribution by a manufacturer, repackager, own label distributor, broker, jobber, warehouse, retail pharmacy that conducts wholesale distribution, or wholesaler. The term does not include:

(A) intracompany sales of prescription drugs, which means transactions or transfers of prescription drugs between a division, subsidiary, parent, or affiliated or related company that is under common ownership and control of a corporate entity;

(B) the sale, purchase, distribution, trade, or transfer of prescription drugs or the offer to sell, purchase, distribute, trade, or transfer a prescription drug for emergency medical reasons;

(C) the distribution of prescription drug samples by a representative of a manufacturer;

(D) the return of drugs by a hospital, health care entity, retail pharmacy, chain pharmacy warehouse, or charitable institution in accordance with 21 C.F.R. Section 203.23; or

(E) the delivery by a retail pharmacy of a prescription drug to a patient or a patient's agent under the lawful order of a licensed practitioner.

Sec. 431.4011. ONGOING RELATIONSHIP. In this subchapter, "ongoing relationship" means an association that exists when a manufacturer and distributor enter into a written agreement under

which the distributor is authorized to distribute the manufacturer's products for a period of time or for a number of shipments. If the distributor is not authorized to distribute the manufacturer's entire product line, the agreement must identify the specific drug products that the distributor is authorized to distribute.

Sec. 431.4012. APPLICABILITY OF SUBCHAPTER. This subchapter applies only to the wholesale distribution of prescription drugs.

Sec. 431.402. LICENSE REQUIRED. (a) A person may not engage in wholesale distribution of prescription drugs in this state unless the person holds a wholesale drug distribution license under this subchapter for each place of business.

(b) A license issued under this subchapter expires on the second anniversary of the date of issuance.

Sec. 431.403. EXEMPTION FROM LICENSING. (a) A person who engages in wholesale distribution of prescription drugs in this state for use in humans is exempt from this subchapter if the person is exempt under:

(1) the Prescription Drug Marketing Act of 1987 (21 U.S.C. Section 353(c)(3)(B));

(2) the regulations adopted by the secretary to administer and enforce that Act; or

(3) the interpretations of that Act set out in the compliance policy manual of the United States Food and Drug Administration.

(b) An exemption from the licensing requirements under this section does not constitute an exemption from the other provisions of this chapter or the rules adopted under this chapter to administer and enforce the other provisions of this chapter.

Sec. 431.4031. EXEMPTION FROM CERTAIN PROVISIONS FOR CERTAIN WHOLESALE DISTRIBUTORS. A wholesale distributor that distributes prescription drugs that are medical gases or a wholesale distributor that is a logistics provider on behalf of a manufacturer is exempt from Sections 431.404(b) and (c), 431.405, 431.407, 431.408, 431.412, and 431.413.

Sec. 431.404. LICENSE APPLICATION. (a) An applicant for a

license under this subchapter must submit an application to the department on the form prescribed by the department. The application must contain:

(1) all trade or business names under which the business is conducted;

(2) the address and telephone number of each place of business that is licensed;

(3) the type of business and the name and residence address of:

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

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

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

(4) the date and place of incorporation, if the business is a corporation;

(5) the names and business addresses of the individuals in an administrative capacity showing:

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

(6) the name, telephone number, and any information necessary to complete a criminal history record check on a designated representative of each place of business;

(7) the state of incorporation, if the business is a corporation;

(8) a list of all licenses and permits issued to the applicant by any other state under which the applicant is permitted to purchase or possess prescription drugs; and

(9) the name of the manager for each place of business.

(b) Each person listed in Subsections (a)(6) and (a)(9)

shall provide the following to the department:

(1) the person's places of residence for the past seven years;

(2) the person's date and place of birth;

(3) the person's occupations, positions of employment, and offices held during the past seven years;

(4) the business name and address of any business, corporation, or other organization in which the person held an office under Subdivision (3) or in which the person conducted an occupation or held a position of employment;

(5) a statement of whether during the preceding seven years the person was the subject of a proceeding to revoke a license and the nature and disposition of the proceeding;

(6) a statement of whether during the preceding seven years the person has been enjoined, either temporarily or permanently, by a court from violating any federal or state law regulating the possession, control, or distribution of prescription drugs, including the details concerning the event;

(7) a written description of any involvement by the person with any business, including any investments, other than the ownership of stock in a publicly traded company or mutual fund during the past seven years, that manufactured, administered, prescribed, distributed, or stored pharmaceutical products and any lawsuits in which the businesses were named as a party;

(8) a description of any felony offense for which the person, as an adult, was found guilty, regardless of whether adjudication of guilt was withheld or whether the person pled guilty or nolo contendere;

(9) a description of any criminal conviction of the person under appeal, a copy of the notice of appeal for that criminal offense, and a copy of the final written order of an appeal not later than the 15th day after the date of the appeal's disposition; and

(10) a photograph of the person taken not earlier than 30 days before the date the application was submitted.

(c) The information submitted under Subsection (b) must be attested to under oath.

(d) An applicant or license holder shall file with the department a written notice of any change in the information required under this section.

Sec. 431.405. QUALIFICATIONS FOR LICENSE. To qualify for the issuance or renewal of a wholesale distributor license under this subchapter, the designated representative of an applicant or license holder must:

(1) be at least 21 years of age;

(2) have been employed full-time for at least three years by a pharmacy or a wholesale distributor in a capacity related to the dispensing or distributing of prescription drugs, including recordkeeping for the dispensing or distributing of prescription drugs;

(3) be employed by the applicant full-time in a managerial-level position;

(4) be actively involved in and aware of the actual daily operation of the wholesale distributor;

(5) be physically present at the applicant's place of business during regular business hours, except when the absence of the designated representative is authorized, including sick leave and vacation leave;

(6) serve as a designated representative for only one applicant at any one time;

(7) not have been convicted of a violation of any federal, state, or local laws relating to wholesale or retail prescription drug distribution or the distribution of controlled substances; and

(8) not have been convicted of a felony under a federal, state, or local law.

Sec. 431.406. EFFECT OF OPERATION IN OTHER JURISDICTIONS; REPORTS. (a) A person who engages in the wholesale distribution of drugs outside this state may engage in the wholesale distribution of drugs in this state if the person holds a license issued by the department.

(b) The department may accept reports from authorities in other jurisdictions to determine the extent of compliance with this subchapter and the minimum standards adopted under this subchapter.

(c) The department may issue a license to a person who engages in the wholesale distribution of drugs outside this state to engage in the wholesale distribution of drugs in this state if, after an examination of the reports of the person's compliance history and current compliance record, the department determines that the person is in compliance with this subchapter and the rules adopted under this subchapter.

(d) The department shall consider each license application and any related documents or reports filed by or in connection with a person who wishes to engage in wholesale distribution of drugs in this state on an individual basis.

Sec. 431.407. CRIMINAL HISTORY RECORD INFORMATION. The department shall submit to the Department of Public Safety the fingerprints provided by a person with an initial or a renewal license application to obtain the person's criminal history record information and may forward the fingerprints to the Federal Bureau of Investigation for a federal criminal history check.

Sec. 431.408. BOND. (a) A wholesale distributor applying for or renewing a license shall submit payable to this state a bond or other equivalent security acceptable to the department, including an irrevocable letter of credit or a deposit in a trust account or financial institution, in the amount of $100,000 payable to this state.

(b) The bond or equivalent security submitted under Subsection (a) shall secure payment of any fines or penalties imposed by the department or imposed in connection with an enforcement action by the attorney general, any fees or other enforcement costs, including attorney's fees payable to the attorney general, and any other fees and costs incurred by this state related to that license holder, that are authorized under the laws of this state and that the license holder fails to pay before the 30th day after the date a fine, penalty, fee, or cost is assessed.

(c) The department or this state may make a claim against a bond or security submitted under Subsection (a) before the first anniversary of the date a license expires or is revoked under this subchapter.

(d) The department shall deposit the bonds and equivalent securities received under this section in a separate account.

Sec. 431.409. FEES. (a) The department shall collect fees for:

(1) a license that is filed or renewed;

(2) a license that is amended, including a notification of a change in the location of a licensed place of business required under Section 431.410; and

(3) an inspection performed in enforcing this subchapter and rules adopted under this subchapter.

(b) The executive commissioner of the Health and Human Services Commission by rule shall set the fees in amounts that are reasonable and necessary and allow the department to recover the biennial expenditures of state funds by the department in:

(1) reviewing and acting on a license;

(2) amending and renewing a license;

(3) inspecting a licensed facility; and

(4) implementing and enforcing this subchapter, including a rule or order adopted or a license issued under this subchapter.

(c) Fees collected under this section shall be deposited to the credit of the food and drug registration fee account of the general revenue fund and appropriated to the department to carry out this chapter.

Sec. 431.410. CHANGE OF LOCATION OF PLACE OF BUSINESS. (a) Not fewer than 30 days in advance of the change, the license holder shall notify the department in writing of the license holder's intent to change the location of a licensed place of business.

(b) The notice shall include the address of the new location and the name and residence address of the individual in charge of the business at the new location.

(c) Not more than 10 days after the completion of the change of location, the license holder shall notify the department in writing to confirm the completion of the change of location and provide verification of the information previously provided or correct and confirm any information that has changed since

providing the notice of intent.

(d) The notice and confirmation required by this section are considered adequate if the license holder sends the notices by certified mail, return receipt requested, to the central office of the department or submits the notices electronically through the TexasOnline Internet website.

Sec. 431.411. MINIMUM RESTRICTIONS ON TRANSACTIONS. (a) A wholesale distributor shall receive prescription drug returns or exchanges from a pharmacy or chain pharmacy warehouse in accordance with the terms and conditions of the agreement between the wholesale distributor and the pharmacy or chain pharmacy warehouse. The returns or exchanges received by the wholesale distributor as provided by this subsection are not subject to the pedigree requirement under Section 431.412. In connection with the returned goods process, a wholesale distributor should establish appropriate business practices and exercise due diligence designed to prevent the entry of adulterated or counterfeit drugs into the distribution channel.

(b) A manufacturer or wholesale distributor may distribute prescription drugs only to a person licensed by the appropriate state licensing authorities or authorized by federal law to receive the drug. Before furnishing prescription drugs to a person not known to the manufacturer or wholesale distributor, the manufacturer or wholesale distributor must verify that the person is legally authorized by the appropriate state licensing authority to receive the prescription drugs or authorized by federal law to receive the drugs.

(c) Except as otherwise provided by this subsection, prescription drugs distributed by a manufacturer or wholesale distributor may be delivered only to the premises listed on the license. A manufacturer or wholesale distributor may distribute prescription drugs to an authorized person or agent of that person at the premises of the manufacturer or wholesale distributor if:

(1) the identity and authorization of the recipient is properly established; and

(2) delivery is made only to meet the immediate needs of a particular patient of the authorized person.

(d) Prescription drugs may be distributed to a hospital pharmacy receiving area if a pharmacist or an authorized receiving person signs, at the time of delivery, a receipt showing the type and quantity of the prescription drug received. Any discrepancy between the receipt and the type and quantity of the prescription drug actually received shall be reported to the delivering manufacturer or wholesale distributor not later than the next business day after the date of delivery to the pharmacy receiving area.

Sec. 431.412. PEDIGREE REQUIRED. (a) A person who is engaged in the wholesale distribution of a prescription drug, including a repackager but excluding the original manufacturer and the original labeler of a prescription drug, shall provide a pedigree for each prescription drug that is not distributed through the normal distribution chain and is sold, traded, or transferred to any other person.

(b) A pharmacy that sells a drug to a person other than the final consumer shall provide a pedigree to the person acquiring the prescription drug. The sale of a reasonable quantity of a drug to a practitioner for office use is not subject to this subsection.

(c) The sale, trade, or transfer of a prescription drug between license holders with common ownership or for an emergency is not subject to this section.

(d) A person who is engaged in the wholesale distribution of a prescription drug, including a repackager, and who is in possession of a pedigree for a prescription drug must verify before distributing the prescription drug that each transaction listed on the pedigree has occurred.

Sec. 431.413. PEDIGREE CONTENTS. (a) A pedigree must include all necessary identifying information concerning each sale in the product's chain of distribution from the manufacturer, through acquisition and sale by a wholesale distributor or repackager, until final sale to a pharmacy or other person dispensing or administering the drug. At a minimum, the chain of distribution information must include:

(1) the name, address, telephone number, and, if available, the e-mail address of each person who owns or possesses

the prescription drug, except common carriers and logistics providers;

(2) the signature of each owner of the prescription drug;

(3) the name and address of each location from which the product was shipped, if different from the owner's name and address;

(4) the transaction dates; and

(5) certification that each recipient has authenticated the pedigree.

(b) The pedigree must include, at a minimum, the:

(1) name of the prescription drug;

(2) dosage form and strength of the prescription drug;

(3) size of the container;

(4) number of containers;

(5) lot number of the prescription drug; and

(6) name of the manufacturer of the finished dosage form.

(c) Each pedigree statement must be:

(1) maintained by the purchaser and the wholesale distributor for at least three years; and

(2) available for inspection and photocopying on a request by the department or a peace officer in this state.

(d) The executive commissioner of the Health and Human Services Commission shall adopt rules to implement this section.

(e) The department shall:

(1) conduct a study on the implementation of electronic pedigrees;

(2) in conducting the study under Subdivision (1), consult with manufacturers, distributors, and pharmacies responsible for the sale and distribution of prescription drugs in this state; and

(3) based on the results of the study, establish an implementation date, which may not be earlier than December 31, 2007, for electronic pedigrees.

(f) Subsection (e) and this subsection expire January 1, 2009.

Sec. 431.414. REFUSAL TO LICENSE; SUSPENSION OR REVOCATION OF LICENSE. (a) The commissioner of state health services may refuse an application for a license or may suspend or revoke a license if the applicant or license holder:

(1) has been convicted of a felony or misdemeanor that involves moral turpitude;

(2) is an association, partnership, or corporation and the managing officer has been convicted of a felony or misdemeanor that involves moral turpitude;

(3) has been convicted in a state or federal court of the illegal use, sale, or transportation of intoxicating liquors, narcotic drugs, barbiturates, amphetamines, desoxyephedrine, their compounds or derivatives, or any other dangerous or habit-forming drugs;

(4) is an association, partnership, or corporation and the managing officer has been convicted in a state or federal court of the illegal use, sale, or transportation of intoxicating liquors, narcotic drugs, barbiturates, amphetamines, desoxyephedrine, their compounds or derivatives, or any other dangerous or habit-forming drugs;

(5) has not complied with this subchapter or the rules implementing this subchapter;

(6) has violated Section 431.021(l)(3), relating to the counterfeiting of a drug or the sale or holding for sale of a counterfeit drug;

(7) has violated Chapter 481 or 483; or

(8) has violated the rules of the director of the Department of Public Safety, including being responsible for a significant discrepancy in the records that state law requires the applicant or license holder to maintain.

(b) The executive commissioner of the Health and Human Services Commission by rule shall establish minimum standards required for the issuance or renewal of a license under this subchapter.

(c) The department shall deny a license application that is incomplete, contains false, misleading, or incorrect information, or contains information that cannot be verified by the department.

(d) The refusal to license an applicant or the suspension or revocation of a license by the department and the appeal from that action are governed by the procedures for a contested case hearing under Chapter 2001, Government Code.

Sec. 431.415. ORDER TO CEASE DISTRIBUTION. (a) The commissioner of state health services shall issue an order requiring a person, including a manufacturer, distributor, or retailer of a prescription drug, to immediately cease distribution of the drug if the commissioner determines there is a reasonable probability that:

(1) a wholesale distributor has:

(A) violated this subchapter;

(B) falsified a pedigree; or

(C) sold, distributed, transferred, manufactured, repackaged, handled, or held a counterfeit prescription drug intended for human use that could cause serious adverse health consequences or death; and

(2) other procedures would result in unreasonable delay.

(b) An order under Subsection (a) must provide the person subject to the order with an opportunity for an informal hearing on the actions required by the order to be held not later than the 10th day after the date of issuance of the order.

(c) If, after providing an opportunity for a hearing, the commissioner of state health services determines that inadequate grounds exist to support the actions required by the order, the commissioner shall vacate the order.

(h) Section 431.059, Health and Safety Code, is amended by amending Subsection (a) and adding Subsections (a-1) and (a-2) 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 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 Subsection (a-2) or Section 431.021, as applicable, to establish criminal responsibility for the violation.

(a-1) A person commits an offense if the person engages in the wholesale distribution of prescription drugs in violation of Subchapter N. An offense under this subsection is punishable by a fine not to exceed $50,000.

(a-2) A person commits an offense if the person knowingly engages in the wholesale distribution of prescription drugs in violation of Subchapter N. An offense under this subsection is punishable by imprisonment for not more than 15 years, a fine not to exceed $500,000, or both imprisonment and a fine.

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

(2) prescribe or specify by any means the manner

in which such commodities are packaged or labeled;

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

(f) the dissemination of any false advertisement;

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

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

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

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

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

(l)(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 of this chapter and Section 562.1085, Occupations Code, 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 obtaining a license issued by the department under Subchapter I, L, or N [~~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 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;

(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; [~~or~~]

(aa) making a false statement or false representation in an application for a license or in a statement, report, or other instrument to be filed with or requested by the department [~~the board, the commissioner, or the department~~] under this chapter;

(bb) failing to comply with a requirement or request to provide information or failing to submit an application, statement, report, or other instrument required by the department;

(cc) performing, causing the performance of, or aiding

and abetting the performance of an act described by Subdivision (x);

(dd) purchasing or otherwise receiving a prescription drug from a pharmacy in violation of Section 431.411(a);

(ee) selling, distributing, or transferring a prescription drug to a person who is not authorized under state or federal law to receive the prescription drug in violation of Section 431.411(b);

(ff) failing to deliver prescription drugs to specified premises as required by Section 431.411(c);

(gg) failing to maintain or provide pedigrees as required by Section 431.412 or 431.413;

(hh) failing to obtain, pass, or authenticate a pedigree as required by Section 431.412 or 431.413; or

(ii) the introduction or delivery for introduction into commerce of a drug or prescription device at a flea market.

(j) Section 411.110, Government Code, is amended to read as follows:

Sec. 411.110. ACCESS TO CRIMINAL HISTORY RECORD INFORMATION: [~~TEXAS~~] DEPARTMENT OF STATE HEALTH SERVICES. (a) The [~~Texas~~] Department of State Health Services is entitled to obtain from the department criminal history record information maintained by the department that relates to:

(1) a person who is:

(A) [~~(1)~~] an applicant for a license or certificate under the Emergency Medical Services Act (Chapter 773, Health and Safety Code);

(B) [~~(2)~~] an owner or manager of an applicant for an emergency medical services provider license under that Act; or

(C) [~~(3)~~] the holder of a license or certificate under that Act; or

(2) an applicant for a license or a license holder under Subchapter N, Chapter 431, Health and Safety Code.

(b) Criminal history record information obtained by the [~~Texas~~] Department of State Health Services under Subsection (a) may not be released or disclosed to any person except on court order, with the written consent of the person or entity that is the subject of the criminal history record information, or as provided by Subsection (e).

(c) After an entity is licensed or certified, the [~~Texas~~] Department of State Health Services shall destroy the criminal history record information that relates to that entity.

(d) The Department of State Health Services [~~Texas Board of Health~~] shall destroy criminal history record information that relates to an applicant that is not certified.

(e) The Department of State Health Services [~~Texas Board of Health~~] is not prohibited from disclosing criminal history record information obtained under Subsection (a) in a criminal proceeding or in a hearing conducted by the [~~Texas~~] Department of State Health Services.

(k) Sections 431.2021 and 431.205, Health and Safety Code, are repealed.

(l) Not later than January 1, 2006, the executive commissioner of the Health and Human Services Commission shall adopt the rules necessary to implement the changes in law made by this section by amending Subchapter I, Chapter 431, Health and Safety Code, and adding Subchapter N, Chapter 431, Health and Safety Code.

(m) Not later than January 1, 2006, the Department of State Health Services shall prescribe the forms required to implement the changes in law made by this section by the amendment of Subchapter

I, Chapter 431, Health and Safety Code, and the addition of Subchapter N, Chapter 431, Health and Safety Code.

(n) The change in law made by this section applies only to an offense committed on or after March 1, 2006. An offense committed before that date is covered by the law in effect when the offense was committed, and the former law is continued in effect for that purpose. For purposes of this subsection, an offense was committed before March 1, 2006, if any element of the offense was committed before that date.

(o) Except as provided by Subsection (p) of this section, this section takes effect September 1, 2005.

(p) Subsections (a) through (i) of this section take effect March 1, 2006.