By the Committees on Judiciary; Health Care; and Senator Peaden

590-2484-06

A bill to be entitled

An act relating to drug distribution; amending s. 499.003, F.S.; amending a definition; requiring the Department of Health to approve a document or electronic form relating to pedigree papers; providing requirements for pedigree papers that record certain distributions of legend drugs; amending s. 499.005, F.S.; revising a prohibition relating to pedigree papers; amending s. 499.006, F.S.; providing that a drug is adulterated if it is a certain prescription drug that has been returned by a veterinarian to a limited prescription drug veterinary wholesaler; amending s. 499.01, F.S.; requiring a limited prescription drug veterinary wholesaler to obtain a permit for operation from the Department of Health; providing that a permit for a limited prescription drug veterinary wholesaler may not be issued to the address of certain health care entities; amending s. 499.012, F.S.; revising permit requirements for a veterinary prescription drug wholesaler that distributes prescription drugs; establishing a permit for a limited prescription drug veterinary wholesaler; providing requirements; providing an exception; amending s. 499.0121, F.S.; requiring certain wholesale distributors taking title to a prescription drug to provide an invoice to the purchaser containing certain information; requiring a purchaser of a

prescription drug to obtain from the manufacturer a shipping document containing specified information; requiring a manufacturer to make certain information available to the department; authorizing the department to adopt certain rules relating to the inventory and return of certain prescription drugs; amending s. 499.0122, F.S.; redefining the term "veterinary legend drug retail establishment"; amending s. 499.041, F.S.; requiring the department to assess an annual fee within a certain monetary range for a limited prescription drug veterinary wholesaler permit; amending s. 499.065, F.S.; requiring the department to inspect each limited prescription drug veterinary wholesaler establishment; authorizing the department to determine that a limited prescription drug veterinary wholesaler establishment is an imminent danger to the public; amending s. 499.0661, F.S.; providing for emergency suspension of a permittee if charged with specified violations; requiring the department to publish a list of certain permittee names; amending s. 499.067, F.S.; prohibiting issuance of permits to specified applicants; requiring revocation of permits of specified permittees; providing an effective date.

Be It Enacted by the Legislature of the State of Florida:

Section 1. Subsection (31) of section 499.003, Florida Statutes, is amended to read:

499.003 Definitions of terms used in ss. 499.001-499.081.--As used in ss. 499.001-499.081, the term:

(31) "Pedigree paper" means:

(a) A document required pursuant to s. 499.0121(6)(d) or (e); ~~or~~

(b) Effective July 1, 2006, a document or electronic form approved by the Department of Health and containing information that records each distribution of any given legend drug, from sale by a pharmaceutical manufacturer, through acquisition and sale by any wholesaler or repackager, until final sale to a pharmacy or other person administering or dispensing the drug. The information required to be included on a legend drug's pedigree paper must at least detail the amount of the legend drug; its dosage form and strength; its lot numbers; the name and address of each owner of the legend drug and his or her signature; its shipping information, including the name and address of each person certifying delivery or receipt of the legend drug; an invoice number, a shipping document number, or another number uniquely identifying the transaction; and a certification that the recipient wholesaler has authenticated the pedigree papers. If the manufacturer or repackager has uniquely serialized the individual legend drug unit, that identifier must also be included on the pedigree. It must also include the name, address, telephone number and, if available, e-mail contact information of each wholesaler involved in the chain of the legend drug's custody. The department shall adopt rules and a form relating to the requirements of this paragraph no later than 90 days after the effective date of this act<u>; or</u>~~.~~

(c) Effective July 1, 2006, a document or electronic form approved by the Department of Health and containing information that records each distribution of any given legend drug, from sale by a pharmaceutical manufacturer, through acquisition and sale by any wholesaler or repackager, until final sale to a pharmacy or other person administering or dispensing the drug; or, if a specific unit of the legend drug was purchased by a wholesaler, referred to in this paragraph as a "direct purchase wholesaler," directly from the manufacturer, an invoice for the specific unit of the legend drug together with a certificate under oath in written or electronic form stating that:

1. If the establishment is not a member of an affiliated group: "This establishment purchased the specific unit of the legend drug directly from the manufacturer."

2. If the establishment is a member of an affiliated group: "This establishment or a member of its affiliated group purchased the specific unit of the legend drug directly from the manufacturer."

A document or electronic form that meets the requirements of this paragraph shall constitute a sufficient pedigree paper only for the purpose of a single sale or distribution transaction in the specific unit of legend drug by the direct purchase wholesaler to an entity authorized by law to purchase legend drugs. For each transaction of the specific unit of legend drug, the direct purchase wholesaler is required to create a separate pedigree paper that meets the requirements of this paragraph and furnish such pedigree paper to any subsequent purchaser. The pedigree paper shall be prepared and updated for every transfer following the direct purchase

wholesaler's receipt of the specific unit of legend drug directly from the manufacturer. The information required to be included on the document or electronic form approved by the department pursuant to this paragraph and required of any subsequent transfers of legend drugs received by a direct purchase wholesaler in a transaction described in this paragraph must at least detail the amount of the legend drug; its dosage form and strength; its lot numbers; the name and address of each owner of the legend drug after it has left the possession of the manufacturer and his or her signature; its shipping information, including the name and address of each person certifying delivery or receipt of the legend drug after it has left the possession of the manufacturer; an invoice number, a shipping document number, or another number uniquely identifying the transaction; and a certification that the recipient direct purchase wholesaler has authenticated the pedigree papers as required in this paragraph. If the manufacturer or repackager has uniquely serialized the individual legend drug unit, that identifier must also be included on the form approved by the department and is required of any subsequent transfers of prescription drugs received by a direct purchase wholesaler in a transaction governed by this paragraph. The pedigree paper must also include the name, address, telephone number, and, if available, e-mail contact information of each wholesaler involved in the chain of custody of the legend drug. The department shall adopt rules and a form relating to the requirements of this paragraph.

Section 2. Subsection (29) of section 499.005, Florida Statutes, is amended to read:

499.005 Prohibited acts.--It is unlawful for a person to perform or cause the performance of any of the following acts in this state:

(29) The receipt of a prescription drug pursuant to a wholesale distribution without <u>either</u> first receiving a pedigree paper that was attested to as accurate and complete by the wholesale distributor <u>or complying with the provisions of s. 499.0121(6)(f)6</u>.

Section 3. Section 499.006, Florida Statutes, is amended to read:

499.006 Adulterated drug or device.--A drug or device is adulterated:

(1) If it consists in whole or in part of any filthy, putrid, or decomposed substance;

(2) If it has been produced, prepared, packed, or held under conditions whereby it could have been contaminated with filth or rendered injurious to health;

(3) If it is a drug and the methods used in, or the facilities or controls used for, its manufacture, processing, packing, or holding do not conform to, or are not operated or administered in conformity with, current good manufacturing practices to assure that the drug meets the requirements of ss. 499.001-499.081 and that the drug has the identity and strength, and meets the standard of quality and purity, which it purports or is represented to possess;

(4) If it is a drug and its container is composed, in whole or in part, of any poisonous or deleterious substance which could render the contents injurious to health;

(5) If it is a drug and it bears or contains, for the purpose of coloring only, a color additive that is unsafe within the meaning of the federal act; or, if it is a color

additive, the intended use of which in or on drugs is for the purpose of coloring only, and it is unsafe within the meaning of the federal act;

(6) If it purports to be, or is represented as, a drug the name of which is recognized in the official compendium, and its strength differs from, or its quality or purity falls below, the standard set forth in such compendium. The determination as to strength, quality, or purity must be made in accordance with the tests or methods of assay set forth in such compendium, or, when such tests or methods of assay are absent or inadequate, in accordance with those tests or methods of assay prescribed under authority of the federal act. A drug defined in the official compendium is not adulterated under this subsection merely because it differs from the standard of strength, quality, or purity set forth for that drug in such compendium if its difference in strength, quality, or purity from such standard is plainly stated on its label;

(7) If it is not subject to subsection (6) and its strength differs from, or its purity or quality falls below the standard of, that which it purports or is represented to possess;

(8) If it is a drug:

(a) With which any substance has been mixed or packed so as to reduce the quality or strength of the drug; or

(b) For which any substance has been substituted wholly or in part;

(9) If it is a drug or device for which the expiration date has passed; ~~or~~

(10) If it is a legend drug for which the required pedigree paper is nonexistent, fraudulent, or incomplete under

the requirements of ss. 499.001-499.081 or applicable rules, or that has been purchased, held, sold, or distributed at any time by a person not authorized under federal or state law to do so; or.

(11) If it is a prescription drug subject to, defined by, or described by s. 503(b) of the Federal Food, Drug, and Cosmetic Act which has been returned by a veterinarian to a limited prescription drug veterinary wholesaler.

Section 4. Subsection (1) and paragraph (d) of subsection (2) of section 499.01, Florida Statutes, are amended to read:

499.01 Permits; applications; renewal; general requirements.--

(1) Prior to operating, a permit is required for each person and establishment that intends to operate as:

(a) A prescription drug manufacturer;

(b) A prescription drug repackager;

(c) An over-the-counter drug manufacturer;

(d) A compressed medical gas manufacturer;

(e) A device manufacturer;

(f) A cosmetic manufacturer;

(g) A prescription drug wholesaler;

(h) A veterinary prescription drug wholesaler;

(i) A compressed medical gas wholesaler;

(j) An out-of-state prescription drug wholesaler;

(k) A nonresident prescription drug manufacturer;

(l) A freight forwarder;

(m) A retail pharmacy drug wholesaler;

(n) A veterinary legend drug retail establishment;

(o) A medical oxygen retail establishment;

(p) A complimentary drug distributor; ~~or~~

(q) A restricted prescription drug distributor; or.

(r) A limited prescription drug veterinary wholesaler.

(2)

(d) A permit for a prescription drug manufacturer, prescription drug repackager, prescription drug wholesaler, limited prescription drug veterinary wholesaler, or retail pharmacy wholesaler may not be issued to the address of a health care entity or to a pharmacy licensed under chapter 465, except as provided in this paragraph. The department may issue a prescription drug manufacturer permit to an applicant at the same address as a licensed nuclear pharmacy, which is a health care entity, for the purpose of manufacturing prescription drugs used in positron emission tomography or other radiopharmaceuticals, as listed in a rule adopted by the department pursuant to this paragraph. The purpose of this exemption is to assure availability of state-of-the-art pharmaceuticals that would pose a significant danger to the public health if manufactured at a separate establishment address from the nuclear pharmacy from which the prescription drugs are dispensed. The department may also issue a retail pharmacy wholesaler permit to the address of a community pharmacy licensed under chapter 465 which does not meet the definition of a closed pharmacy in s. 499.003.

Section 5. Paragraph (g) of subsection (2) of section 499.012, Florida Statutes, is amended, and paragraph (h) is added to that subsection, to read:

499.012 Wholesale distribution; definitions; permits; applications; general requirements.--

(2) The following types of wholesaler permits are established:

(g) A veterinary prescription drug wholesaler permit.--A veterinary prescription drug wholesaler permit is required for any person that engages in the distribution of veterinary prescription drugs in or into this state. A veterinary prescription drug wholesaler that also distributes prescription drugs subject to, defined by, or described by s. 503(b) of the Federal Food, Drug, and Cosmetic Act which it did not manufacture must obtain a permit as a prescription drug wholesaler, an ~~or~~ out-of-state prescription drug wholesaler, or a limited prescription drug veterinary wholesaler in lieu of the veterinary prescription drug wholesaler permit. A veterinary prescription drug wholesaler must comply with the requirements for wholesale distributors under s. 499.0121, except those set forth in s. 499.0121(6)(d), (e), or (f).

(h) Limited prescription drug veterinary wholesaler permit.--Unless engaging in the activities of and permitted as a prescription drug manufacturer, nonresident prescription drug manufacturer, prescription drug wholesaler, or out-of-state prescription drug wholesaler, a limited prescription drug veterinary wholesaler permit is required for any person that engages in the distribution in or into this state of veterinary prescription drugs and prescription drugs subject to, defined by, or described by s. 503(b) of the Federal Food, Drug, and Cosmetic Act to veterinarians under the following conditions:

1. The person is engaged in the business of wholesaling prescription and veterinary legend drugs to persons:

a. Licensed as veterinarians practicing on a full-time basis;

b. Regularly and lawfully engaged in instruction in veterinary medicine;

c. Regularly and lawfully engaged in law enforcement;

d. For use in research, not involving clinical use; or

e. For use in chemical analysis or physical testing, for the purposes of instruction in law enforcement, research, or testing.

2. No more than 30 percent of prescription drug sales may be prescription drugs approved for human use which are subject to, defined by, or described by s. 503(b) of the Federal Food, Drug, and Cosmetic Act.

3. The person is not permitted, licensed, or otherwise authorized in any state to wholesale prescription drugs subject to, defined by, or described by s. 503(b) of the Federal Food, Drug, and Cosmetic Act to any person who is authorized to sell, distribute, purchase, trade, or use these drugs on or for humans.

4. A limited prescription drug veterinary wholesaler that applies to the department for a new permit or the renewal of a permit must submit a bond of $20,000, or other equivalent means of security acceptable to the department, such as an irrevocable letter of credit or a deposit in a trust account or financial institution, payable to the Florida Drug, Device, and Cosmetic Trust Fund. The purpose of the bond is to secure payment of any administrative penalties imposed by the department and any fees and costs incurred by the department regarding that permit which are authorized under state law and which the permittee fails to pay 30 days after the fine or costs become final. The department may make a claim against such bond or security until 1 year after the permittee's license ceases to be valid or until 60 days after any

administrative or legal proceeding authorized in ss. 499.001-499.081 which involves the permittee is concluded, including any appeal, whichever occurs later.

5. A limited prescription drug veterinary wholesaler must maintain at all times a license or permit to engage in the wholesale distribution of prescription drugs in compliance with laws of the state in which it is a resident.

6. A limited prescription drug veterinary wholesaler must comply with the requirements for wholesale distributors under s. 499.0121, except that a limited prescription drug veterinary wholesaler is not required to provide a pedigree paper as required by s. 499.0121(6)(f) upon the wholesale distribution of a prescription drug to a veterinarian.

7. A limited prescription drug veterinary wholesaler may not return to inventory for subsequent wholesale distribution any prescription drug subject to, defined by, or described by s. 503(b) of the Federal Food, Drug, and Cosmetic Act which has been returned by a veterinarian.

8. An out-of-state prescription drug wholesaler's permit or a limited prescription drug veterinary wholesaler permit is not required for an intracompany sale or transfer of a prescription drug from an out-of-state establishment that is duly licensed to engage in the wholesale distribution of prescription drugs in its state of residence to a licensed limited prescription drug veterinary wholesaler in this state if both wholesalers conduct wholesale distributions of prescription drugs under the same business name. The recordkeeping requirements of s. 499.0121(6) must be followed for this transaction.

Section 6. Paragraph (f) of subsection (6) of section 499.0121, Florida Statutes, is amended to read:

499.0121 Storage and handling of prescription drugs; recordkeeping.--The department shall adopt rules to implement this section as necessary to protect the public health, safety, and welfare. Such rules shall include, but not be limited to, requirements for the storage and handling of prescription drugs and for the establishment and maintenance of prescription drug distribution records.

(6) RECORDKEEPING.--The department shall adopt rules that require keeping such records of prescription drugs as are necessary for the protection of the public health.

(f)1. Effective July 1, 2006, each person who is engaged in the wholesale distribution of a prescription drug and who is not the manufacturer of that drug must, before each wholesale distribution of such drug, provide to the person who receives the drug a pedigree paper as defined in s. 499.003(31).

2. A repackager must comply with this paragraph.

3. The pedigree paper requirements in this paragraph do not apply to compressed medical gases or veterinary legend drugs.

4. Each wholesale distributor of prescription drugs must maintain separate and distinct from other required records all statements that are required under subparagraph 1.

5. In order to verify compliance with subparagraph (d)1., each manufacturer of a prescription drug sold in this state must make available upon request distribution documentation related to its sales of prescription drugs, regardless of whether the prescription drug was sold directly by the manufacturer to a person in Florida.

6. Subparagraph 1. does not apply to a wholesale distributor that takes title to, but not possession of, a

prescription drug and the prescription drug's manufacturer ships the prescription drug directly to a person authorized by law to administer or dispense prescription drugs or a member of an affiliated group, except a repackager, described in paragraph (h).

a. The wholesale distributor must send an invoice to the purchaser of the prescription drug that contains a clear cross-reference to the shipping document sent by the manufacturer to the purchaser of the prescription drug.

b. The purchaser of the prescription drug must obtain a shipping document from the manufacturer that contains, at a minimum:

(I) The name and address of the manufacturer, including the point of origin of the shipment; the wholesaler; and the purchaser.

(II) The name of the prescription drug as it appears on the label.

(III) The quantity, dosage form, and strength of the prescription drug.

(IV) The date of the shipment.

c. The manufacturer must also make available to the department, upon request, the lot number of the prescription drug if the lot number is not contained in the shipping document received by the purchaser.

7. The department may by rule define alternatives to compliance with subparagraph 1. for a prescription drug in the inventory of a permitted prescription drug wholesaler as of June 30, 2006, and the return of a prescription drug purchased prior to July 1, 2006. The department may specify time limits for such alternatives.

Section 7. Paragraph (d) of subsection (1) of section 499.0122, Florida Statutes, is amended to read:

499.0122 Medical oxygen and veterinary legend drug retail establishments; definitions, permits, general requirements.--

(1) As used in this section, the term:

(d) "Veterinary legend drug retail establishment" means a person permitted to sell veterinary legend drugs to the public ~~or to veterinarians,~~ but does not include a pharmacy licensed under chapter 465.

1. The sale to the public must be based on a valid written order from a veterinarian licensed in this state who has a valid client-veterinarian relationship with the purchaser's animal.

2. Veterinary legend drugs may not be sold in excess of the amount clearly indicated on the order or beyond the date indicated on the order.

3. An order may not be valid for more than 1 year.

4. A veterinary legend drug retail establishment may not purchase, sell, trade, or possess human prescription drugs or any controlled substance as defined in chapter 893.

5. A veterinary legend drug retail establishment must sell a veterinary legend drug in the original, sealed manufacturer's container with all labeling intact and legible. The department may adopt by rule additional labeling requirements for the sale of a veterinary legend drug.

Section 8. Paragraph (h) is added to subsection (2) of section 499.041, Florida Statutes, to read:

499.041 Schedule of fees for drug, device, and cosmetic applications and permits, product registrations, and free-sale certificates.--

(2) The department shall assess an applicant that is required to have a wholesaling permit an annual fee within the ranges established in this section for the specific type of wholesaling.

(h) The fee for a limited prescription drug veterinary wholesaler's permit may not be less than $300 or more than $500 annually.

Section 9. Subsections (1) and (3) of section 499.065, Florida Statutes, are amended to read:

499.065 Imminent danger.--

(1) Notwithstanding s. 499.051, the department shall inspect each prescription drug wholesale establishment, prescription drug repackager establishment, veterinary prescription drug wholesale establishment, limited prescription drug veterinary wholesaler establishment, and retail pharmacy drug wholesaler establishment that is required to be permitted under this chapter as often as necessary to ensure compliance with applicable laws and rules. The department shall have the right of entry and access to these facilities at any reasonable time.

(3) The department may determine that a prescription drug wholesale establishment, prescription drug repackager establishment, veterinary prescription drug wholesale establishment, limited prescription drug veterinary wholesaler establishment, or retail pharmacy drug wholesaler establishment that is required to be permitted under this chapter is an imminent danger to the public health and shall require its immediate closure if the establishment fails to comply with applicable laws and rules and, because of the failure, presents an imminent threat to the public's health, safety, or welfare. Any establishment so deemed and closed

shall remain closed until allowed by the department or by judicial order to reopen.

For purposes of this section, a refusal to allow entry to the department for inspection at reasonable times, or a failure or refusal to provide the department with required documentation for purposes of inspection, constitutes an imminent danger to the public health.

Section 10. Paragraph (e) of subsection (3) of section 499.0661, Florida Statutes, is amended to read:

499.0661 Cease and desist orders; removal of certain persons.--

(3) REMOVAL OF AFFILIATED PARTIES BY THE DEPARTMENT.--

(e)1. The chief executive officer, designated representative, or the person holding the equivalent office, of a permittee shall promptly notify the department if she or he has actual knowledge that any affiliated party is charged with a felony in a state or federal court.

2. Whenever any affiliated party is charged with a felony in a state or federal court or with the equivalent of a felony in the courts of any foreign country with which the United States maintains diplomatic relations, and the charge alleges violation of any law involving prescription drugs, pharmaceuticals, fraud, theft, or moral turpitude, the department may enter an emergency order suspending the affiliated party or restricting or prohibiting participation by the affiliated party in the affairs of the particular permittee or of any other permittee upon service of the order upon the permittee and the affiliated party charged. The order must contain notice of opportunity for a hearing pursuant to ss. 120.569 and 120.57, where the affiliated party may request

a postsuspension hearing to show that continued service to or participation in the affairs of the permittee does not pose a threat to the public health or the interests of the permittee and does not threaten to impair public confidence in the permittee. In accordance with applicable departmental rules, the department shall notify the affiliated party whether the order suspending or prohibiting the person from participation in the affairs of a permittee will be rescinded or otherwise modified. The emergency order remains in effect, unless otherwise modified by the department, until the criminal charge is disposed of. The acquittal of the person charged, or the final, unappealed dismissal of all charges against the person, dissolves the emergency order but does not prohibit the department from instituting proceedings under paragraph (a). If the person charged is convicted or pleads guilty or nolo contendere, whether or not an adjudication of guilt is entered by the court, the emergency order shall become final.

3. Whenever a permittee is charged with violation of s. 499.0051 or s. 499.0052, the department may enter an emergency order suspending the permittee's permit. The order must contain notice of opportunity for a hearing pursuant to ss. 120.569 and 120.57, where a permittee may request a postsuspension hearing to show that continued operation by the permittee under his or her permit does not pose a threat to the public health and does not threaten to impair public confidence in the permittee. In accordance with applicable departmental rules, the department shall notify the permittee whether the order suspending the permit of the permittee will be rescinded or otherwise modified. The emergency order remains in effect, unless otherwise modified by the department, until the criminal charge is disposed of. The

acquittal of the permittee charged, or the final, unappealed dismissal of all charges against the permittee, dissolves the emergency order but does not prohibit the department from instituting proceedings under paragraph (a). If a permittee charged with a violation of s. 499.0051 or s. 499.0052 is convicted or pleads guilty or nolo contendere, whether or not an adjudication of guilt is entered by the court, the emergency order shall become final.

4. The department shall publish on its website a list of all permittees against whom an emergency order or a permanent order under this section is entered.

Section 11. Subsections (8) and (9) are added to section 499.067, Florida Statutes, to read:

499.067 Denial, suspension, or revocation of permit, certification, or registration.--

(8) The department shall deny an application for a permit for an establishment if the applicant, any person named pursuant to s. 499.012(3)(k) in the applicant's application, or the person designated pursuant to s. 499.012(11) by the applicant has been convicted or pleaded guilty or nolo contendere to a violation of s. 499.0051 or s. 499.0052, whether or not an adjudication of guilt is entered by the court.

(9) The department shall revoke the permit of an establishment if the permittee, any person named pursuant to s. 499.012(3)(k) in the permittee's application, or the person designated pursuant to s. 499.012(11) by the permittee has been convicted or pleaded guilty or nolo contendere to a violation of s. 499.0051 or s. 499.0052, whether or not an adjudication of guilt is entered by the court.

Section 12. This act shall take effect July 1, 2006.

STATEMENT OF SUBSTANTIAL CHANGES CONTAINED IN COMMITTEE SUBSTITUTE FOR CS for Senate Bill 926

The committee substitute changes the underlying committee substitute in that it:

-- Requires the use of detailed pedigree papers for redistributions of prescription drugs purchased from a wholesaler who purchased them directly from a manufacturer;

-- Removes provisions pertaining to authorized distributors of record of prescription drug manufacturers;

-- Creates a limited prescription drug veterinary wholesaler permit and provides for regulation of permit-holders; and

-- Provides that holders of a limited prescription drug veterinary wholesaler permit generally are not required to use pedigree papers.