Bill No. <u>SB 1654</u>

	CHAMBER ACTION <u>Senate</u> <u>House</u>
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11	The Committee on Regulated Industries (Wise) recommended the
12	following amendment:
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14	Senate Amendment (with title amendment)
15	Delete everything after the enacting clause
16	
17	and insert:
18	Section 1. Section 499.006, Florida Statutes, is
19 20	amended to read:
20	499.006 Adulterated drug or deviceA drug or device
22	(1) If it consists in whole or in part of any filthy,
23	putrid, or decomposed substance;
24	(2) If it has been produced, prepared, packed, or held
25	under conditions whereby it could have been contaminated with
26	filth or rendered injurious to health;
27	(3) If it is a drug and the methods used in, or the
28	facilities or controls used for, its manufacture, processing,
29	packing, or holding do not conform to, or are not operated or
30	administered in conformity with, current good manufacturing
31	practices to assure that the drug meets the requirements of 1
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1	ss. 499.001-499.081 and that the drug has the identity and					
2	strength, and meets the standard of quality and purity, which					
3	it purports or is represented to possess;					
4	(4) If it is a drug and its container is composed, in					
5	whole or in part, of any poisonous or deleterious substance					
6	which could render the contents injurious to health;					
7	(5) If it is a drug and it bears or contains, for the					
8	purpose of coloring only, a color additive that is unsafe					
9	within the meaning of the federal act; or, if it is a color					
10	additive, the intended use of which in or on drugs is for the					
11	purpose of coloring only, and it is unsafe within the meaning					
12	of the federal act;					
13	(6) If it purports to be, or is represented as, a drug					
14	the name of which is recognized in the official compendium,					
15	and its strength differs from, or its quality or purity falls					
16	below, the standard set forth in such compendium. The					
17	determination as to strength, quality, or purity must be made					
18	in accordance with the tests or methods of assay set forth in					
19	such compendium, or, when such tests or methods of assay are					
20	absent or inadequate, in accordance with those tests or					
21	methods of assay prescribed under authority of the federal					
22	act. A drug defined in the official compendium is not					
23	adulterated under this subsection merely because it differs					
24	from the standard of strength, quality, or purity set forth					
25	for that drug in such compendium if its difference in					
26	strength, quality, or purity from such standard is plainly					
27	stated on its label;					
28	(7) If it is not subject to subsection (6) and its					
29	strength differs from, or its purity or quality falls below					
30	the standard of, that which it purports or is represented to					
31	possess;					
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1 (8) If it is a drug: (a) With which any substance has been mixed or packed 2 so as to reduce the quality or strength of the drug; or 3 4 (b) For which any substance has been substituted wholly or in part; 5 б (9) If it is a drug or device for which the expiration 7 date has passed; or 8 (10) If it is a legend drug for which the required 9 pedigree paper is nonexistent, fraudulent, or incomplete under the requirements of ss. 499.001-499.081 or applicable rules, 10 or that has been purchased, held, sold, or distributed at any 11 time by a person not authorized under federal or state law to 12 13 do so; or. (11) If it is a prescription drug subject to, defined 14 15 by, or described by s. 503(b) of the Federal Food, Drug, and Cosmetic Act which has been returned by a veterinarian to a 16 limited veterinary prescription drug wholesaler. 17 Section 2. Subsection (1) and paragraph (d) of 18 subsection (2) of section 499.01, Florida Statutes, are 19 amended to read: 20 21 499.01 Permits; applications; renewal; general 22 requirements. --Prior to operating, a permit is required for each 23 (1) 24 person and establishment that intends to operate as: 25 (a) A prescription drug manufacturer; (b) A prescription drug repackager; 26 (c) An over-the-counter drug manufacturer; 27 (d) A compressed medical gas manufacturer; 28 29 (e) A device manufacturer; (f) A cosmetic manufacturer; 30 (g) A prescription drug wholesaler; 31 8:26 AM 04/06/05 s1654d-ri05-ta1

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1	(h) A veterinary prescription drug wholesaler;					
2						
3	(j) An out-of-state prescription drug wholesaler;					
4	(k) A nonresident prescription drug manufacturer;					
5	(1) A freight forwarder;					
б	(m) A retail pharmacy drug wholesaler;					
7	(n) A veterinary legend drug retail establishment;					
8	(o) A medical oxygen retail establishment;					
9	(p) A complimentary drug distributor; or					
10	(q) A restricted prescription drug distributor; or.					
11	(r) A limited veterinary prescription drug wholesaler.					
12	(2)					
13	(d) A permit for a prescription drug manufacturer,					
14	prescription drug repackager, prescription drug wholesaler,					
15	limited veterinary prescription drug wholesaler, or retail					
16	pharmacy wholesaler may not be issued to the address of a					
17	health care entity or to a pharmacy licensed under chapter					
18	465, except as provided in this paragraph. The department may					
19	issue a prescription drug manufacturer permit to an applicant					
20	at the same address as a licensed nuclear pharmacy, which is a					
21	health care entity, for the purpose of manufacturing					
22	prescription drugs used in positron emission tomography or					
23	other radiopharmaceuticals, as listed in a rule adopted by the					
24	department pursuant to this paragraph. The purpose of this					
25	exemption is to assure availability of state-of-the-art					
26	pharmaceuticals that would pose a significant danger to the					
27	public health if manufactured at a separate establishment					
28	address from the nuclear pharmacy from which the prescription					
29	drugs are dispensed. The department may also issue a retail					
30	pharmacy wholesaler permit to the address of a community					
31	pharmacy licensed under chapter 465 which does not meet the					
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1 definition of a closed pharmacy in s. 499.003. Section 3. Paragraph (h) is added to subsection (2) of 2 section 499.012, Florida Statutes, to read: 3 4 499.012 Wholesale distribution; definitions; permits; applications; general requirements.--5 б (2) The following types of wholesaler permits are 7 established: (h) Limited veterinary prescription drug wholesaler 8 permit.--Unless engaging in the activities of and permitted as 9 10 a prescription drug manufacturer, nonresident prescription 11 drug manufacturer, prescription drug wholesaler, or out-of-state prescription drug wholesaler, a limited 12 13 veterinary prescription drug wholesaler permit is required for any person that engages in the distribution in or into this 14 15 state of veterinary prescription drugs and prescription drugs subject to, defined by, or described by s. 503(b) of the 16 Federal Food, Drug, and Cosmetic Act to veterinarians under 17 18 the following conditions: 19 1. The person is engaged in the business of wholesaling prescription and veterinary legend drugs to 20 veterinarians on a full-time basis. 21 22 2. No more than 30 percent of prescription drug sales may be prescription drugs approved for human use which are 23 24 subject to, defined by, or described by s. 503(b) of the Federal Food, Drug, and Cosmetic Act. 25 3. The person is not permitted, licensed, or otherwise 2.6 authorized in any state to wholesale prescription drugs 27 subject to, defined by, or described by s. 503(b) of the 28 29 Federal Food, Drug, and Cosmetic Act to any person who is authorized to sell, distribute, purchase, trade, or use these 30 31 drugs on or for humans. 5 8:26 AM 04/06/05 s1654d-ri05-ta1

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1	4. A limited veterinary prescription drug wholesaler					
2	that applies to the department for a new permit or the renewal					
3	of a permit must submit a bond of \$20,000, or other equivalent					
4	means of security acceptable to the department, such as an					
5	irrevocable letter of credit or a deposit in a trust account					
6	or financial institution, payable to the Florida Drug, Device,					
7	and Cosmetic Trust Fund. The purpose of the bond is to secure					
8	payment of any administrative penalties imposed by the					
9	department and any fees and costs incurred by the department					
10	regarding that permit which are authorized under state law and					
11	which the permittee fails to pay 30 days after the fine or					
12	costs become final. The department may make a claim against					
13	such bond or security until 1 year after the permittee's					
14	license ceases to be valid or until 60 days after any					
15	administrative or legal proceeding authorized in ss.					
16	499.001-499.081 which involves the permittee is concluded,					
17	including any appeal, whichever occurs later.					
17 18	including any appeal, whichever occurs later. 5. A limited veterinary prescription drug wholesaler					
18	5. A limited veterinary prescription drug wholesaler					
18 19	5. A limited veterinary prescription drug wholesaler must maintain at all times a license or permit to engage in					
18 19 20	5. A limited veterinary prescription drug wholesaler must maintain at all times a license or permit to engage in the wholesale distribution of prescription drugs in compliance					
18 19 20 21	5. A limited veterinary prescription drug 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.					
18 19 20 21 22	5. A limited veterinary prescription drug 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. 6. A limited veterinary prescription drug wholesaler					
18 19 20 21 22 23	5. A limited veterinary prescription drug 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. 6. A limited veterinary prescription drug wholesaler must comply with the requirements for wholesale distributors					
18 19 20 21 22 23 24	5. A limited veterinary prescription drug 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. 6. A limited veterinary prescription drug wholesaler must comply with the requirements for wholesale distributors under s. 499.0121, except that a limited veterinary					
18 19 20 21 22 23 24 25	5. A limited veterinary prescription drug 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. 6. A limited veterinary prescription drug wholesaler must comply with the requirements for wholesale distributors under s. 499.0121, except that a limited veterinary prescription drug wholesaler is not required to provide a					
 18 19 20 21 22 23 24 25 26 	5. A limited veterinary prescription drug 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. 6. A limited veterinary prescription drug wholesaler must comply with the requirements for wholesale distributors under s. 499.0121, except that a limited veterinary prescription drug wholesaler is not required to provide a pedigree paper as required by s. 499.0121(6)(f) upon the					
 18 19 20 21 22 23 24 25 26 27 	5. A limited veterinary prescription drug 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. 6. A limited veterinary prescription drug wholesaler must comply with the requirements for wholesale distributors under s. 499.0121, except that a limited veterinary prescription drug 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					
 18 19 20 21 22 23 24 25 26 27 28 	5. A limited veterinary prescription drug 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. 6. A limited veterinary prescription drug wholesaler must comply with the requirements for wholesale distributors under s. 499.0121, except that a limited veterinary prescription drug 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.					
 18 19 20 21 22 23 24 25 26 27 28 29 	5. A limited veterinary prescription drug 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. 6. A limited veterinary prescription drug wholesaler must comply with the requirements for wholesale distributors under s. 499.0121, except that a limited veterinary prescription drug 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. 7. A limited veterinary prescription drug wholesaler					

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1 described by s. 503(b) of the Federal Food, Drug, and Cosmetic Act which has been returned by a veterinarian. 2 8. An out-of-state prescription drug wholesaler's 3 4 permit is not required for an intracompany sale or transfer of a prescription drug from an out-of-state establishment that is 5 duly licensed as a limited veterinary prescription drug 6 7 wholesaler in its state of residence to a licensed prescription drug wholesaler in this state if both wholesalers 8 conduct wholesale distributions of prescription drugs under 9 the same business name. The recordkeeping requirements of s. 10 11 499.0121(6) must be followed for this transaction. Section 4. Paragraph (d) of subsection (1) of section 12 13 499.0122, Florida Statutes, is amended to read: 499.0122 Medical oxygen and veterinary legend drug 14 15 retail establishments; definitions, permits, general 16 requirements. --(1) As used in this section, the term: 17 (d) "Veterinary legend drug retail establishment" 18 means a person permitted to sell veterinary legend drugs to 19 the public or to veterinarians, but does not include a 20 21 pharmacy licensed under chapter 465. 22 1. The sale to the public must be based on a valid written order from a veterinarian licensed in this state who 23 24 has a valid client-veterinarian relationship with the 25 purchaser's animal. 2. Veterinary legend drugs may not be sold in excess 26 of the amount clearly indicated on the order or beyond the 27 date indicated on the order. 28 29 3. An order may not be valid for more than 1 year. 4. A veterinary legend drug retail establishment may 30 31 not purchase, sell, trade, or possess human prescription drugs 8:26 AM 04/06/05 s1654d-ri05-ta1

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1 or any controlled substance as defined in chapter 893. 5. A veterinary legend drug retail establishment must 2 sell a veterinary legend drug in the original, sealed 3 4 manufacturer's container with all labeling intact and legible. The department may adopt by rule additional labeling 5 requirements for the sale of a veterinary legend drug. 6 7 Section 5. Paragraph (h) is added to subsection (2) of section 499.041, Florida Statutes, to read: 8 9 499.041 Schedule of fees for drug, device, and 10 cosmetic applications and permits, product registrations, and 11 free-sale certificates.--(2) The department shall assess an applicant that is 12 13 required to have a wholesaling permit an annual fee within the ranges established in this section for the specific type of 14 15 wholesaling. 16 (h) The fee for a limited veterinary prescription drug wholesaler's permit may not be less than \$300 or more than 17 \$500 annually. 18 Section 6. Subsections (1) and (3) of section 499.065, 19 20 Florida Statutes, are amended to read: 21 499.065 Imminent danger.--22 (1) Notwithstanding s. 499.051, the department shall inspect each prescription drug wholesale establishment, 23 24 prescription drug repackager establishment, veterinary prescription drug wholesale establishment, limited veterinary 25 prescription drug wholesaler establishment, and retail 26 pharmacy drug wholesaler establishment that is required to be 27 28 permitted under this chapter as often as necessary to ensure 29 compliance with applicable laws and rules. The department shall have the right of entry and access to these facilities 30 31 at any reasonable time. 8 8:26 AM 04/06/05 s1654d-ri05-ta1

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1	(3) The department may determine that a prescription					
2	drug wholesale establishment, prescription drug repackager					
3	establishment, veterinary prescription drug wholesale					
4	establishment, limited veterinary prescription drug wholesaler					
5	establishment, or retail pharmacy drug wholesaler					
6	establishment that is required to be permitted under this					
7	chapter is an imminent danger to the public health and shall					
8	require its immediate closure if the establishment fails to					
9	comply with applicable laws and rules and, because of the					
10	failure, presents an imminent threat to the public's health,					
11	safety, or welfare. Any establishment so deemed and closed					
12	shall remain closed until allowed by the department or by					
13	judicial order to reopen.					
14						
15	For purposes of this section, a refusal to allow entry to the					
16	department for inspection at reasonable times, or a failure or					
17	refusal to provide the department with required documentation					
18	for purposes of inspection, constitutes an imminent danger to					
19	the public health.					
20	Section 7. This act shall take effect July 1, 2005.					
21						
22						
23	========= TITLE AMENDMENT ==========					
24	And the title is amended as follows:					
25	Delete everything before the enacting clause					
26						
27	and insert:					
28	A bill to be entitled					
29	An act relating to veterinary drug					
30	distribution; amending s. 499.006, F.S.;					
31	providing that a drug is adulterated if it is a 9					
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<pre>22 establishment; authorizing the department to 23 determine that a limited veterinary 24 prescription drug wholesaler establishment is 25 an imminent danger to the public; providing an 26 effective date. 27 28 29 30 31 10</pre>						
3veterinary prescription drug wholesaler;4amending s. 499.01, F.S.; requiring a limited5veterinary prescription drug wholesaler to6obtain a permit for operation from the7Department of Health; providing that a permit8for a limited veterinary prescription drug9wholesaler may not be issued to the address of10certain health care entities; amending s.11499.012, F.S.; establishing a permit for a12limited veterinary prescription drug13wholesaler; amending s. 499.0122, F.S.;14redefining the term "veterinary legend drug15retail establishment"; amending s. 499.041,16F.S.; requiring the department to assess an17annual fee within a certain monetary range for18a limited veterinary prescription drug19wholesaler permit; amending s. 499.065, F.S.;20requiring the department to inspect each21limited veterinary prescription drug wholesaler22establishment; authorizing the department to23determine that a limited veterinary24prescription drug wholesaler establishment is25an imminent danger to the public; providing an26effective date.2728303132	1		certain pre	escription drug that has	s been	
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5 veterinary prescription drug wholesaler to 6 obtain a permit for operation from the 7 Department of Health; providing that a permit 8 for a limited veterinary prescription drug 9 wholesaler may not be issued to the address of 10 certain health care entities; amending s. 11 499.012, F.S.; establishing a permit for a 12 limited veterinary prescription drug 13 wholesaler; amending s. 499.0122, F.S.; 14 redefining the term "veterinary legend drug 15 retail establishment"; amending s. 499.041, 16 F.S.; requiring the department to assess an 17 annual fee within a certain monetary range for 18 a limited veterinary prescription drug 19 wholesaler permit; amending s. 499.065, F.S.; 20 requiring the department to inspect each 21 limited veterinary prescription drug wholesaler 22 establishment; authorizing the department to 23 determine that a limited veterinary 24 prescription drug wholesaler establishment is 25 an imminent danger to the public; providing an 26 eff	3	veterinary prescription drug wholesaler;				
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