



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 514 and 558

[Docket No. FDA-2010-N-0155]

RIN 0910-AG95

Veterinary Feed Directive

AGENCY: Food and Drug Administration, HHS.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is proposing to amend its animal drug regulations regarding veterinary feed directive (VFD) drugs. FDA's VFD regulation, which became effective on January 8, 2001, established requirements relating to the distribution and use of VFD drugs and animal feeds containing such drugs. This proposed amendment is intended to improve the efficiency of FDA's VFD program.

DATES: Submit either electronic or written comments on the proposed rule by [INSERT DATE 90 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER]. Submit comments on information collection issues under the Paperwork Reduction Act of 1995 (the PRA) by [INSERT DATE 30 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER], (see the "Paperwork Reduction Act of 1995" section).

ADDRESSES: You may submit comments, identified by Docket No. FDA-2010-N-0155, by any of the following methods, except that comments on information collection issues under the PRA must be submitted to the Office of Information and Regulatory Affairs, Office of Management and Budget (OMB) (see the "Paperwork Reduction Act of 1995" section).

### Electronic Submissions

Submit electronic comments in the following way

- Federal eRulemaking Portal: <http://www.regulations.gov>. Follow the instructions for submitting comments.

### Written Submissions

Submit written submissions in the following way:

- Mail/Hand delivery/Courier (for paper or CD-ROM submissions): Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

Instructions: All submissions received must include the Agency name and Docket No. FDA-2010-N-0155 for this rulemaking. All comments received may be posted without change to <http://www.regulations.gov>, including any personal information provided. For additional information on submitting comments, see the "Comments" heading of the SUPPLEMENTARY INFORMATION section.

Docket: For access to the docket to read background documents or comments received, go to <http://www.regulations.gov> and insert the docket number, found in brackets in the heading of this document, into the "Search" box and follow the prompts and/or go to the Division of Dockets Management, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Sharon Benz, Center for Veterinary Medicine (HFV-220), Food and Drug Administration, 7519 Standish Pl., Rockville, MD 20855, 240-453-6864, email: [Sharon.Benz@fda.hhs.gov](mailto:Sharon.Benz@fda.hhs.gov).

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Purpose of Proposed Rule

The purpose of this rulemaking is to revise FDA's VFD regulations to improve the efficiency of the VFD program.

In 1996, Congress enacted the Animal Drug Availability Act (ADAA) (Public Law 104-250) to facilitate the approval and marketing of new animal drugs and medicated feeds. In passing the ADAA, Congress created a new regulatory category for certain animal drugs used in animal feed called veterinary feed directive drugs or VFD drugs. VFD drugs are new animal drugs intended for use in or on animal feed which are limited to use under the professional supervision of a licensed veterinarian in the course of the veterinarian's professional practice. FDA published final regulations implementing the VFD-related provisions of the ADAA in 2000 (see § 558.6 (21 CFR 558.6)). In the decade since those regulations were issued, stakeholders informed FDA that the VFD process is overly burdensome. In response to those concerns, FDA published an advance notice of proposed rulemaking in March 2010, and a draft proposed regulation in April 2012.

As FDA begins to implement the judicious use principles for medically important antimicrobial new animal drugs approved for use in food-producing animals, based on the framework set forth in Guidance for Industry (GFI) #209 (published April 13, 2012), it is critical that the Agency makes the VFD program as efficient as possible for stakeholders while maintaining adequate protection for human and animal health. The provisions included in this proposed rule are based on stakeholder input received in response to multiple opportunities for public comment, including an advance notice of proposed rulemaking (ANPRM) (75 FR 15387, March 29, 2010) and draft text of proposed amendments to the current VFD regulations (77 FR 22247, April 13, 2012). FDA proposes that if this rule is finalized, it will become effective 60 days after publication of the final rule in the Federal Register.

## Summary of Major Provisions

The proposed rule, if finalized, will make several major changes to the current VFD regulations in 21 CFR part 558:

- In order to provide increased flexibility for licensed veterinarians issuing VFDs, FDA is proposing to revise the definition of the term "Veterinary Feed Directive" in § 558.3 (21 CFR 558.3) which currently includes a relatively prescriptive, federally defined, code of veterinary professional conduct known as the veterinarian-client-patient relationship (VCPR). Specifically, the Agency proposes to remove the explicit VCPR provision and replace it with the requirement that veterinarians ordering the use of VFD drugs must do so "in compliance with all applicable veterinary licensing and practice requirements." The purpose of this revision is to provide greater flexibility for veterinarians by deferring to the veterinary profession and individual states for the specific criteria for acceptable veterinary professional conduct, rather than relying on a more rigid, one-size-fits-all, Federal standard. From a practical standpoint, this enables the veterinary profession and individual states to adjust the specific criteria for a VCPR to appropriately align with current veterinary practice standards, technological and medical advances, and other regional considerations. For example, greater flexibility could allow veterinarians to more effectively provide services to food animal producers in remote geographical areas where veterinary professional resources are limited and distances are great.

- In order to prevent potential shortages of antimicrobial drugs needed by food animal producers for judicious therapeutic uses on their farms and ranches, FDA is proposing to revise the definition of "Category II" drugs in § 558.3. Under current regulations, all animal drugs approved for use in or on animal feed are assigned to one of two categories, depending on their potential to create unsafe drug residues in edible tissues--Category I drugs having the lowest

potential and Category II drugs having the highest potential. In order to reduce the potential of creating unsafe drug residues, access to Category II drugs is restricted to licensed feed mills because these facilities are technically better suited to handle these drugs in a concentrated form. However, existing regulations include a provision that says all VFD drugs, regardless of their potential to create unsafe drug residues, are Category II drugs. Thus, under current regulations, if an over-the-counter (OTC) Category I drug changes to VFD status, it automatically becomes a Category II drug, which, in turn, limits its availability only to licensed feed mills. FDA is concerned that the automatic recategorization of drugs from Category I to Category II once they switch to VFD status is likely to cause a supply chain obstruction for VFD feeds once the Agency's policy regarding the judicious use of medically important antimicrobial drugs in food-producing animals is fully implemented. To avoid this outcome, FDA proposes to revise the definition of Category II to eliminate the automatic classification of VFD drugs into Category II. This would permit those medically important antimicrobials used in animal feed that are currently Category I drugs to become VFD drugs consistent with FDA's judicious use policy. At the same time, products containing these drugs would remain available through the current feed mill distribution system.

- In order to lower the recordkeeping burden associated with the use of VFD drugs, FDA is proposing to align the recordkeeping requirements for VFD drugs with the current Good Manufacturing Practices (cGMP) recordkeeping requirements for medicated feeds, thus reducing the recordingkeeping burden for VFD drugs from 2 years to 1 year. Under current § 558.6, all involved parties (the veterinarian, the distributor, and the client) must keep their copy of the VFD on file and available for FDA inspection for 2 years. In addition, VFD feed distributors must also keep receipt and distribution records of the VFD feeds they manufacture and make

them available for FDA inspection for 2 years. However, the cGMP regulations for medicated feed manufacturing in 21 CFR part 225 require that such records be kept for only 1 year. Feed mill operators have told FDA that this discrepancy is difficult to manage and that they would like to see all feed manufacturing record retention requirements kept the same at 1 year. Based on our experience, FDA does not believe the extra 1 year of recordkeeping for VFD drugs is warranted for any of the involved parties. The value added by the second year of record retention has not been shown to justify the associated paperwork burden. Therefore, FDA is proposing to reduce the recordkeeping requirement for copies of VFDs for all involved parties, and for manufacturing receipt and distribution records for VFD distributors, from 2 years to 1 year.

### Costs and Benefits

The estimated one-time costs to industry from this proposed rule, if finalized, are \$920,000, most of which are costs to review the rule and prepare a compliance plan. This equates to annualized costs of about \$131,000 at a 7 percent discount rate over 10 years. We estimate that the total government costs associated with reviewing the VFD drug labeling supplements that are expected to be submitted by all four VFD drug sponsors to be \$1,200.

The expected benefit of this proposal is a general improvement in the efficiency of the VFD process. FDA estimates the annualized cost savings associated with the reduced requirements of the VFD process to be \$19,000 over 10 years at a 7 percent discount rate (annualized at \$16,000 over 10 years at a 3 percent discount rate). Additionally, the reduction in veterinarian labor costs due to this rule is expected to result in a cost savings of about \$5.55 million annually.

### I. Background

### A. History

Before 1996, FDA had only two options for regulating the distribution of animal drugs: (1) OTC and (2) prescription (Rx). Drugs used in animal feeds were generally approved as OTC drugs. Although the Federal Food, Drug, and Cosmetic Act (the FD&C Act) did not prohibit the approval of prescription drugs for use in animal feed, such approvals have historically been impractical because many states have laws prohibiting feed manufacturers from dispensing prescription drugs. As newer animal drugs were developed, FDA determined that the existing regulatory options--OTC and Rx--did not provide the needed flexibility and safety for these drugs to be prescribed or administered through medicated feed. FDA believed that such drugs should be subject to greater control than provided by OTC status, particularly certain antimicrobial drugs. This control is critical to reducing unnecessary use of such drugs in animals and to slowing or preventing any potential for the development of bacterial resistance to antimicrobial drugs.

After considerable deliberation between FDA and the animal agriculture industry, and with the support of State regulatory Agencies, in 1996 Congress enacted the ADAA to facilitate the approval and marketing of new animal drugs and medicated feeds. As part of the ADAA, Congress determined that certain new animal drugs should be approved for use in animal feed but only if these medicated feeds were administered under a veterinarian's order and professional supervision. Therefore, the ADAA created a new category of products called veterinary feed directive drugs (or VFD drugs). VFD drugs are new animal drugs intended for use in or on animal feed, which are limited to use under the professional supervision of a licensed veterinarian in the course of the veterinarian's professional practice. For animal feed containing a VFD drug to be used in animals, a licensed veterinarian must first issue an order, called a

veterinary feed directive (or VFD), providing for such use. In the Federal Register of December 8, 2000 (65 FR 76924), FDA issued a final rule amending the new animal drug regulations to implement the VFD-related provisions of the ADAA. In that final rule, FDA stated that because veterinarian oversight is so important for assuring the safe and appropriate use of certain new animal drugs, the Agency should approve such drugs for use in animal feed only if these medicated feeds are administered under a veterinarian's order and professional supervision. As an example, the final rule noted that safety concerns relating to the difficulty of disease diagnosis, drug toxicity, drug residues, antimicrobial resistance, or other reasons may dictate that the use of a medicated feed be limited to use by order and under the supervision of a licensed veterinarian.

It has been over a decade since FDA began implementing the final rule relating to VFDs. Although currently there are few approved VFD drugs, FDA has received comments from stakeholders characterizing the current VFD process as being overly burdensome. When veterinary oversight of a medicated feed is determined to be necessary, it is essential that such oversight be facilitated through an efficient VFD process.

In response to these concerns, the Agency began exploring ways to improve the VFD program's efficiency. To that end, FDA initiated the rulemaking process through the publication of an ANPRM in the Federal Register of March 29, 2010 (75 FR 15387). The ANPRM requested public comment on whether efficiency improvements are needed and, if so, what specific revisions should be made to the VFD regulations. Subsequent to this, FDA published draft text of a proposed VFD regulation (hereinafter, "draft proposed regulation") in the Federal Register of April 13, 2012 (77 FR 22247), based on the considerable public input provided to the ANPRM docket, and requested comment on this draft text. The provisions included in this

proposed rule reflect the public input FDA received. FDA proposes that if this rule is finalized, it will become effective 60 days after publication of the final rule in the Federal Register.

#### B. Judicious Use Policy for Medically Important Antimicrobials

On April 13, 2012, FDA finalized a guidance document entitled "The Judicious Use of Medically Important Antimicrobial Drugs in Food-Producing Animals" (GFI #209). This final guidance represents the Agency's current thinking regarding antimicrobial drugs that are medically important in human medicine and used in food-producing animals. Specifically, GFI #209 discusses FDA's concerns regarding the development of antimicrobial resistance in human and animal bacterial pathogens when medically important antimicrobial drugs are used in food-producing animals in an injudicious manner. In addition, GFI #209 provides two recommended principles regarding the appropriate or judicious use of medically important antimicrobial drugs: (1) Limit medically important antimicrobial drugs to uses in animals that are considered necessary for assuring animal health and (2) limit medically important antimicrobial drugs to uses in animals that include veterinary oversight or consultation.

Implementation of these judicious use principles, particularly the second principle, reinforces the need for FDA to reconsider the current VFD program and how best to make the program more efficient and less burdensome for stakeholders while maintaining adequate protection for human and animal health. Currently, the vast majority of the antimicrobial animal drug products that are the focus of GFI #209 are feed-use drugs--that is, they are products approved for use in or on animal feed. All but a few of these products are currently available OTC without veterinary oversight or consultation and would be affected by the recommendation to switch to VFD status. It is critical, therefore, that the VFD process be as efficient as possible

when FDA's judicious use policy is fully implemented because an overly burdensome VFD process could lead to unanticipated disruptions in the current channels of commercial feed distribution.

## II. Highlights of the Proposed Rule

The primary purpose of this rulemaking is to improve the efficiency of the VFD program, while still ensuring that VFD drugs are used in a manner that affords adequate protection for human and animal health. The key changes in this proposal include:

- User-friendly reorganization of the VFD regulation;
- increased flexibility for licensed veterinarians issuing VFDs;
- continued access to Category I Type A medicated articles by unlicensed feed mills;
- increased flexibility for animal producers purchasing VFD feeds; and
- lower recordkeeping burden for all involved parties.

### A. User-Friendly Reorganization of the VFD Regulation

The proposed rule, if finalized, will revise and reorganize the existing VFD regulation at § 558.6 to make it more user-friendly. Proposed § 558.6 includes only three subsections, (a), (b), and (c), in contrast to the existing regulation, which has six subsections. In addition, for ease in identifying what is expected from each party involved in the VFD process, the proposed rule organizes the provisions by affected party or stakeholder group. Subsection (a) contains general provisions that are common to all affected parties, including veterinarians, distributors, and clients (including clients that are on-farm mixers handling VFD drugs and feeds for use in their own animals). Subsection (b) contains specific provisions for veterinarians and subsection (c) contains specific provisions for animal feed distributors. Consistent with public comments we received on the ANPRM and draft regulation, these revisions are intended to make it clearer

what is expected from each of these parties. Important aspects of subsection (b) include that the veterinarian issuing the VFD must be licensed and must assure that the VFD is complete and accurate before it is issued. The veterinarian must also assure that the terms of the VFD are in compliance with the conditions for use approved, conditionally approved, or indexed for the VFD drug. Important aspects of subsection (c) include that the VFD feed distributor is responsible for assuring that the VFD is complete before filling the order. The VFD feed distributor must also assure that the medicated feed is manufactured and labeled in accordance with the VFD and in conformity with the approved, conditionally approved, or indexed conditions of use. See section III for a more detailed description of these provisions.

#### B. Increased Flexibility for Licensed Veterinarians Issuing VFDs

FDA proposes to modify provisions in the existing regulation at 21 CFR part 558 relating to professional conduct by veterinarians issuing orders for VFD drugs in several important ways. First, in order to provide greater flexibility for veterinarians, FDA is proposing to revise the definition of the term "Veterinary Feed Directive" in § 558.3(b)(7) which currently includes a relatively prescriptive, federally-defined, code of veterinary professional conduct known as the VCPR. Specifically, the Agency proposes to remove the explicit VCPR provision and replace it 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 is to provide greater flexibility for veterinarians by deferring to the veterinary profession and individual states for the specific criteria for acceptable veterinary professional conduct, rather than relying on a more rigid, one-size-fits-all, Federal standard. As discussed further below, the veterinary profession and individual state veterinary medical licensing boards already embrace the concept of a VCPR as an element of veterinary licensing and practice requirements. From a

practical standpoint, this proposal would enable the veterinary profession and individual states to adjust the specific criteria for a VCPR to appropriately align with current practice standards, technological and medical advances, and other regional considerations. For example, providing for this greater degree of flexibility is of particular importance for those veterinarians providing services to producers in remote geographical areas where veterinary professional resources are limited and distances are great. Further, this proposal provides greater flexibility for veterinarians working in consultation with other animal health professionals, such as poultry pathologists and fish health biologists. The need for greater flexibility in a veterinarian's professional relationship with his or her clients and patients will become increasingly important as FDA's judicious use policy for medically important antimicrobial drugs is implemented.

Second, FDA is proposing to further revise the definition of the term "Veterinary Feed Directive" in § 558.3(b)(7) to explicitly incorporate the concept of veterinary "supervision or oversight." Section 504(a)(1) of the FD&C Act (21 U.S.C. 354(a)(1)) states that a veterinary feed directive drug is a drug intended for use in or on animal feed which is limited to use under the professional "supervision" of a licensed veterinarian. In addition, the second judicious use principle of GFI #209 recommends veterinary "oversight" when using medically important antimicrobial drugs in food-producing animals. Therefore, to better align the VFD regulations with the statute and with the judicious use principles outlined in GFI #209, we propose to incorporate the phrase "supervision or oversight" in the revised definition of VFD. Thus, the proposed revised definition for VFD would require that a veterinarian may only issue a VFD for the use of VFD drugs in animals that are under his or her "supervision or oversight."

Third, the current definition of "Veterinary Feed Directive" in § 558.3(b)(7) includes another requirement for professional veterinary conduct, which also is derived from the VFD

provisions in section 504 of the FD&C Act. This requirement is found in the phrase "...licensed veterinarian in the course of the veterinarian's professional practice..." which also appears in the first sentence of the current definition in § 558.3(b)(7). (See section 504(a)(1) of the FD&C Act.) FDA proposes to retain this provision in the revised definition of the term "VFD."

By combining these three elements, the proposed revised requirement for veterinarians issuing orders for the use of VFD drugs found in this rule, as derived from the proposed revised definition of the term "VFD," would include language stating that a licensed veterinarian may only issue a VFD for the use of VFD drugs in animals "under his or her supervision or oversight in the course of his or her professional practice, and in compliance with all applicable veterinary licensing and practice requirements."

It is important to remember that this provision would only apply to on-label animal drug use. The statutory provision for an explicit, federally defined VCPR, which was introduced with the Animal Medicinal Use Clarification Act of 1994 (AMDUCA) (Public Law 103-396) (see section 512(a)(4)(A)(i) of the FD&C Act (U.S.C. 360b(a)(4)(A)(i))) and defined by regulation (see § 530.3(i)), continues to apply in circumstances involving extralabel animal drug use. However, because AMDUCA specifically prohibits extralabel use of animal drugs in or on animal feed, including VFD drugs, FDA does not believe that the explicit VCPR requirement as defined in § 530.3(i) is necessary in the context of VFD drug use.

Furthermore, since extralabel use is not an option for medicated feeds, including medicated feeds containing VFD drugs, the final use and labeling of such feeds must also conform to an FDA-approved, or conditionally approved, new animal drug application or index listing (see section 512(a)(2) of the FD&C Act). In other words, the terms of the VFD, such as intended use or dosage regimen, are constrained by the conditions of use found in an approved

application, conditionally approved application, or index listing. Therefore, when completing the VFD order, the veterinarian needs to make sure the VFD is consistent with the conditions of use in the approved application, conditionally approved application, or index listing; similarly, when filling a valid VFD, the medicated feed manufacturer must assure that the final medicated feed is manufactured and labeled in conformity with both the VFD and the approved, conditionally approved, or indexed conditions for use. If the conditions of use specified on a VFD are not in conformity with an approved new animal drug application, conditionally approved application, or index listing, the VFD is considered invalid and the medicated feed described on the VFD may not be manufactured or distributed.

This proposed revision is not intended to lower the standard for professional conduct by veterinarians. Instead of continuing to impose explicit, federally defined VCPR requirements on veterinarians using VFD drugs in their professional practice, these proposed revisions would, consistent with the approach to regulating veterinary professional conduct in the context of prescription animal drug use, recognize and appropriately defer to existing regulatory oversight standards for veterinary professional conduct. This includes VCPR standards that have been established by the veterinary profession and individual state veterinary medical licensing boards. The Agency believes that state veterinary medical licensing boards are well suited for this role because of their unique perspective on factors such as the local availability of professional veterinary medical resources and the needs of their individual agricultural communities. However, while each state's veterinary medical practice code may be somewhat different, the practice of veterinary medicine in the United States is, to a great extent, guided by the American Veterinary Medical Association (AVMA) and its Principles of Veterinary Medical Ethics<sup>1</sup>,

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<sup>1</sup><https://www.avma.org/KB/Policies/Pages/Principles-of-Veterinary-Medical-Ethics-of-the-AVMA.aspx>.

which acts as a unifying standard for all veterinarians. AVMA's Principles of Veterinary Medical Ethics include an explicit VCPR provision.

As noted earlier, the Agency intends to provide for greater flexibility by deferring to the veterinary profession and individual states for the specific criteria for complying with the concept of a VCPR as an element of veterinary licensing and practice requirements. This would allow the specific criteria for a VCPR to be adjusted as appropriate to align with the most recent practice standards, technological and medical advances, and practical considerations in particular regions of the country.

### C. Continued Access to Category I Type A<sup>2</sup> Medicated Articles by Unlicensed Feed Mills

Under the current VFD regulations, all medicated feed distributors, licensed or unlicensed, are able to manufacture and sell medicated feeds containing VFD drugs. The only difference is that licensed facilities are able to start the manufacturing process with a VFD Type A medicated article and unlicensed facilities must start with a VFD Type B<sup>3</sup> or Type C<sup>4</sup> medicated feed. In other words, unlicensed feed mills are not allowed access to any VFD Type A medicated articles under current regulations. FDA proposes to amend the VFD regulations to allow unlicensed feed mills to have continued access to the Type A medicated articles they currently use when these drugs change from OTC to VFD status.

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<sup>2</sup>A "Type A medicated article" is intended solely for use in the manufacture of another Type A medicated article or a Type B or Type C medicated feed. It consists of a new animal drug(s), with or without carrier (e.g., calcium carbonate, rice hull, corn, gluten) with or without inactive ingredients.

<sup>3</sup>A "Type B medicated feed" is intended solely for the manufacture of other medicated feeds (Type B or Type C). It contains a substantial quantity of nutrients including vitamins and/or minerals and/or other nutritional ingredients in an amount not less than 25 percent of the weight. It is manufactured by diluting a Type A medicated article or another Type B medicated feed.

<sup>4</sup>A "Type C medicated feed" is intended as the complete feed for the animal or may be fed "top dressed" on (added on top of usual ration) or offered "free-choice" (e.g., supplement) in conjunction with other animal feed. It contains a substantial quantity of nutrients including vitamins, minerals, and/or other nutritional ingredients. It is manufactured by diluting a Type A medicated article or a Type B medicated feed. A Type C medicated feed may be further diluted to produce another Type C medicated feed.

For many years, FDA has restricted access to certain Type A medicated articles in an effort to avoid creating unsafe levels of drug residues in edible animal tissues. Under current regulations, all animal drugs approved for use in or on animal feed are assigned to one of two categories, depending on their potential to create unsafe residues--Category I drugs having the lowest potential and Category II drugs having the highest potential. FDA regulations at § 558.3(b)(1)(i) (21 CFR 558.3(b)(1)(i)) define Category I as those drugs that require no withdrawal period at the lowest use level in each species for which they are approved. Section 558.3(b)(1)(ii) (21 CFR 558.3(b)(1)(ii)) defines Category II, in part, as those drugs that require a withdrawal period at the lowest use level for at least one species for which they are approved, or are regulated on a "no-residue" basis or with a zero tolerance because of a carcinogenic concern regardless of whether a withdrawal period is required. In order to reduce the potential of creating unsafe drug residues, access to Category II Type A medicated articles is restricted to licensed feed mills (see § 558.4(a)) because these facilities are technically better suited to handle these drugs in this concentrated form. Unlicensed facilities can safely handle Category II drugs after they have been diluted to a Type B or Type C feed, as well as Category I Type A medicated articles. But the current definition of Category II drugs also includes a provision that says all VFD drugs, regardless of their potential to create unsafe residues, are Category II drugs. Thus, under current regulations, if an OTC Category I drug changes to VFD status, it automatically becomes a Category II drug which, in turn, limits the availability of its Type A medicated article to licensed feed mills.

FDA is concerned that the automatic recategorization of drugs to Category II once they switch to VFD status is likely to cause a supply chain obstruction for VFD feeds once the Agency's judicious use policy regarding medically important antimicrobial drugs is fully

implemented. This is because the majority of the OTC feed-use antimicrobials that are the focus of GFI #209 are currently Category I drugs, making their Type A medicated articles readily available to tens of thousands of unlicensed feed mills, including on-farm mixers, located throughout the United States. Therefore, if all of these drugs were to switch dispensing status from OTC to VFD, and automatically become Category II drugs, these unlicensed facilities will now be forced to purchase VFD drugs as Type B or Type C medicated feeds from licensed facilities, which currently number fewer than 1,000. This limited number of licensed facilities would have great difficulty meeting the demands of the tens of thousands of unlicensed facilities in the United States. FDA believes this would result in shortages of antimicrobial drugs needed by food animal producers for judicious therapeutic uses on their farms and ranches, thus compromising animal health. To avoid this outcome, FDA proposes to revise the definition of Category II in § 558.3(b)(1)(ii) by removing the final clause that currently reads "...or are a veterinary feed directive drug," thereby eliminating the automatic classification of VFD drugs to Category II. This would permit those medically important antimicrobials used in animal feed that are already Category I drugs to become VFD drugs consistent with FDA's judicious use policy, but remain available through the current feed mill distribution system.

Furthermore, FDA has reconsidered its previous position that all VFD drugs should be classified as Category II drugs (see final rule of December 8, 2000 (65 FR 76924 at 76926)). Based on our experience with VFD drugs (e.g., investigating animal drug residue violations, cGMP inspections), the Agency no longer believes that the enhanced inspection requirements for licensed feed mills are necessary to assure the safe and effective use of VFD drugs that would otherwise be classified as Category I drugs. This is because (as noted in section II.E) feed-use drugs, in general, have a very safe record of use and Category I feed-use drugs, because of their

extremely safe pharmacological and toxicological profile, have the lowest potential of creating unsafe drug residues at their approved dose levels.

D. Increased Flexibility for Food Animal Producers Purchasing VFD Feeds

A number of stakeholders responding to the ANPRM and draft proposed regulation requested that FDA remove the requirement for veterinarians to include the amount of medicated feed to be dispensed on the VFD, as is currently required in § 558.6(a)(4)(vi). Although this request was voiced by respondents from several different food animal production industries, each of them based their request on the difficulty of predicting, prior to feeding, exactly how much medicated feed a particular flock, herd, pen, house, or tank of animals will actually consume during a specific period of drug administration. Feed consumption rates can vary significantly depending on several factors, including environmental conditions. However, the most important sources of variability lie in the animals' health status at the beginning of drug administration and how quickly these animals respond to treatment. Regardless of species, healthy animals generally eat more than sick animals. It is difficult to predict how quickly animals will respond to treatment and how quickly they will return to their normal feed consumption rate. In an effort to purchase or manufacture the right amount of medicated feed, food animal producers often monitor feed consumption rates during the treatment period and later make adjustments in feed orders accordingly.

As noted by several stakeholders, if the veterinarian is required to specify on the VFD the amount of medicated feed to be dispensed, he or she may overestimate that amount in order to make sure the food animal producer does not run out of feed before the end of the treatment period. Unfortunately, this will often times result in leftover medicated feed on the farm. Alternatively, if the amount of medicated feed listed on the VFD is too little, the food animal

producer may need to get another VFD to complete the course of treatment. FDA acknowledges stakeholders' concerns about the variability of feed consumption rates and therefore, in response to these concerns, proposes to eliminate the requirement for veterinarians to specify the amount of medicated feed to be dispensed on the VFD. FDA believes that the proposed new requirements for veterinarians to specify on the VFD the duration of use and the approximate number of animals to be fed the medicated feed, along with the current requirement to include the level of VFD drug in the feed, should provide adequate control over the total amount of medicated feed authorized by the VFD.

#### E. Lower Recordkeeping Burden for All Involved Parties

Another commonly heard suggestion from stakeholders responding to the ANPRM and draft proposed regulation is the need to reduce the VFD recordkeeping burden from 2 years to 1 year. Under the current VFD regulation, all involved parties (the veterinarian, the distributor, and the client) must keep their copy of the VFD on file and available for FDA inspection for 2 years (see current § 558.6(c)). In addition, VFD feed distributors must also keep receipt and distribution records of the VFD feeds they manufacture and make them available for FDA inspection for 2 years (see current § 558.6(e)).

As noted in FDA's proposed VFD rule that was published in the Federal Register on July 2, 1999 (64 FR 35966), the usual and customary manufacturing records kept by distributors to comply with the cGMP regulations in 21 CFR part 225 satisfies the VFD receipt and distribution recordkeeping requirement as well (see 21 CFR part 225, subpart E (licensed feed mill distributors) and subpart I (unlicensed feed mill distributors)). However, the cGMP regulations in part 225 only require that such records be kept for 1 year, in contrast to the 2-year requirement for VFD feeds in § 558.6(e). Feed mill operators have told us that this discrepancy is difficult to

manage and that they would like to see all feed manufacturing record retention requirements kept the same at 1 year, thus eliminating the need for two separate filing systems: One for non-VFD feed records (1-year record retention) and one for VFD feed records (2-year record retention).

Based on our experience, FDA does not believe the extra 1 year of recordkeeping for VFD drugs is warranted for any of the involved parties. The value added by the second year of record retention has not been shown to justify the associated paperwork burden. FDA compliance investigations regarding violative drug residues in edible animal tissues are normally completed within the first year of their detection and nearly all of these are associated with dosage form drugs (i.e., non-feed use drugs). Therefore, FDA is proposing to reduce the recordkeeping requirement for copies of VFDs for all involved parties, and for manufacturing receipt and distribution records for VFD distributors, from 2 years to 1 year. Because the usual and customary records of purchase and sales kept by distributors to comply with the cGMP regulations in part 225 adequately support the VFD inspection program, we have not included the VFD receipt and distribution recordkeeping requirement found in current § 558.6(e) in this proposed rule.

### III. Proposed Regulations

#### A. Conforming Changes (Proposed § 514.1(b)(9))

The CFR citation noted in the new animal drug application regulations at 21 CFR 514.1(b)(9) would be revised to reflect the new VFD format provision found in proposed § 558.6(b)(3).

#### B. Definitions (Proposed § 558.3(b))

The definitions of terms used in the medicated feed regulations of part 558, including the VFD drug regulations in § 558.6, can be found in § 558.3(b). FDA proposes to amend § 558.3(b) as follows:

As discussed earlier in section II.C, FDA proposes to revise the definition of Category II in § 558.3(b)(1)(ii) by removing the final clause that currently reads "...or are a veterinary feed directive drug."

The definition of "veterinary feed directive (VFD) drug" in proposed § 558.3(b)(6) would be revised to include animal drugs that have been conditionally approved under section 571 of the FD&C Act (U.S.C. 360ccc), and to clarify that the use of a VFD drug in or on animal feed must be authorized by a valid veterinary feed directive.

FDA also proposes to revise the definition of "veterinary feed directive" in proposed § 558.3(b)(7) to include animal drugs that have been conditionally approved under section 571 of the FD&C Act and to replace the current federally defined VCPR requirement with a more broadly defined standard for veterinary professional conduct, as discussed in section II.B. The revised definition would also clarify that VFDs must be written, meaning nonverbal, and that they may be issued in hardcopy or through electronic media.

Additionally, several stakeholders responding to the ANPRM and draft proposed regulation were unclear about what is a medicated feed distributor. The term "distributor" as used in part 558 is defined in § 558.3(b)(9). We are proposing revisions to that definition for improved clarity. Please note that on-farm mixers that only manufacture medicated feeds for use in their own animals are not distributors.

Proposed § 558.3(b)(11) would revise the definition of "acknowledgement letter" for clarity. Under current regulations, acknowledgement letters must include three affirmation

statements and this proposal would require the same three affirmations. However, two of these three affirmation statement provisions are currently found in § 558.3(b)(11) and one affirmation statement provision is currently found in § 558.6(d)(2). This proposal would simply put all three provisions together in the definition of "acknowledgement letter" for clarity. The revised definition would also clarify that acknowledgement letters must be written, meaning nonverbal, and that they may be sent in hardcopy or through electronic media.

Proposed § 558.3(b)(12) includes the new term "combination veterinary feed directive (VFD) drug" to account for combination animal drugs used in or on animal feed that include one or more VFD drugs.

#### C. General Requirements Related to VFD Drugs (Proposed § 558.6(a))

As noted in section II.A, proposed § 558.6(a) contains general provisions that are common to all involved parties (the veterinarian, the distributor, and the client). This includes clients that are also on-farm mixers that only manufacture VFD feeds for use in their own animals.

Proposed § 558.6(a)(1) establishes that a VFD may only be issued by a licensed veterinarian for the use of VFD drugs in animals under his or her supervision or oversight in the course of his or her professional practice, and in compliance with all applicable veterinary licensing and practice requirements.

Proposed § 558.6(a)(3) reminds stakeholders that the extralabel use (ELU) of any medicated feed, including medicated feeds containing VFD drugs, is not permitted under Federal law. (See section 512(a)(4)(A) of the FD&C Act.) Several stakeholders responding to the ANPRM and draft regulation requested that FDA allow ELU for VFD feeds. AMDUCA

legalized, for the first time, ELU of approved drugs in animals. However, AMDUCA specifically prohibits ELU of such drugs in or on animal feed. (See Public Law 103-396.)

Proposed § 558.6(a)(4) establishes that all involved parties (the veterinarian, the distributor, and the client) must retain their copy of the VFD for 1 year. This proposal would lower the current 2-year recordkeeping requirement, as discussed in section II.E.

Proposed § 558.6(a)(6) revises the required cautionary labeling statement for all VFD drugs and feeds.

D. Responsibilities of the Veterinarian Issuing the VFD (Proposed § 558.6(b))

Proposed § 558.6(b)(1) reiterates that a VFD may only be issued by a licensed veterinarian for the use of VFD drugs in animals under his or her supervision or oversight in the course of his or her professional practice, and in compliance with all applicable veterinary licensing and practice requirements. This would replace the current federally defined VCPR provision that cites § 530.3(i), as discussed in section II.B.

Proposed § 558.6(b)(2) clarifies that, when issuing a VFD, the veterinarian must issue a VFD that is in compliance with the conditions for use approved, conditionally approved, or indexed for the VFD drug. In other words, a VFD that is written for an extralabel use fails to comply with Federal law and is invalid. (See section 504(a)(2)(B) of the FD&C Act.)

Proposed § 558.6(b)(3) includes a revised list of information that the veterinarian would be required to provide on the VFD.

Proposed § 558.6(b)(3)(v) includes a new provision that, in cases where the expiration date is not specified in the approval, conditional approval, or index listing, the expiration date of the VFD cannot exceed 6 months after the date of issuance.

Proposed § 558.6(b)(3)(vii) would require animal identification to include species and production class.

Proposed § 558.6(b)(3)(viii) would revise the current requirement for the number of animals to be treated to mean an approximate number of animals to be fed the medicated feed prior to the expiration date on the VFD, due to the difficulty in determining the exact number of animals to be treated during the duration of the valid VFD.

Proposed § 558.6(b)(3)(x) would remove the existing requirement for veterinarians to specify the amount of feed to be fed to the animals listed on the VFD, as discussed in section II.D. Veterinarians would instead be required to include the duration of drug use on the VFD in addition to the level of drug in the feed, as is currently required.

The proposal would remove the current requirement in § 558.6(a)(4)(xi) for veterinarians to include their license number and name of the issuing state on the VFD. This information is not needed by VFD recipients (clients and distributors) to assure the safe and effective use of VFD drugs and is not customarily used by FDA or state inspectors in compliance investigations.

Proposed § 558.6(b)(3)(xiii) would revise the statement required to be included in each VFD indicating that extralabel use is not permitted.

Proposed § 558.6(b)(3)(xiv) is a new provision that would require a veterinarian who issues a VFD for the use of medicated feed containing a VFD drug that is also one of the component drugs in an approved combination VFD drug to include one of three "affirmation of intent" statements on the VFD. Each of the three statements, found in proposed § 558.6(b)(6), provides a different option for veterinarians regarding their authorization for the use of a VFD drug as a component of an approved combination VFD drug. The definition of "combination VFD drug" can be found in proposed § 558.3(b)(12). The three options are as follows: (1)

§ 558.6(b)(6)(i): The VFD cannot be used to authorize any combination VFD drug (i.e., only medicated feed containing the VFD drug alone can be distributed using the VFD); or (2)

§ 558.6(b)(6)(ii): The VFD may be used for any of the approved combination VFD drugs specifically cited on the VFD; or (3) § 558.6(b)(6)(iii): The VFD may be used for any approved combination VFD drug.

In all cases, the VFD may be used to authorize the distribution and use of medicated feed containing the VFD drug alone.

Proposed § 558.6(b)(4) would allow the veterinarian, at his or her discretion, to enter additional information on the VFD to more specifically identify the animals authorized to be treated with or fed the medicated feed.

Proposed § 558.6(b)(5) would add a new provision for combination VFD drugs that include more than one VFD drug component. No such combinations have yet been approved, conditionally approved, or indexed, but in the event that such combination VFD drug is approved, conditionally approved, or indexed in the future, the veterinarian would need to include in the VFD certain drug-specific information for each component VFD drug in the combination.

The proposal would no longer specifically require that VFDs be produced in triplicate but all three involved parties (the veterinarian, the distributor, and the client) would still be required to receive and keep a copy of the VFD, either electronically or in hardcopy. If the VFD is transmitted electronically, the veterinarian would no longer be required to send a hardcopy to the distributor.

Proposed § 558.6(b)(9) would clarify that veterinarians may not issue a VFD verbally, including verbal transmission by telephone. However, transmission of a written (nonverbal) VFD by telephones that are capable of this function (i.e. smartphones) is allowed.

E. Responsibilities of the Medicated Feed Distributor (Proposed § 558.6(c))

Proposed § 558.6(c)(1) would require medicated feed distributors who handle VFD drugs to make sure all VFDs are completely filled out before manufacturing the specified VFD feed. VFDs that do not include all the information required by proposed § 558.6(b)(3) are incomplete and considered invalid.

Proposed § 558.6(c)(2) reminds medicated feed distributors that they may only distribute an animal feed containing a VFD drug or combination VFD drug that is in compliance with the terms of a valid VFD and is manufactured and labeled in conformity with the approved, conditionally approved, or indexed conditions of use for such drug. This dual responsibility is not new but is a very important concept that all VFD distributors must understand. VFDs that are not in compliance with the conditions of use approved, conditionally approved, or indexed for the VFD drug are invalid and may not be used to authorize the distribution of a medicated feed containing a VFD drug.

Proposed § 558.6(c)(3) reminds distributors that, in addition to other applicable recordkeeping requirements found in this section, they must also keep VFD feed manufacturing records 1 year in accordance with part 225 of this chapter. Such records must be made available for inspection and copying by FDA upon request.

Proposed §§ 558.6(c)(4), (5), and (6) relate to the statutory requirement for one-time notification by distributors of their intent to distribute medicated feed containing VFD drugs. These provisions are very similar to those found at section 558.6(d)(1) of the current regulation.

Proposed § 558.6(c)(7) retains the statutory requirement for medicated feed distributors that consign VFD drug-containing feeds to another distributor to receive an acknowledgement letter from that person. This section references a revised definition of "acknowledgement letter" found in proposed § 558.3(b)(11). Proposed § 558.6(c)(7) also includes an explicit 1-year recordkeeping requirement for acknowledgment letters.

#### IV. Legal Authority

FDA's authority for issuing this proposed rule is provided by section 504 of the FD&C Act. In addition, section 701(a) of the FD&C Act (21 U.S.C. 371(a)) gives FDA general rulemaking authority to issue regulations for the efficient enforcement of the FD&C Act.

#### V. Preliminary Regulatory Impact Analysis

FDA has examined the impacts of the proposed rule under Executive Order 12866, Executive Order 13563, the Regulatory Flexibility Act (5 U.S.C. 601-612), and the Unfunded Mandates Reform Act of 1995 (Public Law 104-4). Executive Orders 12866 and 13563 direct Agencies to assess all costs and benefits of available regulatory alternatives and, when regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety, and other advantages; distributive impacts; and equity). The Agency believes that this proposed rule is not a significant regulatory action as defined by Executive Order 12866. We have developed a preliminary regulatory impact analysis (PRIA) that presents the benefits and costs of this proposed rule to stakeholders and the government.

The summary analysis of benefits and costs included in the Executive Summary of this document is drawn from the detailed PRIA, which is available at <http://www.regulations.gov>

(enter Docket No. FDA-2010-N-0155), and is also available on FDA's Web site at

<http://www.fda.gov/AboutFDA/ReportsManualsForms/Reports/EconomicAnalyses/default.htm>.

## VI. Paperwork Reduction Act of 1995

This proposed rule contains information collection provisions that are subject to review by OMB under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501-3520). A description of these provisions is given in the Description section that follows with estimates of the annual reporting, recordkeeping, and third-party disclosure burden. Included in each burden estimate is the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing each collection of information.

FDA invites comments on these topics: (1) Whether the proposed collection of information is necessary for the proper performance of FDA's functions, including whether the information will have practical utility; (2) the accuracy of FDA's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology.

Title: Veterinary Feed Directives

Description: The proposed rule would revise existing OMB control number 0910-0363 (expiration date December 31, 2014) for veterinary feed directives by lowering the recordkeeping burden without compromising human or animal safety, providing greater deference and flexibility to the veterinary profession for licensing and veterinary practice

requirements, and ensuring continued access to Category I Type A medicated articles by unlicensed feed mills.

In 1996, the ADAA was enacted to facilitate the approval and marketing of new animal drugs and medicated feeds. Among other things, the ADAA created a new category of new animal drugs called veterinary feed directive drugs (or VFD drugs). VFD drugs are new animal drugs intended for use in or on animal feed, which are limited to use under the professional supervision of a licensed veterinarian in the course of the veterinarian's professional practice.

Currently, there are few approved VFD drugs. However, FDA has received feedback from stakeholders characterizing the current VFD process as being overly burdensome. In response to these concerns, FDA began exploring ways to improve the VFD program's efficiency. To this end, FDA published an ANPRM inviting public comment on possible VFD program efficiency improvements in March 2010. Based on the considerable public input received in response to the ANPRM, in April 2012 FDA issued for public comment draft text for proposed revisions to the current VFD regulation.

#### Current and Proposed Information Collection Requirements

The current veterinary feed directive regulation, § 558.6, has information collection provisions contained at OMB control number 0910-0363 (expiration date December, 31, 2014). Many of these provisions will be unaffected by the proposed rule, if finalized; therefore, this Paperwork Reduction Act section will concentrate on the changes being proposed in this rulemaking and will describe how the paperwork reduction implications will be affected.

#### Proposed Reporting Requirements

##### Description of Respondents: VFD Feed Distributors

Currently, under § 558.6(d)(1) (and proposed § 558.6(c)(4)) a distributor of animal feed containing VFD drugs must notify FDA prior to the first time it distributes such animal feed and this notification is required one time per distributor. Therefore, all active distributors of animal feed must have already made notification to FDA of their intention to distribute animal feed containing VFD drugs in order to be in compliance with the current regulation. In addition, a distributor must provide updated information to FDA within 30 days of a change in ownership, business name, or business address.

Because the reporting requirements for distributors under proposed § 558.6(c)(4) are the same as the current requirements under § 558.6(d)(1), there is no new reporting burden. FDA understands that VFD feed distributors must review the rule in order to determine what actions are necessary to comply with the new regulation. For VFD feed distributors we estimate administrative review of the rule will take 4 hours to complete.

Table 1.--Estimated One-Time Reporting Burden<sup>1</sup>

21 CFR 558.6/ Activity	No. of Respondents	No. of Responses per Respondent	Total Responses	Average Burden per Respondent in Hours	Total Hours	Total Costs
Administrative Review of the Rule (VFD Feed Distributors)	1,366	1	1,366	4	5,464	\$387,000 <sup>2</sup>

<sup>1</sup>There are no operating and maintenance costs associated with this collection of information.

<sup>2</sup>A total of 1,366 VFD feed distributors times approximately \$71 per hour times 4 hours of one-time review equals approximately \$387,000. Estimate rounded to be in accordance with the PRIA.

Number of Respondents multiplied by Number of Responses per Respondent equals  
Total Responses. Total Responses multiplied by Average Burden per Response equals Total  
Hours.

#### Proposed Recordkeeping Requirements

Description of Respondents: VFD Feed Distributors, Food Animal Veterinarians, and  
Clients (Food Animal Producers)

Under current § 558.6(f) and proposed § 558.6(a)(1), an animal feed containing a VFD drug or a combination VFD drug may be fed to animals only by or upon a lawful VFD issued by a licensed veterinarian. Veterinarians issue three copies of the VFD: One for their own records, one for their client, and one to the client's VFD feed distributor (current § 558.6(b)(1-3) and proposed § 558.6(a)(4) and proposed § 558.6(b)(7-8)). Under current § 558.6(b)(4), if the veterinarian sends the VFD to the client or distributor by electronic means, he or she must assure that the distributor receives the original, signed VFD within 5 working days. Also, under current § 558.6(c), all involved parties (the veterinarian, the distributor, and the client) must retain a copy of the VFD for 2 years. In addition, VFD feed distributors must also keep receipt and distribution records of VFD feeds they manufacture and make them available for FDA inspection for 2 years (see current § 558.6(e)).

Veterinarians and clients must review the rule to ensure compliance with their respective new requirements. In table 2 we estimate the hourly burden of this administrative review for both groups. (Administrative review of the rule by VFD feed distributors is accounted for in table 1)

Recordkeeping costs are calculated as follows: 750,000 VFDs (an average of 375,000 VFDs issued per VFD drug) issued in triplicate equals 2,250,000 VFDs issued and stored in files per year.<sup>5</sup>

Assuming that currently all VFDs are issued and stored in hardcopy, we estimate it takes 300 large file cabinets to currently store these paper copy VFDs for 2 years, assuming 15,000 copies can be stored in a large file cabinet (see 64 FR 35966 at 35970). We estimate the average

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<sup>5</sup>Distributors may receive an acknowledgment letter in lieu of a VFD when consigning VFD feed to another distributor. Such letters, like VFDs, would also be subject to a 1-year record retention requirement (see proposed § 558.6(c)(7)). Thus, the recordkeeping burden for acknowledgment letters is included as a subset of the VFD recordkeeping burden.

cost of a new file cabinet to be \$600. Thus, we estimate that the current capital outlay for industry to store hardcopy VFDs for the required 2 years is \$180,000 (\$600 times 300 equals \$180,000).

In response to public comment to the ANPRM, FDA is proposing to reduce the recordkeeping requirement for copies of VFDs for all involved parties (proposed § 558.6(a)(4)) from 2 years to 1 year. Additionally, as included in proposed § 558.6(b)(7), the veterinarian would also no longer be required to assure that a paper copy is received by the distributor within 5 days of writing the VFD if the original was faxed or otherwise transmitted electronically. This hardcopy requirement has become outdated by modern electronic communication and presents an unnecessary burden on the industry. This proposed provision would further reduce the number of paper copies requiring physical recordkeeping space.

We anticipate approximately one-half of the food animal industry will use electronic VFD generation and recordkeeping during the next 3 years of the information collection. As the use of computers for electronic storage of records has increased substantially since 2000 and is expected to continue to do so regardless of this proposed rule, the only marginal cost that would offset some of the reduction in file cabinet storage space costs would be the additional computer storage space that may be needed for electronic VFD forms. Because the cost of electronic storage capacity on computers has become extremely low, FDA regards this as a negligible cost and has not estimated it.

We anticipate that computer storage will eliminate the need for large amounts of physical space devoted to file cabinets. If, as we expect, one-half of the VFD recordkeepers (veterinarians, distributors, and clients) use electronic recordkeeping, this would result in a cost savings of \$19,575 annually (\$21.75 per square foot per year rental cost of space times 6 square

feet per file cabinet times 150 filing cabinets equals \$19,575 annual savings for switching to computer storage) (Thorpe, K., Edwards, J., and Bondarenko, E. Cassidy Turley Commercial Real Estate Services. "U.S. Office Trends Report--2nd Quarter 2013." Page 10.

[http://www.cassidyurley.com/Research/MarketReports/Report.aspx?topic=U\\_S\\_Office\\_Trends\\_Report&action=download](http://www.cassidyurley.com/Research/MarketReports/Report.aspx?topic=U_S_Office_Trends_Report&action=download), 2nd Quarter 2013).

In addition, the proposed reduction in the amount of time records would be required to be kept from 2 years to 1 year would further reduce the need for physical space and file cabinets. The recordkeepers still filing hardcopy VFDs would save \$9,788 annually (\$21.75 per square foot per year rental cost of space times 6 square feet per file cabinet times 75 filing cabinets equals \$9,788 annual savings for reducing recordkeeping from 2 years to 1 year).

In summary, we anticipate that the capital costs for recordkeeping will be reduced from \$180,000 (storing all VFD copies in file cabinets for 2 years) to \$45,000 (storing hardcopy VFD files in 75 file cabinets for 1 year), and an annual total cost savings of \$29,363 for one-half of the industry filing VFDs electronically for 1 year (\$19,575 savings for filing electronically plus \$9,788 for reducing recordkeeping to 1 year).

As stated previously, both the current and proposed requirements state that the veterinarian, the distributor, and the client must keep a copy of the VFD. Whether a paper copy is filed or whether the VFD is filed electronically, we calculate that the time spent to file the VFD is the same at 0.167 hours. Therefore, no revision to the paperwork burden for filing the VFD is needed.

Table 2.--Estimated One-time Recordkeeping Burden<sup>1</sup>

21 CFR 558.6/ Activity	No. of Recordkeepers	No. of Records per Recordkeeper	Total Records	Average Burden per Recordkeeper in Hours	Total Hours	Total Costs
Administrative Review of the Rule (Food Animal	3,050	1	3,050	1	3,050	\$180,000 <sup>2</sup>

Veterinarians)						
Administrative Review of the Rule (Clients)	10,000	1	10,000	0.5	5,000	\$154,000 <sup>3</sup>
Recordkeeping by Electronic Storage for 1 Year						\$45,000 <sup>4</sup>
Total					8,050	\$379,000

<sup>1</sup>There are no operating and maintenance costs associated with this collection of information.

<sup>2</sup>A total of 3,050 veterinarians times approximately \$59 per hour times 1 hour of one-time review equals approximately \$180,000. Estimate rounded to be in accordance with the PRIA (see PRIA).

<sup>3</sup>A total of 10,000 clients times approximately \$31 per hour times 0.5 hours one-time review equals approximately \$154,000. Estimate rounded to be in accordance with the PRIA (see PRIA).

<sup>4</sup>We estimate that the capital costs for recordkeeping will be reduced from \$180,000 (storing paper copies of all VFDs in file cabinets for 2 years) to \$45,000 (one-half of VFDs stored as paper copies in 75 file cabinets for 1 year), and an annual cost savings of \$29,363 for one-half of the industry filing VFDs electronically for 1 year (\$19,575 savings for filing electronically plus \$9,788 for reducing recordkeeping to 1 year).

Number of Recordkeepers multiplied by Number of Records per Recordkeeper equals

Total Records. Total Records multiplied by Average Burden per Recordkeeper equals Total

Hours.

### Proposed Third-Party Disclosure Requirements

Description of Respondents: VFD Drug Sponsors, Food Animal Veterinarians, VFD Feed Distributors, and Clients (Food Animal Producers)

VFD drug sponsors manufacture and label VFD drugs for use in medicated animal feed. FDA understands that sponsors must review the rule to ensure compliance with their disclosure requirements. In table 3 we estimate the hourly burden of this administrative review. (Administrative review of the rule by VFD feed distributors is accounted for in table 1 and by veterinarians and clients in table 2.)

All labeling and advertising for VFD drugs, combination VFD drugs, and feeds containing VFD drugs or combination VFD drugs must prominently and conspicuously display the following cautionary statement: "Caution: Federal law restricts medicated feed containing this VFD drug to use by or on the order of a licensed veterinarian" (proposed § 558.6(a)(6)).

This verbatim statement is exempt from burden under the PRA because the Federal Government has provided the exact language for the cautionary statement. Therefore, the hourly and cost burdens for label supplement changes to the new specimen labeling for the Type A medicated article and the representative label for use by the feed manufacturer will not be counted.

The VFD must also include the following statement (proposed § 558.6(b)(3)(xiii): "Extralabel use (i.e., use of this VFD feed in a manner other than as directed on the labeling) is not permitted." This verbatim statement is also exempt from burden under the PRA.

The veterinarian may restrict VFD authorization to only include the VFD drug(s) cited on the VFD or such authorization may be expanded to allow the use of the cited VFD drug(s) along with one or more OTC animal drugs in an approved, conditionally approved, or indexed combination VFD drug. The veterinarian must affirm his or her intent regarding combination VFD drugs by including one of the following statements on the VFD:

(i) "The VFD drug(s) cited in this order may not be used in combination with any other animal drugs."

(ii) "The VFD drug(s) cited in this order may be used in combination with the following OTC animal drugs to manufacture an FDA-approved, conditionally approved, or indexed combination medicated feed." [List OTC drugs immediately following this statement.]

(iii) "The VFD drug(s) cited in this order may be used in combination with any OTC animal drugs to manufacture an FDA-approved, conditionally approved, or indexed combination medicated feed" (proposed § 558.6(b)(6))

These verbatim statements are also exempt from burden under the PRA. The hourly and cost burdens to include these statements on the VFD as part of the rule are considered de

minimis, however, as there are several other changes to the VFD form itself that will occur as the result of this proposed rulemaking, if finalized.

Proposed § 558.6(b)(3) includes various changes to the information that would need to be included on the VFD form that is filled out by the veterinarian in order for the VFD to be valid, including but not limited to, deleting the requirement that the veterinarian must include the amount of feed needed to treat the animals. Proposed § 558.6(b)(7) would allow veterinarians to send VFDs to the client or distributor via fax or other electronic means (as is currently permitted under § 558.6(b)(4)). However, if a VFD is transmitted electronically, the veterinarian would no longer be required to assure that the original, signed VFD is given to the distributor within 5 days. FDA estimates that a veterinarian currently requires about 0.25 hours to issue a VFD (i.e., research, fill out, and deliver all copies, including the original, signed VFD to the distributor). At a compensation rate of about \$59 (veterinarian wage rate, see PRIA), the labor cost of currently issuing VFDs is estimated at \$11.09 million (the estimated average of 750,000 VFDs issued annually times 0.25 hours to issue each VFD times \$59 per hour equals approximately \$11.09 million (rounded to be in accordance with the PRIA)). FDA estimates that the effect of this rule would be to reduce the average time to issue a VFD by 50 percent, or about 0.125 hours per VFD. This would result in a cost of about \$5.55 million annually (the estimated average of 750,000 VFDs issued annually times 0.125 hours to issue each VFD times \$59 per hour equals approximately \$5.55 million (rounded to be in accordance with the PRIA)), a cost savings of about \$5.55 million ( $\$11.09 \text{ million} - \$5.55 \text{ million} = \text{approximately } \$5.55 \text{ million}$ ).

Currently, a distributor may only consign a VFD feed to another distributor if the originating distributor (consignor) first obtains a written acknowledgement letter from the receiving distributor (consignee) before the feed is shipped (§ 558.6(d)(2)). Because this current

requirement is the same as that being proposed in § 558.6(c)(7), there is no new reporting burden.

Proposed § 558.6(c)(7), also includes an explicit recordkeeping requirement for acknowledgment letters. While the VFD final rule issued in December 2000 did not explicitly require distributors to retain acknowledgment letters for any specified period of time, a 2-year recordkeeping burden was accounted for in the PRA section of the final rule for this function as part of the VFD recordkeeping burden in Table 2, noted as § 558.6(d)(2) (65 FR 76928).<sup>6</sup> FDA continues to believe, as we did in 2000, that medicated feed distributors customarily retain both acknowledgment letters and VFDs as a normal business practice. The purpose of this provision is to clarify that acknowledgment letters, like VFDs, must be retained only for 1 year.

Table 3.--Estimated Annual Third-party Disclosure Burden<sup>1</sup>

21 U.S.C. 343m 21 CFR Section (Labeling Activity)	No. of Respondents	No. of Disclosures per Respondent	Total Annual Disclosures	Average Burden per Disclosure in Hours	Total Hours	Total Costs
Administrative Review of the Rule, Current VFD Drug Sponsors (General and Operations Managers) <sup>2</sup>	2	1	2	6	12	\$1,200 <sup>2</sup>
558.6(b)(3) Changes to VFD Form by Drug Sponsors <sup>3</sup>	2	2	4	16	64	\$5,308 <sup>3</sup>
Veterinarian issues VFD <sup>4</sup>	3,050	245.9	750,000	0.125	93,750	\$5,550,000
Total					93,826	\$5,556,508

<sup>1</sup>There are no operating and maintenance costs associated with this collection of information.

<sup>2</sup>Two current drug sponsors times \$102 per hour times 6 hours of one-time review time equals approximately \$1,200. Estimate rounded to be in accordance with the PRIA.

<sup>3</sup>Two drug sponsors times two VFD forms per respondent equals four changes to the VFD form. With 16 hours per respondent to make form changes and correct Web site, equals 64 total hours to change the VFD forms. NOTE: The hourly and cost burdens to include the revised verbatim statements noted in this document (on the VFD form itself)

<sup>6</sup>The recordkeeping burdens for VFDs and acknowledgement letters were combined because distributors may receive an acknowledgement letter in lieu of a VFD before distributing a medicated feed containing a VFD drug. This combined recordkeeping burden, estimated at 18,788 hours in the 2000 final rule, is still cited in Table 2 of the currently approved Information Collection Request (ICR) for § 558.6 (0910-0363). As noted in the PRA section of the December 2000 final rule, "[a]ny person who distributes medicated feed containing VFD drugs must file with [FDA] a one-time notification letter of intent to distribute, and retain a copy of each VFD serviced or each consignee's acknowledgment letter for 2 years." (65 FR 76928).

are exempt under the PRA. We are unable to measure these hours and costs separately, but consider them to be de minimus. The cost to change the VFD form is considered to include these statement changes. Changes to the VFD form for the four approved VFD forms (there are separate VFD forms for each of the two indications per VFD drug) are four VFD forms times \$1,327 cost per form equals \$5,308.

<sup>4</sup>A total of 3,050 veterinarians times 245.9 VFDs issued per year (on average) times 0.125 hours per form equals 93,750 hours per year times \$59 per hour equals approximately \$5,550,000. Estimate rounded to be in accordance with the PRA.

Number of Respondents multiplied by Number of Disclosures per Respondent equals Total Annual Disclosures. Total Annual Disclosures multiplied by Average Burden per Disclosure equals Total Hours.

Additionally, as the usual and customary records of purchase and sales kept by distributors to comply with the cGMP regulations adequately supports the VFD inspection program, we have eliminated the VFD manufacturing recordkeeping requirement currently found in § 558.6(e) and instead refer to the 1-year manufacturing receipt and distribution recordkeeping requirement for medicated feed manufacturers in part 225 (proposed § 558.6(c)(3)). These record requirements are currently found at OMB control number 0910-0152.

Paperwork approval of new animal drug applications is contained under OMB control number 0910-0032, for Indexing of Legally Marketed Unapproved New Animal Drugs for Minor Species under OMB control number 0910-0620, and for veterinary feed directives, OMB approval is contained under OMB control number 0910-0363.

Interested persons are requested to send comments regarding information collection by [INSERT DATE 30 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER] to the Office of Information and Regulatory Affairs, OMB. To ensure that comments on information collection are received, OMB recommends that written comments be faxed to the Office of Information and Regulatory Affairs, OMB, Attn: FDA Desk Officer, FAX: 202-395-6974, or emailed to [oir\\_submission@omb.eop.gov](mailto:oir_submission@omb.eop.gov). All comments should be identified

with the title, "Veterinary Feed Directives, Reporting, Recordkeeping and Third Party Disclosure."

In compliance with the PRA (44 U.S.C. 3407(d)), the Agency has submitted the information collection provisions of this proposed rule to OMB for review. These requirements will not be effective until FDA obtains OMB approval. FDA will publish a notice concerning OMB approval of these requirements in the Federal Register.

#### VII. Environmental Impact

The Agency has determined under 21 CFR 25.30(h) that this action is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

#### VIII. Federalism

FDA has analyzed this proposed rule in accordance with the principles set forth in Executive Order 13132. FDA has determined that the proposed rule, if finalized, would not contain policies that would have substantial direct effects on the States, on the relationship between the National Government and the States, or on the distribution of power and responsibilities among the various levels of government. Accordingly, the Agency tentatively concludes that the proposed rule does not contain policies that have federalism implications as defined in the Executive order and, consequently, a federalism summary impact statement is not required.

#### IX. Comments

Interested persons may submit either electronic comments regarding this document to <http://www.regulations.gov> or written comments to the Division of Dockets Management (see ADDRESSES). It is only necessary to send one set of comments. Identify comments with the

docket number found in brackets in the heading of this document. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday, and will be posted to the docket at <http://www.regulations.gov>.

List of Subjects

21 CFR Part 514

Administrative practice and procedure, Animal drugs, Confidential business information, Reporting and recordkeeping requirements.

21 CFR Part 558

Animal drugs, Animal feeds.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, it is proposed that 21 CFR parts 514 and 558 be amended as follows:

PART 514--NEW ANIMAL DRUG APPLICATIONS

1. The authority citation for 21 CFR part 514 is revised to read as follows:

Authority: 21 U.S.C. 321, 331, 351, 352, 354, 356a, 360b, 371, 379e, 381.

2. Amend § 514.1 by revising paragraph (b)(9) to read as follows:

§ 514.1 Applications.

\* \* \* \* \*

(b) \* \* \*

(9) Veterinary feed directive. Three copies of a veterinary feed directive (VFD) must be submitted in the format described under §558.6(b)(3) of this chapter.

\* \* \* \* \*

PART 558--NEW ANIMAL DRUGS FOR USE IN ANIMAL FEEDS

3. The authority citation for 21 CFR part 558 is revised to read as follows:

Authority: 21 U.S.C. 354, 360b, 360ccc, 360ccc-1, 371.

4. Amend § 558.3 by revising paragraphs (b)(1)(ii), (b)(6), (b)(7), (b)(9), and (b)(11) and by adding new paragraph (b)(12) to read as follows:

§ 558.3 Definitions and general considerations applicable to this part.

\* \* \* \* \*

(b) \* \* \*

(1) \* \* \*

(ii) Category II--These drugs require a withdrawal period at the lowest use level for at least one species for which they are approved, or are regulated on a "no-residue" basis or with a zero tolerance because of a carcinogenic concern regardless of whether a withdrawal period is required.

\* \* \* \* \*

(6) A "veterinary feed directive (VFD) drug" is a new animal drug approved under section 512(c) of the Federal Food, Drug, and Cosmetic Act (the FD&C Act), conditionally approved under section 571 of the FD&C Act, or listed in the index under section 572 of the FD&C Act, for use in or on animal feed. Use of a VFD drug in or on animal feed must be authorized by a valid veterinary feed directive.

(7) A "veterinary feed directive" is a written (nonverbal) statement issued by a licensed veterinarian that orders the use of a VFD drug or combination VFD drug in or on an animal feed. This statement authorizes the client (the owner of the animal or animals or other caretaker) to obtain and use the VFD drug or combination VFD drug in or on an animal feed to treat the client's animals only in accordance with the conditions for use approved, conditionally approved,

or indexed by the Food and Drug Administration (FDA). A veterinarian may only issue a VFD for the use of VFD drugs in animals under his or her supervision or oversight in the course of his or her professional practice, and in compliance with all applicable veterinary licensing and practice requirements. A veterinary feed directive may be issued in hardcopy or through electronic media.

\* \* \* \* \*

(9) For the purposes of this part, a "distributor" means any person who consigns a medicated feed containing a VFD drug to another person. Such other person may be another distributor or the client-recipient of a VFD.

\* \* \* \* \*

(11) An "acknowledgment letter" is a written (nonverbal) communication sent to a distributor (consignor) from another distributor (consignee) who is not the ultimate user of the medicated feed containing a VFD drug. An acknowledgment letter may be sent in hardcopy or through electronic media and must affirm:

(i) That the consignee will not ship such medicated animal feed to an animal production facility that does not have a VFD,

(ii) That the consignee will not ship such feed to another distributor without receiving a similar written acknowledgment letter, and

(iii) That the consignee has complied with the distributor notification requirements of § 558.6(c)(4) of this chapter.

(12) A "combination veterinary feed directive (VFD) drug" is a combination new animal drug (as defined in § 514.4(c)(1)(i) of this chapter) approved under section 512(c) of the Federal Food, Drug, and Cosmetic Act (the FD&C Act), conditionally approved under section 571 of the

FD&C Act, or listed in the index under section 572 of the act, for use in or on animal feed, and at least one of the component new animal drugs is a VFD drug. Use of a combination VFD drug in or on animal feed must be authorized by a valid veterinary feed directive.

5. Revise § 558.6 to read as follows:

§ 558.6 Veterinary feed directive drugs.

(a) General requirements related to veterinary feed directive (VFD) drugs:

(1) A feed containing a VFD drug or a combination VFD drug (a VFD feed or combination VFD feed) shall be fed to animals only by or upon a lawful VFD issued by a licensed veterinarian. A veterinarian may only issue a VFD for the use of VFD drugs in animals under his or her supervision or oversight in the course of his or her professional practice, and in compliance with all applicable veterinary licensing and practice requirements.

(2) VFDs may not be filled after the expiration date on the VFD.

(3) Use and labeling of a VFD drug or a combination VFD drug in feed is limited to the approved, conditionally approved, or indexed conditions of use. Extralabel use (i.e., actual or intended use other than as directed on the labeling) is not permitted.

(4) All involved parties (the veterinarian, the distributor, and the client) must retain a copy of the VFD for 1 year.

(5) All involved parties must make the VFD and any other records specified in this section available for inspection and copying by FDA.

(6) All labeling and advertising for VFD drugs, combination VFD drugs, and feeds containing VFD drugs or combination VFD drugs must prominently and conspicuously display the following cautionary statement: "Caution: Federal law restricts medicated feed containing this VFD drug to use by or on the order of a licensed veterinarian."

(b) Responsibilities of the veterinarian issuing the VFD:

(1) The veterinarian must be licensed to practice veterinary medicine and may only issue a VFD for the use of VFD drugs in animals under his or her supervision or oversight in the course of his or her professional practice, and in compliance with all applicable veterinary licensing and practice requirements.

(2) The veterinarian must only issue a VFD that is in compliance with the conditions for use approved, conditionally approved, or indexed for the VFD drug.

(3) The veterinarian must assure that the following information is fully and accurately included on the VFD:

(i) The veterinarian's name, address, and telephone number;

(ii) The client's name, telephone number, and business or home address;

(iii) The premises at which the animals specified in the VFD are located;

(iv) The date of VFD issuance;

(v) The expiration date of the VFD. This date cannot extend beyond the expiration date specified in the approval, conditional approval, or index listing, if such date is specified. In cases where the expiration date is not specified in the approval, conditional approval, or index listing, the expiration date of the VFD cannot exceed 6 months after the date of issuance;

(vi) The name of the animal drug;

(vii) The species and production class of animals to be fed the medicated feed;

(viii) The approximate number of animals to be fed the medicated feed prior to the expiration date on the VFD;

(ix) The indication for which the VFD is issued;

(x) The level of drug in the feed and duration of use;

(xi) The withdrawal time, special instructions, and cautionary statements necessary for use of the drug in conformance with the approval;

(xii) The number of reorders (refills) authorized, if permitted by the drug approval, conditional approval, or index listing;

(xiii) The statement: "Extralabel use (i.e., use of this VFD feed in a manner other than as directed on the labeling) is not permitted";

(xiv) An affirmation of intent for combination VFD drugs as described in paragraph (6);  
and

(xv) The veterinarian's electronic or written signature.

(4) The veterinarian may, at his or her discretion, enter the following information on the VFD to more specifically identify the animals authorized to be treated/fed the medicated feed:

(i) A more specific description of the location of animals (e.g., by site, pen, barn, stall, tank, or other descriptor that the veterinarian deems appropriate);

(ii) The approximate age range of the animals;

(iii) The approximate weight range of the animals; and

(iv) Any other information the veterinarian deems appropriate to identify the animals specified in the VFD.

(5) For VFDs intended to authorize the use of an approved, conditionally approved, or indexed combination VFD drug that includes more than one VFD drug, the veterinarian must include the drug-specific information required in paragraphs (b)(2)(vi), (ix), (x), and (xi) for each component VFD drug in the combination.

(6) The veterinarian may restrict VFD authorization to only include the VFD drug(s) cited on the VFD or such authorization may be expanded to allow the use of the cited VFD

drug(s) along with one or more over-the-counter (OTC) animal drugs in an approved, conditionally approved, or indexed combination VFD drug. The veterinarian must affirm his or her intent regarding combination VFD drugs by including one of the following statements on the VFD:

(i) "The VFD drug(s) cited in this order may not be used in combination with any other animal drugs."

(ii) "The VFD drug(s) cited in this order may be used in combination with the following OTC animal drugs to manufacture an FDA-approved, conditionally approved, or indexed combination medicated feed." [List OTC drugs immediately following this statement.]

(iii) "The VFD drug(s) cited in this order may be used in combination with any OTC animal drugs to manufacture an FDA-approved, conditionally approved, or indexed combination medicated feed."

(7) The veterinarian must send the VFD to the feed distributor via hardcopy, fax, or electronically. If in hardcopy, the veterinarian may send the VFD to the distributor either directly or through the client.

(8) The veterinarian must provide a copy of the VFD to the client.

(9) The veterinarian may not issue a VFD verbally.

(c) Responsibilities of any person who distributes an animal feed containing a VFD drug or a combination VFD drug:

(1) The distributor may only fill a VFD if the VFD contains all the information required in paragraph (b)(3) of this section.

(2) The distributor may only distribute an animal feed containing a VFD drug or combination VFD drug that complies with the terms of the VFD and is manufactured and labeled

in conformity with the approved, conditionally approved, or indexed conditions of use for such drug.

(3) In addition to other applicable recordkeeping requirements found in this section, the distributor must also keep VFD feed manufacturing records for 1 year in accordance with part 225 of this chapter. Such records must be made available for inspection and copying by FDA upon request.

(4) A distributor of animal feed containing VFD drugs must notify FDA prior to the first time it distributes animal feed containing VFD drugs. The notification is required one time per distributor and must include the following information:

- (i) The distributor's complete name and business address;
- (ii) The distributor's signature or the signature of the distributor's authorized agent; and
- (iii) The date the notification was signed;

(5) A distributor must also notify FDA within 30 days of any change in ownership, business name, or business address.

(6) The notifications cited in paragraphs (c)(4) and (c)(5) of this section must be submitted to the Food and Drug Administration, Center for Veterinary Medicine, Division of Animal Feeds (HFV-220), 7519 Standish Pl., Rockville, MD 20855. FAX: 240-453-6882.

(7) A distributor may only consign a VFD feed to another distributor if the originating distributor (consignor) first obtains a written (nonverbal) acknowledgment letter, as defined in § 558.3(b)(11), from the receiving distributor (consignee) before the feed is shipped. Consignor distributors must retain a copy of each consignee distributor's acknowledgment letter for 1 year.

Dated: December 9, 2013.

Leslie Kux,

Assistant Commissioner for Policy.

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