

Amendment No.

CHAMBER ACTION

Senate

House

1 Representative(s) Coley offered the following:

2
3 **Amendment (with title amendment)**

4 Between lines 923 and 924, insert:

5 Section 9. Paragraph (h) of subsection (2) of section
6 499.012, Florida Statutes, is amended to read:

7 499.012 Wholesale distribution; definitions; permits;
8 applications; general requirements.--

9 (2) The following types of wholesaler permits are
10 established:

11 (h) Limited prescription drug veterinary wholesaler
12 permit.--Unless engaging in the activities of and permitted as a
13 prescription drug manufacturer, nonresident prescription drug
14 manufacturer, prescription drug wholesaler, or out-of-state
15 prescription drug wholesaler, a limited prescription drug
16 veterinary wholesaler permit is required for any person that
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17 engages in the distribution in or into this state of veterinary
18 prescription drugs and prescription drugs subject to, defined
19 by, or described by s. 503(b) of the Federal Food, Drug, and
20 Cosmetic Act under the following conditions:

21 1. The limited prescription drug veterinary wholesaler,
22 after being permitted as a limited prescription drug veterinary
23 wholesaler, only distributes ~~person is engaged in the business~~
24 ~~of wholesaling~~ prescription and veterinary legend drugs to
25 persons:

26 a. Licensed as veterinarians practicing on a full-time
27 basis;

28 b. Owning a veterinary establishment permitted pursuant to
29 s. 474.215;

30 ~~c.d.~~ Regularly and lawfully engaged in instruction in
31 veterinary medicine;

32 ~~d.e.~~ Regularly and lawfully engaged in law enforcement
33 activities;

34 ~~e.f.~~ For use in research not involving clinical use; ~~or~~

35 ~~f.g.~~ For use in chemical analysis or physical testing or
36 for purposes of instruction in law enforcement activities,
37 research, or testing;

38 g. Holding a prescription drug veterinary wholesaler
39 permit or a limited prescription drug veterinary wholesaler
40 permit; or

41 h. Holding an authorization, license, or permit issued by
42 another state to engage in the purchase or sale of prescription
43 drugs for wholesale distribution, provided such persons are
44 located outside of this state and are not authorized to purchase
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45 | or sell prescription drugs for wholesale distribution in or into
46 | this state except as otherwise authorized in this subparagraph.

47 | 2. No more than 30 percent of total annual prescription
48 | drug sales may be prescription drugs approved for human use
49 | which are subject to, defined by, or described by s. 503(b) of
50 | the Federal Food, Drug, and Cosmetic Act.

51 | 3. The limited prescription drug veterinary wholesaler
52 | certifies under oath to the department that the wholesaler will
53 | not knowingly distribute prescription drugs defined in s. 503(b)
54 | of the Federal Food, Drug, and Cosmetic Act in any state to any
55 | person other than those specified in subparagraph 1. The person
56 | is not permitted, licensed, or otherwise authorized in any state
57 | to wholesale prescription drugs subject to, defined by, or
58 | described by s. 503(b) of the Federal Food, Drug, and Cosmetic
59 | Act to any person who is authorized to sell, distribute,
60 | purchase, trade, or use these drugs on or for humans.

61 | 4. A limited prescription drug veterinary wholesaler that
62 | applies to the department for a new permit or the renewal of a
63 | permit must submit a bond of \$20,000, or other equivalent means
64 | of security acceptable to the department, such as an irrevocable
65 | letter of credit or a deposit in a trust account or financial
66 | institution, payable to the Florida Drug, Device, and Cosmetic
67 | Trust Fund. The purpose of the bond is to secure payment of any
68 | administrative penalties imposed by the department and any fees
69 | and costs incurred by the department regarding that permit which
70 | are authorized under state law and which the permittee fails to
71 | pay 30 days after the fine or costs become final. The department
72 | may make a claim against such bond or security until 1 year

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73 after the permittee's license ceases to be valid or until 60
74 days after any administrative or legal proceeding authorized in
75 ss. 499.001-499.081 which involves the permittee is concluded,
76 including any appeal, whichever occurs later.

77 5. A limited prescription drug veterinary wholesaler must
78 maintain at all times a license or permit to engage in the
79 wholesale distribution of prescription drugs in compliance with
80 laws of the state in which it is a resident.

81 6. A limited prescription drug veterinary wholesaler must
82 comply with the requirements for wholesale distributors under s.
83 499.0121, except that a limited prescription drug veterinary
84 wholesaler is not required to provide a pedigree paper as
85 required by s. 499.0121(6)(f) upon the wholesale distribution of
86 a prescription drug to a veterinarian or to the owner of a
87 veterinary establishment permitted pursuant to s. 474.215.

88 7. A limited prescription drug veterinary wholesaler may
89 not return to inventory for subsequent wholesale distribution
90 any prescription drug subject to, defined by, or described by s.
91 503(b) of the Federal Food, Drug, and Cosmetic Act which has
92 been returned by a veterinarian or by the owner of a veterinary
93 establishment permitted pursuant to s. 474.215.

94 8. An out-of-state prescription drug wholesaler's permit
95 or a limited prescription drug veterinary wholesaler permit is
96 not required for an intracompany sale or transfer of a
97 prescription drug from an out-of-state establishment that is
98 duly licensed to engage in the wholesale distribution of
99 prescription drugs in its state of residence to a licensed
100 limited prescription drug veterinary wholesaler in this state if
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HOUSE AMENDMENT

Bill No. CS/HB 1575

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101 both wholesalers conduct wholesale distributions of prescription
102 drugs under the same business name. The recordkeeping
103 requirements of s. 499.0121(6) must be followed for this
104 transaction.

105

106 ===== T I T L E A M E N D M E N T =====

107 Remove line 55 and insert:

108 language; amending s. 499.012, F.S.; revising permit
109 requirements for a limited prescription drug veterinary
110 wholesaler; providing for certain certification to the
111 Department of Health by a limited prescription drug veterinary
112 wholesaler; amending ss. 408.07, 409.9116, and 1009.65,

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