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October 22, 2015

Bernadette M. Dunham, DVM, Ph.D.
DHHS – Public Health Service
Director, Center for Veterinary Medicine
Food and Drug Administration
Silver Spring, MD 20993

Re: Response to Your Letter of 6/11/2015
FDA Veterinary Feed Directive Final Rule

Dear Dr. Dunham:

I write on behalf of the North Carolina Veterinary Medical Board to respond to the questions posed in your letter to me of 6/11/15.

Your two questions are:

- (1) *Do the statutes, rules or regulations governing the practice of veterinary medicine in North Carolina require a veterinarian-client-patient relationship (VCPR) for a veterinarian to write a lawful veterinary feed directive (VFD)?; and*
- (2) *If the answer to the foregoing question is yes, does the VCPR defined in North Carolina statutes and administrative rules contain the key elements of the VCPR defined in the federal regulation set forth in 21 CFR § 530.3(i)?*

Response

The answer to both questions is “yes.”

Your letter explains that on June 3, 2015 (80 FR 31708) the Food and Drug Administration (FDA) published the Final Rule amending the FDA regulations. You note that, as revised,

the VFD regulation at 21 CFR § 558.6 now provides the veterinarians must be licensed to practice veterinary medicine and

must issue VFDs in accordance with the applicable State veterinary licensing and practice requirements, including ordering the use of VFD drugs in the context of a VCPR as defined by the State. However, in those instances in which the applicable VCPR requirements as defined by such State do not sufficiently include the key elements of a valid VCPR as defined in FDA 21 CFR § 530.3(i), the veterinarian issuing the VFD must issue the VFD in the context of a valid VCPR as defined in federal regulations at 21 CFR § 530.3(i). [footnote omitted]

The relevant definitions in 21 CFR § 558.3(b)(6) and (b)(7) are:

(6) A "veterinary feed directive (VFD) drug" is a new animal drug approved under section 512(b) of the Federal Food, Drug, and Cosmetic Act (the act) or listed in the index under section 572 of the act for use in or on animal feed. Use of a VFD drug must be under the professional supervision of a licensed veterinarian.

(7) A "veterinary feed directive" is a written statement issued by a licensed veterinarian in the course of the veterinarian's professional practice that orders the use of a VFD drug in or on an animal feed. This written statement authorizes the client (the owner of the animal or animals or other caretaker) to obtain and use the VFD drug in or on an animal feed to treat the client's animals only in accordance with the directions for use approved or indexed by the Food and Drug Administration (FDA). A veterinarian may issue a VFD only if a valid veterinarian-client-patient relationship exists, as defined in 530.3(i) of this chapter.

The N.C. Veterinary Medical Board administers the N.C. Veterinary Practice Act [N.C.G.S. § 90-179 *et seq.*]. In the Act, the term "practice of veterinary medicine" includes "the prescription or administration of any drug, medicine, biologic, apparatus, application, anesthetic, or other therapeutic or diagnostic substance or techniques on any animal."¹

Moreover, under the Act, a veterinarian may be disciplined for "selling, dispensing, prescribing, or allowing the sale, dispensing, or prescription of biologics, controlled substances, drugs, or medicines without a veterinarian-client-patient relationship."²

¹ N.C.G.S. § 90-181(6a)

² N.C.G.S. § 90-187.8(c)(18)

In my opinion, the foregoing establishes that the Veterinary Practice Act requires that a licensee must write a veterinary feed directive (VFD) within the scope of a veterinarian-client-patient relationship.

With respect to your second question, the definition of “veterinarian-client-patient relationship” in the Veterinary Practice Act,³ set forth below, contains the key elements of a valid VCPR as defined in 21 CFR § 530.3(i).

- a. The veterinarian has assumed the responsibility for making medical judgments regarding the health of the animal and the need for medical treatment, and the client (owner or other caretaker) has agreed to follow the instruction of the veterinarian.
- b. There is sufficient knowledge of the animal by the veterinarian to initiate at least a general or preliminary diagnosis of the medical condition of the animal. This means that the veterinarian has recently seen and is personally acquainted with the keeping and care of the animal by virtue of an examination of the animal, or by medically appropriate and timely visits to the premises where the animal is kept.
- c. The practicing veterinarian is readily available or provides for follow-up in case of adverse reactions or failure of the regimen of therapy.

In summary, I believe that the Veterinary Practice Act and Board rules require a veterinarian-client-patient relationship (VCPR) in order for a veterinarian to write a lawful VFD, and that the Act’s definition of a VCPR includes the key elements of a VCPR as defined in applicable federal regulations.

³ N.C.G.S. § 90-181(7a)

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Please let me know if we can provide further information to you.

Very truly yours,

A handwritten signature in black ink, appearing to read "Tom M Mickey". The signature is fluid and cursive, with the first name "Tom" and last name "Mickey" clearly legible.

Thomas M. Mickey,
Executive Director

TMM/dbb

cc: Dr. Mike Murphy, via electronic mail: Michael.murphy@FDA.HHS.gov
Board Members
George G. Hearn, Attorney