Amendment No. (for drafter's use only)

CHAMBER ACTION

Senate	House
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Representative(s) Homan offered the following:

Amendment (with title amendment)

Remove everything after the enacting clause and insert:

Section 1. Subsections (28) and (31) of section 499.003, Florida Statutes, are amended to read:

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

(28) "Manufacturer" means a person who prepares, derives, manufactures, or produces a drug, device, or cosmetic. The term excludes pharmacies that are operating in compliance with pharmacy practice standards as defined in chapter 465 and rules adopted under that chapter. This term also means the holder of an approved new drug application, abbreviated new drug application, or new animal drug application; a private label distributor if the private label distributor's prescription drugs are originally manufactured and labeled for the

distributor and have not been repackaged; or the distribution point establishment for the manufacturer, contract manufacturer, or private label distributor, whether the establishment is a member of the manufacturer's affiliated group or is a contract distribution site, only to the extent that the contract distribution distributes the drugs of the manufacturer.

(31) "Pedigree paper" means:

(a) A document required pursuant to s. 499.0121(6)(d) or (e); or

(b)1. Effective July 1, 2006, a document or electronic form approved by the Department of Health and containing information that records each distribution of any given legend drug, from sale by a pharmaceutical manufacturer, through acquisition and sale by any wholesaler or repackager, until final sale to a pharmacy or other person administering or dispensing the drug; or.

2. Effective July 1, 2006, a statement, under oath, in written or electronic form, given when a wholesale distribution company purchases and receives the specific unit of the prescription drug directly from the manufacturer of the prescription drug, and distributes the prescription drug directly to a chain pharmacy warehouse or a person authorized by law to purchase prescription drugs, for the purpose of administering or dispensing the drug pursuant to s. 465.003.

a. For purposes of this subparagraph, the term "wholesale distribution company" means a wholesale distributor, as defined in s. 499.012(1)(b) that performs intracompany transfers of specific units of prescription drugs to another wholesale

distributor that is a member of its affiliated group as described in s. 499.012(1)(d)2.b.

b. For purposes of this subparagraph, the term "intracompany transfers" may not include transfers of prescription drugs if those specific units of the prescription drugs were not purchased directly from the manufacturer.

c. For purposes of this subparagraph, "chain pharmacy warehouse" means a wholesale distributor permitted pursuant to s. 499.012 that maintains a physical location for prescription drugs that functions solely as a central warehouse to perform intra-company transfers of such drugs to a member of its affiliated group, as described in s. 499.0121(6)(h)1.

(c) The information required to be included on the form approved by the department pursuant to subparagraph (b)1. ~~a legend drug's pedigree paper~~ must at least detail the amount of the legend drug; its dosage form and strength; its lot numbers; the name and address of each owner of the legend drug and his or her signature; its shipping information, including the name and address of each person certifying delivery or receipt of the legend drug; an invoice number, a shipping document number, or another number uniquely identifying the transaction; and a certification that the recipient wholesaler has authenticated the pedigree papers. If the manufacturer or repackager has uniquely serialized the individual legend drug unit, that identifier must also be included on the form approved by the department pursuant to subparagraph (b)1. ~~pedigree.~~ It must also include the name, address, telephone number and, if available, e-mail contact information of each wholesaler involved in the chain of the legend drug's custody. ~~The department shall adopt~~

~~rules and a form relating to the requirements of this paragraph no later than 90 days after the effective date of this act.~~

(d)1. The information required to be included pursuant to subparagraph (b)2. must include:

a. A written statement that states: "This wholesale distribution company purchased the specific unit of the prescription drug directly from the manufacturer."

b. The manufacturer's National Drug Code identifier that provides the name of the manufacturer and the name and address of the wholesaler and the purchaser of the prescription drug.

c. The name of the prescription drug as it was provided by the manufacturer.

d. The quantity, dosage form, and strength of the prescription drug.

2. The wholesale distribution company shall also maintain and make available to the department, upon request, the name and shipping address of the manufacturer from whom the prescription drugs were purchased; the dates of shipment and invoice numbers from the manufacturer to the wholesale distribution company for such prescription drugs; lot numbers of such prescription drugs received by the wholesale distribution company; and any records of any intracompany transfers within the wholesale distribution company of such prescription drugs.

(e) The department may adopt rules and forms relating to the requirements of this subsection.

Section 2. Subsection (29) of section 499.005, Florida Statutes, is amended to read:

499.005 Prohibited acts.--It is unlawful for a person to perform or cause the performance of any of the following acts in this state:

(29) The receipt of a prescription drug pursuant to a wholesale distribution without either first receiving a pedigree paper that was attested to as accurate and complete by the wholesale distributor or complying with the provisions of s. 499.0121(6)(f)6.

Section 3. Section 499.006, Florida Statutes, is amended to read:

499.006 Adulterated drug or device.--A drug or device is adulterated:

(1) If it consists in whole or in part of any filthy, putrid, or decomposed substance;

(2) If it has been produced, prepared, packed, or held under conditions whereby it could have been contaminated with filth or rendered injurious to health;

(3) If it is a drug and the methods used in, or the facilities or controls used for, its manufacture, processing, packing, or holding do not conform to, or are not operated or administered in conformity with, current good manufacturing practices to assure that the drug meets the requirements of ss. 499.001-499.081 and that the drug has the identity and strength, and meets the standard of quality and purity, which it purports or is represented to possess;

(4) If it is a drug and its container is composed, in whole or in part, of any poisonous or deleterious substance which could render the contents injurious to health;

(5) If it is a drug and it bears or contains, for the purpose of coloring only, a color additive that is unsafe within the meaning of the federal act; or, if it is a color additive, the intended use of which in or on drugs is for the purpose of coloring only, and it is unsafe within the meaning of the federal act;

(6) If it purports to be, or is represented as, a drug the name of which is recognized in the official compendium, and its strength differs from, or its quality or purity falls below, the standard set forth in such compendium. The determination as to strength, quality, or purity must be made in accordance with the tests or methods of assay set forth in such compendium, or, when such tests or methods of assay are absent or inadequate, in accordance with those tests or methods of assay prescribed under authority of the federal act. A drug defined in the official compendium is not adulterated under this subsection merely because it differs from the standard of strength, quality, or purity set forth for that drug in such compendium if its difference in strength, quality, or purity from such standard is plainly stated on its label;

(7) If it is not subject to subsection (6) and its strength differs from, or its purity or quality falls below the standard of, that which it purports or is represented to possess;

(8) If it is a drug:

(a) With which any substance has been mixed or packed so as to reduce the quality or strength of the drug; or

(b) For which any substance has been substituted wholly or in part;

(9) If it is a drug or device for which the expiration date has passed; ~~or~~

(10) If it is a legend drug for which the required pedigree paper is nonexistent, fraudulent, or incomplete under the requirements of ss. 499.001-499.081 or applicable rules, or that has been purchased, held, sold, or distributed at any time by a person not authorized under federal or state law to do so; or~~.~~

(11) If it is a prescription drug subject to, defined by, or described by s. 503(b) of the Federal Food, Drug, and Cosmetic Act which has been returned by a veterinarian to a limited prescription drug veterinary wholesaler.

Section 4. Subsection (1) and paragraph (d) of subsection (2) of section 499.01, Florida Statutes, are amended to read:

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

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

(a) A prescription drug manufacturer;

(b) A prescription drug repackager;

(c) An over-the-counter drug manufacturer;

(d) A compressed medical gas manufacturer;

(e) A device manufacturer;

(f) A cosmetic manufacturer;

(g) A prescription drug wholesaler;

(h) A veterinary prescription drug wholesaler;

(i) A compressed medical gas wholesaler;

(j) An out-of-state prescription drug wholesaler;

(k) A nonresident prescription drug manufacturer;

(l) A freight forwarder;

(m) A retail pharmacy drug wholesaler;

(n) A veterinary legend drug retail establishment;

(o) A medical oxygen retail establishment;

(p) A complimentary drug distributor; ~~or~~

(q) A restricted prescription drug distributor; or~~.~~

(r) A limited prescription drug veterinary wholesaler.

(2)

(d) A permit for a prescription drug manufacturer, prescription drug repackager, prescription drug wholesaler, limited prescription drug veterinary wholesaler, or retail pharmacy wholesaler may not be issued to the address of a health care entity or to a pharmacy licensed under chapter 465, except as provided in this paragraph. The department may issue a prescription drug manufacturer permit to an applicant at the same address as a licensed nuclear pharmacy, which is a health care entity, for the purpose of manufacturing prescription drugs used in positron emission tomography or other radiopharmaceuticals, as listed in a rule adopted by the department pursuant to this paragraph. The purpose of this exemption is to assure availability of state-of-the-art pharmaceuticals that would pose a significant danger to the public health if manufactured at a separate establishment address from the nuclear pharmacy from which the prescription drugs are dispensed. The department may also issue a retail pharmacy wholesaler permit to the address of a community pharmacy licensed under chapter 465 which does not meet the definition of a closed pharmacy in s. 499.003.

Section 5. Paragraph (g) of subsection (2) of section 499.012, Florida Statutes, is amended, and paragraph (h) is added to that subsection, to read:

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

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

(g) A veterinary prescription drug wholesaler permit.--A veterinary prescription drug wholesaler permit is required for any person that engages in the distribution of veterinary prescription drugs in or into this state. A veterinary prescription drug wholesaler that also distributes prescription drugs subject to, defined by, or described by s. 503(b) of the Federal Food, Drug, and Cosmetic Act which it did not manufacture must obtain a permit as a prescription drug wholesaler, an ~~or~~ out-of-state prescription drug wholesaler, or a limited prescription drug veterinary wholesaler in lieu of the veterinary prescription drug wholesaler permit. A veterinary prescription drug wholesaler must comply with the requirements for wholesale distributors under s. 499.0121, except those set forth in s. 499.0121(6)(d), (e), or (f).

(h) Limited prescription drug veterinary wholesaler permit.--Unless engaging in the activities of and permitted as a prescription drug manufacturer, nonresident prescription drug manufacturer, prescription drug wholesaler, or out-of-state prescription drug wholesaler, a limited prescription drug veterinary wholesaler permit is required for any person that engages in the distribution in or into this state of veterinary prescription drugs and prescription drugs subject to, defined

by, or described by s. 503(b) of the Federal Food, Drug, and Cosmetic Act to veterinarians under the following conditions:

1. The person is engaged in the business of wholesaling prescription and veterinary legend drugs to persons:

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

b. Regularly and lawfully engaged in instruction in veterinary medicine;

c. Regularly and lawfully engaged in law enforcement;

d. For use in research, not involving clinical use; or

e. For use in chemical analysis or physical testing, for the purposes of instruction in law enforcement, research, or testing.

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

3. The person is not permitted, licensed, or otherwise 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 authorized to sell, distribute, purchase, trade, or use these drugs on or for humans.

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.

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.

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.

7. A limited prescription drug veterinary wholesaler may not return to inventory for subsequent wholesale distribution any prescription drug subject to, defined by, or described by s. 503(b) of the Federal Food, Drug, and Cosmetic Act which has been returned by a veterinarian.

8. An out-of-state prescription drug wholesaler's permit or a limited prescription drug veterinary wholesaler 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 limited prescription drug veterinary wholesaler in this state if both wholesalers conduct wholesale distributions of prescription drugs under the same business name. The recordkeeping requirements of s. 499.0121(6) must be followed for this transaction.

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

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

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

(f)1. Effective July 1, 2006, each person who is engaged in the wholesale distribution of a prescription drug and who is not the manufacturer of that drug must, before each wholesale distribution of such drug, provide to the person who receives the drug a pedigree paper as defined in s. 499.003(31).

2. A repackager must comply with this paragraph.

3. The pedigree paper requirements in this paragraph do not apply to compressed medical gases or veterinary legend drugs.

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

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

6. The provisions of subparagraph (f)1. are satisfied when a wholesale distributor takes title to, but not possession of, a prescription drug, and the prescription drug's manufacturer ships the prescription drug directly to a person authorized by law to purchase prescription drugs for the purpose of administering or dispensing the drug pursuant to s. 465.003 or a member of an affiliated group, as described in subparagraph (h)1.

a. The wholesale distributor must deliver to the recipient of the prescription drug, within 14 days of the shipment notification from the manufacturer, an invoice and that the following sworn statement: "This wholesale distribution company purchased the specific unit of the prescription drug, listed on the invoice, directly from the manufacturer and has been notified by the manufacturer that the specific unit of prescription drug was shipped by the manufacturer directly to a person authorized by law to administer or dispense the legend drug pursuant to s. 465.003, Florida Statutes, or a member of an affiliated group, as described in s. 499.0121(6)(h)1., Florida Statutes." The invoice must contain a clear cross-reference to

the shipping document sent by the manufacturer to the recipient of the prescription drug.

b. The recipient of the prescription drug must acquire, within 14 days of receipt of the prescription drug, a shipping document from the manufacturer that contains, at a minimum:

(I) The name and address of the manufacturer, including the point of origin of the shipment, the wholesaler, and such purchaser.

(II) The name of the prescription drug as it appears on the label.

(III) The quantity, dosage form, and strength of the prescription drug.

(IV) The date of the shipment from the manufacturer.

c. The wholesale distributor must also maintain and make available to the department, upon request, the lot number of such drug if the applicable lot numbers are provided to the wholesale distributor by the manufacturer and are not contained in the shipping document received by such recipient.

7. Failure of the purchaser to acquire, or the wholesale distributor or manufacturer to deliver, the documentation required under subparagraph (f)6. shall constitute failure to acquire or deliver a pedigree paper under s. 499.0051. Forgery by the purchaser, wholesale distributor, or manufacturer of the documentation required to be acquired or delivered under subparagraph (f)6. shall constitute forgery of a pedigree paper under s. 499.0051.

8. The department may by rule define alternatives to compliance with subparagraph (f)1. for a prescription drug in the inventory of a permitted prescription drug wholesaler as of

June 30, 2006, and the return of a prescription drug purchased prior to July 1, 2006. The department may specify time limits for such alternatives.

Section 7. Paragraph (d) of subsection (1) of section 499.0122, Florida Statutes, is amended to read:

499.0122 Medical oxygen and veterinary legend drug retail establishments; definitions, permits, general requirements.--

(1) As used in this section, the term:

(d) "Veterinary legend drug retail establishment" means a person permitted to sell veterinary legend drugs to the public ~~or to veterinarians,~~ but does not include a pharmacy licensed under chapter 465.

1. The sale to the public must be based on a valid written order from a veterinarian licensed in this state who has a valid client-veterinarian relationship with the purchaser's animal.

2. Veterinary legend drugs may not be sold in excess of the amount clearly indicated on the order or beyond the date indicated on the order.

3. An order may not be valid for more than 1 year.

4. A veterinary legend drug retail establishment may not purchase, sell, trade, or possess human prescription drugs or any controlled substance as defined in chapter 893.

5. A veterinary legend drug retail establishment must sell a veterinary legend drug in the original, sealed manufacturer's container with all labeling intact and legible. The department may adopt by rule additional labeling requirements for the sale of a veterinary legend drug.

Section 8. Paragraph (h) is added to subsection (2) of section 499.041, Florida Statutes, to read:

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

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

(h) The fee for a limited prescription drug veterinary wholesaler's permit may not be less than $300 or more than $500 annually.

Section 9. Subsections (1) and (3) of section 499.065, Florida Statutes, are amended to read:

499.065 Imminent danger.--

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

(3) The department may determine that a prescription drug wholesale establishment, prescription drug repackager establishment, veterinary prescription drug wholesale establishment, limited prescription drug veterinary wholesaler establishment, or retail pharmacy drug wholesaler establishment that is required to be permitted under this chapter is an

imminent danger to the public health and shall require its immediate closure if the establishment fails to comply with applicable laws and rules and, because of the failure, presents an imminent threat to the public's health, safety, or welfare. Any establishment so deemed and closed shall remain closed until allowed by the department or by judicial order to reopen.

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

Section 10. This act shall take effect July 1, 2006.

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

Remove the entire title and insert:

A bill to be entitled

An act relating to drug distribution; amending s. 499.003, F.S.; amending definitions; requiring the Department of Health to approve a document or electronic form relating to pedigree papers; providing requirements for pedigree papers that record certain distributions of legend drugs; amending s. 499.005, F.S.; revising a prohibition relating to pedigree papers; amending s. 499.006, F.S.; providing that a drug is adulterated if it is a certain prescription drug that has been returned by a veterinarian to a limited prescription drug veterinary wholesaler; amending s. 499.01, F.S.; requiring a limited prescription drug

476 veterinary wholesaler to obtain a permit for operation
477 from the Department of Health; providing that a permit for
478 a limited prescription drug veterinary wholesaler may not
479 be issued to the address of certain health care entities;
480 amending s. 499.012, F.S.; revising permit requirements
481 for a veterinary prescription drug wholesaler that
482 distributes prescription drugs; establishing a permit for
483 a limited prescription drug veterinary wholesaler;
484 providing requirements; providing an exception; amending
485 s. 499.0121, F.S.; requiring certain wholesale
486 distributors taking title to a prescription drug to
487 provide an invoice to the purchaser containing certain
488 information; requiring a purchaser of a prescription drug
489 to obtain from the manufacturer a shipping document
490 containing specified information; requiring a manufacturer
491 to make certain information available to the department;
492 providing a penalty; authorizing the department to adopt
493 certain rules relating to the inventory and return of
494 certain prescription drugs; amending s. 499.0122, F.S.;
495 redefining the term "veterinary legend drug retail
496 establishment"; amending s. 499.041, F.S.; requiring the
497 department to assess an annual fee within a certain
498 monetary range for a limited prescription drug veterinary
499 wholesaler permit; amending s. 499.065, F.S.; requiring
500 the department to inspect each limited prescription drug
501 veterinary wholesaler establishment; authorizing the
502 department to determine that a limited prescription drug
503 veterinary wholesaler establishment is an imminent danger
504 to the public; providing an effective date.