We, the undersigned groups, appreciate this opportunity to comment upon the Food and Drug Administration’s Veterinary Feed Directive; Draft Text of Proposed Regulation (hereinafter Draft VFD Regulation). We are commenting because we understand the threat that antibiotic resistance creates for public health and the role that inappropriate antibiotic use in food animals plays in that threat.

While we support steps to improve efficiency in the issuing of veterinary feed directives, several of the proposed changes do nothing to improve efficiency, and are unnecessary and unjustified. Specifically, we oppose 1) the removal of requirements that veterinary feed directive (VFD) drugs only be issued in the context of a valid veterinarian-client-patient relationship, and 2) the removal of the requirement that distributors keep records of the receipt and distribution of feeds containing VFD drugs.

In addition, we recommend that the Food and Drug Administration (FDA), in developing the final VFD rule, include a new requirement that distributors submit to the Agency records of distribution of all animal feed containing a VFD drug. This new requirement will close the widely recognized gap on species-specific antibiotic use data that is needed to better characterize the impact of use on resistance and to monitor efforts to reduce antibiotic overuse.

We support other aspects of the Draft VFD Regulation, such as the allowance of electronic signature and the removal of the requirement that all VFD drugs be considered category II independent of the residue risk.

Valid Veterinarian-Client-Patient Relationship

The current VFD regulations\(^1\) require that VFDs only be issued when a valid veterinarian-client-patient relationship exists, but the Draft VFD Regulation has removed this requirement.

We strongly oppose the removal of the requirement that a VFD only be issued when valid veterinarian-client-patient relationship exists. The April 13, 2012 Federal Register Notice announcing the Draft VFD Regulation provides no information as to why the

\(^1\) 21 C.F.R. 558.3; 21 C.F.R. 558.6
Agency has decided that this requirement is no longer needed. Existing regulations² define a valid veterinarian-client-patients relationship as:

(1) A veterinarian has assumed the responsibility for making medical judgments regarding the health of (an) animal(s) and the need for medical treatment, and the client (the owner of the animal or animals or other caretaker) has agreed to follow the instructions of the veterinarian;

(2) There is sufficient knowledge of the animal(s) by the veterinarian to initiate at least a general or preliminary diagnosis of the medical condition of the animal(s); and

(3) The practicing veterinarian is readily available for follow up in case of adverse reactions or failure of the regimen of therapy. Such a relationship can exist only when the veterinarian has recently seen and is personally acquainted with the keeping and care of the animal(s) by virtue of examination of the animal(s), and/or by medically appropriate and timely visits to the premises where the animal(s) are kept.

The purpose of the Draft VFD Regulation is to improve the efficiency of the FDA’s VFD program. However, the FDA has failed to explain: 1) what part of the valid veterinary-client-patient relationship is creating an efficiency problem; and 2) how the efficiency benefits of removing this current requirement outweigh the animal and human health benefits of defining what level of veterinary oversight is required for using VFD drugs.

The requirements in the existing VFD regulations are not controversial and describe the minimum conditions required for a veterinarian to provide sound medical advice. The American Veterinary Medical Association’s (AVMA) Model Veterinary Practice Act³, which was updated in January 2012, includes the same definition of a valid veterinarian-patient-client relationship and states “No person may practice veterinary medicine in the State except within the context of a veterinarian-client-patient relationship.”

If the AVMA recognizes that this type of relationship is needed for veterinary practice, it is difficult to understand why the FDA has decided to eliminate it from the requirements of VFD use in a document aimed at improving efficiency. While some states have adopted the provisions in the AVMA’s Model Veterinary Practice Act on the valid veterinarian-client-patient relationship, others have not. Therefore, a set of minimum federal standards is still needed.

In the related documents Guidance for Industry #209⁴ and Draft Guidance for Industry #213,⁵ the FDA has placed the responsibility for determining appropriate antimicrobial

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² 21 C.F.R. 530.3(i).
⁴ Guidance for Industry #209, The Judicious Use of Medically Important Antimicrobial Drugs in Food-Producing Animals at 21.
use on veterinarians. A valid veterinarian-client-patient relationship is absolutely essential for veterinarians to effectively fulfill this responsibility.

**Record Keeping Requirements for Distributors of Medicated Animal Feed Containing VFD Drugs**

Under the current VFD rule, distributors of medicated feed containing VFD drugs must keep records of “receipt and distribution of all medicated animal feed containing a VFD drug” for two years and make these records available for inspection by the FDA. The Draft VFD removes this requirement that distributors keep records on feed distribution and instead requires only that the VFD itself be kept. Because a single VFD can be refilled multiple times for up to six months, the VFD alone does not provide enough information to determine how the drug was actually used if problems arise after distribution. Therefore, the FDA should maintain the existing requirement that distributors keep records on the distribution of feeds as well as the VFD.

**Reporting of Medicated Animal Feed Containing VFD Drugs**

A 2011 report by the Government Accountability Office (GAO) on the progress made by the federal government in addressing antibiotic use in food animals found that data collected under the existing efforts to monitor antibiotic use in animals lack crucial needed details about “the species in which antibiotics are used and the purpose of their use.”

In 2000, Congress directed the Secretary of Health & Human Services (HHS) to create an interagency Antimicrobial Resistance Task Force to advise the Secretary on steps “to address the public health threat of antimicrobial resistance,” including “the need for improved information and data collection.” The Government Accountability Office observed that, in 2001, the Task Force said that the agencies “would develop and implement procedures for monitoring antibiotic use in agriculture.” The GAO pointed out that “[t]he 2001 interagency plan set a “top priority” action item of monitoring antibiotic use in veterinary medicine, including monitoring data regarding species and purpose of use.” However, the FDA still does not collect such data.

The GAO found that animal feed mills currently “maintain records on antibiotics mixed into animal feed, including the amount of antibiotic used and the type of feed the

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5 Draft Guidance for Industry #213, New Animal Drugs and New Animal Drug Combination Products Administered in or on Medicated Feed or Drinking Water of Food-Producing Animals: Recommendations for Drug Sponsors for Voluntarily Aligning Product Use Conditions with GFI#209 at 6.

6 21 C.F.R. 558.6 (e)(1).


8 Public Health Improvement Act, P.L. 106-505, section 319E.


10 GAO Report at 10.
antibiotic went into…[T]his information could be used to track antibiotic use by species.”

The VFD regulation should include a requirement that distributors of medicated feeds containing VFD drugs be required to report the amounts of antibiotics distributed in feed, along with information contained in the VFD on species, approximate number of animals treated, production class, and purpose of use. Drug distributors already are required to both maintain the records and to make them available on inspection.

Conclusion

The FDA should support efforts to improve the efficiency of the use of medicated feeds containing VFD drugs, but increasing efficiency does not require that veterinary oversight be weakened. The FDA should not remove the non-controversial requirement that a valid veterinarian-client-patient relationship exist for the issuing of a VFD. The FDA also should not eliminate the current requirement that distributors of medicated feeds containing VFD drugs maintain records of the receipt and distribution of such feeds. Finally, the FDA should include in the new VFD regulation a requirement that feed distributors report data on drug use to the FDA.

Sincerely,

Alliance for the Prudent Use of Antibiotics
Center for Food Safety
Center for Science in the Public Interest
Consumers Union
Food Animal Concerns Trust
Food & Water Watch
Humane Society of the United States
Humane Society Veterinary Medical Association
Institute for Agriculture & Trade Policy
Keep Antibiotics Working
Natural Resources Defense Council
The Pew Charitable Trusts
STOP Foodborne Illness
Union of Concerned Scientists

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12 21 C.F.R 558.6 (e).