12 KAR 3:037. Drugs and pet food additives.

RELATES TO: KRS 250.501, 250.511, 250.541(1)(a), (b), (c), (d), (e), (f), (j), (2)(c), (d), (e), 21 C.F.R. Parts 70, 71, 73, 74, 80, 81, 82, 501.22, 570.3(1), 570.30, 582, 21 U.S.C. 360(b)

STATUTORY AUTHORITY: KRS 250.571(1)

NECESSITY, FUNCTION, AND CONFORMITY: KRS 250.571(1) authorizes the Director of the Agricultural Experiment Station to promulgate administrative regulations necessary for efficient enforcement of KRS 250.491 to 250.631. KRS 250.541 defines adulterated commercial feeds and states how they may be adulterated by additives. KRS 250.551(1) and (2) prohibits the manufacturing and distribution of adulterated products as animal feeds. This administrative regulation establishes requirements to ensure that a drug or additive used in pet food or specialty pet food is safe and effective for its intended purpose.

Section 1. An artificial color may be used in a pet food or specialty pet food only if it has been shown to be harmless to pets or specialty pets. The permanent or provisional listing of an artificial color in 21 C.F.R. Part 70, 71, 73, 74, 80, 81, or 82, or 501.22 as safe for use, together with the conditions, limitations, and tolerances, if any, shall constitute evidence that the color is harmless to pets or specialty pets.

Section 2. Before approval of a label and a registration application, the distributor of a pet food, containing an additive including a drug, another special purpose additive, or a nonnutritive additive shall, upon request of the director, submit evidence to prove the safety and efficacy of the pet food if used according to label directions. Evidence of the safety and efficacy of a pet food or specialty pet food shall be:

(1) If the pet food or specialty pet food contains an additive that conforms to 21 C.F.R. 570.3(1), 570.30, or Part 582; or

(2) If the pet food or specialty pet food is a drug as defined by KRS 250.501(7) and is generally recognized by the Food and Drug Administration as safe and effective for its labeled use or is marketed subject to an application approved by the Food and Drug Administration under 21 U.S.C. 360(b).

Section 3. If a drug is included in a pet food or specialty pet food, the medicated labeling format recommended by the Association of American Feed Control Officials in its 2018 Official Publication shall be used to insure that adequate labeling is provided.

Section 4. Incorporation by Reference. (1) "2018 Official Publication", (2018 Edition), Association of American Feed Control Officials, is incorporated by reference.

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