

By Senator Fasano

11-1306-05

1                                   A bill to be entitled  
2           An act relating to veterinary drug  
3           distribution; amending s. 499.01, F.S.;  
4           requiring a veterinary drug distributor to  
5           obtain a permit from the Department of Health  
6           before distributing both veterinary legend  
7           drugs and certain human drugs permitted by the  
8           department; amending s. 499.0121, F.S.;  
9           requiring a wholesale distributor of a  
10          prescription drug to provide the recipient of  
11          the drug with pedigree papers if such a drug is  
12          intended for sale to a human recipient;  
13          exempting drugs approved as human drugs sold  
14          directly to veterinarians from the  
15          pedigree-paper requirement; providing an  
16          effective date.

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

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20           Section 1. Subsection (1) of section 499.01, Florida  
21 Statutes, is amended to read:

22           499.01 Permits; applications; renewal; general  
23 requirements.--

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

- 26           (a) A prescription drug manufacturer;
- 27           (b) A prescription drug repackager;
- 28           (c) An over-the-counter drug manufacturer;
- 29           (d) A compressed medical gas manufacturer;
- 30           (e) A device manufacturer;
- 31           (f) A cosmetic manufacturer;

- 1 (g) A prescription drug wholesaler;  
2 (h) A veterinary prescription drug wholesaler;  
3 (i) A compressed medical gas wholesaler;  
4 (j) An out-of-state prescription drug wholesaler;  
5 (k) A nonresident prescription drug manufacturer;  
6 (l) A freight forwarder;  
7 (m) A retail pharmacy drug wholesaler;  
8 (n) A veterinary legend drug retail establishment;  
9 (o) A medical oxygen retail establishment;  
10 (p) A complimentary drug distributor; ~~or~~  
11 (q) A restricted prescription drug distributor; ~~or~~  
12 (r) A veterinary drug distributor distributing both  
13 veterinary legend drugs and certain human drugs permitted by  
14 the department.

15 Section 2. Paragraph (f) of subsection (6) of section  
16 499.0121, Florida Statutes, is amended to read:

17 499.0121 Storage and handling of prescription drugs;  
18 recordkeeping.--The department shall adopt rules to implement  
19 this section as necessary to protect the public health,  
20 safety, and welfare. Such rules shall include, but not be  
21 limited to, requirements for the storage and handling of  
22 prescription drugs and for the establishment and maintenance  
23 of prescription drug distribution records.

24 (6) RECORDKEEPING.--The department shall adopt rules  
25 that require keeping such records of prescription drugs as are  
26 necessary for the protection of the public health.

27 (f)1. Effective July 1, 2006, each person who is  
28 engaged in the wholesale distribution of a prescription drug  
29 intended for sale to a human recipient and who is not the  
30 manufacturer of that drug must, before each wholesale  
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1 distribution of such drug, provide to the person who receives  
2 the drug a pedigree paper as defined in s. 499.003(31).

3           2. A repackager must comply with this paragraph.

4           3. The pedigree paper requirements in this paragraph  
5 do not apply to compressed medical gases, ~~or~~ veterinary legend  
6 drugs, or approved human drugs sold directly to veterinarians.

7           4. Each wholesale distributor of prescription drugs  
8 must maintain separate and distinct from other required  
9 records all statements that are required under subparagraph 1.

10           5. In order to verify compliance with subparagraph  
11 (d)1., each manufacturer of a prescription drug sold in this  
12 state must make available upon request distribution  
13 documentation related to its sales of prescription drugs,  
14 regardless of whether the prescription drug was sold directly  
15 by the manufacturer to a person in Florida.

16           Section 3. This act shall take effect July 1, 2005.

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19           SENATE SUMMARY

20           Requires a veterinary distributor distributing both  
21 veterinary legend drugs and certain human drugs permitted  
22 by the Department of Health to obtain a permit before  
23 operating. Requires a person who is engaged in the  
24 wholesale distribution of a prescription drug to provide  
25 the recipient of such drug with a pedigree paper if the  
26 drug is intended for sale to a human recipient. Exempts  
27 drugs already approved as human drugs sold directly to  
28 veterinarians.  
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