DEPARTMENT OF HEALTH AND HUMAN SERVICES Public Health Service

Food and Drug Administration
Silver Spring, MD 20993

REGISTERED MAIL
RETURN RECEIPT REQUESTED

RE: FDA Veterinary Feed Directive Final Rule

Dear [Executive Director]:

FDA would very much appreciate your assistance in verifying whether the statutes, rules, or regulations governing the practice of veterinary medicine in your jurisdiction (1) require a veterinary-client-patient relationship (VCPR) for a veterinarian to write a lawful veterinary feed directive (VFD), and if so (2) whether the State defined VCPR contains the key elements discussed below.

Background:

On December 12, 2013, (78 Federal Register 75515, December 12, 2013) the Food and Drug Administration (FDA) proposed to amend the Veterinary Feed Directive (VFD) regulation found at section 558.6 of title 21 of the Code of Federal Regulations (21 CFR § 558.6) that became effective on January 8, 2001.[1] In order to provide greater flexibility, FDA proposed to revise the definition of the term "Veterinary Feed Directive" in 21 CFR § 558.3(b)(7) which specified that a VFD could only be issued in the context of a valid veterinary-client-patient relationship (VCPR) as that term is defined in Federal regulations at 21 CFR § 530.3(i). Specifically, the Agency proposed to replace the requirement for veterinarians to comply with the explicit, Federally defined code of veterinary professional conduct with the requirement that veterinarians ordering the use of VFD drugs must be "in compliance with all applicable veterinary licensing and practice requirements." The purpose of this revision was not to eliminate the requirement for a VCPR but rather to provide the flexibility of relying on States' standards for veterinary professional conduct, which are based on current veterinary practice standards, technological and medical advances, and other regional considerations by deferring to individual States for the specific criteria for acceptable veterinary professional conduct, instead of relying on a more rigid, one-size-fits-all, Federal standard.

On June 3, 2015 (80 FR 31708), the FDA published the final rule amending the VFD regulation.[2] In response to comments received on the proposed rule, FDA made revisions in the final rule to address potential gaps in those States that currently lack VCPR requirements applicable to the issuance of VFDs.

[1] http://www.gpo.gov/fdsys/pkg/FR-2013-12-12/pdf/2013-29696.pdf
[2] http://www.gpo.gov/fdsys/pkg/FR-2015-06-03/pdf/2015-13393.pdf

As revised, the VFD regulation at 21 CFR § 558.6 now provides that 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 by FDA in 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).[3]

As described in the preamble of the final rule,[4] in order for the State defined VCPR requirements to sufficiently "include the key elements of a valid VCPR as defined in § 530.3(i)," the State defined VCPR must at least address three concepts, which are that the veterinarian:

(1) Engage with the client to assume responsibility for making clinical judgments about patient health,

(2) have sufficient knowledge of the patient by virtue of patient examination and/or visits to the facility where the patient is managed, and

(3) provide for any necessary follow-up evaluation or care.

In those States with VCPR requirements applicable to VFDs that include the key elements of a VCPR as described in the Federal definition at 21 CFR § 530.3(i), FDA intends to defer to the State VCPR requirements. In other cases where no applicable and appropriate State VCPR requirements are verified to currently exist, the Federally defined VCPR requirements will continue to apply.

Verification of State VCPR Requirements

CVM has made a preliminary determination as to which States' veterinary practice requirements include issuing a VFD in the context of a State defined VCPR that contains the key elements of the Federally defined valid VCPR.

CVM is interested in verifying the accuracy and completeness of this initial determination by contacting each jurisdiction regarding relevant statutory citations, regulatory citations, case law, and policy or guidance documents.[5]

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[3] Specifically, the amended VFD regulation now states with respect to the requirement for a VCPR that in order for a VFD to be lawful, the veterinarian issuing the VFD must be licensed to practice veterinary medicine and must be "operating in the course of the veterinarian's professional practice and in compliance with all applicable veterinary licensing and practice requirements, including issuing the VFD in the context of a veterinarian-client-patient relationship (VCPR) as defined by the State. If applicable VCPR requirements as defined by such State do not include the key elements of a valid VCPR as defined in 530.3(i) of this chapter, the veterinarian must issue the VFD in the context of a valid VCPR as defined in § 530.3(i) of this chapter." (21 CFR § 558.6(b)(1)(ii)).

[4] *See* preamble of the VFD final rule at section III.B.2.a [80 FR 31715]; *see also* the discussion at section II.B.3 of FDA's draft revised guidance for industry (GFI #120) that was issued on June 3, 2015. http://www.fda.gov/downloads/AnimalVeterinary/GuidanceComplianceEnforcement/GuidanceforIndustry/UCM052660.pdf

Once FDA verifies each State's information, we will publish a list of States whose veterinary practice requirements include issuing a VFD in the context of a State defined VCPR that contains the key elements of the Federally defined valid VCPR.

CVM anticipates that we will receive requests from the public for the information you provide. CVM plans to post a copy of this letter and verified information regarding each State's VCPR provisions (including any correspondence we receive from state regulatory authorities) on its Veterinary Feed Directive website[6] prior to the October 1, 2015, effective date of the VFD final rule. You will be contacted by Dr. Mike Murphy (240-402-6217; Michael.Murphy@fda.hhs.gov) regarding this verification process.

Thank you for all of your help with this effort, which is vital to the successful implementation of the VFD final rule.

Sincerely,

Bernadette M. Dunham, D.V.M., Ph.D.
Director, Center for Veterinary Medicine

[5] We identified some State defined VCPR requirements that are specifically applicable to prescription drug products. Please note, however, that Section 5, paragraph (c) of the Animal Drug Availability Act of 1996 relating to VFD drugs states: "Neither a drug subject to this section, nor animal feed bearing or containing such a drug, shall be deemed to be a prescription article under any Federal or State law." Animal Drug Availability Act of 1996, PL 104-250, 110 Stat. 3151 (1996) http://www.gpo.gov/fdsys/pkg/PLAW-104publ250/html/PLAW-104publ250.htm; *see also* section 504(c) of the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. 354(c).

[6] http://www.fda.gov/animalveterinary/developmentapprovalprocess/ucm071807.htm