

1 A bill to be entitled

2 An act relating to veterinary prescription drugs; amending
3 s. 499.003, F.S.; providing a definition; amending s.
4 499.01, F.S.; requiring a person or establishment to
5 obtain a permit in order to operate as a veterinary
6 prescription drug wholesaler; amending s. 499.012, F.S.;
7 requiring a person to have a veterinary prescription drug
8 wholesaler permit to distribute veterinary prescription
9 drugs in or into this state; requiring a veterinary
10 prescription drug wholesaler who also distributes human
11 prescription drugs that it did not manufacture to obtain a
12 prescription drug wholesaler or out-of-state prescription
13 drug wholesaler permit in lieu of the veterinary
14 prescription drug wholesaler permit; amending s. 499.0121,
15 F.S.; requiring certain prescription wholesalers and
16 repackagers to use due diligence when purchasing
17 prescription drugs from certain distributors; amending s.
18 499.041, F.S.; requiring an annual fee for a veterinary
19 prescription drug wholesaler's permit; amending s.
20 499.065, F.S.; requiring the Department of Health to
21 inspect veterinary prescription drug wholesale
22 establishments; authorizing the department to close the
23 establishment if it creates an imminent danger to the
24 public health; providing an effective date.

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26 Be It Enacted by the Legislature of the State of Florida:
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28 Section 1. Subsection (40) is added to section 499.003,
 29 Florida Statutes, to read:

30 499.003 Definitions of terms used in ss. 499.001-
 31 499.081.--As used in ss. 499.001-499.081, the term:

32 (40) "Veterinary prescription drug wholesaler" means any
 33 person engaged in wholesale distribution of veterinary
 34 prescription drugs in or into this state.

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

37 499.01 Permits; applications; renewal; general
 38 requirements.--

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

- 41 (a) A prescription drug manufacturer;
- 42 (b) A prescription drug repackager;
- 43 (c) An over-the-counter drug manufacturer;
- 44 (d) A compressed medical gas manufacturer;
- 45 (e) A device manufacturer;
- 46 (f) A cosmetic manufacturer;
- 47 (g) A prescription drug wholesaler;
- 48 (h) A veterinary prescription drug wholesaler;
- 49 (i)-(h) A compressed medical gas wholesaler;
- 50 (j)-(i) An out-of-state prescription drug wholesaler;
- 51 (k)-(j) A nonresident prescription drug manufacturer;
- 52 (l)-(k) A freight forwarder;
- 53 (m)-(l) A retail pharmacy drug wholesaler;
- 54 (n)-(m) A veterinary legend drug retail establishment;
- 55 (o)-(n) A medical oxygen retail establishment;

56 | ~~(p)(e)~~ A complimentary drug distributor; or
 57 | ~~(q)(p)~~ A restricted prescription drug distributor.

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

60 | 499.012 Wholesale distribution; definitions; permits;
 61 | applications; general requirements.--

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

64 | (g) A veterinary prescription drug wholesaler permit. A
 65 | veterinary prescription drug wholesaler permit is required for
 66 | any person who engages in the distribution of veterinary
 67 | prescription drugs in or into this state. A veterinary
 68 | prescription drug wholesaler who also distributes prescription
 69 | drugs subject to, defined by, or described by s. 503(b) of the
 70 | Federal Food, Drug, and Cosmetic Act that it did not manufacture
 71 | must obtain a permit as a prescription drug wholesaler or out-
 72 | of-state prescription drug wholesaler in lieu of the veterinary
 73 | prescription drug wholesaler permit. A veterinary prescription
 74 | drug wholesaler must comply with the requirements for wholesale
 75 | distributors under s. 499.0121, except those set forth in s.
 76 | 499.0121(6)(d), (e), and (f).

77 | Section 4. Subsection (12) of section 499.0121, Florida
 78 | Statutes, is amended to read:

79 | 499.0121 Storage and handling of prescription drugs;
 80 | recordkeeping.--The department shall adopt rules to implement
 81 | this section as necessary to protect the public health, safety,
 82 | and welfare. Such rules shall include, but not be limited to,
 83 | requirements for the storage and handling of prescription drugs

84 and for the establishment and maintenance of prescription drug
 85 distribution records.

86 (12) DUE DILIGENCE OF SUPPLIERS.--Prior to purchasing any
 87 prescription drugs from another wholesale drug distributor, a
 88 prescription drug wholesaler, an out-of-state prescription drug
 89 wholesaler, or a prescription drug repackager ~~a wholesale drug~~
 90 ~~distributor~~ must:

91 (a) Enter an agreement with the selling wholesale drug
 92 distributor by which the selling wholesale drug distributor will
 93 indemnify the purchasing wholesale drug distributor for any loss
 94 caused to the purchasing wholesale drug distributor related to
 95 the purchase of drugs from the selling wholesale drug
 96 distributor which are determined to be counterfeit or to have
 97 been distributed in violation of any federal or state law
 98 governing the distribution of drugs.

99 (b) Determine that the selling wholesale drug distributor
 100 has insurance coverage of not less than the greater of 1 percent
 101 of the amount of total dollar volume of the prescription drug
 102 sales reported to the department under ~~pursuant to~~ s.
 103 499.012(3)(g) or \$500,000; however the coverage need not exceed
 104 \$2 million.

105 (c) Obtain information from the selling wholesale drug
 106 distributor, including the length of time the selling wholesale
 107 drug distributor has been licensed in this state, a copy of the
 108 selling wholesale drug distributor's licenses or permits, and
 109 background information concerning the ownership of the selling
 110 wholesale drug distributor, including the experience of the

111 wholesale distributor in the wholesale distribution of
 112 prescription drugs.

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

115 (e) Inspect the selling wholesale drug distributor's
 116 licensed establishment to document that it has a policies and
 117 procedures manual relating to the distribution of drugs, the
 118 appropriate temperature controlled environment for drugs
 119 requiring temperature control, an alarm system, appropriate
 120 access restrictions, and procedures to ensure that records
 121 related to the wholesale distribution of prescription drugs are
 122 maintained as required by law:

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

125 2. Before purchasing any drug from the wholesale drug
 126 distributor, and each subsequent year obtain a complete copy of
 127 the most recent inspection report for the establishment which
 128 was prepared by the department or the regulatory authority
 129 responsible for wholesale drug distributors in the state in
 130 which the establishment is located.

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

133 499.041 Schedule of fees for drug, device, and cosmetic
 134 applications and permits, product registrations, and free-sale
 135 certificates.--

136 (2) The department shall assess an applicant that is
 137 required to have a wholesaling permit an annual fee within the

138 | ranges established in this section for the specific type of
 139 | wholesaling.

140 | (g) The fee for a veterinary prescription drug
 141 | wholesaler's permit may not be less than \$300 nor more than \$500
 142 | annually.

143 | Section 6. Section 499.065, Florida Statutes, is amended
 144 | to read:

145 | 499.065 Imminent danger.--

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

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

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

167 (3) The department may determine that a prescription drug
168 wholesale establishment, prescription drug repackager
169 establishment, veterinary prescription drug wholesale
170 establishment, or retail pharmacy drug wholesaler establishment
171 that is required to be permitted under this chapter is an
172 imminent danger to the public health and shall require its
173 immediate closure if the ~~such~~ establishment fails to comply with
174 applicable laws and rules and, because of the ~~such~~ failure,
175 presents an imminent threat to the public's health, safety, or
176 welfare. Any establishment so deemed and closed shall remain
177 closed until allowed by the department or by judicial order to
178 reopen.

179
180 For purposes of this section, a refusal to allow entry to the
181 department for inspection at reasonable times, or a failure or
182 refusal to provide the department with required documentation
183 for purposes of inspection, constitutes an imminent danger to
184 the public health.

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