

CHAMBER ACTION

1 The Committee on Health Care recommends the following:

2
3 **Committee Substitute**

4 Remove the entire bill and insert:

5 A bill to be entitled

6 An act relating to veterinary prescription drugs; amending
7 s. 499.003, F.S.; providing a definition; amending s.
8 499.01, F.S.; requiring a person or establishment to
9 obtain a permit in order to operate as a veterinary
10 prescription drug wholesaler; amending s. 499.012, F.S.;
11 requiring a person to have a veterinary prescription drug
12 wholesaler permit to distribute veterinary prescription
13 drugs in or into this state; requiring a veterinary
14 prescription drug wholesaler who also distributes human
15 prescription drugs that it did not manufacture to obtain a
16 prescription drug wholesaler or out-of-state prescription
17 drug wholesaler permit in lieu of the veterinary
18 prescription drug wholesaler permit; amending s. 499.0121,
19 F.S.; requiring certain prescription wholesalers and
20 repackagers to use due diligence when purchasing
21 prescription drugs from certain distributors; amending s.
22 499.041, F.S.; requiring an annual fee for a veterinary
23 prescription drug wholesaler's permit; amending s.

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24 499.065, F.S.; requiring the Department of Health to
 25 inspect veterinary prescription drug wholesale
 26 establishments; authorizing the department to close the
 27 establishment if it creates an imminent danger to the
 28 public health; providing an effective date.

29

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

31

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

34 499.003 Definitions of terms used in ss. 499.001-
 35 499.081.--As used in ss. 499.001-499.081, the term:

36 (40) "Veterinary prescription drug wholesaler" means any
 37 person engaged in wholesale distribution of veterinary
 38 prescription drugs in or into this state.

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

41 499.01 Permits; applications; renewal; general
 42 requirements.--

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

- 45 (a) A prescription drug manufacturer;
- 46 (b) A prescription drug repackager;
- 47 (c) An over-the-counter drug manufacturer;
- 48 (d) A compressed medical gas manufacturer;
- 49 (e) A device manufacturer;
- 50 (f) A cosmetic manufacturer;
- 51 (g) A prescription drug wholesaler;

- 52 (h) A veterinary prescription drug wholesaler;
- 53 ~~(i)(h)~~ A compressed medical gas wholesaler;
- 54 ~~(j)(i)~~ An out-of-state prescription drug wholesaler;
- 55 ~~(k)(j)~~ A nonresident prescription drug manufacturer;
- 56 ~~(l)(k)~~ A freight forwarder;
- 57 ~~(m)(l)~~ A retail pharmacy drug wholesaler;
- 58 ~~(n)(m)~~ A veterinary legend drug retail establishment;
- 59 ~~(o)(n)~~ A medical oxygen retail establishment;
- 60 ~~(p)(o)~~ A complimentary drug distributor; or
- 61 ~~(q)(p)~~ A restricted prescription drug distributor.

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

64 499.012 Wholesale distribution; definitions; permits;
65 applications; general requirements.--

66 (2) The following types of wholesaler permits are
67 established:

68 (g) A veterinary prescription drug wholesaler permit. A
69 veterinary prescription drug wholesaler permit is required for
70 any person who engages in the distribution of veterinary
71 prescription drugs in or into this state. A veterinary
72 prescription drug wholesaler who also distributes prescription
73 drugs subject to, defined by, or described by s. 503(b) of the
74 Federal Food, Drug, and Cosmetic Act that it did not manufacture
75 must obtain a permit as a prescription drug wholesaler or out-
76 of-state prescription drug wholesaler in lieu of the veterinary
77 prescription drug wholesaler permit. A veterinary prescription
78 drug wholesaler must comply with the requirements for wholesale

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79 distributors under s. 499.0121, except those set forth in s.
80 499.0121(6)(d), (e), and (f).

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

83 499.0121 Storage and handling of prescription drugs;
84 recordkeeping.--The department shall adopt rules to implement
85 this section as necessary to protect the public health, safety,
86 and welfare. Such rules shall include, but not be limited to,
87 requirements for the storage and handling of prescription drugs
88 and for the establishment and maintenance of prescription drug
89 distribution records.

90 (12) DUE DILIGENCE OF SUPPLIERS.--Prior to purchasing any
91 prescription drugs from another wholesale drug distributor, a
92 wholesale drug distributor, a prescription drug wholesaler, an
93 out-of-state prescription drug wholesaler, or a prescription
94 drug repackager must:

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

103 (b) Determine that the selling wholesale drug distributor
104 has insurance coverage of not less than the greater of 1 percent
105 of the amount of total dollar volume of the prescription drug
106 sales reported to the department under ~~pursuant to~~ s.

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107 499.012(3)(g) or \$500,000; however the coverage need not exceed
108 \$2 million.

109 (c) Obtain information from the selling wholesale drug
110 distributor, including the length of time the selling wholesale
111 drug distributor has been licensed in this state, a copy of the
112 selling wholesale drug distributor's licenses or permits, and
113 background information concerning the ownership of the selling
114 wholesale drug distributor, including the experience of the
115 wholesale distributor in the wholesale distribution of
116 prescription drugs.

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

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

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

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

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

137 499.041 Schedule of fees for drug, device, and cosmetic
138 applications and permits, product registrations, and free-sale
139 certificates.--

140 (2) The department shall assess an applicant that is
141 required to have a wholesaling permit an annual fee within the
142 ranges established in this section for the specific type of
143 wholesaling.

144 (g) The fee for a veterinary prescription drug
145 wholesaler's permit may not be less than \$300 nor more than \$500
146 annually.

147 Section 6. Section 499.065, Florida Statutes, is amended
148 to read:

149 499.065 Imminent danger.--

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

159 (2) To protect the public from prescription drugs that are
160 adulterated or otherwise unfit for human or animal consumption,
161 the department may examine, sample, seize, and stop the sale or
162 use of prescription drugs to determine the condition of those

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163 | drugs. The department may immediately seize and remove any
164 | prescription drugs if the Secretary of Health or his or her
165 | designee determines that the ~~such~~ prescription drugs represent a
166 | threat to the public health. The owner of any property seized
167 | under this section may, within 10 days after the seizure, apply
168 | to a court of competent jurisdiction for whatever relief is
169 | appropriate. At any time after 10 days, the department may
170 | destroy the drugs as contraband.

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

183 |
184 | For purposes of this section, a refusal to allow entry to the
185 | department for inspection at reasonable times, or a failure or
186 | refusal to provide the department with required documentation
187 | for purposes of inspection, constitutes an imminent danger to
188 | the public health.

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