

VIRGINIA ACTS OF ASSEMBLY -- 1994 SESSION

CHAPTER 910

An Act to amend and reenact §§ 3.1-829 through 3.1-835, 3.1-837, 3.1-839, and 3.1-842 through 3.1-845 of the Code of Virginia, relating to animal remedies; penalties.

[H 704]

Approved April 20, 1994

Be it enacted by the General Assembly of Virginia:

1. That §§ 3.1-829 through 3.1-835, 3.1-837, 3.1-839, and 3.1-842 through 3.1-845 of the Code of Virginia are amended and reenacted as follows:

§ 3.1-829. Definitions.

As used in this chapter the following terms shall have the meanings respectively ascribed to them::

(a) "Person" includes any individual, firm, partnership, corporation, association, or organized group of persons whether incorporated or not.

(b) "Animal" means any animate being, which is not human, endowed with the power of voluntary action.

(c) "Animal remedies" means all drugs, combinations of drugs, proprietary medicines, and combinations of drugs and other ingredients, other than for food purposes or cosmetic purposes, which are prepared or compounded for animal use; except those exempted by the Commissioner.

(d) "Drug" means:

(1) Articles recognized in the Official United States Pharmacopoeia, the official Homeopathic Pharmacopoeia of the United States, Official National Formulary, or any supplement to any of them.

(2) Articles intended for use in the diagnosis, cure, mitigation, treatment or prevention of disease in animals.

(3) Articles (other than food or cosmetics) intended to affect the structure or any function of the body of animals.

(4) Articles intended for use as a component of any articles specified in subdivision (1) or (2) of this subsection.

(e) "Label" means a display of written, printed, or graphic matter upon the immediate container of any article; and a requirement made under authority of this chapter that any word, statement, or other information appearing on the label is not complied with unless such word, statement or other information also appears on the outside container or wrapper of the retail package of such article, or is easily legible through the outside container or wrapper.

(f) "Labeling" means all labels and other written, printed, or graphic matter.

(1) Upon any article or any of its containers or wrappers;

(2) Accompanying such article at any time.

(g) "Dosage form" means any animal remedy prepared in tablet, pills, capsules, ampules, or other units suitable for administration as an animal remedy.

(h) "Advertisement" means all representations, other than those on the label, disseminated in any manner or by any means, relating to animal remedies as defined in this chapter.

(i) "Commissioner" means Commissioner of Agriculture and Consumer Services of the Commonwealth of Virginia.

(j) "Board" means the Virginia Board of Agriculture and Consumer Services.

(k) "Medicated feed" means a product obtained by mixing a commercial feed and a drug, and is subject to all provisions of this chapter, except as otherwise determined by the Commissioner as provided in § 3.1-834 (e).

(l) A word importing the singular number only may extend and be applied to several persons or things, as well as to one person or thing, and a word importing the plural number only may extend and be applied to one person or thing, as well as to several persons or things.

(m) "Sell" or "sale" includes exchange.

"Advertisement" means all representations, other than those on the label, disseminated in any manner or by any means, relating to animal remedies.

"Animal" means any animate being, which is not human, endowed with the power of voluntary action.

"Animal remedies" means all drugs, combinations of drugs, proprietary medicines, and combinations of drugs and other ingredients, other than for food purposes or cosmetic purposes, which are prepared or compounded for animal use; except those exempted by the Commissioner.

"Board" means the Board of Agriculture and Consumer Services.

"Commissioner" means Commissioner of Agriculture and Consumer Services.

"Department" means the Virginia Department of Agriculture and Consumer Services.

"Dosage form" means any animal remedy prepared in tablets, pills, capsules, ampules, or other units

suitable for administration as an animal remedy.

"Drug" means (i) articles recognized in the latest addition or any supplement thereto of the Official United States Pharmacopoeia, the official Homeopathic Pharmacopoeia of the United States, or the Official National Formulary, (ii) articles intended for use in the diagnosis, cure, mitigation, treatment or prevention of disease in animals, (iii) articles, other than food or cosmetics, intended to affect the structure or any function of the body of animals, or (iv) articles intended for use as a component of any articles specified in clauses (i) or (ii) of this definition.

"Label" means a display of written, printed, or graphic matter upon the immediate container of any article; and a requirement made under authority of this chapter that any word, statement, or other information appearing on the label is not complied with unless such word, statement or other information also appears on the outside container or wrapper of the retail package of such article, or is easily legible through the outside container or wrapper.

"Labeling" means all labels and other written, printed, or graphic matter (i) upon any article or any of its containers or wrappers or (ii) accompanying such article at any time.

"Medicated feed" means a product obtained by mixing a commercial feed and a drug.

"Quantity statement" means the net weight (mass), net volume (liquid or dry), count or other form of measurement of a commodity.

"Sell" or "sale" includes exchange.

"Stop sale, use, removal, or seizure order" means an order which prohibits the distributor from selling, relocating, using, or disposing of an animal remedy in any manner, until the Commissioner, or his agent, or the court gives written permission to sell, relocate, use or dispose of the animal remedy.

§ 3.1-830. Authority and delegation vested in Commissioner.

The Commissioner shall administer and enforce this chapter, which shall be known as the "Virginia Animal Remedies Law of 1956." All authority vested in the Commissioner by virtue of the provisions of this chapter may with like force and effect be executed by such employees of the Department of Agriculture and Consumer Services as the Commissioner may from time to time designate for said purpose. The Commissioner may appoint agents to assist in carrying out the provisions of this chapter and the regulations promulgated pursuant thereto.

§ 3.1-831. Adulterated remedy.

An animal remedy is adulterated if:

(a) 1. If It was prepared, or held under unsanitary conditions whereby it may have become contaminated with filth, or whereby it may have been rendered injurious to animal health.

(b) 2. If Its composition, purity, strength, or quality falls below or differs from that which it is purported or is represented to possess by its labeling; but the Commissioner shall allow a reasonable tolerance from such representation as is in accordance with good manufacturing practices.

(c) 3. If It consists in whole or in part of any filthy, putrid or decomposed substance.

(d) 4. If It bears or contains any poisonous or deleterious substance which may render it injurious to health under such conditions of use as are customary or usual.

(e) 5. If Its container is composed of any injurious or deleterious substance which may render it injurious to health.

§ 3.1-832. Misbranded remedy.

An animal remedy is misbranded:

(a) 1. Unless the label bears, in the English language:

(1) a. The name and principal addresses of the manufacturer or person responsible for placing such animal remedy on the market.

(2) b. The name, brand, or trademark under which the animal remedy is sold.

(3) c. An accurate quantity statement of the ~~minimum~~ net contents of the package, lot, or parcel, such contents stated by weight in the case of solids, by volume in the case of liquids, and by both count and weight or volume per dose in the case of dosage forms.

(4) d. The common or usual name of each active ingredient; in the case of a drug or drugs intended to be mixed with or in a feed for animals, and in the case of mixtures of a drug or drugs with or in a feed for animals, the English name of each active ingredient shall be stated and also the percentage of each active ingredient, or, in the case of antibiotics, the number of grams of each such active ingredient present in one pound of the product.

(5) e. Adequate directions for use.

(6) f. Adequate warnings against use in those conditions, whether pathological or normal, where its use may be dangerous to the health of animals, or against unsafe dosage, methods or duration of methods, administration, or application, in such manner and form, as are necessary for the protection of animals.

(b) 2. If the labeling is false or misleading in any particular.

(c) 3. If its container is so made, formed, or filled as to be deceptive or misleading as to the amount of contents.

(d) 4. If it is dangerous to the health of animals when used in the dosage or with the frequency or duration prescribed, recommended, or suggested in the labeling of such remedy.

(e) 5. If any word, statement, or other information required to appear on the label is not prominently placed on such label with such conspicuousness, as compared with other words, statements, designs, or devices in the labeling, and in such terms, as to render it likely to be read and understood by the ordinary individual under customary conditions of purchase and use.

Any animal remedy that is manufactured and distributed under license from and under the supervision of the United States Department of Agriculture, and in compliance with the regulations of such department complies with this section.

§ 3.1-833. Withholding noncomplying remedies from sale; tagging, condemnation and destruction of adulterated or misbranded remedies; correction of adulteration or misbranding.

The Commissioner, *or his agent*, shall cause animal remedies, which are found or believed not to comply with §§ 3.1-829 through 3.1-844, inclusive, to be withheld from sale pending compliance with such sections.

(a) 1. Whenever the Commissioner, *or his agent*, finds or has reasonable cause to believe an animal remedy is adulterated or misbranded he shall affix to such article a tag or other appropriate marking, giving notice that such article is, or is suspected of being, adulterated or misbranded and has been detained and warning all persons not to dispose of such article in any manner until permission is given by the Commissioner, *or his agent*, or the court. Any such article may be removed from display by the manufacturer or vendor, but must be left on the premises.

(b) 2. If such a detained article is found, after examination and analysis, to be adulterated or misbranded, the Commissioner may petition the judge of any court of competent jurisdiction in whose jurisdiction the article is detained for condemnation of such article. If the Commissioner finds that such detained article is not adulterated or misbranded, he shall remove the tag or other marking.

(c) 3. If the court finds that a detained animal remedy is adulterated or misbranded, such article shall, after entry of the decree, be destroyed at the expense of the defendant, under the supervision of the Commissioner, *or his agent*; all court costs and fees, and storage and other proper expenses, shall be levied against the defendant or his agent.

(d) 4. If the adulteration or misbranding can be corrected by proper processing or labeling of the article, the court, after entry of the decree and after such costs, fees and expenses have been paid and a sufficient bond, conditioned that such article shall be so processed or labeled, has been executed, may order such article to be delivered to the defendant for such processing or labeling under the supervision of the Commissioner, *or his agent*. The expense of such supervision shall be paid by the defendant. The bond shall be returned to the defendant on the representation to the court by the Commissioner that the article no longer violates §§ 3.1-829 through 3.1-844, inclusive, and that expenses incident to such proceeding were paid.

§ 3.1-834. Registration required.

A. All animal remedies offered for sale in Virginia shall be registered by the manufacturer or person responsible for placing such animal remedy on the market. *The manufacturer or person responsible for distributing an animal remedy in the Commonwealth shall obtain a registration from the Commissioner or his agent for the animal remedy before placing such remedy on the market, except for medicated feeds registered under subdivision A 3 of § 3.1-828.7 of the Virginia Commercial Feed Law.*

(a) B. Any person may make application for registration of any animal remedy by filing with the Commissioner, on forms furnished *or approved* by him, a statement with respect to such animal remedy setting forth:

(1) 1. The name and principal address of the manufacturer or person responsible for placing such animal remedy on the market with the name and address of the person to whom correspondence should be directed.

(2) 2. The name, brand, or trademark under which the animal remedy will be sold.

(b) C. A label for any animal remedy shall accompany each application for registration, and, when requested by the Commissioner, *or his agent*, a representative and true sample or specimen of each animal remedy to be registered shall accompany such application. A statement of claims made or to be made which differ from the label submitted shall be filed with the Commissioner prior to use.

(c) D. If the Commissioner, *or his agent*, after examination and investigation, finds that the application and labeling comply with §§ 3.1-829 through 3.1-844, ~~inclusive~~, a certificate of registration shall be issued to the applicant on payment of an inspection fee as provided in § 3.1-842. ~~All such certificates shall be issued for a period not exceeding one year, expiring December 31 of each year; but no such certificate is a recommendation or endorsement of the animal remedy registered.~~

(d) E. This section does not apply to an animal remedy intended solely for investigational, experimental, or laboratory use by qualified persons, provided such remedy is plainly labeled "for investigational use only."

(e) F. The Commissioner may determine whether a preparation intended for animal use and subject to registration shall be registered as a commercial feed and ~~or~~ as an animal remedy.

(f) G. The manufacturer or person responsible for placing on the market an animal remedy which is offered for sale, sold or otherwise distributed in this Commonwealth before it has been properly registered shall be subject to a ~~penalty~~ late inspection fee of ~~twenty-five~~ fifty dollars payable to the

Commissioner, who shall deposit the same in the state treasury to the credit of the Literary Fund in addition to the inspection fee. This penalty shall be paid before the animal remedy is registered. The registrant shall pay the late inspection fee before the registration is issued.

§ 3.1-835. Investigations by Commissioner; right of access; securing and examining samples; obstructing Commissioner or agent; penalty.

The Commissioner shall make all necessary investigations pertinent to the enforcement of §§ 3.1-829 to 3.1-844, inclusive.

The Commissioner, or his agent, shall have free access at all reasonable during operating hours to any establishment in which animal remedies are manufactured, processed, packed, sold or offered for sale, to inspect such premises and to determine whether such sections are being violated.

The Commissioner, or his agent, may secure samples or specimens of any animal remedy after paying or offering to pay for them, and he shall have an examination or analysis made of such sample to determine whether such sections are being violated. Any person who hinders or obstructs in any way the Commissioner or his agent in the performance of his official duties shall be guilty of a Class 3 misdemeanor.

§ 3.1-837. Prohibitions.

A. No person shall:

(a) 1. Sell, deliver, hold, or offer for sale any animal remedy which has not been registered with the Commissioner as provided in § 3.1-834, except that any biological product for use on or testing of any livestock, poultry, or any animal, manufactured under a license issued by the United States Department of Agriculture, shall not be considered as being subject to the registration requirements of such section.

(b) 2. Manufacture, sell, deliver, hold, or offer for sale any animal remedy that is adulterated or misbranded.

(c) 3. Compound, manufacture, make, produce, pack, package, or prepare within this Commonwealth any animal remedy to be offered for sale or distribution unless such compounding, manufacture, making, producing, packaging, packing or preparing is done with adequate equipment under the supervision of a licensed veterinarian, a graduate chemist, a licensed pharmacist, a licensed physician, or some other person as may be approved by the Commissioner after an investigation and a determination by the Commissioner that they are qualified by scientific or technical training or by experience to perform such duties of supervision as may be necessary to protect animal health and public safety.

(d) 4. Disseminate any advertisement which is false or misleading in any respect, but no person or medium for the dissemination of any advertisement, except the manufacturer, packer, distributor, or seller of the article to which a false advertisement relates, is subject to the penalties for violations of §§ 3.1-829 to 3.1-844, inclusive, by reason of the dissemination by him of such false advertisement, unless he refused, on the request of the Commissioner to furnish the name and address of the manufacturer, packer, distributor, seller, or advertising agency which caused him to disseminate such advertisement.

(e) Refuse to permit entry or inspection, or to permit the acquisition of a sample or specimen of an animal remedy, as authorized by § 3.1-835.

(f) 5. Dispose of a detained article in violation of § 3.1-833.

(g) 6. Give a guaranty which is false, except a person who relied on a guaranty to the same effect signed by, and containing the name and address of, the person from whom he received the animal remedy in good faith.

(h) 7. Alter, mutilate, destroy, obliterate, or remove any part of the labeling of any animal remedy if such acts result in such animal remedy being misbranded, or do any other act, while such animal remedy is being held for sale, which results in the misbranding of such article.

(i) 8. Forge, counterfeit, simulate, or falsely represent, or without proper authority use, any mark, stamp, tag, label, or other identification device required by § 3.1-832.

(j) 9. Sell or offer to sell any biological product for use on any livestock, poultry, or other animal, unless such product is manufactured under a license issued by the United States Department of Agriculture or a registration issued by the Commissioner, or unless such product meets the requirements of the federal "Food, Drug and Cosmetic Act."

(k) 10. Sell or offer to sell any biological product that has not been kept in refrigeration under conditions prescribed by the rules and regulations of the Board.

B. The Commissioner, or his agent, shall make an assessment upon any person who commits a prohibited act under this chapter ten percent of the retail price of the animal remedy at the time of sampling on the product found in violation, or fifty dollars, whichever is greater, not to exceed \$5,000 per occurrence. The person on whom the assessment is made shall pay the assessment to the Commissioner within sixty days from the date of notice to the person whose name appears on the label. Any person who fails to pay the assessment within the specified time shall pay a late fee of fifty dollars to the Commissioner in addition to the assessment. The Commissioner shall revoke the registration of any person who fails to pay the assessment.

§ 3.1-839. Authority of Board.

The Commissioner shall enforce this chapter, and the Board may promulgate and adopt such

reasonable rules and regulations as are necessary to carry out the provisions of this chapter.

§ 3.1-842. Inspection fees; renewal of registration.

A. The Commissioner shall before issuing a certificate of registration for any animal remedy, collect from the applicant for such certificate, an inspection fee of ~~twenty~~ twenty-five dollars for each separate ~~article~~ animal remedy registered. When an animal remedy has been registered and the inspection fee paid by the manufacturer or distributor, no other person shall be required to pay such fee.

Registration of any animal remedy may be continued in force upon the payment of an annual inspection fee of twenty dollars for each separate product registered. Such renewal of registration must be applied for and all inspection fees paid on or before the thirty-first day of December of each year.

Registration must be applied for and all inspection fees paid prior to distributing an animal remedy in the Commonwealth.

Any retailer of animal remedies who has bought a supply of such remedies at a time, as shown by invoice dates, when such remedies were registered, may sell or otherwise dispose of such remedies without reregistering them.

B. The registrant shall pay an inspection fee for the registration year of January 1 through December 31. Each registration shall expire on December 31 of the year for which it is issued. A registration is valid through January 31 of the next ensuing year or the issuance of the renewal registration, whichever event first occurs, if the holder thereof has filed a renewal application with the Commissioner on or before December 31 of the year for which the current registration was issued and has paid the inspection fee to the Commissioner. The Commissioner makes no recommendation or endorsement of the animal remedy by granting registration.

C. If the Commissioner, or his agent, identifies any unregistered animal remedy in commerce in the Commonwealth during the registration year, the Commissioner, or his agent, shall give the person who is required to register the animal remedy, a grace period of fifteen working days from issuance of notification within which to register the animal remedy. Any person required to register an animal remedy who fails to register the animal remedy within the grace period shall pay to the Commissioner a fifty-dollar late fee in addition to the inspection fee. The Commissioner, or his agent, may issue a stop sale, use, removal, or seizure order upon any animal remedy until the registration is issued.

§ 3.1-843. Disposition of funds collected.

All funds collected by the Department of Agriculture and Consumer Services under this chapter except under § 3.1-834 shall be paid into the state treasury to the credit of the general fund. All fees and assessments under this chapter received by the Commissioner shall be paid into a dedicated special fund in the state treasury to the credit of the Department, to be used in carrying out the purpose and provisions of this chapter.

§ 3.1-844. Report of violations; duty of attorney for the Commonwealth.

The Commissioner shall report violations of this chapter, to the proper prosecuting authorities.

Each attorney for the Commonwealth to whom the Commissioner reports any violation of such sections, shall institute appropriate proceedings in any court of competent jurisdiction without delay. Before any such violation is reported to any such attorney for the institution of criminal proceedings, the person against whom the proceeding is contemplated shall be given appropriate notice and an opportunity to present his views before the Commissioner either orally or in writing, in person or by attorney, with regard to such contemplated proceeding. It shall be the duty of every attorney for the Commonwealth, to whom the Commissioner shall report any violation of this chapter, to cause proceedings to be prosecuted without delay.

This section shall not require the Commissioner, or his agent, to report, for the institution of prosecution under such sections, minor violations of this chapter if he believes the public interest will be adequately served in the circumstances by a suitable written notice of warning.

In all prosecutions under this chapter involving the composition of an animal remedy, a certified copy of the official analysis signed by the analyst shall be accepted as prima facie evidence of the composition, provided the defendant has been furnished a copy thereof in advance of the trial.

§ 3.1-845. Violation of chapter or rules and regulations a misdemeanor.

Any person convicted of violating any provisions of this chapter or the rules and regulations issued thereunder shall be ~~adjudged~~ guilty of a Class 1 misdemeanor.