SENATE FILE NO. SF0065

Animal remedies.

Sponsored by: Joint Agriculture, State and Public Lands and Water Resources Interim Committee

A BILL

for

AN ACT relating to livestock; repealing existing livestock remedy provisions and creating animal remedy provisions; providing definitions; providing exemptions; providing for powers and duties of the director of the department of agriculture; providing for registration and fees; providing for audits; providing requirements for packaging and labeling; providing for inspections and sampling; providing for rulemaking; providing for notice and seizure; providing for penalties; and providing for an effective date.

Be It Enacted by the Legislature of the State of Wyoming:

Section 1. W.S. 11-17-201 through 11-17-209 are created to read:

ARTICLE 2

ANIMAL REMEDIES

11-17-201. Short title.

This article is known and may be cited as the "Wyoming Animal Remedies Act."

11-17-202. Definitions; exemptions.

(a) As used in this article:

(i) "Advertisement" means any representation, other than on the label, disseminated in any manner or by any means, relating to animal remedies as defined in this article;

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

(iii) "Animal remedy" means any drug, combination of drugs, proprietary medicine, biological product and combinations of drugs and other ingredients, other than for food or cosmetic purposes, which is prepared

or compounded for animal use, except as exempted by the director;

(iv) "Antimicrobial resistance" means the result of microbes changing in ways that reduce or eliminate the effectiveness of drugs, chemicals or other agents intended to cure or prevent infections;

(v) "Brand name" means any word, name, symbol or device, or any combination thereof, identifying the animal remedy of a distributor or registrant and distinguishing it from that of others;

(vi) "Department" means the Wyoming department of agriculture;

(vii) "Director" means the director of the Wyoming department of agriculture;

(viii) "Distribute" means to offer for sale, sell, exchange or barter any animal remedy;

(ix) "Distributor" means any person who distributes animal remedies;

(x) "Dosage form" means an animal remedy prepared in tablets, pills, capsules, ampules, boluses or other units suitable for administration as an animal remedy;

(xi) "Drug" means an animal remedy:

(A) Recognized in the official United States pharmacopoeia, the official United States homeopathic pharmacopoeia, the official national formulary, or any supplement to any of these publications;

(B) Recognized by the United States food and drug administration;

(C) Intended for use in the diagnosis, cure, mitigation, treatment or prevention of disease in animals;

(D) Prepared for external or internal use in the mitigation of parasites in or on animals;

(E) Intended to affect the structure or any

function of the body of animals;

(F) Intended for use as a component of any combined animal remedy specified in subparagraphs (A) through (E) of this paragraph.

(xii) "Drug" does not include a device or its components, parts or accessories;

(xiii) "Label" means a display of written, printed or graphic matter upon or affixed to the immediate container of any animal remedy;

(xiv) "Labeling" means any label and other written, printed or graphic matter upon an animal remedy and any of its containers or wrappers accompanying the animal remedy. "Labeling" also includes any advertisement or brochure promoting the animal remedy including but not limited to television, internet, other electronic medium or pamphlets;

(xv) "Medicated feed" means commercial or custom feed which contains drug ingredients intended for the cure, mitigation, treatment or prevention of diseases of animals

or which contains drug ingredients intended to affect the structure or any function of the body of animals;

(xvi) "Official sample" means any sample of an animal remedy taken by and designated as official by the director or his agent;

(xvii) "Product name" means the name of the animal remedy which identifies it as to kind, class or specific use;

(xviii) "Registrant" means the person who registers animal remedies under the provisions of this article. The registrant may also be the distributor;

(xix) "This act" means W.S. 11-17-201 through 11-17-209.

(b) Nothing in this article shall apply to:

(i) A medicated feed;

(ii) A product registered with the department and recognized as a pesticide;

(iii) Any animal remedy intended solely for investigational, experimental or laboratory use by qualified persons, provided the animal remedy is plainly labeled "for investigational use only";

(iv) Any person licensed to practice veterinary medicine in Wyoming, when acting within the scope of that license.

11-17-203. Powers and duties of the director; promulgation of rules; interagency cooperation.

(a) The director shall enforce the provisions of this article and may prescribe the form of tags, stamps or labels to be used to show that the registration has been properly filed.

(b) The director may refuse to register any application not in compliance with this article and may cancel any registration subsequently found not to be in compliance with the law. No registration shall be refused or cancelled until the registrant has been given an opportunity to be heard before the director and to amend

his application in order to bring the application into compliance.

(c) The director may sample any animal remedy as he deems necessary.

(d) The director shall conduct any investigation he deems necessary to enforce this article.

(e) The director may refuse the registration of any animal remedy if available facts indicate that the product proposed is of negligible or no value for correcting, alleviating or mitigating animal injuries or diseases for which it is intended, or the director may suspend or revoke any use for flagrant violation of this article.

(f) The director may determine whether a manufacturer or distributor shall be registered under the commercial feed or an animal remedy law.

(g) The director shall cause animal remedies, which are found or believed not to comply with this article to be withheld from sale pending compliance with this article.

(h) Whenever the director or his authorized agent finds or has reasonable cause to believe an animal remedy is adulterated or misbranded under any provision of W.S. 11-17-207(d), he shall affix to the animal remedy a tag or other appropriate marking, giving notice that the animal remedy is, or is suspected of being, adulterated or misbranded and has been detained and warning all persons not to dispose of the animal remedy in any manner until permission is given by the director or the court. Any animal remedy suspected of being adulterated or misbranded may be removed from display by the manufacturer or vendor, but shall be left on the premises. No person shall dispose of a detained animal remedy in violation of this section.

(j) If an animal remedy detained pursuant to subsection (g) or (h) of this section is found, after examination and analysis, to be adulterated or misbranded, the director may petition the judge of any court of competent jurisdiction in whose jurisdiction the animal remedy is detained for an order to condemn the animal remedy. If the director finds that the detained animal remedy is not adulterated or misbranded he shall remove the tag or marking.

(k) The director may promulgate rules and regulations for animal remedies necessary for the efficient enforcement of this article. Procedures for promulgation shall be those outlined in the Wyoming Administrative Procedure Act.

(m) The director may cooperate with and enter into agreements with other Wyoming agencies, other states and agencies of the federal government in order to carry out the purpose and provisions of this article.

11-17-204. Registration; fees; audit.

(a) Any manufacturer of animal remedies, except the United States department of agriculture, shall register each product before distribution in Wyoming. The application for registration shall be submitted on forms furnished by the director and shall be accompanied by a label or other printed matter describing the product. Upon approval by the director or his agent, a copy of the registration shall be furnished to the applicant. All registrations are effective from the date of approval and expire on December 31 each year.

(b) Every registrant of animal remedies shall pay a

registration fee of twenty dollars ($20.00) per product.

(c) An applicant may appeal the denial of a registration in accordance with the Wyoming Administrative Procedure Act.

(d) The department may conduct a product compliance audit to assure compliance of this article. The audit shall consist of label and registration reviews. A registrant may appeal any negative audit in accordance with the Wyoming Administrative Procedure Act.

11-17-205. Labeling.

(a) Any animal remedy distributed in Wyoming shall be accompanied by a legible label bearing the following information:

(i) The name and principal address of the manufacturer or person responsible for placing the animal remedy on the market;

(ii) The name, brand or trade-mark under which the animal remedy is sold;

(iii) An accurate statement of the minimum net contents of the package, lot or parcel, the 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;

(iv) The common or usual name and quantity of each active ingredient;

(v) Adequate directions for use;

(vi) Adequate warnings against use in 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) Any word, statement or other information appearing on the label shall also appear on the outside container or wrapper, if any, of the retail package of the animal remedy or shall be easily legible through the outside container or wrapper of the animal remedy.

11-17-206. Professional supervision required for preparation and packaging of remedies.

(a) No person shall compound, manufacture, make, produce, pack, package or prepare within Wyoming any animal remedy to be offered for sale or distribution unless the 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 director after an investigation and a determination by the director that he is qualified by scientific or technical training or by experience to perform the duties of supervision as may be necessary to protect animal health and public safety.

(b) No person shall make a claim that an animal remedy is antimicrobial resistant without verification and support documentation of the American Veterinary Medical Association.

11-17-207. Right of access to establishments and information relating to manufacturing; sampling and analysis.

(a) The director or his agent shall have access during normal business hours to any establishment or facility in which an animal remedy is manufactured, transported or held for distribution and to information relating to the manufacture, transportation and distribution of the animal remedy for purposes of sampling and inspection.

(b) Any method of sampling and analysis shall be as approved by the director from current established methods. In any case not covered by an approved method, or in any case where methods are available in which improved applicability has been demonstrated, the director may approve the appropriate methods from other sources. The director, in determining whether an animal remedy is deficient in any component, shall be guided solely by the official sample analyzed in accordance with approved methods. For purposes of this article, the results of official analysis shall be final, unless it is determined by the director that a resample is warranted. If a

distributor or registrant requests a resample of an animal remedy based upon the director's findings of a deficiency, all costs associated with the resampling and analysis shall be borne by the distributor or registrant. If the results of the resampling establish the result of the first analysis was invalid, the department shall bear the costs associated with the resampling. Any requests for a resample to the director shall be made in writing.

(c) The director shall make or cause to be made under his direction, analysis and examinations of samples of animal remedies furnished to him by the director to determine whether the animal remedy sampled conforms with this article and shall certify the results of the examinations to the director.

(d) When the inspection and analysis of an official sample indicates an animal remedy has been adulterated or misbranded, the results of analysis shall be forwarded by the director to the distributor and the purchaser.

(e) Any animal remedy that is manufactured and distributed under registration from and under the supervision of the United States department of agriculture,

and in compliance with the regulations of that department shall not be considered adulterated or misbranded.

(f) An animal remedy shall be deemed to be misbranded under the following circumstances:

(i) It is not properly labeled;

(ii) It is not labeled as required in W.S. 11-17-205 and in regulations promulgated under this article;

(iii) If the label is false or misleading;

(iv) If the information required on the label is not conspicuous and clear and if any word, statement or other information required to appear on the label is not prominently placed conspicuously on the label, 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;

(v) It is distributed under the name of another

animal remedy;

(vi) If the recommended dosage 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 the animal remedy.

(g) An animal remedy shall be deemed to be adulterated if:

(i) It consists in whole or in part of any filthy, putrid or decomposed substance;

(ii) It bears or contains any poisonous or deleterious substance which may render it injurious to health under customary or usual use;

(iii) Its container is composed of any injurious or deleterious substance which may render the animal remedy injurious to health;

(iv) It was prepared, packed or held under unsanitary conditions where the animal remedy may have become contaminated with filth or where the animal remedy

may have been rendered injurious to animal health;

(v) Its composition, purity, strength or quality falls below or differs from that which it is purported or is represented to possess by its labeling. The director shall allow a reasonable tolerance from such representation as is in accordance with good manufacturing practices.

(h) No person shall forge, counterfeit, simulate or falsely represent or without proper authority use, any mark, stamp, tag, label or other identification device required by W.S. 11-17-205.

(j) No person shall alter, mutilate, destroy, obliterate or remove any part of the labeling of any animal remedy if the act results in the animal remedy being misbranded, or do any other act, while the animal remedy is being held for sale, which results in the misbranding of the animal remedy.

(k) All provisions for enforcement of animal remedies found to be short weight shall be administered by the department under W.S. 40-10-117 through 40-10-136 of the Wyoming weights and measures law.

11-17-208. Warning to distributor; seizure and order of disposition; application for release; hearing.

(a) When the director or his authorized agent finds that an animal remedy is mislabeled, misbranded or adulterated, or that it does not conform to its label guarantee, he may issue a written statement warning the distributor or registrant that the animal remedy is considered to be in violation of the law. This statement is a warning only to the distributor or registrant that if the animal remedy is distributed further the director may pursue further action. If the distributor, registrant or manufacturer heeds the warning and corrects the violation within the time allowed by the director, no further action shall be taken.

(b) If it appears that any manufacturer, distributor, registrant or any other person responsible for animal remedies has not corrected the reason for the warning in subsection (a) of this section or has violated this article, the director shall cause notice to be given to the manufacturer, distributor, registrant or person that a hearing will be had at a date and place named in the

notice. The director or his authorized agent shall hold a hearing in accordance with the Wyoming Administrative Procedure Act. If the manufacturer, distributor, registrant or person fails to appear at the time and place designated in the notice, the director or his authorized agent shall conduct the hearing as though the manufacturer, distributor, registrant or person were present. If it is established by the hearing to the satisfaction of the director that prosecution is warranted the director shall provide to the Wyoming attorney general:

(i) A certification of the facts;

(ii) An official report of the result of the hearing; and

(iii) A copy of the analysis or other examination which bears on the case.

(c) Any lot of an animal remedy not in compliance with requirements of laws or regulations is subject to seizure on complaint of the director to a court of competent jurisdiction in the county in which the animal remedy is located. If the court finds the animal remedy in

violation and orders the condemnation of the animal remedy, it shall be disposed of in any manner consistent with the quality of the animal remedy and the laws of Wyoming. In no instance shall the disposition of the animal remedy be ordered by the court without first giving the manufacturer, distributor or registrant an opportunity to apply to the court for release of the animal remedy or for permission to process or relabel the animal remedy to bring it into compliance with the law.

11-17-209. Prohibited acts; penalty; additional sanctions.

(a) It is unlawful for any person to:

(i) Sell or distribute in Wyoming any animal remedy without having attached or furnished such stamps, labels or tags as required by this article;

(ii) Impede, prevent or attempt to prevent the director or his agent in the performance of his lawful duties;

(iii) Sell, offer for sale or distribute in

Wyoming any animal remedy without complying with the requirements of this article;

(iv) Sell or distribute in Wyoming any animal remedy when the manufacturer or distributor is not registered with the department as required by this article;

(v) Manufacture, sell, deliver, hold or offer for sale any animal remedy that is adulterated or misbranded;

(vi) 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;

(vii) 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 animal remedy to which a false advertisement relates, is subject to the penalties for violations of this article, by reason of the dissemination by him of the false advertisement, unless he refused, on the request of the director to

furnish the name and address of the manufacturer, packer, distributor, seller or advertising agency which caused him to disseminate the advertisement;

(viii) Sell or offer to sell any biological product that has not been kept in refrigeration under conditions prescribed by the rules and regulations promulgated and adopted by the director.

(b) Any person violating any provision of W.S. 11-17-201 through 11-17-209 or rules or regulations thereunder is guilty of a misdemeanor and upon conviction shall be fined not more than five hundred dollars ($500.00) or imprisoned in the county jail for not more than one (1) year, or both, for the first offense, and upon conviction for a subsequent offense shall be fined not more than one thousand dollars ($1,000.00) or imprisoned in the county jail for not more than one (1) year, or both. Any offense committed more than three (3) years after a previous conviction shall be considered a first offense.

(c) In addition to the penalty provided in subsection (b) of this section, the distribution of any animal remedy mixed or adulterated with any substance injurious to

animals is subject to seizure and condemnation as the court may direct. The court may in its discretion release the animal remedy seized when the requirements of law have been complied with, and upon payment of all costs and expenses incurred by the state in any proceedings connected with the seizure.

Section 2. W.S. 11-17-101 through 11-17-108 are repealed.

Section 3. This act shall be effective July 1, 2011.

(END)