

1                                   A bill to be entitled  
2           An act relating to veterinary prescription  
3           drugs; amending s. 499.003, F.S.; defining the  
4           term "veterinary prescription drug wholesaler";  
5           amending s. 499.01, F.S.; requiring a person or  
6           establishment to obtain a permit in order to  
7           operate as a veterinary prescription drug  
8           wholesaler; amending s. 499.012, F.S.;  
9           requiring a person to have a veterinary  
10          prescription drug wholesaler permit to  
11          distribute veterinary prescription drugs in or  
12          into this state; requiring a veterinary  
13          prescription drug wholesaler that also  
14          distributes human prescription drugs that it  
15          did not manufacture to obtain a prescription  
16          drug wholesaler or out-of-state prescription  
17          drug wholesaler permit in lieu of the  
18          veterinary prescription drug wholesaler permit;  
19          amending s. 499.0121, F.S.; requiring certain  
20          prescription wholesalers to use due diligence  
21          when purchasing prescription drugs from others;  
22          amending s. 499.041, F.S.; requiring an annual  
23          fee for a veterinary prescription drug  
24          wholesaler's permit; amending s. 499.065, F.S.;  
25          requiring the Department of Health to inspect  
26          veterinary prescription drug wholesale  
27          establishments; authorizing the department to  
28          close such establishment if it creates an  
29          imminent danger to the public health; providing  
30          an effective date.  
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1 Be It Enacted by the Legislature of the State of Florida:

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3 Section 1. Subsection (40) is added to section  
4 499.003, Florida Statutes, to read:

5 499.003 Definitions of terms used in ss.  
6 499.001-499.081.--As used in ss. 499.001-499.081, the term:

7 (40) "Veterinary prescription drug wholesaler" means  
8 any person engaged in wholesale distribution of veterinary  
9 prescription drugs in or into this state.

10 Section 2. Subsection (1) of section 499.01, Florida  
11 Statutes, is amended to read:

12 499.01 Permits; applications; renewal; general  
13 requirements.--

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

- 16 (a) A prescription drug manufacturer;
- 17 (b) A prescription drug repackager;
- 18 (c) An over-the-counter drug manufacturer;
- 19 (d) A compressed medical gas manufacturer;
- 20 (e) A device manufacturer;
- 21 (f) A cosmetic manufacturer;
- 22 (g) A prescription drug wholesaler;
- 23 (h) A veterinary prescription drug wholesaler;
- 24 (i)(h) A compressed medical gas wholesaler;
- 25 (j)(i) An out-of-state prescription drug wholesaler;
- 26 (k)(j) A nonresident prescription drug manufacturer;
- 27 (l)(k) A freight forwarder;
- 28 (m)(l) A retail pharmacy drug wholesaler;
- 29 (n)(m) A veterinary legend drug retail establishment;
- 30 (o)(n) A medical oxygen retail establishment;
- 31 (p)(o) A complimentary drug distributor; or

1           ~~(g)(p)~~ A restricted prescription drug distributor.

2           Section 3. Paragraph (g) is added to subsection (2) of  
3 section 499.012, Florida Statutes, to read:

4           499.012 Wholesale distribution; definitions; permits;  
5 applications; general requirements.--

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

8           (g) A veterinary prescription drug wholesaler  
9 permit.--A veterinary prescription drug wholesaler permit is  
10 required for any person that engages in the distribution of  
11 veterinary prescription drugs in or into this state. A  
12 veterinary prescription drug wholesaler that also distributes  
13 prescription drugs subject to, defined by, or described by s.  
14 503(b) of the Federal Food, Drug, and Cosmetic Act which it  
15 did not manufacture must obtain a permit as a prescription  
16 drug wholesaler or out-of-state prescription drug wholesaler  
17 in lieu of the veterinary prescription drug wholesaler permit.  
18 A veterinary prescription drug wholesaler must comply with the  
19 requirements for wholesale distributors under s. 499.0121,  
20 except those set forth in s. 499.0121(6)(d), (e), or (f).

21           Section 4. Subsection (12) of section 499.0121,  
22 Florida Statutes, is amended to read:

23           499.0121 Storage and handling of prescription drugs;  
24 recordkeeping.--The department shall adopt rules to implement  
25 this section as necessary to protect the public health,  
26 safety, and welfare. Such rules shall include, but not be  
27 limited to, requirements for the storage and handling of  
28 prescription drugs and for the establishment and maintenance  
29 of prescription drug distribution records.

30           (12) DUE DILIGENCE OF SUPPLIERS.--Prior to purchasing  
31 any prescription drugs from another wholesale drug

1 distributor, a prescription drug wholesaler, an out-of-state  
2 prescription drug wholesaler, or a prescription drug  
3 repackager ~~a wholesale drug distributor~~ must:

4 (a) Enter an agreement with the selling wholesale drug  
5 distributor by which the selling wholesale drug distributor  
6 will indemnify the purchasing wholesale drug distributor for  
7 any loss caused to the purchasing wholesale drug distributor  
8 related to the purchase of drugs from the selling wholesale  
9 drug distributor which are determined to be counterfeit or to  
10 have been distributed in violation of any federal or state law  
11 governing the distribution of drugs.

12 (b) Determine that the selling wholesale drug  
13 distributor has insurance coverage of not less than the  
14 greater of 1 percent of the amount of total dollar volume of  
15 the prescription drug sales reported to the department under  
16 ~~pursuant to~~ s. 499.012(3)(g) or \$500,000; however the coverage  
17 need not exceed \$2 million.

18 (c) Obtain information from the selling wholesale drug  
19 distributor, including the length of time the selling  
20 wholesale drug distributor has been licensed in this state, a  
21 copy of the selling wholesale drug distributor's licenses or  
22 permits, and background information concerning the ownership  
23 of the selling wholesale drug distributor, including the  
24 experience of the wholesale distributor in the wholesale  
25 distribution of prescription drugs.

26 (d) Verify that the selling wholesale drug  
27 distributor's Florida permit is valid.

28 (e) Inspect the selling wholesale drug distributor's  
29 licensed establishment to document that it has a policies and  
30 procedures manual relating to the distribution of drugs, the  
31 appropriate temperature controlled environment for drugs

1 requiring temperature control, an alarm system, appropriate  
2 access restrictions, and procedures to ensure that records  
3 related to the wholesale distribution of prescription drugs  
4 are maintained as required by law:

5 1. Before purchasing any drug from the wholesale drug  
6 distributor, and at least once each subsequent year; or

7 2. Before purchasing any drug from the wholesale drug  
8 distributor, and each subsequent year obtain a complete copy  
9 of the most recent inspection report for the establishment  
10 which was prepared by the department or the regulatory  
11 authority responsible for wholesale drug distributors in the  
12 state in which the establishment is located.

13 Section 5. Paragraph (g) is added to subsection (2) of  
14 section 499.041, Florida Statutes, to read:

15 499.041 Schedule of fees for drug, device, and  
16 cosmetic applications and permits, product registrations, and  
17 free-sale certificates.--

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

22 (g) The fee for a veterinary prescription drug  
23 wholesaler's permit may not be less than \$300 or more than  
24 \$500 annually.

25 Section 6. Section 499.065, Florida Statutes, is  
26 amended to read:

27 499.065 Imminent danger.--

28 (1) Notwithstanding s. 499.051, the department shall  
29 inspect each prescription drug wholesale establishment,  
30 prescription drug repackager establishment, veterinary  
31 prescription drug wholesale establishment, and retail pharmacy

1 drug wholesaler establishment that is required to be permitted  
2 under this chapter as often as necessary to ensure compliance  
3 with applicable laws and rules. The department shall have the  
4 right of entry and access to these facilities at any  
5 reasonable time.

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

18 (3) The department may determine that a prescription  
19 drug wholesale establishment, prescription drug repackager  
20 establishment, veterinary prescription drug wholesale  
21 establishment, or retail pharmacy drug wholesaler  
22 establishment that is required to be permitted under this  
23 chapter is an imminent danger to the public health and shall  
24 require its immediate closure if the such establishment fails  
25 to comply with applicable laws and rules and, because of the  
26 ~~such~~ failure, presents an imminent threat to the public's  
27 health, safety, or welfare. Any establishment so deemed and  
28 closed shall remain closed until allowed by the department or  
29 by judicial order to reopen.

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

6 Section 7. This act shall take effect July 1, 2004.  
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