

**AGRICULTURAL EXPERIMENT STATION
(Amendment)**

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)

CERTIFICATION STATEMENT: This certifies that this administrative regulation complies with the requirements of 2025 RS HB 6, Section 8.

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 2023 Official Publication shall be used to insure that adequate labeling is provided.

Section 4. Incorporation by Reference.

- (1) "2023 Official Publication", (2023 Edition), Association of American Feed Control Officials, is incorporated by reference.
- (2) This material may be inspected, copied, or obtained, subject to applicable copyright law, at the Division of Regulatory Services, 103 Regulatory Services Building, College of Agriculture, University of Kentucky, Lexington, Kentucky 40546-0275, Monday through Friday, 8 a.m. to 4:30 p.m.

DR. JAMES MATTHEWS, Director

APPROVED BY AGENCY: September 10, 2025

FILED WITH LRC: September 11, 2025 at 10:50 a.m.

PUBLIC HEARING AND COMMENT PERIOD: A public hearing on this administrative regulation shall be held on November 24, 2025, at 9:00 a.m., at the offices of the Division of Regulatory Services, 1600 University Court, Lexington, Kentucky 40546. Individuals interested in being heard at this hearing shall notify this agency in writing by five workdays prior to the hearing of their intent to attend. If no notification of intent to attend the hearing was received by that date, the hearing may be cancelled. A transcript of the public hearing will not be made unless a written request for a transcript is made. If you do not wish to be heard at the public hearing, you may submit written comments on the proposed administrative regulation. Written comments shall be accepted through November 30, 2025. Send written notification of intent to be heard at the public hearing or written comments on the proposed administrative regulation to the contact person.

CONTACT PERSON: G. Alan Harrison, Feed & Milk Director, University of Kentucky Division of Regulatory Services, 103 Regulatory Services Building, Lexington, Kentucky 40546, phone (859) 257-2785, fax (859) 323-9931, email alan.harrison@uky.edu.