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**TEXAS  
CATTLE  
FEEDERS  
ASSOCIATION**

5501 I-40 W.  
Amarillo, TX 79106-4617  
(806) 358-3681  
FAX (806) 352-6026  
info@tcfa.org  
www.tcfa.org

**Mike Engler**  
Chairman

**Bo Kizziar**  
Chairman-Elect

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Vice Chairman

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Richard A. Winter

Division of Dockets Management Branch (HFA-305)  
Food & Drug Administration  
5630 Fishers Lane, Room 1061  
Rockville, MD 20852

Re: Advance Notice of Proposed Rulemaking – Veterinary Feed Directive  
(Docket No. FDA 2010N0155)

Texas Cattle Feeders Association (TCFA) appreciates the opportunity to provide the following comments on the Advance Notice of Proposed Rulemaking to solicit comments from the public regarding potential changes to its current regulation relating to veterinary feed directive (VFD) drugs. TCFA is a trade association that represents cattle feeders and feedyards in Texas, Oklahoma and New Mexico. TCFA members feed and market approximately 6.5 million head of cattle annually – roughly 30% of total U.S. fed beef production.

TCFA members have developed strong working relationships with veterinarians, nutritionists, animal health companies, feed manufacturers and technology providers to ensure the health, safety and quality of the cattle that they feed and market. TCFA members judiciously use antimicrobials and other animal health products to prevent or treat diseases. As such, our members have a great interest in the VFD regulation and potential changes that could improve the applicability and efficiency of the process should it be imposed on our industry. We appreciate that FDA is seeking public input on how best to accomplish these goals.

While the cattle industry has not dealt directly with the VFD process, we have observed its implementation for the limited number of products currently listed for other species. Based on those observations and given the inherent administrative burdens required under 21 CFR 558.6, TCFA is concerned that if the number of approved VFD animal drugs increases, particularly for those drugs labeled for multiple species and indications, the process will become problematic to administer and could create distribution problems throughout the animal feed system.

The current VFD regulations are too restrictive to permit the smooth transition and adoption of procedures for this potentially increased number and uses of approved drugs that would require a VFD prior to mixing into feed. We have enumerated several changes to the current regulations that we believe must take place in order to make the transition viable and not overly disruptive to the efficient management of animal diseases and cattle production. We have grouped our comments according to the categories suggested in the notice:

**A. Conditions that must be met by veterinarians issuing a VFD**

Under 21 CFR 558.6 (vi) the requirement for "...the amount of feed to treat the animals..." should state that it will be consistent with the levels in grams per ton as indicated on the current FDA approved label to treat a disease and achieve the intended therapeutic outcome.

Likewise, veterinarians should be allowed to write one VFD order with refills to cover the use of a VFD drug at a facility for the duration of the disease period once the disease for which it is approved is diagnosed. A veterinarian should also be allowed to write a standing VFD if a drug treatment protocol is indicated for all animals or specific segments of the animal production population to prevent or control specific diseases or ailments. Any limits on the duration or expiry of the specific VFD, should be related to the characteristics of the drug, its use, and disease or illness for which it is administered.

#### **B. What veterinarians must do with a VFD (disposition of original VFD and copies)**

VFD authorizations should be consistent with human and veterinary prescription methods where verbal or electronic orders with data or paper follow-up should be allowed.

#### **C. Records that must be kept related to the VFDs**

Modifications should be made to exchange the current data submission and retention requirement for "original" paper documents with a secure digital format. This would reduce the paperwork and administrative burdens while preserving the data currently captured and maintained by feed distributors and veterinarians. This is a shift to digital record for those feed and veterinary participants that elect to adopt an electronic platform.

TCFA recommends that the recordkeeping requirements be changed to be consistent with that required for Good Manufacturing Practices (GMP). Specifically, GMP records are required to be maintained for 1 year, while VFD records are required to be maintained for 2 years. This places a burden on feedmills to maintain two separate record keeping systems. Thus, it is proposed to align VFD requirements to that of GMP requirements (i.e., to maintain records for 1 year).

In order to transition to a record inspection requirement that is accommodating for electronic records TCFA recommends striking the word "copy" from the regulation. Specifically, 21 CFR §558.6(c) (2) should be modified to read, "The veterinarian and feed distributor must make the VFD records available for inspection by FDA."

#### **E. Additional recordkeeping requirements that apply to distributors**

As in comments under C, above, TCFA recommends that the recordkeeping requirements be changed to be consistent with that required for GMP. Specifically, GMP records are required to be maintained for 1 year, while VFD records are required to be maintained for 2 years. This places a burden on feedmills to maintain two separate record keeping systems. Thus, it is proposed to align VFD requirements to that of GMP requirements (i.e., to maintain records for 1 year).

In order to transition to a record inspection requirement that is accommodating for electronic records, TCFA recommends striking the word "copy" from the regulation. Specifically, 21 CFR §558.6(e) (3) should be modified to read, "The veterinarian and feed distributor must make the VFD records available for inspection by FDA."

## **G. Veterinary Feed Directive Form Requirements**

The Final Rule for the VFD (65 FR 76924) includes requirements for the elements to be included in a valid VFD form. A sponsor is required to include in a New Animal Drug Application (“NADA”) or an Abbreviated New Animal Drug Application (“ANADA”) an order form for a new VFD drug in order for the Center for Veterinary Medicine to approve it prior to marketing. This form is required by statute and regulation to include specific items. 21 CFR 1 §558.6(a)(4) includes a detailed listing of the requirements to be incorporated in a VFD form. An inconsistency with the current VFD regulations and business practices in veterinary medicine, animal production, and in the feed industry is that recordkeeping has migrated to electronic platforms. TCFA’s perspective is that the VFD should also move toward supporting electronic records and transactions, to be aligned with customer needs and technology. Federal and state statutes are replete with citations of support for the legal basis in using electronic communications. A specific example is the Uniform Commercial Code’s §2-211, §2-212, and §2-213i all outline legal obligations, rights and responsibilities of parties who utilize electronic communications in common contractual transactions. Further, Section 504(3)(A)ii of the VFD authorizing statute expressly uses the term “copy” in describing the requirements to maintain records. It is important to note that it is not written copy, but copy - thereby allowing for the use of electronic records.

TCFA recommends that FDA consider minimizing paperwork associated with administration of the VFD and maintain its accountability by providing for the electronic communication of the data. Specifically, §558.6(a)(3) should be modified to read “You must complete the VFD in writing, as a facsimile, or electronically or it will be invalid.” §558.6(a)(5) should be modified to read, “You must produce the VFD in writing or electronically within five business days if communicated verbally to feed distributor.” §558.6(b)(1) should be modified to read, “You must communicate the VFD in writing or electronically to a feed distributor or within five business days if VFD instructions were communicated verbally to feed distributor. You may submit a written VFD to a feed distributor through a client.” Lastly, §558.6(b)(5) should be modified to read, “You may transmit a VFD by telephone, facsimile, or other electronic means. A VFD communicated by telephone requires you to provide the feed distributor a written or electronic VFD within five business days.”

## **H. Other**

Although not specified in 21 CFR 558.6, CVM has required that the current approved VFD drugs be treated as Category II, Type A medicated articles requiring they only be mixed into a Type B or Type C medicated feed by feed manufacturing facilities holding a Feed Mill License (FML). TCFA believes that the categorization of veterinary feed directive drugs should be dependent on the characteristics of the drug and its ability to contribute to a residue as outlined for all non-veterinary feed directive drugs. We propose that the current categorization of drugs be retained and that the agency not require all VFD drugs to be Category II drugs that require recipients to be licensed feed mills (or distributors who certify they will ship only to FML holders), which could be an impediment to improving the efficiency of the VFD process. Specifically, §558.3(b)(1)(ii) could be modified to, “Category II--These drugs require a withdrawal period at the lowest use level for at least one species for they are approved or are regulated on a “no-residue” basis or with a zero tolerance because of a carcinogenic concern regardless of a whether a withdrawal period is required.”

In addition to the disruptions likely to occur as VFD status is extended to additional drugs with multi-species labels, multiple claims, and multiple use levels, CVM should carefully consider how VFD will be applied to approved drugs (Type A medicated articles) administered in feed in approved combinations with other drugs. The currently approved drugs that require VFDs do not have approved combinations with other drugs, thus there is no experience to guide how best to make this work under a VFD system.

TCFA is concerned that significant policy changes without appropriate attention to infrastructure could create an environment where veterinarians and producers may be limited from accessing medicines that they judiciously utilize to treat, control and /or prevent animal diseases. FDA must work closely with technology providers, feed manufacturers, animal health companies, producers and veterinarians to assess technological capabilities and clearly communicate expectations of compliance for each of the segments. Additionally, it is imperative that FDA provide adequate time, training and communications for the regulated community to make necessary adjustments in their disease management programs and other changes to accommodate this transition.

Thank you again for providing us with an opportunity to comment on this Advance Notice of Proposed Rulemaking. TCFA members have a great interest in the VFD regulation and potential changes that could greatly improve the applicability and efficiency of the process should it be imposed on our industry. We look forward to continuing this dialogue and working with you as this rulemaking process continues.

Sincerely,

A handwritten signature in cursive script that reads "Ross Wilson".

Ross Wilson  
President & CEO