

By the Committee on Health, Aging, and Long-Term Care; and
Senator Fasano

317-2104-04

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 ~~(q)(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 wholesale drug distributor, a prescription drug
2 wholesaler, an out-of-state prescription drug wholesaler, or a
3 prescription drug repackager, 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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8 STATEMENT OF SUBSTANTIAL CHANGES CONTAINED IN
9 COMMITTEE SUBSTITUTE FOR
10 Senate Bill 1824

11 The Committee Substitute revises the definition of "veterinary
12 prescription drug wholesaler" to delete a prohibition that a
13 veterinary prescription drug wholesaler may not sell any
14 veterinary prescription drugs to an person or entity other
15 than an animal health entity. Veterinary prescription drug
16 wholesalers are no longer made exempt from the definition of
17 "wholesale distribution" and "wholesale distributor."

18 A veterinary prescription drug wholesaler that also
19 distributes prescription drugs approved or intended for human
20 use which the wholesaler did not manufacture must obtain a
21 permit as a prescription drug wholesaler or out-of-state
22 prescription drug wholesaler. A veterinary prescription drug
23 wholesaler must comply with the requirements for wholesale
24 distributors under s. 499.0121, F.S., except the pedigree
25 paper requirements in subsection (6)(d), (e), or (f) of s.
26 499.0121, F.S., and the requirements for due diligence in s.
27 499.0121(12), F.S.