

1 establishment is an imminent danger to the
2 public; providing an effective date.

3
4 Be It Enacted by the Legislature of the State of Florida:

5
6 Section 1. Section 499.006, Florida Statutes, is
7 amended to read:

8 499.006 Adulterated drug or device.--A drug or device
9 is adulterated:

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

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

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

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

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

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

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

20 (8) If it is a drug:

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

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

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

27 (10) If it is a legend drug for which the required
28 pedigree paper is nonexistent, fraudulent, or incomplete under
29 the requirements of ss. 499.001-499.081 or applicable rules,
30 or that has been purchased, held, sold, or distributed at any
31

1 time by a person not authorized under federal or state law to
2 do so ; or-

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

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

10 499.01 Permits; applications; renewal; general
11 requirements.--

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

- 14 (a) A prescription drug manufacturer;
15 (b) A prescription drug repackager;
16 (c) An over-the-counter drug manufacturer;
17 (d) A compressed medical gas manufacturer;
18 (e) A device manufacturer;
19 (f) A cosmetic manufacturer;
20 (g) A prescription drug wholesaler;
21 (h) A veterinary prescription drug wholesaler;
22 (i) A compressed medical gas wholesaler;
23 (j) An out-of-state prescription drug wholesaler;
24 (k) A nonresident prescription drug manufacturer;
25 (l) A freight forwarder;
26 (m) A retail pharmacy drug wholesaler;
27 (n) A veterinary legend drug retail establishment;
28 (o) A medical oxygen retail establishment;
29 (p) A complimentary drug distributor; ~~or~~
30 (q) A restricted prescription drug distributor; or-
31 (r) A limited prescription drug veterinary wholesaler.

1 (2)
2 (d) A permit for a prescription drug manufacturer,
3 prescription drug repackager, prescription drug wholesaler,
4 limited prescription drug veterinary wholesaler, or retail
5 pharmacy wholesaler may not be issued to the address of a
6 health care entity or to a pharmacy licensed under chapter
7 465, except as provided in this paragraph. The department may
8 issue a prescription drug manufacturer permit to an applicant
9 at the same address as a licensed nuclear pharmacy, which is a
10 health care entity, for the purpose of manufacturing
11 prescription drugs used in positron emission tomography or
12 other radiopharmaceuticals, as listed in a rule adopted by the
13 department pursuant to this paragraph. The purpose of this
14 exemption is to assure availability of state-of-the-art
15 pharmaceuticals that would pose a significant danger to the
16 public health if manufactured at a separate establishment
17 address from the nuclear pharmacy from which the prescription
18 drugs are dispensed. The department may also issue a retail
19 pharmacy wholesaler permit to the address of a community
20 pharmacy licensed under chapter 465 which does not meet the
21 definition of a closed pharmacy in s. 499.003.

22 Section 3. Paragraph (g) of subsection (2) of section
23 499.012, Florida Statutes, is amended, and paragraph (h) is
24 added to that subsection, to read:

25 499.012 Wholesale distribution; definitions; permits;
26 applications; general requirements.--

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

29 (g) A veterinary prescription drug wholesaler
30 permit.--A veterinary prescription drug wholesaler permit is
31 required for any person that engages in the distribution of

1 | veterinary prescription drugs in or into this state. A
2 | veterinary prescription drug wholesaler that also distributes
3 | prescription drugs subject to, defined by, or described by s.
4 | 503(b) of the Federal Food, Drug, and Cosmetic Act which it
5 | did not manufacture must obtain a permit as a prescription
6 | drug wholesaler, an ~~or~~ out-of-state prescription drug
7 | wholesaler, or a limited prescription drug veterinary
8 | wholesaler in lieu of the veterinary prescription drug
9 | wholesaler permit. A veterinary prescription drug wholesaler
10 | must comply with the requirements for wholesale distributors
11 | under s. 499.0121, except those set forth in s.
12 | 499.0121(6)(d), (e), or (f).

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

24 | 1. The person is engaged in the business of
25 | wholesaling prescription and veterinary legend drugs to
26 | veterinarians on a full-time basis.

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

31 |

1 3. The person is not permitted, licensed, or otherwise
2 authorized in any state to wholesale prescription drugs
3 subject to, defined by, or described by s. 503(b) of the
4 Federal Food, Drug, and Cosmetic Act to any person who is
5 authorized to sell, distribute, purchase, trade, or use these
6 drugs on or for humans.

7 4. A limited prescription drug veterinary wholesaler
8 that applies to the department for a new permit or the renewal
9 of a permit must submit a bond of \$20,000, or other equivalent
10 means of security acceptable to the department, such as an
11 irrevocable letter of credit or a deposit in a trust account
12 or financial institution, payable to the Florida Drug, Device,
13 and Cosmetic Trust Fund. The purpose of the bond is to secure
14 payment of any administrative penalties imposed by the
15 department and any fees and costs incurred by the department
16 regarding that permit which are authorized under state law and
17 which the permittee fails to pay 30 days after the fine or
18 costs become final. The department may make a claim against
19 such bond or security until 1 year after the permittee's
20 license ceases to be valid or until 60 days after any
21 administrative or legal proceeding authorized in ss.
22 499.001-499.081 which involves the permittee is concluded,
23 including any appeal, whichever occurs later.

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

28 6. A limited prescription drug veterinary wholesaler
29 must comply with the requirements for wholesale distributors
30 under s. 499.0121, except that a limited prescription drug
31 veterinary wholesaler is not required to provide a pedigree

1 paper as required by s. 499.0121(6)(f) upon the wholesale
2 distribution of a prescription drug to a veterinarian.

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

8 8. An out-of-state prescription drug wholesaler's
9 permit or a limited prescription drug veterinary wholesaler
10 permit is not required for an intracompany sale or transfer of
11 a prescription drug from an out-of-state establishment that is
12 duly licensed to engage in the wholesale distribution of
13 prescription drugs in its state of residence to a licensed
14 limited prescription drug veterinary wholesaler in this state
15 if both wholesalers conduct wholesale distributions of
16 prescription drugs under the same business name. The
17 recordkeeping requirements of s. 499.0121(6) must be followed
18 for this transaction.

19 Section 4. Paragraph (d) of subsection (1) of section
20 499.0122, Florida Statutes, is amended to read:

21 499.0122 Medical oxygen and veterinary legend drug
22 retail establishments; definitions, permits, general
23 requirements.--

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

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

29 1. The sale to the public must be based on a valid
30 written order from a veterinarian licensed in this state who
31

1 has a valid client-veterinarian relationship with the
2 purchaser's animal.

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

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

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

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

15 Section 5. Paragraph (h) is added to subsection (2) of
16 section 499.041, Florida Statutes, to read:

17 499.041 Schedule of fees for drug, device, and
18 cosmetic applications and permits, product registrations, and
19 free-sale certificates.--

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

24 (h) The fee for a limited prescription drug veterinary
25 wholesaler's permit may not be less than \$300 or more than
26 \$500 annually.

27 Section 6. Subsections (1) and (3) of section 499.065,
28 Florida Statutes, are amended to read:

29 499.065 Imminent danger.--

30 (1) Notwithstanding s. 499.051, the department shall
31 inspect each prescription drug wholesale establishment,

1 prescription drug repackager establishment, veterinary
2 prescription drug wholesale establishment, limited
3 prescription drug veterinary wholesaler establishment, and
4 retail pharmacy drug wholesaler establishment that is required
5 to be permitted under this chapter as often as necessary to
6 ensure compliance with applicable laws and rules. The
7 department shall have the right of entry and access to these
8 facilities at any reasonable time.

9 (3) The department may determine that a prescription
10 drug wholesale establishment, prescription drug repackager
11 establishment, veterinary prescription drug wholesale
12 establishment, limited prescription drug veterinary wholesaler
13 establishment, or retail pharmacy drug wholesaler
14 establishment that is required to be permitted under this
15 chapter is an imminent danger to the public health and shall
16 require its immediate closure if the establishment fails to
17 comply with applicable laws and rules and, because of the
18 failure, presents an imminent threat to the public's health,
19 safety, or welfare. Any establishment so deemed and closed
20 shall remain closed until allowed by the department or by
21 judicial order to reopen.

22
23 For purposes of this section, a refusal to allow entry to the
24 department for inspection at reasonable times, or a failure or
25 refusal to provide the department with required documentation
26 for purposes of inspection, constitutes an imminent danger to
27 the public health.

28 Section 7. This act shall take effect July 1, 2006.
29
30
31