A bill to be entitled

An act relating to veterinary prescription drugs; amending s. 499.003, F.S.; providing a definition; amending s. 499.01, F.S.; requiring a person or establishment to obtain a permit in order to operate as a veterinary prescription drug wholesaler; amending s. 499.012, F.S.; providing that the distribution of veterinary prescription drugs is not included within the meaning of the terms "wholesale distribution" or "wholesale distributor" of prescription drugs; amending s. 499.041, F.S.; requiring an annual fee for a veterinary prescription drug wholesaler's permit; amending s. 499.065, F.S.; requiring the Department of Health to inspect veterinary prescription drug wholesale establishments; authorizing the department to close such establishment if it creates an imminent danger to the public health; providing an effective date.

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

Section 1. Subsection (40) is added to section 499.003, Florida Statutes, to read:

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

(40) "Veterinary prescription drug wholesaler" means any person engaged in wholesale distribution of veterinary prescription drugs in or into this state. A veterinary prescription drug wholesaler may not sell any veterinary

prescription drugs to any person or entity other than an animal health entity.

Section 2. Subsection (1) of section 499.01, Florida Statutes, is 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 compressed medical gas wholesaler;

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

(j) A nonresident prescription drug manufacturer;

(k) A freight forwarder;

(l) A retail pharmacy drug wholesaler;

(m) A veterinary legend drug retail establishment;

(n) A medical oxygen retail establishment;

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

(p) A restricted prescription drug distributor; or~~.~~

(q) A veterinary prescription drug wholesaler.

Section 3. Paragraphs (a) and (b) of subsection (1) of section 499.012, Florida Statutes, are amended to read:

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

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

(a) "Wholesale distribution" means distribution of prescription drugs to persons other than a consumer or patient, but does not include:

1. Any of the following activities, which is not a violation of s. 499.005(21) if such activity is conducted in accordance with s. 499.014:

a. The purchase or other acquisition by a hospital or other health care entity that is a member of a group purchasing organization of a prescription drug for its own use from the group purchasing organization or from other hospitals or health care entities that are members of that organization.

b. The sale, purchase, or trade of a prescription drug or an offer to sell, purchase, or trade a prescription drug by a charitable organization described in s. 501(c)(3) of the Internal Revenue Code of 1986, as amended and revised, to a nonprofit affiliate of the organization to the extent otherwise permitted by law.

c. The sale, purchase, or trade of a prescription drug or an offer to sell, purchase, or trade a prescription drug among hospitals or other health care entities that are under common control. For purposes of this section, "common control" means the power to direct or cause the direction of the management and policies of a person or an organization, whether by ownership of stock, by voting rights, by contract, or otherwise.

d. The sale, purchase, trade, or other transfer of a prescription drug from or for any federal, state, or local government agency or any entity eligible to purchase prescription drugs at public health services prices pursuant to

Pub. L. No. 102-585, s. 602 to a contract provider or its subcontractor for eligible patients of the agency or entity under the following conditions:

(I) The agency or entity must obtain written authorization for the sale, purchase, trade, or other transfer of a prescription drug under this sub-subparagraph from the Secretary of Health or his or her designee.

(II) The contract provider or subcontractor must be authorized by law to administer or dispense prescription drugs.

(III) In the case of a subcontractor, the agency or entity must be a party to and execute the subcontract.

(IV) A contract provider or subcontractor must maintain separate and apart from other prescription drug inventory any prescription drugs of the agency or entity in its possession.

(V) The contract provider and subcontractor must maintain and produce immediately for inspection all records of movement or transfer of all the prescription drugs belonging to the agency or entity, including, but not limited to, the records of receipt and disposition of prescription drugs. Each contractor and subcontractor dispensing or administering these drugs must maintain and produce records documenting the dispensing or administration. Records that are required to be maintained include, but are not limited to, a perpetual inventory itemizing drugs received and drugs dispensed by prescription number or administered by patient identifier, which must be submitted to the agency or entity quarterly.

(VI) The contract provider or subcontractor may administer or dispense the prescription drugs only to the eligible patients of the agency or entity or must return the prescription drugs

for or to the agency or entity. The contract provider or subcontractor must require proof from each person seeking to fill a prescription or obtain treatment that the person is an eligible patient of the agency or entity and must, at a minimum, maintain a copy of this proof as part of the records of the contractor or subcontractor required under sub-sub-subparagraph (V).

(VII) In addition to the departmental inspection authority set forth in s. 499.051, the establishment of the contract provider and subcontractor and all records pertaining to prescription drugs subject to this sub-subparagraph shall be subject to inspection by the agency or entity. All records relating to prescription drugs of a manufacturer under this sub-subparagraph shall be subject to audit by the manufacturer of those drugs, without identifying individual patient information.

2. Any of the following activities, which is not a violation of s. 499.005(21) if such activity is conducted in accordance with rules established by the department:

a. The sale, purchase, or trade of a prescription drug among federal, state, or local government health care entities that are under common control and are authorized to purchase such prescription drug.

b. The sale, purchase, or trade of a prescription drug or an offer to sell, purchase, or trade a prescription drug for emergency medical reasons. For purposes of this sub-subparagraph, the term "emergency medical reasons" includes transfers of prescription drugs by a retail pharmacy to another retail pharmacy to alleviate a temporary shortage.

c. The transfer of a prescription drug acquired by a medical director on behalf of a licensed emergency medical services provider to that emergency medical services provider and its transport vehicles for use in accordance with the provider's license under chapter 401.

d. The revocation of a sale or the return of a prescription drug to the person's prescription drug wholesale supplier.

e. The donation of a prescription drug by a health care entity to a charitable organization that has been granted an exemption under s. 501(c)(3) of the Internal Revenue Code of 1986, as amended, and that is authorized to possess prescription drugs.

f. The transfer of a prescription drug by a person authorized to purchase or receive prescription drugs to a person licensed or permitted to handle reverse distributions or destruction under the laws of the jurisdiction in which the person handling the reverse distribution or destruction receives the drug.

g. The transfer of a prescription drug by a hospital or other health care entity to a person licensed under this chapter to repackage prescription drugs for the purpose of repackaging the prescription drug for use by that hospital, or other health care entity and other health care entities that are under common control, if ownership of the prescription drugs remains with the hospital or other health care entity at all times. In addition to the recordkeeping requirements of s. 499.0121(6), the hospital or health care entity that transfers prescription drugs pursuant to this sub-subparagraph must reconcile all drugs

transferred and returned and resolve any discrepancies in a timely manner.

3. The distribution of prescription drug samples by manufacturers' representatives or distributors' representatives conducted in accordance with s. 499.028.

4. The sale, purchase, or trade of blood and blood components intended for transfusion. As used in this subparagraph, the term "blood" means whole blood collected from a single donor and processed either for transfusion or further manufacturing, and the term "blood components" means that part of the blood separated by physical or mechanical means.

5. The lawful dispensing of a prescription drug in accordance with chapter 465.

6. The distribution of veterinary prescription drugs.

(b) "Wholesale distributor" means any person engaged in wholesale distribution of prescription drugs, other than veterinary prescription drugs, in or into this state, including, but not limited to, manufacturers; repackagers; own-label distributors; jobbers; private-label distributors; brokers; warehouses, including manufacturers' and distributors' warehouses, chain drug warehouses, and wholesale drug warehouses; independent wholesale drug traders; exporters; retail pharmacies; and the agents thereof that conduct wholesale distributions.

Section 4. Paragraph (h) is added to subsection (1) 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.--

(1) The department shall assess applicants requiring a manufacturing permit an annual fee within the ranges established in this section for the specific type of manufacturer.

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

Section 5. Section 499.065, Florida Statutes, is 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, 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.

(2) To protect the public from prescription drugs that are adulterated or otherwise unfit for human or animal consumption, the department may examine, sample, seize, and stop the sale or use of prescription drugs to determine the condition of those drugs. The department may immediately seize and remove any prescription drugs if the Secretary of Health or his or her designee determines that such prescription drugs represent a threat to the public health. The owner of any property seized under this section may, within 10 days after the seizure, apply to a court of competent jurisdiction for whatever relief is

appropriate. At any time after 10 days, the department may destroy the drugs as contraband.

(3) The department may determine that a prescription drug wholesale establishment, prescription drug repackager establishment, veterinary prescription drug wholesale 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 require its immediate closure if such establishment fails to comply with applicable laws and rules and, because of such 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 6. This act shall take effect July 1, 2004.