



STATE OF TENNESSEE
DEPARTMENT OF HEALTH
OFFICE OF GENERAL COUNSEL

665 Mainstream Drive
Nashville, Tennessee 37243
Telephone: (615) 741-8218
Facsimile: (615) 532-3386 or (615) 532-7749

BILL HASLAM
GOVERNOR

John J. Dreyzehner, MD, MPH, FACOEM
COMMISSIONER

Writer's email address: keith.d.hodges@tn.gov

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**VIA USPS FIRST CLASS MAIL
AND EMAIL AT
michael.murphy@fda.hhs.gov**

Bernadette M. Dunham, DVM, PhD
U.S. Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, Maryland 20993

Bernadette M. Dunham, DVM, PhD
Center for Veterinary Medicine
Communications Staff (CVM)
Food and Drug Administration
7519 Standish Place
HFV-12
Rockville, Maryland 20855

Re: FDA Veterinary Feed Directive Final Rule

Dear Dr. Dunham:

This letter is in response to your letter of June 11, 2015 seeking verification of Tennessee's VCPR requirements. Your letter poses the following questions:

1. Do the statutes, rules, or regulations governing the practice of veterinary medicine in Tennessee require a veterinary-client-patient relationship (VCPR) for a veterinarian to write a lawful veterinary feed directive (VFD)?

Rule 1730-01-.21 (<http://www.state.tn.us/sos/rules/1730/1730-01.20140821.pdf>) requires the elements of a VCPR as a prerequisite to a veterinarian "prescribing" any animal drug. While the State would consider VFD orders to be prescriptions for purposes of the rule, it intends to amend the rule to clarify that VFD orders can only be issued in the context of a valid VCPR, as that term is defined under T.C.A. § 63-12-103(17).

2. Does the State-defined VCPR contain the key elements of a valid VCPR as defined in 21 CFR 530.3(i)?

Yes. Under T.C.A. § 63-12-103(17), a “veterinary-client-patient relationship” means:

- (A) The veterinarian has assumed responsibility for making clinical judgments regarding the health of the animal and the need for medical treatment, has obtained informed consent, and the client has agreed to follow the veterinarian's instructions;
- (B) The veterinarian has sufficient knowledge of the animal to initiate at least a general or preliminary diagnosis of the medical condition of the animal;
- (C) The veterinarian has seen the animal within the last twelve (12) months or is personally acquainted with the keeping and care of the animal, either by virtue of an examination of the animal or by medically appropriate visits to the premises where the animal is maintained within the last twelve (12) months;
- (D) The veterinarian is readily available or has arranged for emergency coverage for follow-up evaluation in the event of adverse reactions or the failure of the treatment regimen;
- (E) The veterinarian must maintain medical records as required by the board of veterinary medical examiners; and
- (F) The veterinarian-client-patient relationship cannot be established or maintained solely by telephone or other electronic means;

Please feel free to contact me should you have any questions.

Sincerely,



Keith D. Hodges
Assistant General Counsel

Cc: Lisa Lampley, Director
Board of Veterinary Medical Examiners