A bill to be entitled

An act relating to drug distribution; 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.; removing an expiration date on a provision relating to prescription drug recordkeeping; requiring certain information to be provided by certain prescription drug wholesalers to drug recipients; requiring drug manufacturers to file a list of authorized distributors with the department; requiring the department to publish certain information; 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; providing an effective date.

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

Section 1. 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 2. 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 3. 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 veterinarians on a full-time basis.

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 4. Paragraphs (d) and (f) of subsection (6) of section 499.0121, Florida Statutes, are 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.

(d)1. Each person who is engaged in the wholesale distribution of a prescription drug, and who is not an authorized distributor of record for the drug manufacturer's products, must provide to each wholesale distributor of such drug, before the sale is made to such wholesale distributor, a written statement under oath identifying each previous sale of the drug back to the last authorized distributor of record, the lot number of the drug, and the sales invoice number of the invoice evidencing the sale of the drug. The written statement must accompany the drug to the next wholesale distributor. The department shall adopt rules relating to the requirements of this written statement. This paragraph does not apply to a

manufacturer unless the manufacturer is performing the manufacturing operation of repackaging prescription drugs.

2. Each wholesale distributor of prescription drugs must maintain separate and distinct from other required records all statements that are required under subparagraph 1. and paragraph (e).

3. Each manufacturer of a prescription drug sold in this state must maintain at its corporate offices a current list of authorized distributors and must make such list available to the department upon request.

4. Each manufacturer shall file a written list of all of the manufacturer's authorized distributors of record with the department. A manufacturer shall notify the department not later than 10 days after any change to the list. The department shall publish a list of all authorized distributors of record on its website.

5. For the purposes of this subsection, the term "authorized distributors of record" means a wholesale distributor with whom a manufacturer has established an ongoing relationship to distribute the manufacturer's products. Effective March 1, 2004, an ongoing relationship is deemed to exist when a wholesale distributor, including any affiliated group, as defined in s. 1504 of the Internal Revenue Code, of which the wholesale distributor is a member:

a. Is listed on the manufacturer's current list of authorized distributors of record.

b. Annually purchases not less than 90 percent of all of its purchases of a manufacturer's prescription drug products,

based on dollar volume, directly from that manufacturer and has total annual prescription drug sales of $100 million or more.

c. Has reported to the department pursuant to s. 499.012(3)(g)2. that the wholesale distributor has total annual prescription drug sales of $100 million or more, and has a verifiable account number issued by the manufacturer authorizing the wholesale distributor to purchase the manufacturer's drug products directly from that manufacturer and that wholesale distributor makes not fewer than 12 purchases of that manufacturer's drug products directly from the manufacturer using said verifiable account number in 12 months. The provisions of this sub-subparagraph apply with respect to a manufacturer that fails to file a copy of the manufacturer's list of authorized distributors of record with the department by July 1, 2003; that files a list of authorized distributors of record which contains fewer than 10 wholesale distributors permitted in this state, excluding the wholesale distributors described in sub-subparagraph b.; or that, as a result of changes to the list of authorized distributors of record filed with the department, has fewer than 10 wholesale distributors permitted in this state as authorized distributors of record, excluding the wholesale distributors described in sub-subparagraph b.

A wholesale distributor that satisfies the requirements of sub-subparagraph b. or sub-subparagraph c. shall submit to the department documentation substantiating its qualification pursuant to sub-subparagraph b. or sub-subparagraph c. The

department shall add those wholesale distributors that the department has determined have met the requirements of sub-subparagraph b. or sub-subparagraph c. to the list of authorized distributors of record on the department's website.

~~6. This paragraph expires July 1, 2006.~~

(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 either:

a. A pedigree paper as defined in s. 499.003(31); or

b. Until December 31, 2008, if the prescription drug was purchased directly from the manufacturer, a statement in written or electronic form stating that the wholesale distributor or member of its affiliated group has purchased the specific unit of the prescription drug directly from the manufacturer, as defined in s. 499.012(1)(e), and is an authorized distributor of record as specified in subparagraph (d)5. In accordance with subparagraph (d)5., each manufacturer shall file a written list of all of the manufacturer's authorized distributors of record with the department by July 1, 2006. A manufacturer shall notify the department not later than 10 days after any change to the list. The department shall publish a list of all authorized distributors of record on its website.

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.

Section 5. 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 6. 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 7. 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 8. This act shall take effect July 1, 2006.