20-1330A-07

1	A bill to be entitled
2	An act relating to the distribution of
3	veterinary drugs; amending s. 499.012, F.S.;
4	revising the list of persons who are required
5	to have a limited prescription drug veterinary
6	wholesaler permit in order to engage in the
7	distribution of veterinary prescription drugs;
8	deleting a provision that requires that certain
9	persons obtain a limited prescription drug
10	veterinary wholesaler permit; providing an
11	effective date.
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13	Be It Enacted by the Legislature of the State of Florida:
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15	Section 1. Paragraph (h) of subsection (2) of section
16	499.012, Florida Statutes, is amended to read:
17	499.012 Wholesale distribution; definitions; permits;
18	applications; general requirements
19	(2) The following types of wholesaler permits are
20	established:
21	(h) Limited prescription drug veterinary wholesaler
22	permit Unless engaging in the activities of and permitted as
23	a prescription drug manufacturer, nonresident prescription
24	drug manufacturer, prescription drug wholesaler, or
25	out-of-state prescription drug wholesaler, a limited
26	prescription drug veterinary wholesaler permit is required for
27	any person that engages in the distribution in or into this
28	state of veterinary prescription drugs and prescription drugs
29	subject to, defined by, or described by s. 503(b) of the
30	Federal Food, Drug, and Cosmetic Act under the following
31	conditions:

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drugs on or for humans.

1	1. The person is engaged in the business of
2	wholesaling prescription and veterinary legend drugs to
3	persons:
4	a. Licensed as veterinarians practicing on a full-time
5	basis;
6	b. Regularly and lawfully engaged in instruction in
7	veterinary medicine;
8	c. Regularly and lawfully engaged in law enforcement
9	activities;
10	d. For use in research not involving clinical use; or
11	e. For use in chemical analysis or physical testing or
12	for purposes of instruction in law enforcement activities,
13	research, or testing; or-
14	f. Holding a veterinary prescription drug wholesaler
15	permit, limited prescription drug veterinary wholesaler
16	permit, a substantially equivalent authorization, permit, or
17	license issued by another state, or an authorization, license,
18	or permit to engage in the wholesale distribution of
19	prescription drugs issued by another state that does not issue
20	a substantially equivalent permit.
21	2. No more than 30 percent of total annual
22	prescription drug sales may be prescription drugs approved for
23	human use which are subject to, defined by, or described by s.
24	503(b) of the Federal Food, Drug, and Cosmetic Act.
25	3. The person is not permitted, licensed, or otherwise

authorized to sell, distribute, purchase, trade, or use these

authorized in any state to wholesale prescription drugs

subject to, defined by, or described by s. 503(b) of the Federal Food, Drug, and Cosmetic Act to any person who is

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3.4. A limited prescription drug veterinary wholesaler that applies to the department for a new permit or the renewal of a permit must submit a bond of \$20,000, or other equivalent means of security acceptable to the department, such as an irrevocable letter of credit or a deposit in a trust account or financial institution, payable to the Florida Drug, Device, and Cosmetic Trust Fund. The purpose of the bond is to secure payment of any administrative penalties imposed by the department and any fees and costs incurred by the department regarding that permit which are authorized under state law and which the permittee fails to pay 30 days after the fine or costs become final. The department may make a claim against such bond or security until 1 year after the permittee's license ceases to be valid or until 60 days after any administrative or legal proceeding authorized in ss. 499.001-499.081 which involves the permittee is concluded, including any appeal, whichever occurs later.

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

5.6. A limited prescription drug veterinary wholesaler must comply with the requirements for wholesale distributors under s. 499.0121, except that a limited prescription drug veterinary wholesaler is not required to provide a pedigree paper as required by s. 499.0121(6)(f) upon the wholesale distribution of a prescription drug to a veterinarian.

6.7. A limited prescription drug veterinary wholesaler may not return to inventory for subsequent wholesale distribution any prescription drug subject to, defined by, or

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described by s. 503(b) of the Federal Food, Drug, and Cosmetic Act which has been returned by a veterinarian. 3 7.8. An out-of-state prescription drug wholesaler's 4 permit or a limited prescription drug veterinary wholesaler 5 permit is not required for an intracompany sale or transfer of a prescription drug from an out-of-state establishment that is duly licensed to engage in the wholesale distribution of prescription drugs in its state of residence to a licensed 8 limited prescription drug veterinary wholesaler in this state 9 10 if both wholesalers conduct wholesale distributions of prescription drugs under the same business name. The 11 12 recordkeeping requirements of s. 499.0121(6) must be followed 13 for this transaction. Section 2. This act shall take effect upon becoming a 14 15 law. 16 17 SENATE SUMMARY 18 Revises the list of certain persons who are required to 19 have a limited prescription drug veterinary wholesaler permit. Deletes a provision that requires certain persons 2.0 to have a limited prescription drug veterinary wholesaler 21 permit. 22 23 2.4 25 26 27 28 29 30