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: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is amending its animal drug regulations regarding veterinary feed directive (VFD) drugs. FDA's current VFD regulation established requirements relating to the distribution and use of VFD drugs and animal feeds containing such drugs. This amendment is intended to improve the efficiency of FDA's VFD program while protecting human and animal health.

DATES: This rule is effective October 1, 2015.

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SUPPLEMENTARY INFORMATION:

Executive Summary

Purpose of Final Rule

The purpose of this rulemaking is to revise FDA's VFD regulations to improve the efficiency of the VFD program while continuing to protect public health (human and animal health).

In 1996, Congress enacted the Animal Drug Availability Act (ADAA) (Pub. L. 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 or on animal food (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. Any animal feed containing a VFD drug can only be fed to animals based upon an order, called a veterinary feed directive (VFD), issued by 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)) (65 FR 76924, December 8, 2000). In the decade since FDA published its VFD regulations, various stakeholders have informed the Agency that the existing VFD process is overly burdensome. In response to those concerns, FDA published several documents inviting public input on ways to improve the VFD process, including an advance notice of proposed rulemaking (ANPRM) (75 FR 15387, March 29, 2010) (March 2010 ANPRM); draft regulatory text for proposed regulation (77 FR 22247, April 13, 2012) (April 2012 draft proposed regulation); and a notice of proposed rulemaking (NPRM) (78 FR 75515, December 12, 2013) (December 2013 NPRM).

The VFD rule is the third of three core documents that FDA is using to announce and implement its policy framework for the judicious use of medically important antimicrobial drugs in food-producing animals. The first document, Guidance for Industry (GFI) #209, entitled ''The Judicious Use of Medically Important Antimicrobial Drugs in Food-Producing Animals,'' published April 2012, set forth FDA's framework for instituting several key measures for ensuring the appropriate or judicious use of medically important antimicrobial drugs in food-producing animals. These measures include eliminating the feed and water use of medically important antimicrobial drugs for production purposes in food-producing animals and bringing all remaining therapeutic uses under the oversight of licensed veterinarians. The second document, GFI #213, entitled ''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,'' published December 2013, outlined a detailed process and timeline for implementing the measures identified in GFI #209. Once GFI #213 is fully implemented, affected feed-use antimicrobial drugs are expected to transition from over-the-counter (OTC) to VFD marketing status. Given that most of the products affected by this effort are feed-use antimicrobial drugs this VFD regulation plays an important role since it outlines the requirements associated with veterinary authorization, distribution, and use of VFD drugs in animal feed.

The VFD drug process as outlined in this final rule includes important controls regarding the distribution and use of VFD drugs. In addition to providing accountability, this final rule also updates the VFD requirements to improve the efficiency of the process. These regulatory enhancements are important for facilitating the transition of a large number of OTC feed-use antimicrobial drugs to their new VFD status.

FDA intends to use a phased enforcement strategy for implementation of this final rule as OTC drugs become VFD drugs under GFI #213. FDA first intends to provide education and training for stakeholders subject to this final rule such as veterinarians, clients (animal producers), feed mill distributors and other distributors. Such education and training efforts are important for supporting effective implementation and compliance with the final rule. FDA will then engage in risk-based general surveillance, as well as for-cause inspection assignments. FDA intends to use information such as history of VFD use and the volume of VFD feed being produced to focus inspectional resources within the industry based on risk. FDA anticipates that it will utilize various sources for obtaining such information including such sources as FDA food and drug registration information, feed mill licensing information, the VFD distributor notifications FDA receives, and VFD distribution records maintained by drug sponsors and VFD distributors.

The provisions included in this final rule are based on stakeholder input received in response to multiple opportunities for public comment, including the March 2010 ANPRM, April 2012 draft proposed regulation, and the December 2013 NPRM.

Summary of Major Provisions

This final rule makes several important changes from the proposed rule and several major changes to the current VFD regulations in part 558 (21 CFR part 558):

- The definition of ''Category II'' in part 558 is revised to remove the automatic Category II designation for VFD drugs. Instead, the categorization of VFD drugs will be determined on a case-by-case basis based on the likelihood that the particular drug at issue will produce an unsafe residue in edible products derived from treated animals, as is currently the case for non-VFD feed use drugs.
- The definition of veterinary feed directive (VFD) drug is revised to simply refer to the statutory definition to provide further clarity.
- The proposed definition of combination veterinary feed directive (VFD) drug is revised to reflect the

changes to the veterinary feed directive (VFD) drug definition.

- The proposed definition of a ''veterinary feed directive'' is revised to remove language that is duplicated in the responsibilities of a veterinarian issuing a VFD.
- The proposed definition of the term ''distributor'' is revised to use the word ''distributes'' instead of the word ''consigns'' as had been proposed.
- The regulatory text proposed for § 558.6(a)(4) and (b)(8) is revised to clarify that the veterinarian is required to keep the original VFD (in hardcopy or electronically) and the distributor and client must keep a copy of the VFD (in hardcopy or electronically).
- The current requirement that copies of the VFD and records of the receipt and distribution of VFD feed must be kept for a period of 2 years is retained instead of being changed to 1 year as was proposed.
- The final rule provides that the veterinarian must issue the VFD in the context of a valid veterinarian-client-patient relationship (VCPR) as defined by the State requirements applicable to where the veterinarian practices veterinary medicine. In States that lack appropriate VCPR requirements applicable to VFDs, the veterinarian must issue the VFD consistent with the Federally defined VCPR standard, which is set forth in FDA's regulations at § 530.3(i) (21 CFR 530.3(i)).
- The VFD expiration date requirement in the final rule specifies that this is the date that authorization to feed the VFD feed to animals expires. Animals must not be fed the VFD feed after the expiration date of the VFD.
- The VFD requirement for approximate number of animals in the final rule specifies how the approximate number of animals should be determined.
- The final rule clarifies the affirmation of intent statements to be used in VFDs issued by licensed veterinarians to indicate whether a VFD drug may be used in conjunction with another drug in an approved, conditionally approved, or indexed combination VFD feed.
- The final rule clarifies the recordkeeping requirements to differentiate what records are required to be kept for distributors who manufacture VFD feed and those who do not manufacture the VFD feed.

Costs and Benefits

The estimated one-time costs to industry from this final rule are $1,411,000, most of which are simply costs to review the rule and prepare a compliance plan. This equates to annualized costs of about $201,000 at a 7 percent discount rate over 10 years. We estimate that the government costs associated with reviewing the six VFD drug labeling supplements that are expected to be submitted by the three current VFD drug sponsors to be $1,900.

The expected benefit of this final rule is a general improvement in the efficiency of the VFD process. FDA estimates the annualized cost savings associated with the more efficient requirements of the VFD process to be $13,000 over 10 years at a 7 percent discount rate (annualized at $11,000 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 $7.87 million annually.

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I. Background

A. History

Before 1996, FDA had only two options for regulating the distribution of animal drugs: (1) Over-the-counter (OTC) and (2) by 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 would be impractical because many States have laws that would require a feed mill to have a pharmacist onsite to dispense prescription drugs. As additional animal drugs were developed, FDA determined the existing regulatory options—OTC and Rx—did not provide the needed safeguards or flexibility for these drugs to be prescribed or administered through medicated feed. FDA believed that these drugs, particularly certain antimicrobial drugs, should be subject to greater control than provided by OTC status. FDA believed this control would be critical to reducing unnecessary use of such drugs in animals and to slowing or preventing the potential for the development of bacterial resistance to antimicrobial drugs administered through medicated feed.

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 recognized that certain new animal drugs intended for use in animal feed should only be 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 by an approved application, conditionally approved application, or index listing to use under the professional supervision of a licensed veterinarian. In order for animal feed containing a VFD drug (VFD feed) to be fed to 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 regulations in part 558 (21 CFR part 558) relating to new animal drugs for use in animal feed 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. In addition, 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 issued the final rule relating to VFDs. Although currently there are only a few approved VFD drugs, FDA has received comments from stakeholders characterizing the current VFD process as being overly burdensome. 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 the March 2010 ANPRM. The March 2010 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 the

April 2012 draft proposed regulation based on the considerable public input it had received in response to the March 2010 ANPRM, and the Agency requested comment on this draft language also.

Recognizing that there would be challenges faced by animal producers and veterinarians as FDA phases in veterinary oversight of the therapeutic use of certain medically important antimicrobials, in the spring of 2013, FDA and the U.S. Department of Agriculture's (USDA) Animal and Plant Health Inspection Service jointly sponsored a series of public meetings in various locations throughout the country (2013 public meetings). These meetings provided a forum to discuss potential challenges faced by animal producers in areas that may lack access to adequate veterinary services and to explore possible options for minimizing adverse impacts.

After considering the feedback received during the 2013 public meetings, as well as comments received on our March 2010 ANPRM and April 2012 draft proposed regulation, FDA published the December 2013 NPRM.

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) (Ref. 1). This guidance document 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 recommends two principles for assuring the appropriate or judicious use of medically important antimicrobial drugs in food-producing animals in order to help minimize antimicrobial resistance development: (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.

On December 13, 2013, FDA finalized a second guidance document, GFI #213, entitled ''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'' (Ref. 2). GFI #213 outlined a timeline and provided sponsors with specific recommendations on how they could voluntarily modify the use conditions of their medically important antimicrobial drug products administered in feed or water to align with the two judicious use principles announced in GFI #209. Once the use conditions of the affected products are changed, these products can no longer be legally used for production purposes, and can only be used for therapeutic purposes with the supervision of a licensed veterinarian.

Implementation of the judicious use principles set forth in GFI #209, particularly the second principle recommending that affected products be limited to uses in animals that include veterinarian oversight or consultation, 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. The majority of the antimicrobial animal drug products that are the focus of GFI #209 and GFI #213 are drugs approved for use in or on animal feed. All but a few of these drugs are currently available OTC without veterinary oversight or consultation and would be affected by the Agency's recommendation in the guidances to switch these products' marketing status from OTC to VFD. Therefore, it is important that the VFD process be as efficient as possible when FDA's judicious use policy is fully implemented to facilitate transition of these products from OTC to VFD marketing status. In addition, an overly burdensome VFD process could disrupt the movement of medicated feeds through commercial feed distribution channels, thereby impacting the availability of medicated feed products needed for addressing animal health issues.

II. Overview of the Final Rule

This final rule amends FDA's regulations found in parts 514 and 558 (21 CFR parts 514 and 558) to change and clarify certain definitions (§ 558.3 (21 CFR 558.3)), clarify the general requirements for VFD drugs (§ 558.6(a) (21 CFR 558.6(a))), clarify the responsibilities of the VFD drug sponsor (§ 514.1(b) (21 CFR 514.1(b)), and clarify specific responsibilities of the veterinarian issuing the VFD (§ 558.6(b) (21 CFR 558.6(b))). Also, in this final rule we clarify the specific responsibilities of any person who distributes an animal feed containing a VFD drug (§ 558.6(c) (21 CFR 558.6(c))).

In this rulemaking, the Agency finalizes many of the provisions in the December 2013 NPRM. In addition, the final rule reflects revisions the Agency made in response to comments on the December 2013 NPRM and certain revisions made by the Agency on its own initiative after considering all of the comments it received. Based on the changes to the final rule from the proposed rule, the Agency has determined that the effective date for the final rule should be 120 days after publication.

III. Comments on the Proposed Rule

This section summarizes comments FDA received in response to the December 2013 NPRM and the Agency's response to those comments. FDA received about 2,000 individual comments submitted to the docket on the December 2013 NPRM. Some of the comments contained signatures by multiple individuals or organizations. Comments were received from veterinary, feed manufacturing, and animal production associations, as well as consumer advocacy groups and individuals. Many of the comments received from veterinarian, feed manufacturing, animal production associations, and individuals generally supported the changes and requested some additional changes or clarification on particular issues. Many of the comments received from consumer advocacy groups and individuals raised concerns over whether the changes would sufficiently protect public health. FDA is making changes in the final rule to address these concerns where the Agency has determined such changes to be appropriate.

The order of the discussion reflects the order in the regulatory text and not the order of significance of a particular issue. To make it easier to identify comments and FDA's responses, the word ''Comment,'' in parentheses, appears before the comment's description, and the word ''Response,'' in parentheses, appears before FDA's response. Each comment is numbered to help distinguish between different comments. The number assigned to each comment is for organizational purposes and does not signify the comment's value or importance.

In addition to the comments specific to this rulemaking that we address in the following paragraphs, we received general comments expressing views about public health, the use of antimicrobials, antimicrobial resistance, antibiotic alternatives, animal husbandry practices, meat consumption,

food labeling, genetically modified organisms, chemicals in food, hormones in food, food (feed) additives, pesticides, fertilizers, trade policy, inspection frequency, violation penalties, and Agency funding. These comments express broad policy views and do not address specific points related to this rulemaking. Therefore, these general comments do not require a response.

A. Definitions Section (§ 558.3)

1. Category II Drug (§ 558.3(b)(1)(ii))

The December 2013 NPRM proposed to remove VFD drugs from the definition of Category II drugs. In this final rule, we are keeping our proposed definition, which means that VFD drugs will no longer be automatically designated as Category II drugs. Category I drugs will remain defined as drugs that do not require a withdrawal period at the lowest use level in each species for which they are approved. Category II drugs will be defined as 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. As a result of this change, VFD drugs will be designated as either Category I or II based on the definitions in the final rule, including the existing VFD drug products that previously were automatically designated as Category II drugs.

(Comment 1) There were multiple comments supporting FDA's proposed change to the definition of ''Category II'' drugs to discontinue the automatic designation of VFD drugs as Category II drugs. These comments supported Category I and II definitions that use a public health risk-based approach to designate drugs based on the potential for unsafe drug residues in edible tissues as reflected by drug withdrawal periods. At least one comment also recognized that without this change, farm animals may be unable to receive the treatment they need due to supply chain disruptions. This comment noted that limiting the manufacturing of VFD feed from Type A medicated articles to licensed feed mills by automatically designating them as Category II would cause a serious disruption in VFD feed availability and unnecessarily cause harm to animals. The comment further noted that the proposed change to remove the automatic designation should greatly reduce the supply chain consequences.

(Response 1) We agree that this approach provides a consistent scientific rationale for designating VFD drugs as Category I or II and will help prevent potential VFD feed supply chain concerns. Therefore, in this final rule, we are keeping the definition proposed in the December 2013 NPRM.

The definitions proposed in the December 2013 NPRM designate drugs as Category II if a withdrawal period is required at the lowest approved use level for any species, or if the drug is regulated on a ''no-residue'' basis or with a zero tolerance because of a carcinogenic concern regardless of whether a withdrawal period is required. The category in which a new animal drug is placed determines whether the Type A medicated article of that drug can be handled by a licensed or unlicensed mill. Type A medicated articles are the most concentrated form of the new animal drug and are used in the manufacture of another Type A medicated article, or a Type B or C medicated feed. A Type B medicated feed is intended solely for the manufacture of other Type B or Type C medicated feeds and contains a substantial quantity of nutrients with the new animal drug. A Type C medicated feed is intended as the complete feed for the animal or may be added on top of a usual ration, or offered as a supplement with other animal feed. A Type C medicated feed has the lowest concentration of the new animal drug. In order to reduce the potential to create unsafe drug residues, the manufacturing of medicated feeds with Category II Type A medicated articles is restricted to licensed feed mills. Licensed feed mills are generally better suited technically to manufacture feeds containing Category II drugs and are subject to more extensive good manufacturing practice requirements than unlicensed feed mills.

When the VFD regulations were implemented, FDA stated that ''classifying a drug as Category II adds additional regulatory controls because feed manufacturing facilities must possess a medicated feed mill license and be registered with FDA. . . . Registered feed mills are required to be inspected at least every 2 years. Such inspections will help the Agency to ensure that VFD requirements are met'' (65 FR 76924 at 76926). Since the regulations for VFD drugs were implemented over a decade ago, FDA's experience has not shown a continued need to ensure VFD requirements are met by automatically designating all VFD drugs as Category II drugs. Since January 8, 2001, when the initial VFD regulations became effective, FDA has only issued three warning letters for violations related to noncompliance with the VFD regulations (Ref. 3). Furthermore, licensed feed mills are now required to be inspected according to risk instead of at a set frequency. Drug categorization determines whether a facility needs to be licensed to handle the drug in the Type A form and is meant to provide additional regulatory oversight for the manufacturing of the drug to minimize the potential for drug residues to occur. In contrast, VFD designation is intended primarily to provide for veterinary supervision of the use of medicated feeds containing VFD drugs (VFD feeds). For VFD drugs that would otherwise be categorized as Category I drugs (*i.e.,* do not require a withdrawal period at the lowest use level), FDA does not believe it is necessary to limit the manufacture of VFD feeds to licensed feed mills. Whether manufactured at a licensed or unlicensed feed mill, VFD feeds can only be used when authorized by a lawful VFD issued by a veterinarian.

In addition, we agree this change will help prevent the potential supply chain disruptions for VFD feeds that otherwise are likely to occur once the Agency's policy regarding the judicious use of medically important antimicrobial drugs in food-producing animals is fully implemented. The existing definition of Category II drugs includes a provision that says *all* VFD drugs are Category II drugs, regardless of their potential to create unsafe drug residues. Thus, if FDA's policy regarding the judicious use of medically important antimicrobials were implemented with the definitions in the current regulations, drugs currently designated as Category I drugs that transition from OTC to VFD marketing status would automatically move from Category I to Category II. FDA is concerned that this automatic designation would cause supply chain disruptions for VFD feeds because the Type A medicated articles would be restricted to use by licensed feed mills, which number less than 1,000. Currently, since these drugs are OTC Category I drugs, they are able to be used in the Type A form by unlicensed feed mills, which number in the tens of thousands, including farms that manufacture their own medicated feed for their own animals.

For these reasons, FDA is revising the definition of Category II to eliminate the automatic designation of VFD drugs into Category II. Once those medically important antimicrobial drugs that are currently marketed OTC are converted to VFD status as part of the implementation of FDA's judicious use policy, they will be placed in Category

I or II based on whether they have a withdrawal period at the lowest use level for at least 1 species in which they are approved or whether they are regulated on a ''no residue'' basis or with a zero tolerance because of carcinogenic concern, as defined in § 558.3. As a result, five of these medically important antimicrobial new animal drugs are expected to remain in Category I; approximately three drugs are expected to move from Category I into Category II. Each of these drugs account for multiple drug product approvals, conditional approvals, or index listings. Type A medicated articles for the drugs that remain in Category I will continue to be available for use by the unlicensed feed mills currently using these drugs as OTC drugs in medicated feeds, thus reducing the potential for supply chain disruption.

(Comment 2) FDA also received multiple comments opposing the proposed change to the definition of a ''Category II'' drug. Most of these comments stated a concern about unlicensed feed mills handling Type A medicated articles for drugs that are VFDs or antimicrobials. The shared concern was that there would not be sufficient controls in place, or oversight over unlicensed feed mills, to ensure that these drugs are handled according to the requirements of the VFD regulation. One comment was concerned that without requiring VFD drugs to first go through a licensed feed mill, coupled with the proposed removal of the explicit Federal VCPR requirement and the proposed change to the definition of distributor, FDA would have no way to monitor the majority of VFD drug use.

(Response 2) At the time VFD regulations were initially issued in December 2000, FDA was concerned that adherence to VFD regulations would require additional regulatory oversight for the proper use of VFD drugs in VFD feed. After over a decade of experience, FDA has only issued three warning letters for compliance issues in the handling of VFD drugs as Type A medicated articles by licensed feed mills, or as Type B or C VFD feed by unlicensed feed mills (Ref. 3). Furthermore, unlicensed feed mills routinely handle Category I Type A medicated articles and are also required to adhere to current good manufacturing practices (CGMPs). Although FDA may not inspect unlicensed feed mills at the same frequency as licensed feed mills, they are inspected for cause when surveillance tools, such as tissue residue or feed sampling, determine that a problem has occurred (Ref. 4). State regulatory Agencies also inspect licensed and unlicensed feed mills (Ref. 5). Therefore, FDA does not believe VFD drugs require continued automatic designation as Category II drugs.

FDA recognizes that feed mill licensing is one method for FDA to maintain an inventory of feed mills that handle and use Type A VFD medicated articles; however, feed mill licensing is not the only way for FDA to be aware of VFD drug use. Furthermore, with respect to the concern raised in one of the comments that the change in the Category II definition, taken together with other proposed changes would diminish FDA's ability to monitor VFD use, the Agency is taking measures to address that concern. First, FDA has reintroduced an explicit VCPR requirement into the provisions for veterinarian supervision and oversight in the regulatory text. Second, FDA has also chosen not to proceed with the proposed changes to the definition of distributor outlined in the December 2013 NPRM and has clarified elsewhere in this document particular actions of on-farm processors that make them distributors.

FDA intends to use a phased enforcement strategy for implementation of this final rule as OTC drugs become VFD drugs under GFI #213. FDA first intends to provide education and training for stakeholders subject to this final rule, such as veterinarians, clients (animal producers), feed mill distributors and other distributors. These education and training efforts are important for supporting effective implementation and compliance with the final rule. As products change to VFD status under the process outlined in GFI #213, FDA will engage in general surveillance, as well as for-cause inspection assignments. These assignments will be risk-based and in response to adverse observations. In order to engage in a risk-based work planning approach, FDA intends to gather information, such as VFD use and the volume of VFD feed being produced within the industry. This information would be gathered through multiple sources, such as FDA food and drug registration information, feed mill licensing information, the VFD distributor notifications FDA receives, and VFD distribution records maintained by drug sponsors and VFD distributors. This information will allow FDA to focus inspectional resources within the industry based on risk.

Therefore, FDA is removing VFD drugs from the definition of Category II drugs. Instead of automatic Category II designation, VFD drugs will now be categorized according to the risk of drug residues based on whether they have a withdrawal period at the lowest level use in any species for which they are approved, or whether they are regulated on a ''no residue'' basis or with a zero tolerance because of carcinogenic concern. This includes the existing approved VFD drug products, each of which will either remain in Category II or be redesignated as Category I drugs based on whether they meet the definition of Category I or the revised definition of Category II.

2. Veterinary Feed Directive Drug (§ 558.3(b)(6))

In the December 2013 NPRM, we proposed changes to better align the definition of ''veterinary feed directive (VFD) drug'' in FDA's regulations with the statutory definition in section 504 of the FD&C Act (21 U.S.C. 354) and to provide additional clarity. We did not receive comments specifically related to our proposed change in definition. However, upon further review we are providing more clarity to the VFD drug definition in this final rule by using the statutory definition in the FD&C Act. That definition of a ''veterinary feed directive (VFD) drug'' states that it is ''[a] drug intended for use in or on animal feed which is limited by an approved application filed pursuant to section 512(b), a conditionally-approved application filed pursuant to section 571, or an index listing pursuant to section 572 to use under the professional supervision of a licensed veterinarian. . . .'' This change in § 558.3(b)(6) provides consistency between the statute and the regulation and helps to reduce the potential for confusion.

3. Veterinary Feed Directive (§ 558.3(b)(7))

FDA did not receive specific comments regarding the addition of language in the proposed VFD definition in § 558.3(b)(7) stating that a VFD may be issued in hardcopy or through electronic means. However, upon further review, we are removing this duplicative language because similar language appears in § 558.6(b) concerning the responsibilities of the veterinarian issuing the VFD. Section 558.6(b) provides more clarity by specifying that a fax also can be used. This change avoids duplication in the regulatory text and helps to reduce potential reader confusion about whether transmitting a VFD by fax is allowed.

Also to help reduce the potential for confusion, FDA is removing the duplicative language concerning the oversight and supervision requirements

for issuing a VFD from the definition of a veterinary feed directive (§ 558.3(b)(7)) and from the general requirements related to veterinary feed directive drugs (§ 558.6(a)(1)), because the same requirements are also in the provision (§ 558.6(b)) that discusses the responsibilities of the veterinarian issuing the VFD. FDA received many comments concerning the oversight and supervision requirements for veterinarians issuing a VFD, which are addressed in the discussion of the responsibilities of the veterinarian issuing the VFD (558.6(b)). This change eliminates duplication in the regulatory text and clarifies that the requirement for oversight and supervision is the responsibility of the veterinarian.

4. Distributor (§ 558.3(b)(9))

In the December 2013 NPRM, we proposed to change the definition of ''distributor.'' In particular, we proposed to change the phrase ''any person who distributes a medicated feed containing a VFD drug to another person'' to ''any person who consigns a medicated feed containing a VFD drug to another person.'' Many of the comments we received expressed concern that this definitional change was meant to narrow the scope of who is defined as a distributor.

(Comment 3) Some comments requested that we maintain the current definition that a distributor is any person who distributes a medicated feed containing a VFD drug to another distributor or to the client-recipient of the VFD. These comments were concerned that use of the term ''consigns'' instead of ''distributes'' in the proposed definition would exempt operations that were previously considered to be distributors. Some of these comments thought that the proposed changes would narrow the scope of the definition such that it would exclude from the distributor notification requirements the majority of facilities where medicated feeds are mixed. One comment supported the definition of distributor proposed in the December 2013 NPRM.

(Response 3) We used the term ''consigns'' in place of the term ''distributes'' with the intent to provide additional clarity; however, the comments we received indicated this proposed terminology was more confusing. In addition, many comments perceived this change as an attempt to narrow the definition of distributor. As stated in the December 2013 NPRM, our intent was to improve the clarity of this definition, not to narrow the scope. As a result of the comments received and the discussions that occurred at public meetings about this proposed change, we are retaining the existing term ''distributes'' as part of the definition of distributor.

In the December 2013 NPRM, we noted that ''on-farm mixers that only manufacture medicated feeds for use in their own animals are not distributors.'' Based on the comments, we would like to provide additional clarity. Some comments perceived this statement to exempt all on-farm mixers from requirements that apply to distributors. However, this statement was intended to describe a limited and specific situation in which FDA does not intend to consider on-farm mixers to be distributors. By on-farm mixers, we were specifically referring to any person who is mixing VFD feed on a ''farm'' as that term is defined in 21 CFR 1.227, who is only feeding that VFD feed to their own animals on that farm. In addition, the on-farm mixer must only be manufacturing VFD feed for their use in their own animals on their own farm (*e.g.,* animal production facility), meaning that the ownership of the feed mill, the animals, and the animal production facility must be the same and the on-farm mixer must be the person using the VFD feed. In contrast, for example, when Person A mixes VFD feed on their farm for their own animals, but also mixes feed and distributes it to Person B's farm, Person A is acting as a ''distributor'' as that term is defined in § 558.3 and, therefore, will be required to comply with the distributor requirements. Another example is when Person C operates a feed mill and owns animals, but distributes the feed to Person D who raises Person C's animals on Person D's farm (*e.g.,* a contract grower), that person (Person C) who operates the feed mill would also be a distributor under the definition.

(Comment 4) Some comments requested that all facilities that dispense feed to an animal production facility be required to submit a notification to FDA. One comment suggested we define a distributor as ''any person who consigns a medicated feed containing a VFD drug to another distributor or to an animal production facility.''

(Response 4) FDA does not believe it is necessary to require that all persons who dispense VFD feed to an animal production facility submit a notification to FDA. For example, if a person purchases a Type B VFD feed and then mixes it on their farm into a Type C VFD feed and feeds it to their own animals on their farm in accordance with a lawful VFD, they are dispensing VFD feed to an animal production facility because the mixing operations are not part of the animal production facility. However, they are not acting as a ''distributor'' as that term is defined in § 558.3 because they are not distributing to another person. When a person who dispenses VFD feed to an animal production facility obtains the VFD feed from a distributor, they are required to submit a VFD or acknowledgment letter to the distributor from whom they obtained the VFD feed. This documentation allows FDA to identify users of VFD feed from the distributor's records for purposes of surveillance, inspection, or investigation. In addition, should a person who dispenses VFD feed to an animal production facility obtain a VFD Type A medicated article for manufacture of the VFD feed, the sponsor of the VFD Type A medicated article is required to maintain a record of distribution.

(Comment 5) One comment was concerned that the required one-time notification to FDA that someone is a distributor of VFD feeds could discourage distribution and sale of floor stock.

(Response 5) The requirement for a person distributing VFD feed to notify FDA when they first engage in such distribution is a statutory requirement. (See section 504(a)(3)(C) of the FD&C Act.) We understand that some businesses may choose not to engage in the sale of floor stock. However, in order to adequately protect public and animal health, FDA must be able to track the distribution of VFD feed, and one-time notification to FDA upon first engaging in the distribution of a VFD feed provides the minimum information needed for this tracking. We do not agree that the minimal burden of a one-time notification to FDA would be a significant factor in discouraging the distribution of floor stock. Furthermore, FDA believes there is no compelling reason to treat distributors who only sell floor stock differently from distributors who distribute VFD feed through other sales models.

(Comment 6) One comment requested clarification on whether a manufacturer of a Type B VFD feed who distributes the Type B VFD feed to an animal producer who then makes a Type C VFD feed needs to get an acknowledgement letter from the animal producer as opposed to a VFD.

(Response 6) When a manufacturer of a Type B VFD feed distributes the Type B VFD feed to an animal producer, the animal producer may manufacture a Type C VFD feed to either feed the VFD feed to his or her own animals and/or further distribute the Type C VFD feed to another distributor or client-recipient. If the Type B VFD feed is being shipped to an animal producer who is not a

distributor, the animal producer must provide a VFD for the receipt of the Type B VFD feed from the distributor. If the Type B VFD feed is being shipped to an animal producer who is a distributor that has sent a one-time notification to FDA, the animal producer must supply either an acknowledgment letter or a VFD for the receipt of the Type B VFD feed from the distributor. (**Note:** In order for the animal producer to receive a Type B or Type C VFD feed without a VFD in hand, he or she must have previously notified FDA that he or she is a distributor.) If the animal producer provides an acknowledgment letter to the distributor from whom the animal producer receives the VFD feed, the animal producer must either receive an acknowledgment letter or a VFD prior to further distributing the VFD feed to another person, or have a VFD on hand prior to feeding the Type C VFD feed to his or her own animals. We have revised the definition of acknowledgment letter in (§ 558.3(b)(11)) to clarify that when an animal producer is acting as a distributor as defined in (§ 558.3(b)(9)), they may provide an acknowledgment letter even if they are the ultimate user of some of the VFD feed.

5. Animal Production Facility (§ 558.3(b)(10))

The December 2013 NPRM did not propose a change to the definition of animal production facility. However, we received comment on the definition.

(Comment 7) A few comments requested that FDA define ''animal production facility'' more broadly to include the location where the medicated feed is made. These comments cited a concern that movement of VFD feed would be limited by this definition because shipment of VFD feed to an animal production facility must frequently go beyond the gate to a facility or feed mill where the animals are not housed.

(Response 7) The term animal production facility is defined as ''a location where animals are raised for any purpose, but does not include the specific location where medicated feed is made.'' (§ 558.3(b)(10)). The definition of animal production facility does not hinder the movement of feed between a feed mill and an animal production facility. VFD feed may be shipped from a distributor directly to an animal production facility, or may first be delivered to a facility or feed mill that is located where the animals are not housed. Provided the recipient of such feed has a lawful VFD and is the owner of both the facility or feed mill to which the feed was delivered and the animal production facility, further movement of that VFD feed to the actual animal production facility would not be limited and we would not consider such further movement to be the activity of a ''distributor.''

6. Combination VFD Drug (§ 558.3(b)(12))

In the December 2013 NPRM, we added a definition for the term ''combination veterinary feed directive (VFD) drug.'' In the final rule, we have further clarified that definition to align the language with the statutory definition of a veterinary feed directive drug.

B. Veterinary Feed Directive Drugs (§ 558.6)

1. General Requirements Related to VFD Drugs (§ 558.6(a))

a. VFD Retention and Transmission Requirements (§ 558.6(a)(4))

In the December 2013 NPRM, we proposed that VFDs would no longer be specifically required to be produced in triplicate; however, all three involved parties (veterinarian, distributor, and client) still would 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 the original in hardcopy to the distributor.

(Comment 8) Many comments supported these changes. Some comments indicated that there was some confusion about whether an electronic copy of the VFD would satisfy the recordkeeping requirement.

(Response 8) To improve the clarity of this section, we have revised the regulatory text to more precisely indicate the recordkeeping requirements. An electronic copy of the VFD is sufficient for recordkeeping purposes. The original no longer needs to be sent to the distributor. As we stated in the December 2013 NPRM, this hardcopy requirement has become outdated by modern electronic communication and presents an unnecessary burden on the industry.

This revision further reduces the number of paper copies requiring physical recordkeeping space. The December NPRM, however, did not specify who should maintain the original. Because of the confusion indicated in the comments, we are revising the rule to specify that the original should be maintained by the veterinarian who issued the VFD and should be maintained in the manner it was generated, either electronic or hardcopy. The client and distributor should each also have a copy of the VFD, and that copy may be electronic or hardcopy.

(Comment 9) A few comments addressed the regulatory requirements for electronically generated documents. One comment asked what requirements would apply to records with an electronic signature. Another comment urged FDA to not require compliance with 21 CFR part 11 (part 11) for VFDs transmitted and stored electronically.

(Response 9) The regulations in part 11 (Electronic Records; Electronic Signatures) describe FDA's standards for assessing whether electronic records and electronic signatures are trustworthy and reliable and generally equivalent to paper records with handwritten signatures. Electronic records, such as an electronic VFD that meets the requirements of part 11, may be used in lieu of a paper VFD (*i.e.,* VFDs that are generated and signed on paper). As we have previously stated in GFI #120: Veterinary Feed Directive Regulation Questions and Answers, published on March 26, 2009, part 11 applies to records in electronic form that are created, modified, maintained, archived, retrieved, or transmitted, under any FDA records requirements. Therefore, electronic VFDs issued by veterinarians must be compliant with part 11, and VFDs received and electronically stored by distributors and clients must be compliant with part 11. Part 11 does not apply to paper records that are, or have been, transmitted by electronic means (such as facsimile, email attachments, etc.). Part 11 requires a one-time certification that the electronic signatures in their system, used after August 20, 1997, are intended to be the legally binding equivalent of the signer's handwritten signature (Ref. 6). Additional information about part 11 compliance, including information on how FDA intends to exercise enforcement discretion with regard to certain part 11 requirements during the reexamination of part 11, can be found in GFI Part 11, Electronic Records; Electronic Signatures—Scope and Application (Ref. 7).

(Comment 10) One comment suggested that a paper VFD process would be unwieldy, costly, and burdensome.

(Response 10) There are relative advantages and disadvantages to generating and keeping records in either electronic or paper form. We believe that businesses should be able to decide what format (electronic or hard copy) they would like to use to fulfill the recordkeeping requirements. For that reason, we proposed regulations that removed the explicit requirement that

VFDs be issued in triplicate and that the original VFD be transferred from the veterinarian (either directly or through the client) to the distributor. The final regulatory text allows businesses to decide, based on their unique business structure and operation, which recordkeeping format (electronic or paper) to use to fulfill the VFD recordkeeping requirements.

b. Caution Statement on Labeling (§ 558.6(a)(6))

(Comment 11) One comment requested clarification about the caution statement required on labeling and advertising for VFD drugs and feeds containing VFD drugs. The comment recognized that for products in paper bags this would be appropriate, but wondered what would be required for feed that is delivered in bulk where there is no container.

(Response 11) As reflected in the regulatory text, 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 cautionary statement. In section 201(m) of the FD&C Act (21 U.S.C. 321(m)), ''labeling'' is defined as ''all labels and other written, printed, or graphic matter (1) upon any article or any of its containers or wrappers, or (2) accompanying such article.'' Packaged food typically has a label affixed to the package or container; however, any labeling or advertising would also need to contain the statement. Bulk food typically does not have a label affixed to the container, but is accompanied by labeling to meet other requirements of the FD&C Act, such as displaying the common or usual name of the animal food, as well as any other information already required by existing regulations. FDA would expect that the caution statement be on this labeling, as well as any other labeling or advertising for the bulk food.

c. Length of Time VFD and Records Must Be Kept (§ 558.6)

In the December 2013 NPRM, we proposed to reduce the length of time a VFD and records related to a VFD must be kept from the currently required 2 years to 1 year. We received many comments related to this requirement. After further considering this issue, we are retaining the existing 2-year recordkeeping requirement.

(Comment 12) We received many comments requesting FDA to maintain the current 2-year recordkeeping requirement. We also received several comments supporting the proposed 1-year recordkeeping period. Some of these comments supported the 1-year requirement because many VFD records are also required to be kept under the CGMP recordkeeping requirements for medicated feeds found in part 225 (21 CFR part 225), and those requirements specify a 1-year retention period. A few comments requested a requirement that records related to VFDs be kept for a period shorter than 1 year, or longer than 2 years.

(Response 12) In response to comments and after further consideration of the issue, we are requiring that VFDs and all required records related to VFDs for veterinarians, clients, and distributors be kept for a period of 2 years. This record retention period is the same as the current record retention requirement. Our purpose in proposing the 1-year recordkeeping requirement in the December 2013 NPRM was to better align the VFD recordkeeping requirements with those in the CGMP regulations in part 225 for medicated feed. All records required under part 558 of this chapter must be kept for 2 years. In addition, as discussed elsewhere in this document, we believe it is important that all parties be required to maintain VFD receipt and distribution records for 2 years, irrespective of whether the party is required to maintain receipt and distribution records under part 225 of this chapter. We believe that there are several benefits to a 2-year VFD record retention period.

The first benefit is that a 2-year VFD recordkeeping requirement aligns with the recently published Current Good Manufacturing Practice and Hazard Analysis and Risk-Based Preventive Controls for Food for Animals proposed rule (78 FR 64736; October 29, 2013). This proposed rule includes new CGMP requirements for operations that manufacture, process, pack, and hold animal food, including animal feed, and proposes a 2-year records retention period. Some of those recordkeeping requirements would also fulfill the VFD recordkeeping requirements. We believe that, because many operators manufacturing or distributing animal feed bearing or containing VFD drugs may be required to comply with these proposed CGMP requirements, they would benefit from such a recordkeeping requirement alignment.

In addition, while we still believe that a longer retention period ordinarily will not be critical in order to investigate violative drug residues in edible animal tissues, the longer record retention period would provide a more complete history of records, which is useful in identifying patterns of noncompliance with the VFD regulations during regular inspections.

As discussed elsewhere in this document, this final rule adds clarifying language that distributors who manufacture animal feed bearing or containing VFD drugs must keep VFD feed manufacturing records for 1 year in accordance with part 225. These manufacturing records are not required to be kept for 2 years unless they are also required to be kept under part 558 of this chapter (*e.g.,* the VFD and distribution records).

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

a. Veterinarian Oversight, Supervision and the Veterinarian Client-Patient Relationship (VCPR) (§ 558.6)(b)(1)).

FDA is requiring that any veterinarian issuing a VFD be licensed to practice veterinary medicine and operate in compliance with appropriate State defined veterinarian-client-patient relationship (VCPR) requirements or Federally defined VCPR requirements where no applicable and appropriate State VCPR requirements exist. Some States' licensing and practice requirements specify that a VCPR as defined by that State's law must exist before a VFD can be issued. In those States with VCPR requirements that include the key elements of a VCPR as described in the Federal definition (§ 530.3(i)), FDA intends to defer to the State VCPR requirement. This has the advantage of being able to leverage the accountability that comes with State licensing board oversight to ensure compliance with the VCPR requirement, while providing States the flexibility to adapt their VCPR requirements appropriately to local conditions. Although elements of a VCPR are discussed in the paragraphs that follow, FDA believes that in order for the State defined VCPR requirements to sufficiently ''include the key elements of a VCPR as defined in § 530.3(i),'' the State defined VCPR must at least address the concepts that the veterinarian: (1) Engage with the client to assume responsibility for making clinical judgments about patient health, (2) have sufficient knowledge of the patient by virtue of patient examination and/or visits to the facility where patient is managed, and (3) provide for any necessary followup evaluation or care. In States where the practice requirements do not require that a VFD be issued within the context of a State defined VCPR, FDA is requiring that the VFD be issued within the context of a Federally defined valid VCPR.

(Comment 13) The majority of comments supported maintaining a veterinarian-client-patient relationship (VCPR) as a requirement for issuing a VFD. A large number of those comments asked FDA to maintain the Federal definition of a VCPR because some States either do not define VCPR in their State licensing and practice requirements, or they include a VCPR requirement for dispensing prescription drugs or controlled substances, but not for issuing a VFD. Many comments raised the specific concern that the veterinarian who issues a VFD should be required to have recently seen the animals specified in the VFD or visited the farm on which the animals were kept.

(Response 13) FDA agrees that a veterinarian-client-patient relationship is an important element of veterinary supervision and oversight of the VFD process. As stated in the December 2013 NPRM, our intent in revising the VCPR provisions was to ''appropriately defer to existing regulatory oversight standards for veterinary professional conduct,'' which are overseen by the State organizations responsible for the licensing of veterinarians. We did not intend to eliminate requiring a VCPR for the issuance of a lawful VFD. Instead, we intended to broaden the concept of supervision and oversight to include a VCPR and other practice requirements as defined by the State to allow for practice variations and the need for flexibility among State requirements.

After reviewing the comments, it is clear that some people have interpreted our proposed changes as a relaxation of the existing VCPR requirement. We acknowledge that not all States currently require that a VCPR must exist before a VFD can be issued and that there is some uncertainty as to when or if such States will choose to establish such a requirement subsequent to finalization of this rule. To address potential gaps in those States that currently lack VCPR requirements applicable to VFDs, we are changing the regulatory text to specify that in those States that require a VCPR that includes the key elements of the Federally defined VCPR in order for a veterinarian to issue a VFD, the veterinarian issuing the VFD must be operating within the context of a VCPR as that term is defined by the State. In all other cases, the veterinarian must be operating within the context of a valid VCPR as defined by FDA in § 530.3(i).

A review of the States that have VCPR requirements in place that are applicable to the issuance of VFDs reveals that those VCPR requirements typically provide that the animals or premises must recently have been seen by the veterinarian, or that the veterinarian otherwise have on-farm knowledge of the animals sufficient to make a diagnosis. Some States go further, requiring that the animals must have been seen by the veterinarian within a certain timeframe, or that the veterinarian has performed an actual examination of the animals. FDA, therefore, believes that recognizing State professional standards for issuing a VFD in accordance with VCPR requirements as prescribed by State law or, where no applicable State VCPR requirements exist, requiring the VFD to be issued in compliance with Federally defined VCPR requirements, addresses the concern raised by these comments that some States currently lack VCPR requirements applicable to VFDs, as well as the concern that the veterinarian should be required to have recently seen the animals specified in the VFD or visited the farm on which the animals are kept.

(Comment 14) A large number of comments did not specifically mention a VCPR requirement, but more broadly supported veterinary supervision and oversight of the VFD process.

(Response 14) We agree that veterinary supervision and oversight is important in the issuance of a VFD. We believe that the requirements we have included in the regulatory text will help ensure adequate veterinarian oversight and supervision over the use of VFD drugs in animal feed and are responsive to the comments received.

(Comment 15) A number of comments supported the proposed intent of the December 2013 NPRM to defer to State standards for the practice of veterinary medicine. These comments supported allowing flexibility for States to set practice standards that address the particular needs and concerns of the State, including the issue of veterinary shortages. Several comments also supported the intention to recognize professional expertise and oversight by State licensing boards to enforce professional conduct and practice requirements.

(Response 15) We agree that the practice of veterinary medicine has traditionally been regulated at the State level and that the States generally are in a better position to establish and enforce the requirements of the practice of veterinary medicine. However, not all States have appropriate VCPR requirements specifically applicable to the issuance of a VFD. As a result, we believe that the approach we proposed in the December 2013 NPRM to defer to State practice standards needs to be supplemented with Federally defined VCPR requirements that apply to States without such requirements, so that all VFDs will continue to be issued under veterinary supervision and oversight within the context of a defined and appropriate VCPR. This approach addresses both our original intent, as well as the concerns raised in the comments.

(Comment 16) A number of comments raised the concern that there is a shortage of veterinarians, or veterinarians with specialized expertise, in certain geographical areas. One comment said that the regulation did not fully address the veterinary shortage issue. A few comments requested that the rule should include an exemption for farms that have limited access to veterinarians, or FDA should make funds available to ensure the farms have access to veterinarians for treatment of sick animals. One comment requested that FDA work with USDA on an assistance program for small farmers to enable access to veterinary care and support the study of large animal medicine so more veterinarians will enter the field. At least one comment cited studies from the American Veterinary Medical Association (AVMA) and the Cornucopia Institute documenting the lack of access to affordable and competent veterinarians in rural areas. This comment also stated that, according to the American College of Poultry Veterinarians, there are only 235 veterinarians available to the poultry industry in the United States. One comment suggested that an exemption be made for farmers who cannot access a veterinarian and for species where the drug administration route of best efficacy is feed or water.

(Response 16) We recognize and share the concerns raised in the comments regarding the challenges that animal producers may face in accessing qualified veterinary care. In light of these concerns, FDA also carefully considered the feedback received on this issue from the April 2012 draft proposed regulation and the 2013 public meetings with stakeholders in rural areas to identify regulatory changes that might help to mitigate this concern. For example, FDA's intent in proposing in the December 2013 NPRM to remove the ''one-size-fits-all'' Federally defined VCPR standard was to allow the veterinary profession and States the flexibility needed ''to adjust the specific criteria for a VCPR to appropriately align with current veterinary practice standards, technological and medical advances, and other regional considerations'' (78 FR 75515 at 75518). In the NPRM, we stated that this 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'' (78 FR 75515 at 75518). We believe this proposed change provides the flexibility needed for States with a VCPR requirement for VFDs to address the concern regarding access to qualified veterinary care. As stated in ''Response 13,'' of this section, for States that do not have an appropriate VCPR requirement as part of their VFD regulations, we are adding a requirement to this final rule that when issuing VFDs, veterinarians must operate within the context of a valid VCPR as defined by FDA in § 530.3(i). We believe that this approach strikes the appropriate balance, allowing adequate flexibility for States to account for limited veterinary resources while still providing a Federal assurance of appropriate oversight.

As veterinary oversight of the therapeutic use of certain medically important antimicrobials is phased in, FDA will continue to seek opportunities to work with our Federal, State, and other stakeholder partners to help address the practical issues associated with limited access to veterinary services in certain parts of the country.

(Comment 17) A few comments raised the concern that requiring veterinarian supervision and oversight would impose an unreasonable financial burden on small farmers. As a solution, these comments stated that a VCPR should be required only for confinement agricultural feeding operations and farms with more than $300,000 turnover, and small producers should be exempt from VCPR requirements. One comment suggested an exemption for species where the feed or water route of administration is the only practical means of effectively administering antimicrobial therapy.

(Response 17) We disagree that the requirements for veterinarian supervision and oversight should not apply to the VFDs issued to small farmers or for certain species. Section 504 of the FD&C Act (21 U.S.C. 354) requires that VFD drugs be used under a veterinarian's supervision. As a result, veterinary supervision for the use of VFD drugs is required, whether or not certain animal producers or operations would be exempt from State or Federally defined VCPR requirements. Therefore, exempting small animal producers or certain species from VCPR requirements would not likely result in any cost savings for their use of VFD drugs because the statute requires the veterinarian to be involved in the issuance of a VFD. In addition, it would be difficult and confusing for veterinarians to determine whether such an exemption would apply. For these reasons, FDA does not believe that this proposal is a viable solution.

Furthermore, FDA does not believe that continuing to require a VCPR, whether State or Federally defined, to issue a VFD results in an unreasonable financial burden on animal producers. FDA continues to believe that veterinary oversight of the use of medically important antimicrobial drugs in feed is a critical measure for ensuring judicious use of these drugs in support of efforts to minimize antimicrobial resistance. Maintaining a requirement for an appropriate VCPR is a fundamental element of providing for meaningful veterinary oversight. FDA will continue to seek opportunities to work with our Federal, State, and other stakeholder partners to help address the practical issues that arise as veterinary oversight of the therapeutic use of certain medically important antimicrobials is phased in.

(Comment 18) A few comments stated that the requirement for supervision and oversight was not clear, or advocated for specific requirements to be included as part of supervision and oversight. These comments requested more specific guidelines describing the amount of time the veterinarian must spend on the farm or ranch, how recently the veterinarian must have seen the animals or farm, whether the veterinarian needs to see the animals or visit the farm in person, and what it means for a veterinarian to be familiar with the client's operation. The comments also expressed concern that veterinarians be licensed in each State where there is a facility under the operation, and that the facility should be recently visited so that the veterinarian is familiar with the local conditions in which the animals are raised.

(Response 18) We have addressed these concerns by including more specific language about the requirements for veterinary supervision and oversight, including compliance with State licensing and practice requirements and the continued role of a VCPR in § 558.6(b)(1). The State and Federal definitions of VCPR set out the requirements for the veterinarian to establish an appropriate relationship with the client and the animal(s) for which services are being provided.

The first element of the Federal VCPR is that ''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'' (§ 530.3(i)(1)). For the States that define a VCPR, all but one State includes in their definition a statement about the responsibility the veterinarian assumes in making medical judgments about the animal's health. Many of the States go further and specify the owner or animal producer's responsibility to follow the veterinarian's instructions.

The second element of the Federal definition of VCPR states that ''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) . . .'' (§ 530.3(i)(2)). In addition, the definition states that ''[s]uch 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'' (§ 530.3(i)(3)). Typically, a veterinarian has an ongoing relationship with the client and the client's animals being treated such that the veterinarian is familiar with the animal production operation and has made previous visits to their facility(s). This relationship also allows the veterinarian to provide education to the client about appropriate use of medication, including storage, use, and withdrawal times. FDA expects that a veterinarian will only authorize use of a VFD feed in animals for which he or she has such knowledge and familiarity. For the States that define a VCPR, all but one State includes in their definition a statement about the veterinarian's knowledge of or acquaintance with the animal or operations. Most of the States that incorporate this knowledge or acquaintance criterion in their VCPR definition provide similar detail to the Federal definition about what constitutes sufficient knowledge, such as requirements that the veterinarian has recently seen and is personally acquainted with the keeping and care of the animal(s) by an examination or medically appropriate and timely visits. Some States are even more specific and specify the time period in which the animal must have been seen by the veterinarian. A few States do not have a knowledge or acquaintance criterion, but instead require that the veterinarian has actually examined the animal or a representative segment of the consignment or herd. Thus, in most States, these requirements regarding responsibility are the same or similar to the current Federal definition.

The third element of the Federal VCPR is that ''The practicing veterinarian is readily available for followup in case of adverse reactions or failure of the regimen of therapy'' (§ 530.3(i)(3)). The State VCPR definitions vary the most among each other and from the Federal definition in what they require regarding followup care. Seven States that define VCPR do not specify in their VCPR a requirement for followup veterinary availability. The primary role of the veterinarian in issuing a VFD is the supervision and oversight needed for the issuance of the VFD and feeding of the VFD feed. Even though some States do not have specific requirements about how readily available the veterinarian must be for followup, these States all have a requirement that the veterinarian is knowledgeable of, or acquainted with the animals, or farm, and/or the veterinarian has assumed the responsibility for making medical judgments regarding the health of the animal and its need for medical treatment.

Most of the States that have a VCPR requirement that applies to the issuance of VFDs define a VCPR in a manner consistent with the Federal VCPR. Like the Federally defined VCPR, the key elements of a VCPR for many of these States includes the requirements that the veterinarian issuing a VFD assume responsibility for the medical care of the animal and have sufficient knowledge of the animal or herd based on having recently seen and being personally acquainted with the keeping and care of the animals and/or perform an actual examination of the animal or herd or make timely visits to the operation. For that reason, we believe that deferring to the State VCPR standard for those States that define an appropriate VCPR applicable to VFDs will allow States the needed flexibility to factor regional considerations into their VCPR requirements while, at the same time, continuing to provide sufficient protection for human and animal health. In those States that do not define a VCPR that includes the key elements in the Federally defined VCPR, or in the States that define a VCPR but do not require it for the issuance of a VFD, the veterinarian is required to issue the VFD within the context of a valid VCPR as that term is defined by FDA at § 530.1(i). FDA will work with States to finalize its list of the States that have an appropriate VCPR that applies to VFDs. Once that task is complete, FDA will communicate that information to the public as part of the implementation of this final rule. FDA will also continue to work with the States and veterinary associations to foster the adoption of VCPR definitions that are sufficiently rigorous to ensure meaningful veterinary supervision and oversight.

With respect to the comment suggesting that a veterinarian who writes VFDs for a particular animal production operation needs to be licensed in each State where that operation has a facility, we disagree that such a requirement is necessary unless such licensing is required by the States where those facilities are situated. In other words, the veterinarian needs to be in compliance with the licensing requirements in the State(s) in which he or she is practicing veterinary medicine. The State laws and rules for licensing and practice determine for what activities a license is necessary and whether reciprocity or other programs that recognize licensure in another State may apply. It is the responsibility of the veterinarian to be familiar with the licensing and practice requirements for his or her activities in each State in which he or she practices veterinary medicine. A client who operates in multiple States may engage with one veterinarian who is in compliance with all of those States' licensing requirements, or may choose to engage more than one veterinarian to ensure that a veterinarian is available who complies with each of those States' licensing and practice requirements.

(Comment 19) Some comments raised concerns with FDA's proposed language and the potential impacts on public health if the Federal VCPR standard is eliminated. Comments also expressed concern with the lack of a description or explanation in the NPRM of how the Federal standard is overly burdensome, how State regulations and voluntary ethical principles will adequately substitute for a VCPR, and why a Federally defined VCPR is unnecessary to ensure appropriate use of VFD drugs when it is appropriate to guide drug use in other contexts.

(Response 19) As discussed elsewhere in this document, our intention was not to eliminate a VCPR standard, but instead to provide the flexibility of relying on States' standards for veterinary professional conduct, which are based on current veterinary practice standards, technological and medical advances, and other regional considerations. As discussed elsewhere in this document, based on the State defined VCPR standards that exist currently, we believe that an appropriate State defined VCPR standard affords a level of veterinarian supervision and oversight similar to the Federal VCPR standard, and helps ensure animals are being provided VFD drugs judiciously and for approved indications. Therefore, we do not think that this change will affect public health.

We stated in the December 2013 NPRM that our intent was to provide greater flexibility for veterinarians by deferring to the individual States for the specific criteria for acceptable veterinary professional conduct. In the final rule, the Agency has affirmed its decision to defer to State practice standards for acceptable veterinary professional conduct when those standards require a VCPR for the issuance of a VFD that includes the key elements of the Federally defined VCPR standard. In response to comments that some State practice standards do not require a VCPR for the issuance of a VFD, and because a VCPR is an important part of veterinarian supervision and oversight in the VFD process, we will require adherence to the Federally defined VCPR if an applicable and appropriate State VCPR standard is not in place.

As we have stated previously, many States have defined VCPR, and require a VCPR to exist in order for a veterinarian to issue a VFD. Many States also explicitly adopt the AVMA Principles of Veterinary Medicinal Ethics as part of their practice requirements, which includes a VCPR definition (Ref. 8). For States with a VCPR definition that does not include key elements of the Federally defined VCPR, or who do not require a VCPR for issuing a VFD, language in the regulatory text requires veterinarians to issue VFDs in compliance with the Federally defined valid VCPR. For the reasons stated previously, FDA believes a hybrid State and Federal VCPR approach is appropriate to help ensure sufficient veterinary oversight and supervision for the use of VFD drugs in or on animal feed.

(Comment 20) Several comments were concerned that the elimination of the Federally defined VCPR as proposed in the NPRM would result in FDA no longer being able to take enforcement action against veterinarians who issue a VFD for animals outside the context of a VCPR. Several comments supported FDA engaging in outreach and education to feed mills and veterinarians on the subject of veterinarian supervision and oversight as it pertains to VFDs as part of this Agency's compliance and enforcement processes.

(Response 20) We agree that it is important for regulations to be enforceable. The approach in the regulatory text allows either the States

or FDA to take enforcement action, depending upon the VCPR requirements at issue. If a veterinarian issues a VFD without complying with applicable State licensing and practice requirements, including VCPR, the State may take enforcement action and FDA may determine the resulting animal food to be adulterated or misbranded. If the Federally defined valid VCPR standard is applicable and the veterinarian fails to comply, FDA may act to enforce compliance. In addition, if the veterinarian is not complying with State licensing or practice requirements, or is not issuing a VFD within the context of the applicable State or Federally defined VCPR, the VFD issued will not be lawful. A VFD drug is limited by the terms of its approval, conditional approval, or index listing to use in or on animal feed only under a lawful VFD. If animal feed containing a VFD drug is fed to animals without a lawful VFD, then the VFD drug would be considered unsafe under section 512(a)(1) of the FD&C Act (21 U.S.C. 360b(a)(1)) and adulterated under section 501(a)(5) (21 U.S.C. 351(a)(5)) of the FD&C Act. In addition, the animal feed bearing or containing the VFD drug will be considered adulterated under section 501(a)(6) of the FD&C Act. A VFD drug and animal feed containing such a drug also will be considered misbranded under section 502(f) of the FD&C Act (21 U.S.C. 352(f)) unless the drug and feed are labeled, distributed, held, and used in compliance with the applicable VFD requirements.

FDA is committed to working with the State entities that license veterinarians in order to ensure that appropriate action is taken if the veterinarian does not issue VFDs in the context of an appropriate VCPR, or does not follow State licensing or practice requirements.

(Comment 21) A few comments requested clarification about the use of the terms ''veterinary supervision'' and ''veterinary oversight'' as used in the VFD regulation. The comments asked whether ''oversight'' means something different than the term ''supervision'' which is used in section 504, or whether the two terms are meant to be synonymous. The comments were concerned that oversight could be performed in place of supervision and that it was a less-stringent standard. One comment requested that FDA define ''supervision or oversight'' to mean that the veterinarian has visited the premises at least once per year or documented why an alternative visitation schedule is more appropriate.

(Response 21) For purposes of this regulation, the term ''oversight'' is meant to be a synonym of ''supervision.'' The phrase ''supervision or oversight'' was introduced in order to tie the oversight language FDA has used in other documents to the concept of veterinary ''supervision,'' which is the term used in section 504 of the FD&C Act. As discussed previously, the VCPR which is required for issuing a VFD controls how recently a veterinarian needs to have examined the animals or operation. As a result, FDA does not find it necessary to define the phrase ''supervision or oversight'' to mean that the veterinarian has visited the premises within a specific timeframe.

(Comment 22) A few comments were concerned about a potential conflict of interest between the veterinarian and the client. One comment said that the veterinarian should not have a fiduciary tie to production. One comment said that an oversight committee should be established to independently approve antibiotic use.

(Response 22) We understand the concern raised by these comments. However, most State practice requirements have a standard of ethics that addresses what constitutes a conflict of interest and the ethical standards veterinarians must observe in such circumstances. The requirement for the veterinarian issuing the VFD to comply with all State practice requirements includes compliance with standards of ethical conduct.

We disagree that an oversight committee should be established to independently approve antibiotic use. Currently, there are several points of oversight in the use of antibiotics. The drug is first reviewed for safety and effectiveness as part of the approval or indexing process. During this process, parameters are set that limit the drug's use to certain conditions and for certain approved uses, as reflected on the drug's approved labeling (Refs. 9, 10, and 11). In addition, VFD drugs are required to be used under a veterinarian's supervision. The veterinarian's role is to make a medically-based decision as to whether a particular VFD drug or combination VFD drug is appropriate for the treatment, control, or prevention of a specific disease. Should the veterinarian determine that a VFD drug should be used, he or she can only use the drug as stated on the approved labeling of that drug. Extralabel use (ELU) of medicated feed, including VFD feed, is prohibited by statute.

Furthermore, as part of the effort to implement the objectives of the National Strategy for Combating Antibiotic Resistance published in September 2014, FDA will be working with veterinary organizations, animal producer organizations, and other partners to identify and implement measures to foster stewardship of antibiotics in animals. These measures include educational outreach to veterinarians and animal producers to advance antibiotic stewardship and judicious use of antibiotics in agricultural settings (Ref. 12).

(Comment 23) Several comments supported ELU being allowed by veterinarians for VFD drugs.

(Response 23) ELU of a new animal drug in or on animal feed is illegal and results in the drug and feed being deemed unsafe under section 512(a) of the FD&C Act and adulterated under sections 501(a)(5) and (6) of the FD&C Act.

b. Veterinarian Licensing Information

In the December 2013 NPRM, we proposed to remove the requirement that veterinarians include their license number and the name of the issuing State on the VFD. We received several comments on this issue and, after consideration of these comments, we are finalizing our proposal to not require veterinary licensing information on the VFD.

(Comment 24) One comment requested that we require the veterinarian to list their license number and State of licensure on the VFD for traceability and accountability. This comment indicated that these requirements were not a burden on the veterinarian because veterinarians use preprinted forms, and adding this information to their electronic signature is a one-time effort that takes only minutes to complete. A few comments supported the proposed change because they thought the required name and address of the veterinarian on the VFD would be sufficient if follow up with the veterinarian ever became necessary.

(Response 24) We disagree that including the veterinarian's license number and State of issuance on the VFD is necessary for traceability or accountability. The issuing veterinarian's name and address is sufficient for FDA to work with the State veterinary licensing boards to determine licensure status, in the event that there is a concern that a VFD has been illegally issued. Also, many State licensing boards maintain an online database that allows the public to search for a veterinarian's licensing status by their name.

We disagree that the low burden is outweighed by the benefit of requiring this information, because we do not believe that this information provides any additional benefit to determining the licensure status of veterinarians.

Even if this information were to be required on the VFD, we would still need to perform an investigation into the licensing status of the issuing veterinarian in the event that there was a concern and the veterinarian's name and address is sufficient information to perform that investigation. In addition, some veterinarians may choose not to use preprinted forms or electronic signatures. For veterinarians who do not use preprinted forms or electronic signatures, the recordkeeping burden would be substantially greater than the comment suggests. Because this information would create a time burden for the veterinarian and does not provide information that aids our ability to investigate a veterinarian's licensure status, we are not including this requirement in the final regulatory text.

c. Name of Animal Drug (§ 558.6(b)(3)(vi))

(Comment 25) One comment requested clarification on whether it is allowable to use an approved generic VFD drug as a substitute for an approved pioneer VFD drug in cases where the pioneer VFD drug is identified on a VFD.

(Response 25) The veterinarian is required to write the name of the VFD drug on the VFD. The veterinarian may choose to write the name of the pioneer or a generic (if available) VFD drug to complete this requirement. The veterinarian may choose to specify that a substitution by the feed manufacturer of either the pioneer or generic VFD drug identified on the form is not allowed. If the veterinarian does not specify that a substitution is not allowed, the feed manufacturer may use either the approved pioneer or an approved generic VFD drug to manufacture the VFD feed. However, the feed manufacturer may not substitute a generic VFD drug for a pioneer VFD drug in a combination VFD feed if the generic VFD drug is not part of an approved combination VFD drug.

d. Client Name and Address (§ 558.6(b)(3)(ii))

(Comment 26) A few comments requested clarification about whether the feedlot manager's information is the correct information for the client name and address.

(Response 26) The client name and address should reflect the client in the veterinarian-client-patient relationship, which is typically the person responsible for feeding the animals the VFD feed. In many cases, a feedlot manager may be the appropriate individual.

e. Premises at Which the Animals Specified in the VFD Are Located (§ 558.6(b)(3)(iii))

The December 2013 NPRM proposed to retain the existing requirement that the location of the animals be specified on the VFD. In the proposed language, this requirement was listed separately from the required information about the number and species of animals. The NPRM also proposed to allow the issuing veterinarian, at his or her discretion, to provide more detailed information about the location of the animals to be fed the VFD feed. The regulatory text in this final rule reflects the approach proposed in the NPRM.

(Comment 27) A few comments suggested that the site or location at which the animals are located be determined broadly (*i.e.,* the location of the premises where animals are located, but not the specific pen or confinement unit). A few comments were concerned that animals move throughout their life cycle and it may be difficult to identify one location.

(Response 27) We expect that, in response to the requirement to enter information describing the premises where the animals are located, the veterinarian would enter information about the location of the animals that would allow someone to locate the animals. Typically, the address would be an appropriate way to identify the location; however, other generally recognized geographical indicators such a global positioning system (GPS) coordinate may be appropriate if a street address does not exist.

We recognize that an address for a facility may not provide enough information to identify the location of animals in a case where the VFD is meant to authorize that a very specific group of animals receive the animal feed bearing or containing the VFD drug. As a result, the veterinarian may use his or her discretion to enter additional information on the VFD that more specifically describes the location of the animals such as the site, pen, barn, stall, tank, or other descriptor. The veterinarian should consult with the client to determine whether the animals will remain at this more specific location until the expiration date of the VFD.

We understand that some groups of animals that are of similar age, weight range, etc., are managed in a similar manner, but may be housed in different physical locations. For example, a group of weaned pigs may be moved out of a nursery facility and transferred to multiple grow-out facilities for finishing. If a VFD is intended to authorize the use of a VFD feed in an identified group (approximate number) of animals that are located at more than one physical location, it is acceptable for a veterinarian to include multiple specified locations for that group of animals on the VFD. The veterinarian may write a VFD that covers animals in multiple locations (animal production facilities) to be fed the VFD feed by the expiration date on the VFD, provided he or she can do so in compliance with professional licensing and practice standards and provided the VFD feed is supplied to such multiple locations by a single feed manufacturer (distributor).

f. Expiration Date (§ 558.6(b)(3)(v))

The December 2013 NPRM proposed to add new language to the requirement that the veterinarian enter the expiration date of the VFD on the form. The new language limits the veterinarian to using the expiration date that is specified in the approval, conditional approval, or index listing. Where such date is not specified, the veterinarian can write a VFD with an expiration date that does not exceed 6 months after the date of issuance of the VFD. The regulatory text in this final rule reflects this approach, with clarified language.

(Comment 28) Many comments supported the 6-month expiration period. Some comments also requested that the VFD expire when an animal is deceased, at 6 months, or based on the expiration date specified in the approved labeling, whichever is shorter.

(Response 28) We agree that a maximum 6-month expiration date in the absence of an expiration date specified in the approval, conditional approval, or index listing is appropriate. The date of expiration should be calculated by the calendar date, not the number of days. This will allow for easy calculation by veterinarians in the field. For example, using a 6-month expiration date for a VFD, if the VFD is written on July 10, then the expiration date would be January 10 of the following year. Using the same 6-month expiration date example, but having the VFD written on the last day of the month, the VFD expiration date would be the last day of the sixth month even if that month has fewer days. Thus, in this example, if the VFD is written on August 31, the expiration date would be the following February 28 during a regular calendar year, or February 29 during a leap year.

With respect to the comments requesting to have the VFD expire when an animal is deceased, at 6 months, or based the expiration date specified in the approved labeling, whichever is shorter, we do not agree with these

comments. Having the VFD expire when an animal is deceased is not practical because one death in a herd or flock of animals would result in an unlawful VFD. However, if there is no expiration date specified in the approval, conditional approval, or index listing, the veterinarian may write an expiration date shorter than 6 months based on their medical judgment and taking into account factors such as the life cycle of the animals being treated. If there is an expiration date specified in the approval, conditional approval, or index listing, then the veterinarian has to use that date and may not write a shorter or longer expiration date for the VFD. Deviating from the expiration date specified by the approval, conditional approval, or index listing would constitute ELU, which is prohibited by section 512(a) of the FD&C Act.

(Comment 29) Many comments requested the expiration period be shorter than 6 months. One comment requested that the VFD expire at the end of treatment. Some comments recommended expiration periods of 21 and 30 days. One comment recommended that the maximum expiration period be shortened to 90 days if VFD drugs are used for unapproved uses or for longer than 6 months, with the possibility of extension upon reassessment.

(Response 29) We disagree that a shorter expiration period is necessary for VFD drugs that do not specify an expiration date in their approval, conditional approval, or index listing. Even though a VFD can be written for a 6-month period does not mean the veterinarian will write all VFDs with a 6-month expiration date. The veterinarian will use his or her medical judgment to determine what expiration date is appropriate for the VFD, based on many factors including, but not limited to, the type of animal production facility and operation, the VFD drug or combination VFD drug at issue, the intended use of the VFD drug, and the health status, treatment history, and life cycle of the animals.

Also, a maximum expiration period of 6 months does not necessarily mean that the animals will consume the feed containing the VFD drug for 6 months. Rather, an expiration period of 6 months means that the authorization to feed the specified VFD product is lawful for 6 months. The veterinarian is also required to include on the VFD the duration of use, which limits the amount of time the animal feed bearing or containing the VFD drug can be fed. The duration of use must follow the duration that is specified in the approval, conditional approval, or index listing even if it is a shorter timeframe than the expiration date. If the veterinarian issues a new VFD after the expiration date of the first VFD, they can use their medical judgment, taking into account factors such as the life cycle and treatment history of the animal, to consider what expiration date would be appropriate for the new VFD, up to the 6-month maximum for VFD drugs that do not specify an expiration date in the approval, conditional approval, or index listing.

We disagree that a shorter VFD expiration period should be in place for VFD drugs used for unapproved uses, or those used longer than 6 months. Medicated feeds, including those bearing or containing a VFD drug, cannot legally be used in an extralabel (unapproved) manner; such use is prohibited by statute. As explained previously, the expiration date of the VFD does not control how long the VFD drug is to be used, but rather defines when it must be used by (*i.e.,* the period of time for which the authorization is lawful).

(Comment 30) Some comments requested that the maximum expiration date of a VFD be longer than 6 months. Most of these comments requested that the VFD expiration date be a maximum of 1 year.

(Response 30) We disagree that a maximum expiration date for a VFD should be longer than 6 months for VFD drugs that do not have an expiration date specified in their approval, conditional approval, or index listing. We think that a 6-month maximum VFD expiration date permits veterinarians, based on their medical judgment and knowledge of the animal production operation, to determine on a case-by case basis whether the maximum 6-month period is an appropriate expiration date for the VFD or whether a more limited period is warranted. When deemed appropriate, we expect that flexibility in applying the VFD expiration date can substantially reduce the administrative burden associated with issuing VFDs for a given animal production operation. Limiting the expiration to a maximum of 6 months ensures that the veterinarian is required, at least every 6 months, to review whether factors such as the type of animal production operation, animal health, or the need to use a VFD drug have changed when considering whether to issue another VFD.

(Comment 31) Several comments requested clarification about how the VFD expiration date relates to refills and reorders, the duration of use and the concept of standing orders. Several comments supported VFD drugs having clear limits on the duration of use. These comments did not specifically recommend an expiration date, but offered support for the risk criteria in GFI #152, ''Evaluating the Safety of Antimicrobial New Animal Drugs with Regard to Their Microbiological Effects on Bacteria of Human Health Concerns.'' Several comments were concerned that a VFD drug could be continuously used. Some of these comments requested that FDA not permit the continuous use of a VFD drug.

(Response 31) As previously discussed, the VFD expiration date defines the period of time for which the authorization to feed an animal feed containing a VFD drug is lawful. This period of time may be specified in the approved labeling of a given VFD drug (*e.g.,* 45 days for tilmicosin) or, if not specified in the labeling, the veterinarian must specify an expiration date that does not exceed 6 months. The duration of use is a separate concept than the expiration date and determines the length of time as established as part of the approval, conditional approval or index listing process that the animal feed containing the VFD drug is allowed to be fed to the animals. This period of time is specified in the labeling of the VFD drug (*e.g.,* 21 days for tilmicosin). For example, the currently approved VFD drug tilmicosin has an expiration date of 45 days, which means the client has 45 days to obtain the VFD feed and complete the 21 day course of therapy (§ 558.618). Animals cannot legally be fed the VFD feed after the VFD expiration date.

We acknowledge the comments seeking limits on the duration of use of VFD drugs. However, the duration of use of VFD drugs (*i.e.,* how long the drug is to be given to the animals) is not determined by the VFD regulation, but rather is established as part of the approval, conditional approval, or index listing process and is based on the scientific information submitted about the VFD drug. A VFD issued by a licensed veterinarian authorizes a client to feed the VFD feed to the client's animals. The expiration date of a VFD is the length of time that such authorization is lawful. In contrast, the duration of use limits the length of time that the animals can be fed the animal feed containing the VFD drug. Thus, in the example of tilmicosin, the approval allows a VFD expiration date of 45 days, but the duration of use (*i.e.,* how long the drug is to be given to the animals) is limited to 21 days.

Similar to the concept of refilling a prescription for 30 tablets with another 30 tablets, a refill or reorder in the VFD

context is meant to apply when the feed authorized under the VFD has been exhausted. The refill or reorder would provide authorization to obtain and feed additional VFD feed in the same total quantity and under the same conditions of the existing VFD by the expiration date of that VFD. A veterinarian can only authorize refills or reorders if the labeling of the product in question explicitly permits them. Currently, there are no approved VFD drugs that allow refills or reorders as a condition of their approval, conditional approval, or index listing.

FDA anticipates that the appropriate use of refills or reorders could vary considerably depending on the VFD drug and its use. Since we cannot predict what disease conditions, and what types of VFD drugs for the treatment, control, or prevention of those diseases, may exist in the future, appropriate limitations regarding refills and reorders and how they relate to the expiration date of the VFD must be considered on a case-by-case basis as part of the new animal drug approval process. In the context of antimicrobial VFD drugs, FDA envisions that the refill/reorder concept will have limited applicability.

The term ''standing order'' is not used in the regulatory text included in this final rule, but has been used in public meetings and by industry to refer to the situation in which a veterinarian issues a VFD for a VFD drug that does not have a label-defined VFD expiration date; therefore, the veterinarian is required to apply a VFD expiration date that does not exceed 6 months from the time the VFD is issued. In such a case, the veterinarian, in the context of a VCPR, would use his or her medical judgment and knowledge of the animal production facility and operation to determine the therapeutic needs for the VFD drug by the expiration date established by the veterinarian. As a result, the client would have the VFD authorization in place and could more quickly get the animal feed containing the VFD drug manufactured if and when the animals needed treatment. In addition, this practice would allow for clients with limited access to veterinarians to be able to receive a VFD within the confines of a VCPR and use it at a later date, but within the expiration date of the VFD, when the need for use of the animal feed containing the VFD drug occurs.

g. Approximate Number of Animals To Be Fed the VFD Feed by the Expiration Date on the VFD (§ 558.6(b)(3))

In the December 2013 NPRM, FDA proposed removing the requirement for a veterinarian to identify the amount of feed to be manufactured under the VFD, and modified the requirement to identify the number of animals to instead require the veterinarian to identify the approximate number of animals to be treated under the VFD.

(Comment 32) Multiple comments supported changing the requirement to identify the amount of feed manufactured to instead identify the approximate number of animals on the VFD. These comments recognized the current problems with calculating the amount of feed, including the need to write additional VFDs when feed volume is underestimated and recordkeeping for delivery of feed that only partially fulfills the amount of feed on the VFD. One comment also stated that this change will allow the amount of feed required to be determined by the feed manufacturer, which is how other feed orders are filled.

(Response 32) FDA agrees that the requirement to state the approximate number of animals instead of the amount of feed resolves the problems noted in the comments. FDA agrees that the feed manufacturer, in consultation with the client, has the experience necessary to determine the amount of feed that should be manufactured in order to treat the approximate number of animals identified by the veterinarian on the VFD.

(Comment 33) Several comments were concerned that the approximate number of animals was not clearly defined and were unsure how FDA intended to use the information in enforcing the VFD regulations. These comments were unsure of the scientific basis for specifying the number of animals. The comments were also concerned that the number of animals can change between the time the VFD is issued and the time it expires, and the requirement would add to increased time and costs. The comments requested clarification on the responsibility of the feed mill to address discrepancies between the number of animals and amount of feed.

(Response 33) FDA agrees that further clarity is needed for stakeholders to correctly calculate the approximate number of animals. Therefore, FDA is including additional language in the regulatory text at § 558.6(b)(3)(viii) to clarify how the approximate number of animals should be calculated. The approximate number of animals is the potential number of animals of the species and production class identified on the VFD that will be fed the VFD feed or combination VFD feed manufactured according to the VFD at the specified premises by the expiration date of the VFD. Because the VFD authorization targets the animals that need to be fed the VFD feed, FDA believes the approximate number of animals is an appropriate mechanism to limit the scope of use authorized by the VFD.

FDA recognizes that the number of animals to be covered under the VFD can change by the expiration date; animals may leave or enter the group being fed the VFD feed manufactured under the VFD for a variety of reasons. This is why FDA chose to include the term ''approximate'' in the requirement. FDA believes that veterinarians typically have enough information about the animal production operation to determine the approximate number of animals that will be entering or leaving the operation over a specific period of time.

FDA does not agree that determining the approximate number of animals will increase time or costs. Calculating the approximate number of animals should take less time than complying with the previous requirement to calculate the amount of feed because the calculation will include fewer factors to take into consideration. Furthermore, using the approximate number of animals may decrease costs because clients will have the flexibility to work directly with their feed supplier to ensure that the appropriate amount of feed is provided for the approximate number of animals authorized by the VFD. This reduces the burden of seeking an additional VFD in those cases where, if the previous requirement to specify the amount of feed on the VFD were still in effect, the veterinarian may have underestimated the amount of VFD feed the animals would consume.

FDA expects the feed mill to share expertise and work with the client and veterinarian to determine the appropriate amount of feed to be manufactured for the approximate number of animals authorized by the VFD and to retain the necessary records to document the amount of feed that was manufactured under the VFD. FDA expects that feed mills will only distribute VFD feeds in quantities that are commensurate with the approximate number of animals as specified by the veterinarian in the VFD. FDA anticipates that, as part of its inspectional activities, it will consider such factors as whether the amount of feed manufactured is reasonable relative to the approximate number of animals specified in the VFD.

(Comment 34) One comment was concerned that using the approximate number of animals would lead to overuse or stockpiling of medicated feeds, and would potentially remove veterinarian oversight from the process.

(Response 34) FDA disagrees with this comment. The veterinarian, with input from the client, will be responsible for identifying the approximate number of animals on the VFD. This level of veterinarian involvement is similar to the veterinarian's current role in identifying the amount of feed. FDA expects that feed mills will only distribute VFD feeds in quantities that are commensurate with the approximate number of animals specified in the VFD. In addition, the client has the responsibility to use the VFD feed within the constraints of the VFD as written by the veterinarian.

Furthermore, FDA does not believe that this change will lead to over-purchasing, stockpiling or unregulated use of VFD drugs or the VFD feeds manufactured with them. Medicated feeds can be susceptible to decomposition if they are stored for lengthy periods of time, making it unlikely that clients would stockpile economically valuable medicated feeds. In addition, other requirements on the VFD limit use of the VFD feed to a specified group of animals for a specified time period, which will help to regulate use and prevent stockpiling. FDA believes that feed mills will be able to more accurately determine the amount of feed to manufacture because they can work with the client as batches of feed are shipped under the VFD to adjust the amount of feed as feed consumption rates change among the animals. The Agency believes this will help to prevent overuse.

Therefore, FDA is revising the current requirement for the number of animals to be treated in § 558.6(b)(3)(viii) to mean an approximate number of animals to be fed the VFD feed by 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 VFD. In addition, FDA is removing the existing requirement in § 558.6(a)(4)(vi) for veterinarians to specify the amount of feed to be fed to the animals listed on the VFD, as discussed elsewhere in this document. Veterinarians will instead be required in § 558.6(b)(3)(x) to include the duration of VFD drug use on the VFD in addition to the level of VFD drug in the feed, as is currently required.

h. Refills or Reorders Authorized on the VFD (§ 558.6(b)(3)(xii))

In the December 2013 NPRM, FDA added to the language that requires the number of refills or reorders to be entered on the VFD to account for refills or reorders allowed as part of a conditional approval, or index listing in addition to an approval. FDA has updated the proposed language to clarify that when an approval, conditional approval, or index listing is silent on refills or reorders, they are not allowed.

(Comment 35) Some comments supported refills or reorders to continue to be entered on the VFD if refills or reorders are permitted by the approval, conditional approval, or index listing. A subset of these comments requested clarification about how refills or reorders relate to the other provisions of the VFD regulation and what the phrase ''permitted by the approval, conditional approval, or index listing'' means. One comment suggested that the need for refills or reorders be determined based on the duration of the disease period. One comment asked FDA to remove this requirement because it is likely to cause confusion among animal producers, veterinarians, and feed mills, as many existing OTC products that are changed to VFD status under the GFI #213 process do not have a refill listed on their label.

(Response 35) We agree that if a refill or reorder is permitted as part of the VFD drug approval, conditional approval, or index listing, the veterinarian is required to indicate on the VFD whether he or she is authorizing a refill or reorder and if so, the number of refills or reorders authorized within the limitations permitted by the approval, conditional approval, or index listing. In order for a refill or reorder to be permitted, it must be explicitly allowed in the VFD drug approval, conditional approval, or index listing. Clarifying language has been added to the regulatory text specifying that when the labeling for an approval, conditional approval, or index listing is silent in regards to refills or reorder, a refill or reorder is not permitted.

A refill or reorder is meant to apply to when the feed authorized under the VFD has been exhausted. The refill or reorder would provide authorization to obtain and feed additional VFD feed in the same total quantity and under the same conditions of the existing VFD by the expiration date of the VFD. Currently, there are no approved VFD drugs that allow refills or reorders as a condition of their approval, conditional approval, or index listing. A veterinarian can only authorize refills or reorders if the labeling of the product in question explicitly permits them. Therefore, refills or reorders are not permitted for an approval, conditional approval, or index listing of a VFD drug if the label of such product is silent on the labeling about refills or reorders.

Although there are no refills or reorders permitted for any current VFD drug approvals, there may be future VFD drugs that may be appropriately refilled or reordered as authorized by the veterinarian on the VFD according to their professional judgment up to the maximum number permitted by the VFD drug approval, conditional approval, or index listing. FDA anticipates that the appropriate use of refills or reorders could vary considerably depending on the VFD drug and its use. Since we cannot predict what disease conditions, and what types of VFD drugs for the treatment, control, or prevention of those diseases, may exist in the future, appropriate limitations regarding refills and reorders and how they relate to the expiration date of the VFD must be considered on a case-by-case basis as part of the new animal drug approval process. In the context of antimicrobial VFD drugs, FDA envisions that the refill/reorder concept will have limited applicability.

If a veterinarian writes a VFD that authorizes a refill or reorder for a VFD drug that does not permit a refill or reorder, or if the authorization exceeds the number of refills or reorders permitted, FDA would consider that to be ELU of the VFD drug. ELU of a drug on or in animal feed is prohibited by statute.

(Comment 36) Some comments supported limiting the number of refills or reorders. Several comments were concerned that without a limit to refills or reorders, the non-specific use of antibiotics for long periods of time would be allowed, or that veterinarians could write unlimited refills. A few comments requested that the requirement to list the number of refills or reorders on the VFD should be removed because it is difficult for the feed manufacturer to track.

(Response 36) FDA agrees that limiting refills or reorders is appropriate. However, those limitations should be based on the safety and effectiveness data, and intended use as evaluated and determined at the time of the VFD drug approval, conditional approval, or index listing. The approvals and index listings for the current VFD drugs do not permit refills or reorders.

FDA disagrees that the requirement to list the number of the refills or reorders on the VFD should be removed. Should a veterinarian authorize refills or reorders for a VFD drug as permitted by its approval, conditional approval, or index listing, this is necessary information for the feed mill to appropriately manufacture and for the

client to appropriately feed the VFD feed.

i. Combination Drugs (§ 558.6(b)(6)(xiv))

In the December 2013 NPRM, FDA proposed a new provision that would require the issuing veterinarian to include one of three ''affirmation of intent'' statements on the VFD regarding the use of a VFD drug in an approved, conditionally approved, or indexed combination in medicated feed. These ''affirmation of intent'' statements would either: (1) Allow the VFD drug to be used in any approved, conditionally approved, or indexed combination in VFD feed; (2) allow the VFD drug to be used only in specific approved, conditionally approved, or indexed combinations in VFD feed; or (3) not allow the VFD drug to be used in any approved, conditionally approved, or indexed combination in VFD feed. We received several comments on this new provision and have revised the language in the regulatory text to provide additional clarity in response to the comments received.

(Comment 37) A few comments expressed concern that the veterinarian would not have sufficient knowledge of approved combination VFD drugs. They were concerned that the veterinarian would write a VFD allowing a combination VFD drug that was not approved, conditionally approved, or indexed, or that he/she would not authorize a VFD for a combination VFD drug that was approved, conditionally approved, or indexed.

(Response 37) We understand this concern and have clarified the language in the regulatory text to more explicitly state the three ''affirmation of intent'' statements the veterinarian may make. These ''affirmation statements'' facilitate the process by which a veterinarian indicates his or her intent for authorizing the use of a VFD drug with other drugs (*i.e.,* approved, conditionally approved, or indexed combination VFD drugs) to make combination VFD feeds. If such statements were prepopulated on the VFD provided by the sponsor, we anticipate that the veterinarian would only have to circle, provide a check mark, or use another method to clearly indicate whether the VFD drug: (1) May be used in any approved, conditionally approved, or indexed combination in VFD feed; (2) may be used in only specific approved, conditionally approved, or indexed combinations in VFD feeds; or (3) may not be used in any approved, conditionally approved, or indexed combination in VFD feed. If the VFD drug is approved, conditionally approved, or indexed for use in multiple combination VFD feeds, and the veterinarian does not want the VFD drug to be used in all approved, conditionally approved, or indexed combinations in medicated feeds, then the veterinarian would need to specify the combination VFD feed(s) in which the veterinarian is authorizing the VFD drug to be used.

This process of affirming intent will reduce the opportunity for a veterinarian to mistakenly authorize an illegal combination of drugs when he or she chooses to only authorize the VFD drug to be used in certain combination VFD feeds. In addition, veterinarians that create their own VFD can rely on the drug labeling to determine whether the drug is approved, conditionally approved, or indexed to be used in combination with another drug or drugs. In the situation where a VFD is authorizing the use of two or more VFD drugs in an approved, conditionally approved, or indexed combination in VFD feed, the VFD must contain information for all of the individual VFD drugs in the combination. A VFD that authorizes an unapproved combination is not a lawful VFD because ELU of medicated feeds, including feeds containing VFD drugs, is prohibited. We think that this approach balances reducing the risk of an illegal combination being mistakenly included on a VFD with the need for a veterinarian to be able use his or her medical judgment to limit the use of a VFD drug in combination with other drugs.

(Comment 38) One comment requested that additional information be provided in the preamble to the final rule explaining how currently approved, conditionally approved, or indexed combinations of drugs would be used when drugs included in such combinations are changed from OTC drugs to VFD drugs.

(Response 38) We agree that it would be helpful to further clarify the use of approved, conditionally approved, or indexed combination new animal drugs containing a VFD drug and one or more OTC or VFD drugs after such drugs in currently used combinations are changed from OTC to VFD. If any component drug in an approved, conditionally approved, or indexed combination drug is a VFD drug, the combination drug is a combination VFD drug and its use must comply with the VFD requirements. This is because combination drug products must meet the requirements of the drug in the combination that is most strictly regulated. In addition, section 504 of the FD&C Act requires a VFD in order to feed an animal feed bearing or containing a VFD drug to an animal. This is the case whether the VFD drug is being used in or on the feed by itself, or in combination with other OTC or VFD drugs.

An analogous situation is when an approved, conditionally approved, or indexed combination drug contains both Category I and Category II drugs. If the animal feed bearing or containing the combination drug is manufactured from a Category II Type A medicated article, the mill must be licensed and follow the requirements for a licensed medicated feed mill (which are stricter requirements).

j. Veterinarian Must Issue a Written VFD (§ 558.6(b)(7))

(Comment 39) One comment requested that FDA modify the requirement that a veterinarian may not transmit a VFD by phone to state that the veterinarian must not verbally transmit a VFD because technology may allow for a written VFD to be transmitted by a phone.

(Response 39) FDA proposed in the December 2013 NPRM to change this provision for the reasons stated in the comment. FDA finalizes this change in the regulatory text.

k. Contents of the VFD

(Comment 40) One comment requested that mixing directions not be allowed on a VFD because they are on the label directions.

(Response 40) We understand that non-required information that is placed on the VFD can create confusion and make it more difficult to locate required information on the form. FDA recommends the amount of information on the VFD be limited to the required and discretionary information listed in § 558.6(b)(3) and (4). FDA also recommends that non-required information the veterinarian chooses to include on a VFD in addition to the mandatory and discretionary information listed in § 558.6(b)(3) and (4) be in a place and manner that does not interfere with the information listed in § 558.6(b).

(Comment 41) A few comments requested that a uniform VFD format be required.

(Response 41) FDA understands that a uniform VFD format would help clients, veterinarians, and distributors (including feed mills) quickly identify relevant information on the VFD. However, FDA believes that requiring a specified format for the VFD would be too prescriptive. In this final rule, FDA is updating the regulatory text in § 514.1(b)(9) to clarify that as part of the application process, the sponsor must

submit a form that accounts for the information in § 558.6(b)(3) that the veterinarian must ensure is on the VFD and the optional information in § 558.6(b)(4) that the veterinarian may include at his or her discretion. This change will help reduce confusion as to whether a specific format is required. It will also ensure that when a company distributes a VFD form tailored to that company's products, the veterinarian will have an opportunity to complete all of the required and optional information specified in the regulation. We believe that having the VFD form that is provided by the VFD drug manufacturer include the required and discretionary information elements in § 558.6(b) is the best approach. Although many companies distribute for use by veterinarians a VFD form that is specific to their own products, a veterinarian may also create or use a different VFD as long as it contains all of the required information.

3. Responsibilities of Any Person Who Distributes an Animal Feed Containing a VFD Drug or a Combination VFD Drug (§ 558.6(c))

In the December 2013 NPRM, we proposed to remove the requirement for distributors to keep records of receipt and distribution from § 558.6(e). We proposed this change because we were changing the retention period for records under the VFD rule from 2 years to 1 year and these records were already required to be kept by manufacturers to comply with the CGMP requirements set forth in part 225. However, as we considered this final rule, it became apparent that a distinction should be made between distributors who manufacture VFD feed and those who do not manufacture VFD feed, but only distribute VFD feed. The final rule provides that all distributors, regardless of whether they manufacture animal feeds bearing or containing VFD drugs or not, must keep records of receipt and distribution for 2 years from the date of issuance in accordance with § 558.6(c)(3). Although this requirement is duplicative for distributors that manufacture animal feeds bearing or containing VFD drugs and must comply with part 225, it is not duplicative for distributors who do not manufacture animal feeds bearing or containing VFD drugs and do not have to comply with part 225. In addition, we believe it is important that all distributors be required to maintain receipt and distribution records because these records are an important tool to trace the animal feed in the event of a recall or investigation of a potentially misbranded or adulterated product. Furthermore, by explicitly stating all VFD recordkeeping requirements in part 558, distributors are not required to refer to another part of the regulation to determine their specific VFD recordkeeping requirements.

Also, we have added clarifying language that distributors who manufacture animal feed bearing or containing VFD drugs must keep VFD feed manufacturing records for 1 year in accordance with part 225 of this chapter. These manufacturing records are not required to be kept for 2 years unless they are also required to be kept under part 558 (*e.g.,* the distributor's copy of the VFDs and receipt and distribution records).

4. Other Comments

(Comment 42) Multiple comments supported the proposed rule's intent to provide additional efficiency and flexibility in issuing VFDs. Several comments mentioned that providing drugs through animal feed is an important drug delivery tool. Several comments stated that the rule was a step in the right direction, but wanted more done to reduce antimicrobial use. Some comments supported the revisions to clarify that conditionally approved and indexed VFD drugs are included.

(Response 42) FDA believes that the rule achieves its intent to provide additional efficiency and flexibility in issuing VFDs. FDA recognizes the importance of animal feed as a drug delivery tool. FDA recognizes that certain revisions to this rule will facilitate a broader effort to assure the judicious use of antimicrobials in food-producing animals. FDA agrees that this rule provides additional clarity that VFD drugs that are conditionally approved or indexed drugs are also subject to the requirements in this final rule.

(Comment 43) Many comments indicated that FDA's approach should be mandatory, not voluntary. Some comments were concerned that the voluntary approach had no mechanism for enforcement or metric for success. Other comments were concerned that there were loopholes in the rule. One comment thought the rule was not strong enough to stop antibiotic use and antimicrobial resistance.

(Response 43) Many of these comments were unclear as to whether they were referring to the implementation of this rule or FDA's efforts to promote the judicious use of antibiotics in food-producing animals as outlined in the Agency's guidance documents GFIs #209 and #213. To the extent that these comments were applicable to the enforceability of this rule, FDA disagrees that this approach is voluntary. The requirements in the regulatory text are mandatory. As stated in the December 2013 NPRM, the Agency is amending the VFD regulations to make the VFD program as efficient as possible for stakeholders while maintaining adequate protection for human and animal health as FDA implements the judicious use principles for medically important antimicrobial new animal drugs approved for use in food-producing animals.

While not directly relevant to this rulemaking, FDA disagrees with the comments that say a voluntary approach to judicious use of antimicrobials cannot be effective. As of June 30, 2014, all sponsors of medically important antimicrobial new animal drug products covered by GFI #213 have agreed in writing that they intend to engage in the judicious use strategy by seeking withdrawal of approvals relating to any production uses and changing the marketing status of their products from OTC to use by VFD or prescription in order to limit the remaining therapeutic uses of these products in food-producing animals to use under the oversight or supervision of a licensed veterinarian. While GFI #213 specified a 3-year timeframe (until December 2016) for drug sponsors to voluntarily complete the recommended changes to their antimicrobial products, some sponsors have already begun to implement these changes (Ref. 13).

(Comment 44) Several comments requested clarification on how FDA intends to enforce the VFD requirements as drugs change from OTC status to VFD status as part of the implementation of GFI #213. These comments asked whether there would be a period of regulatory discretion, or the allowance of in-commerce labeling changes, in order to handle product on the market when the change occurs.

(Response 44) This question touches upon the broader implementation of GFI #213 and does not pertain specifically to the changes in this the December 2013 NPRM. However, we understand the practical implications of accommodating drug products already in distribution channels and are working to develop and provide further guidance to facilitate an orderly transition of medically important antimicrobial drugs from OTC to a marketing status (VFD or prescription) that requires veterinary oversight.

(Comment 45) One comment asked FDA to delay the implementation of the amended VFD regulation until after the implementation of GFI #213. This comment suggested that there was a conflict of interest in FDA issuing this

final rule before stakeholders had committed to GFI #213.

(Response 45) We have carefully considered all comments in finalizing this rule. As discussed in the December 2013 NPRM, it is important that the changes to increase efficiency in the VFD program occur prior to the transition of the existing medically important antimicrobial drugs approved for use in animal feed from their existing OTC status to VFD status as part of the implementation of GFI #213. Furthermore, at this time, all sponsors of the drugs identified in GFI #213 have publicly committed to fully engage in this Agency's judicious use strategy which calls for phasing out the use of medically important antimicrobials in food-producing animals for food production purposes and phasing in the oversight of a licensed veterinarian for the remaining therapeutic uses of such drugs (Ref. 13).

(Comment 46) Some comments suggested that FDA should collect and publicly report data about whether the effort to end subtherapeutic use of antibiotics is working. A few comments thought that VFDs should be submitted to FDA for compilation, analysis, and public reporting. A few comments opposed submitting VFDs to FDA because of the additional reporting burden. One comment further opposed the submission of VFDs to FDA because VFDs would not be an accurate tool in estimating antimicrobial use because they are reflective of the amount of antimicrobials authorized, not the amount of antimicrobials used. Another comment thought that FDA's access to VFDs during inspections was sufficient to assess compliance.

(Response 46) In response to the suggestion that FDA collect and publicly report data about whether the effort to end subtherapeutic use of antibiotics is working, FDA notes that the Agency has already committed to publishing information every 6 months about the progress of GFI #213 implementation (Ref. 13). In addition, FDA provides ongoing updates on its Web site regarding sponsor actions related to GFI #213 implementation (Ref. 13).

FDA does not agree that VFDs should be submitted for compilation, analysis and public reporting. Compliance with VFD regulations cannot be assessed by only reviewing the VFD. The VFD must be considered in the context of the operation. This review is ordinarily done during an inspection or investigation. FDA agrees that VFD data would not be an accurate reflection of antimicrobial use because the VFD only represents the amount of antibiotics authorized to be used, not the amount that actually is used. FDA currently receives antimicrobial sales and distribution data, collects antimicrobial resistance data under NARMS, and is developing additional mechanisms for collecting on-farm information regarding antimicrobial use and resistance (Ref. 15). It would be administratively burdensome for FDA to also receive, compile, and house VFDs in a central location. Furthermore, there are disclosure laws that would require FDA to redact most, if not all, of the information required on a VFD because it is considered confidential commercial information.

(Comment 47) Several comments were concerned that the changes to this rule did not sufficiently protect public health.

(Response 47) As previously discussed, it was not FDA's intention in the December 2013 NPRM to remove or lessen public health protections. The previous and current VFD regulatory text contains many provisions that are designed to protect public health. The VFD drug designation provides public health protection by allowing FDA to limit a drug's use in or on animal feed by requiring administration under a veterinarian's supervision and oversight as authorized in the VFD. When an animal drug has been designated a VFD drug, the veterinarian, distributor, and client must adhere to additional regulatory requirements than are applicable to the use of other animal drugs in medicated feed. These additional regulatory requirements are designed to protect public health by ensuring accountability for those individuals involved in the use of the VFD drug and VFD feed. These regulatory requirements also are designed to allow FDA to review the use of the VFD drug and VFD feed to ensure that the VFD drug and VFD feed are used according to the conditions and indications of use as specified in the approval, conditional approval or index listing, and within the supervision and oversight of a licensed veterinarian.

The veterinarian, distributor, and client all have several joint obligations that are intended to protect public health. The VFD feed may only be fed to animals by or upon a lawful VFD issued by the veterinarian. Public health is protected by limiting use of VFD drugs and VFD feed to use under the supervision of a veterinarian as indicated on the VFD because the veterinarian has medical expertise to determine when and how a VFD drug may be appropriately used in animals. All of these involved parties share responsibility in ensuring that a lawful VFD has been issued and the VFD feed is manufactured and used according to the terms of the VFD as issued by the veterinarian. Moreover, the regulations require that VFD drugs and VFD feed contain a caution statement that the VFD drug and resulting VFD feed are restricted to use by or on the order of a licensed veterinarian. In addition to the VFD, these involved parties also each have their specific responsibilities in ensuring that the VFD drug and resulting VFD feed is labeled and used according to the approval, conditional approval, or indexed conditions of use (not used in an extralabel manner). The VFD, VFD drug, and VFD feed are all required to contain a statement that ELU is not permitted. During the approval, conditional approval, or indexing process, FDA sets limitations on how animal drugs can be used based on the scientific evidence offered by the sponsor to show that the drug is safe and effective for the conditions of use. Public health is protected by limiting use of VFD drugs and VFD feed to conditions of use that are based on scientific evidence of safety and effectiveness that has been reviewed by FDA.

The veterinarian has several specific obligations that are intended to protect public health. The veterinarian is responsible for using his or her professional veterinary judgment to determine whether a VFD should be issued and what terms the VFD should contain as allowed by the relevant approval, conditional approval, or index listing. The veterinarian issuing the VFD is required to be licensed to practice veterinary medicine and be operating in compliance with applicable licensing and practice requirements. FDA has clarified that compliance with applicable licensing and practice requirements includes the expectation that the veterinarian is issuing the VFD in the context of an appropriate VCPR as discussed elsewhere in this document. The veterinarian is required to issue the VFD in writing and ensure that all of the required information is fully and accurately included on the VFD. The required information reflects several public health protections including, but not limited to information that: (1) Describes VFD drug, VFD feed, and the indication for which the VFD feed is authorized to be used; (2) describes the animal or group of animals to receive the VFD feed; (3) limits the use of the VFD feed based on the duration of feeding, the expiration date and the allowance of refills or reorders, if any; (4) allows or limits the use of the VFD drug in combination

with other animal drugs; and (5) limits the use of the VFD feed based on withdrawal times, special instructions or necessary cautionary statements. The veterinarian is also required to provide to the distributor and client a copy of the VFD. By providing the distributor and client with the required information on the written VFD, the veterinarian ensures that the distributor and client have the necessary information to manufacture and use the VFD feed according to the approval, conditional approval, or index listing, and under the veterinarian's supervision and oversight.

The distributor also has several specific obligations that are intended to protect public health. The distributor may only fill a VFD if the VFD contains all of the required information. This requirement provides an additional opportunity for the VFD to be reviewed to ensure that it is complete and prohibits the distribution of the VFD feed if it is not. The distributor is also required to keep for 2 years the records of receipt and distribution of all of the VFD feed it distributes. This requirement protects public health by requiring records that would be important for tracing the VFD feed through the distribution system if a problem with the VFD feed were to occur. The distributor must notify FDA prior to that party's first distribution of VFD feed and must notify FDA of any changes in the distributor's contact information or ownership. This notification allows FDA to protect public health by maintaining an inventory of VFD feed distributors to be used for inspection and investigational purposes.

The VFD regulation also includes requirements specific to the client (animal producer) that are intended to protect public health. For example, the client may only feed the VFD feed to animals by or upon a lawful VFD issued by a licensed veterinarian in the course of the veterinarian's professional practice. As explained previously, the client is obligated to use the VFD feed as indicated on the VFD and as allowed in the VFD drug's approval, conditional approval, or index listing. Furthermore, the VFD feed cannot be fed to the animals after the expiration date of the VFD. These requirements protect public health by ensuring that the VFD feed is being fed to the animals under the veterinarian's supervision and oversight in accordance with the VFD and the conditions of approval, conditional approval, or index listing for the VFD drug or combination VFD drug at issue.

FDA has the responsibility for enforcing these requirements and ensuring that VFD drugs and VFD feeds are used according to these requirements that are intended to protect public health. The requirements for the veterinarian, distributor, and client allow FDA to review the use of VFD drugs and VFD feed in the field to determine whether VFD drugs and VFD feeds are being used consistent with the VFD issued by the veterinarian, as well as in accordance with the VFD drug's approval, conditional approval, or index listing.

FDA intends to use a phased enforcement strategy for implementation of this final rule. FDA first intends to provide education and training for stakeholders subject to this final rule such as veterinarians, clients (animal producers), feed mill distributors, and other distributors. These education and training efforts are important for supporting effective implementation and compliance with the final rule. As products are changed to VFD status under the GFI #213 process, FDA will then engage in general surveillance, as well as for-cause inspection assignments. These assignments will be risk-based and in response to adverse observations.

(Comment 48) A few comments requested that a prescription be required for farmers to use antibiotics for animals.

(Response 48) Congress enacted legislation in 1996 establishing a new class of restricted feed use drugs that may be distributed without invoking State pharmacy laws, veterinary feed directive drugs. The resulting language in section 504(c) of the FD&C Act explicitly states that veterinary feed directive drugs are not prescription drugs. However, use of a VFD drug requires supervision from a veterinarian and other restrictions that control access to the animal feed containing the VFD drug as it moves through the distribution chain. The regulatory text for this final rule continues to implement the restrictions and supervision as required by the statute.

(Comment 49) Several comments were concerned about the potential for the use of antibiotics in animals to result in drug residues in human food.

(Response 49) During the drug approval process, drug withdrawal requirements are considered and withdrawal limitations set. These withdrawal requirements are based on scientific information and state how soon an animal or products derived from an animal can become food for humans after a drug has been administered. FDA works closely with other Federal and State Agencies to monitor human food for unsafe drug residues and has a compliance program to take enforcement action when unsafe drug residues occur (Ref. 16).

(Comment 50) A few comments stated that antibiotic use has an environmental impact.

(Response 50) FDA is required under the National Environmental Policy Act of 1969 (NEPA) to evaluate all major FDA proposed actions to determine if they will have a significant impact on the human environment. To implement NEPA mandates, the FDA's Center for Veterinary Medicine (CVM) requires sponsors to submit to FDA during the approval process for the proposed use of their animal drug either an environmental assessment (EA) or a claim that it is within a categorical exclusion established by FDA. Categorical exclusions apply to classes of actions which FDA has determined do not individually or cumulatively significantly affect the quality of the human environment, and are ordinarily are excluded from the requirement to prepare an EA or an environmental impact statement (EIS). If a sponsor claims a categorical exclusion, CVM will determine whether the categorical exclusion applies and, if so, whether there are extraordinary circumstances that would require at least an EA. When an EA is submitted, CVM will evaluate the information contained in the EA, and may include additional information in the EA when warranted. If CVM determines that the proposed action may significantly impact the quality of the environment, an EIS must be prepared. If CVM makes a finding of no significant impact on the environment (FONSI) based on the EA, it will issue a FONSI, stating CVM's conclusion not to prepare an EIS (Ref. 17).

(Comment 51) Several comments requested training and outreach on the new VFD requirements. One comment specifically requested that we mandate training on the VFD process for veterinarians prior to allowing them to issue VFDs.

(Response 51) We agree that training and outreach are important components in successfully implementing these regulatory changes. We are engaging professional and trade associations, as well as other stakeholders, to leverage our education and outreach opportunities. However, we do not agree that training should be mandated for veterinarians prior to allowing them to lawfully issue VFDs. The requirements for veterinarians issuing a VFD are not very different or more complicated than other veterinary medical activities that veterinarians perform on a daily basis. We think that voluntary training or self-education, using materials developed by

FDA or other organizations, will be sufficient.

IV. Legal Authority

FDA's authority for issuing this final rule is provided by section 504 of the FD&C Act (21 U.S.C. 354) relating to veterinary feed directive drugs. 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. Final Regulatory Impact Analysis

FDA has examined the impacts of the final 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 (Pub. L. 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 final rule is not a significant regulatory action as defined by Executive Order 12866. We have developed a final regulatory impact analysis (FRIA) that presents the benefits and costs of this final rule to stakeholders and the government.

The Regulatory Flexibility Act requires Agencies to analyze regulatory options that would minimize any significant impact of a rule on small entities. Because the final rule would impose average annualized costs that amount to about 0.1 percent or less of average annual revenues on small entities, FDA concludes that it is very unlikely that the final rule will result in a significant impact on a substantial number of small entities.

The summary analysis of benefits and costs included in the Executive Summary of this document is drawn from the detailed FRIA, 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.* Section 202(a) of the Unfunded Mandates Reform Act of 1995 requires that Agencies prepare a written statement, which includes an assessment of anticipated costs and benefits, before proposing ''any rule that includes any Federal mandate that may result in the expenditure by State, local, and tribal governments, in the aggregate, or by the private sector, of $100,000,000 or more (adjusted annually for inflation) in any one year.'' The current threshold after adjustment for inflation is $141 million, using the most current (2013) Implicit Price Deflator for the Gross Domestic Product. FDA does not expect this final rule to result in any 1-year expenditure that would meet or exceed this amount.

VI. Paperwork Reduction Act of 1995

This final rule contains information collection provisions that are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520). The title, description, and respondent description of the information collection provisions are shown in the following paragraphs with an estimate of the burden for annual reporting, recordkeeping, and third-party disclosure, including one-time burdens triggered upon implementation of this final rule. Included in the 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.

Title: Veterinary Feed Directives.

Description: The final rule will revise existing OMB control number 0910–0363 for veterinary feed directives by providing for greater efficiencies to the VFD process.

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 two VFD drugs under five approved animal drug applications. 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 on March 29, 2010 (75 FR 15387). Based on the considerable public input received in response to the ANPRM, on April 13, 2012, FDA issued for public comment draft text for proposed revisions to the current VFD regulation at part 558 (77 FR 22247).

On December 12, 2013 (78 FR 75515), FDA issued a proposed rule which contained proposed revised information collection requirements at 78 FR 75522 to 75525. Many of the information collection requirements carry over from existing OMB control number 0910–0363; however, the section numbers for some of the information collection requirements have been redesignated in this final rule. Those one-time information collection requirements that are the direct result of this final rule are shown in tables under the heading ''One-Time Costs.'' The remaining information collection requirements associated with this final rule are shown in tables under the headings ''Annual'' or ''Recurring Costs.''

A. Reporting Requirements

Description of Respondents: VFD Feed Distributors, VFD Drug Sponsors

Currently, under § 558.6(d)(1) (redesignated as § 558.6(c)(4)) a distributor of animal feed containing a VFD drug must notify FDA prior to the first time he distributes such VFD feed and this notification is required one time per distributor. Therefore, all active distributors of VFD feed must have already made notification to FDA of their intention to distribute such feed 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 redesignated § 558.6(c)(4) are the same as the current requirements under § 558.6(d)(1), there is no new reporting burden for distributors other than the one-time burden hours and costs described in Table 1. FDA understands that current VFD feed distributors must review the final rule in order to determine which actions are necessary to comply with the new regulation. For these current VFD feed distributors we estimate review of the rule will take a one-time hourly burden of 4 hours to complete.

Burden hours and costs are derived from the Final Regulatory Impact Analysis (FRIA) associated with this final rule. Wage rates have been adjusted in the tables throughout to that reported in the FRIA.

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]

21 CFR 558.6/Activity	Number of respondents	Number of responses per respondent	Total responses	Average burden per response in hours	Total hours	Total costs
One-Time Reporting Burden						
Review of the Rule (VFD Feed Distributors).	1,376	1	1,376	4	5,504	[2] $529,000
Total One-time Reporting Burden	.....	.....	.....	.....	5,504	529,000
Annual (Recurring) Reporting Burden						
558.6(c)(4)—A distributor must notify FDA prior to the first time it distributes a VFD drug.	[3] 300	1	300	0.125 (8 minutes)	37.5	NA
558.6(c)(6)—A distributor must notify FDA within 30 days of any change in ownership, business name, or business address.	20	1	20	0.125 (8 minutes)	2.5	N/A
Total Annual Reporting Hours	.....	.....	.....	.....	40	.....

[1] There are no operating and maintenance costs associated with this collection of information.
[2] 1,376 distributors have notified FDA of their intent to distribute a VFD drug and will need to review the rule. 1,376 VFD feed distributors × approximately $96 per hour for review at the general and operations manager level × 4 hours of one-time review = approximately $529,000. Estimate rounded to be in accordance with the FRIA (see FRIA).
[3] 1,376 distributors have already notified FDA of their intent to distribute a VFD drug. FDA expects that 300 new distributors will choose to distribute VFDs each year.

The number of respondents multiplied by the number of responses per respondent equals the total responses. The total responses multiplied by the average burden per response equals the total hours.

There are additional reporting burdens for current VFD drug sponsors under OMB control numbers 0910–0032 (New Animal Drug Applications) and 0910–0669 (Abbreviated New Animal Drug Applications), described as follows:

All labeling and advertising for VFD drugs, combination VFD drugs, and feeds containing VFD drugs or combination VFD drugs also are reported to FDA under OMB control number 0910–0032 and must prominently and conspicuously display the following cautionary statement: ''Caution: Federal law restricts medicated feed containing this veterinary feed directive (VFD) drug to use by or on the order of a licensed veterinarian'' (§ 558.6(a)(6)). This labeling statement is not subject to review by OMB because it is a ''public disclosure[s] of information originally supplied by the Federal government to the recipient for the purpose of disclosure to the public'' (5 CFR 1320.3(c)(2)). Therefore, an hourly and cost burden estimate 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 are not included.

The VFD must also include the following statement (§ 558.6(b)(3)(xiii)): ''Use of feed containing this veterinary feed directive (VFD) drug in a manner other than as directed on the labeling (extralabel use) is not permitted.'' The burden associated with including this verbatim statement is not subject to review by OMB under the PRA (5 CFR 1320.3(c)(2)).

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:

1. ''This VFD only authorizes the use of the VFD drug(s) cited in this order and is not intended to authorize the use of such drug(s) in combination with any other animal drugs.''

2. ''This VFD authorizes the use of the VFD drug(s) cited in this order in the following FDA-approved, conditionally approved, or indexed combination(s) in medicated feed that contains the VFD drug(s) as a component.'' [List specific approved, conditionally approved, or indexed combination medicated feeds following this statement.]

3. ''This VFD authorizes the use of the VFD drug(s) cited in this order in any FDA-approved, conditionally approved, or indexed combination(s) in medicated feed that contains the VFD drug(s) as a component.'' (§ 558.6(b)(6)).

The burden associated with including these verbatim statements is not subject to review by OMB under the PRA (5 CFR 1320.3(c)(2)). 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 information on the VFD form itself that will occur as the result of this final rulemaking.

Section 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. Each of the three drug sponsors that currently market VFD drugs have created VFD forms for their products. Three VFD drug sponsors × six VFD forms × 16 hours per respondent to make form changes = 96 total hours to change the VFD forms. Changes to the VFD form for the six approved VFD forms (for each of the three current VFD drug sponsors, there are separate VFD forms for each approved species and their related indication(s)) equals six VFD forms × $1,331 cost per form = approximately $8,000 one-time cost (see FRIA). NOTE: The hourly and cost burden estimates to include the revised verbatim statements

noted in this document (on the VFD form itself) are not subject to review by OMB under the PRA. We are unable to measure these hours and costs separately, but consider them to be de minimis. The cost to change the VFD form is considered to include these statement changes.

B. Recordkeeping Requirements

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

Under current § 558.6(f) and redesignated § 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 redesignated § 558.6(a)(4) and redesignated § 558.6(b)(8)–(9)). The VFD includes information about the number and species of animals to receive feed containing one or more of the VFD drugs, along with all other information as required under § 558.6. 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 one-time review for both groups. (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 for each of the two VFD drugs) issued in triplicate equals 2,250,000 VFDs issued and stored in files per year.[1]

Assuming that currently all VFDs are issued and stored in hardcopy, we estimate it takes 300 large file cabinets to 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 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 × 300 equals $180,000).

In the 2013 proposed rule, FDA proposed to reduce the recordkeeping requirement for copies of VFDs for all involved parties (proposed § 558.6(a)(4)) from 2 years to 1 year. After considering public comment, FDA has decided not to reduce the recordkeeping requirement from 2 years to 1 year in this final rule. However, as included in § 558.6(b)(8), the veterinarian will no longer be required to assure that a paper copy is received by the distributor within 5 working days of receipt 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 provision reduces 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 final 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.

Also, 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 × 6 square feet per file cabinet × 150 filing cabinets = $19,575 annual savings for switching to computer storage) (Thorpe, K., J. Edwards, and E. Bondarenko, Cassidy Turley Commercial Real Estate Services. ''U.S. Office Trends Report—2nd Quarter 2013.'' Page 10. *http://www.cassidyturley.com/Research/MarketReports/Report.aspx?topic=U_S_Office_Trends_Report&action=download,* 2nd Quarter 2013).

In summary, we anticipate that the capital costs for recordkeeping will be reduced from $180,000 (storing all VFDs as hardcopies in file cabinets for 2 years) to $90,000 (as described in the FRIA, there is a 50 percent reduction in file cabinet costs due to electronic recordkeeping for 2 years (*i.e.,* to $90,000)) plus $19,575 annual savings to keep VFD records, reflecting the reduction in rental and space costs for file cabinets.

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. As stated previously, distributors may receive an acknowledgement letter in lieu of a VFD when distributing VFD feed to another distributor. Such letters, like VFDs, are also subject to a 2-year record retention requirement. Thus, the recordkeeping burden for acknowledgement letters is included as a subset of the VFD recordkeeping burden. 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 (OMB control number 0910–0363).

[1] Distributors may receive an acknowledgement letter in lieu of a VFD when distributing VFD feed to another distributor. Such letters, like VFDs, are also subject to a 2-year record retention requirement. Thus, the recordkeeping burden for acknowledgement letters is included as a subset of the VFD recordkeeping burden.

TABLE 2—ESTIMATED ANNUAL RECORDKEEPING BURDEN

21 CFR Section 558.6/activity	Number of recordkeepers	Number of records per recordkeeper	Total records	Average burden per recordkeeper in hours	Total hours	Total costs
Estimated One-time Recordkeeping Burden [1]						
Review of the Rule (Food Animal Veterinarians).	3,050	1	3,050	1	3,050	[2] $255,000
Review of the Rule (Clients)	10,000	1	10,000	0.5 (30 minutes)	5,000	[3] 244,000
Recordkeeping by Electronic Storage for 2 years.						[4] (90,000)
Total One-time Recordkeeping Burden.					8,050	409,000
Estimated Annual Recordkeeping Burden [5]						
Filing of VFD copies	14,426	156	2,250,000	0.0167 (1 minute)	[6] 37,575	N/A
Total Annual Recordkeeping Hours.					37,575	

[1] There are no operating and maintenance costs associated with this one-time collection of information.
[2] A total of 3,050 veterinarians × approximately $84 per hour × 1 hour of one-time review = approximately $255,000. Estimate rounded to be in accordance with the FRIA (see FRIA).
[3] A total of 10,000 clients × approximately $49 per hour × 0.5 hours one-time review = approximately $244,000. Estimate rounded to be in accordance with the FRIA (see FRIA).
[4] There will be a one-time savings in capital costs for recordkeeping of $90,000 (as described in the FRIA, there is a 50% reduction in cost due to electronic recordkeeping for 2 years (*i.e.,* 50% reduction in cost of file cabinets needed) and there will be $19,575 annual savings, reflecting the reduction in rental and space costs for file cabinets.
[5] There are no capital costs or operating and maintenance costs associated with this annual collection of information.
[6] 14,426 recordkeepers (3,050 food animal veterinarians + 1,376 distributors + 10,000 clients = 14,426) × 156 records per recordkeeper = 2,250,000 records (3 copies × 750,000 VFDs) × 0.0167 hours to file each record = 37,575 hours.

The number of respondents multiplied by the number of records per recordkeeper equals the total records. The total records multiplied by the average burden per recordkeeper equals the total hours.

C. 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 review. (Review of the rule by VFD feed distributors is accounted for in Table 1 and by veterinarians and clients in Table 2.)

Section § 558.6(b)(8) 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 $84, the labor cost of currently issuing VFDs is estimated at $15.70 million (the estimated average of 750,000 VFDs issued annually × 0.25 hours to issue each VFD × $84 per hour = approximately $15.70 million (rounded to be in accordance with the FRIA)). 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 $7.85 million annually (the estimated average of 750,000 VFDs issued annually × 0.125 hours to issue each VFD × $84 per hour = approximately $7.85 million (rounded to be in accordance with the FRIA)), a cost savings of about $7.85 million ($15.70 million − $7.85 million = approximately $7.85 million.

Currently, a distributor may only distribute a VFD feed to another distributor for further distribution if the originating distributor (consignor) first obtains a written acknowledgement letter from the receiving distributor (consignee) before the feed is shipped (current § 558.6(d)(2)). Because this current requirement is the same as that being finalized in § 558.6(c)(8), there is no new reporting burden.

TABLE 3—ESTIMATED ANNUAL THIRD-PARTY DISCLOSURE BURDEN

21 CFR Section/activity	Number of respondents	Number of disclosures per respondent	Total annual disclosures	Average burden per disclosure in hours	Total hours	Total costs
One-Time Third-party Disclosure Burden [1]						
Review of the Rule, Current VFD Drug Sponsors (General and Operations Managers)	3	1	3	6	18	[2] $2,500

TABLE 3—ESTIMATED ANNUAL THIRD-PARTY DISCLOSURE BURDEN—Continued

21 CFR Section/activity	Number of respondents	Number of disclosures per respondent	Total annual disclosures	Average burden per disclosure in hours	Total hours	Total costs
Total One-Time Third-Party Disclosure Burden					18	2,500
Estimated Annual (Recurring) Third-Party Disclosure Burden [1]						
558.6(b)(7)—Veterinarian issues VFD [3]	3,050	245.9	750,000	0.125 (8 minutes)	93,750	N/A
558.6(c)(8)—Acknowledgment letter generation	[4] 1,000	5	5,000	0.125 (8 minutes)	625	N/A
Total Annual Third-Party Disclosure Hours					94,375	

[1] There are no operating and maintenance costs associated with this collection of information.
[2] Three current VFD drug sponsors × $140 × 6 hours of one-time review time = approximately $2,500 one-time cost. Estimate rounded to be in accordance with the FRIA.
[3] A total of 3,050 veterinarians × 245.9 VFDs issued per year per respondent (on average) = 750,000 VFDs issued per year. This figure × 0.125 hours per form = 93,750 hours per year × $84 per hour = approximately $7,850,000 annual cost. Estimate rounded to be in accordance with the FRIA.
[4] 1,000 VFD feed distributors (of the 1,376 total distributors) × 5 disclosures per respondent = 5,000 annual acknowledgement letters × 0.125 hours = approximately 625 hours.

The number of respondents multiplied by the number of disclosures per respondent equals the total annual disclosures. The total annual disclosures multiplied by the average burden per disclosure equals the total hours.

Additionally, we have clarified in the final rule that, if a distributor manufactures the VFD feed, the distributor must also keep VFD manufacturing records for 1 year in accordance with part 225 and that such records must be made available for inspection and copying by FDA upon request (§ 558.6(c)(4)). These record requirements are currently approved under OMB control number 0910–0152, Current Good Manufacturing Practice Regulations for Medicated Feed.

The information collection provisions in this final rule have been submitted to OMB for review as required by section 3507(d) of the Paperwork Reduction Act of 1995.

Before the effective date of this final rule, FDA will publish a notice in the **Federal Register** announcing OMB's decision to approve, modify, or disapprove the information collection provisions in this final rule. An Agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number.

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 final rule in accordance with the principles set forth in Executive Order 13132. FDA has determined that the final rule will 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 concludes that the final 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. References

The following references have been placed on display in the Division of Dockets Management (see **ADDRESSES**) and may be seen by interested persons between 9 a.m. and 4 p.m., Monday through Friday, and are available electronically at *http://www.regulations.gov.* (We have verified the Web site addresses in this reference section, but we are not responsible for any subsequent changes to the Web sites after this document publishes in the **Federal Register**.)

1. ''Guidance for Industry: The Judicious Use of Medically Important Antimicrobial Drugs in Food-Producing Animals'' (GFI #209), April 13, 2012; (*http://www.fda.gov/downloads/AnimalVeterinary/GuidanceComplianceEnforcement/GuidanceforIndustry/UCM216936.pdf*).
2. ''Guidance for Industry: 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'' (GFI #213), December 2013; (*http://www.fda.gov/downloads/AnimalVeterinary/GuidanceComplianceEnforcement/GuidanceforIndustry/UCM299624.pdf*).
3. FDA, Warning Letters (*http://www.fda.gov/ICECI/EnforcementActions/WarningLetters/default.htm*).
4. ''Compliance Program Guidance Manual: Feed Manufacturing'' (CPGM 7371.004); (*http://www.fda.gov/downloads/AnimalVeterinary/GuidanceComplianceEnforcement/ComplianceEnforcement/UCM113430.pdf*).
5. The Association of American Feed Control Officials (AAFCO), Regulatory Page (*http://www.aafco.org/Regulatory*).
6. ''Guidance for Industry: Veterinary Feed Directive Regulation Questions and Answers'' (GFI #120), March 26, 2009; (*http://www.fda.gov/downloads/AnimalVeterinary/GuidanceComplianceEnforcement/GuidanceforIndustry/UCM052660.pdf*).
7. ''Guidance for Industry Part 11, Electronic Records; Electronic Signatures—Scope and Application'' August 2003; (*http://www.fda.gov/downloads/RegulatoryInformation/Guidances/ucm125125.pdf*).
8. AVMA, Principles of Veterinary Medical Ethics of the AVMA (*https://www.avma.org/KB/Policies/Pages/Principles-of-Veterinary-Medical-Ethics-of-the-AVMA.aspx*).

9. FDA, From an Idea to the Marketplace: The Journey of an Animal Drug through the Approval Process (*http://www.fda.gov/AnimalVeterinary/ResourcesforYou/AnimalHealthLiteracy/ucm219207.htm*).
10. FDA, Conditional Approval Explained: A Resource for Veterinarians (*http://www.fda.gov/animalveterinary/resourcesforyou/ucm413948.htm*).
11. FDA, Drug Indexing (*http://www.fda.gov/AnimalVeterinary/DevelopmentApprovalProcess/MinorUseMinorSpecies/ucm070206.htm*).
12. White House, National Strategy for Combating Antibiotic-Resistant Bacteria (*http://www.whitehouse.gov/sites/default/files/docs/carb_national_strategy.pdf*).
13. FDA, FDA Secures Full Industry Engagement on Antimicrobial Resistance Strategy (*http://www.fda.gov/AnimalVeterinary/NewsEvents/CVMUpdates/ucm403285.htm*).
14. FDA, List of Affected Products (*http://www.fda.gov/AnimalVeterinary/SafetyHealth/AntimicrobialResistance/JudiciousUseofAntimicrobials/ucm390429.htm*).
15. FDA, FDA's Plans to Monitor Progress (*http://www.fda.gov/AnimalVeterinary/SafetyHealth/AntimicrobialResistance/JudiciousUseofAntimicrobials/ucm378256.htm*).
16. FDA, Compliance Policy Guide Sec. 615.200 Proper Drug Use and Residue Avoidance by Non-Veterinarians (*http://www.fda.gov/ICECI/ComplianceManuals/CompliancePolicyGuidanceManual/ucm074660.htm*).
17. FDA, Environmental Impact Considerations (*http://www.fda.gov/AnimalVeterinary/DevelopmentApprovalProcess/EnvironmentalAssessments/default.htm*).

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, 21 CFR parts 514 and 558 are 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. In § 514.1, revise 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 a form that accounts for the information described under §§ 558.6(b)(3) and 558.6(b)(4) 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. In § 558.3, revise paragraphs (b)(1)(ii), (b)(6), (b)(7), (b)(9), and (b)(11); and add 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 drug intended for use in or on animal feed which is limited by an approved application filed pursuant to section 512(b) of the Federal Food, Drug, and Cosmetic Act, a conditionally approved application filed pursuant to section 571 of the Federal Food, Drug, and Cosmetic Act, or an index listing under section 572 of the Federal Food, Drug, and Cosmetic Act to use under the professional supervision of a licensed veterinarian. Use of animal feed bearing or containing a VFD drug must be authorized by a lawful veterinary feed directive.

(7) A ''veterinary feed directive'' is a written (nonverbal) statement issued by a licensed veterinarian in the course of the veterinarian's professional practice that orders the use of a VFD drug or combination VFD drug in or on an animal feed. This written statement authorizes the client (the owner of the animal or animals or other caretaker) to obtain and use animal feed bearing or containing a VFD drug or combination VFD drug 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.

* * * * *

(9) For the purposes of this part, a ''distributor'' means any person who distributes 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 provided to a distributor (consignor) from another distributor (consignee). An acknowledgment letter must be provided either in hardcopy or through electronic media and must affirm:

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

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

(iii) That the distributor has complied with the distributor notification requirements of § 558.6(c)(5).

(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) intended for use in or on animal feed which is limited by an approved application filed under section 512(b) of the Federal Food, Drug, and Cosmetic Act, a conditionally approved application filed under section 571 of the Federal Food, Drug, and Cosmetic Act, or an index listing under section 572 of the Federal Food, Drug, and Cosmetic Act to use under the professional supervision of a licensed veterinarian, and at least one of the new animal drugs in the combination is a VFD drug. Use of animal feed bearing or containing a combination VFD drug must be authorized by a lawful VFD.

■ 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) Animal feed bearing or containing a VFD drug or a combination VFD drug (a VFD feed or combination VFD feed) may be fed to animals only by or upon a lawful VFD issued by a licensed veterinarian.

(2) A VFD feed or combination VFD feed must not be fed to animals 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. Use of feed containing this veterinary feed directive (VFD) drug in a manner other than as directed on the labeling (extralabel use) is not permitted.

(4) All involved parties (the veterinarian, the distributor, and the

client) must retain a copy of the VFD for 2 years. The veterinarian must retain the original VFD in its original form (electronic or hardcopy). The distributor and client copies may be kept as an electronic copy or hardcopy.

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

(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 veterinary feed directive (VFD) drug to use by or on the order of a licensed veterinarian.''

(b) *Responsibilities of the veterinarian issuing the VFD.* (1) In order for a VFD to be lawful, the veterinarian issuing the VFD must:

(i) Be licensed to practice veterinary medicine; and

(ii) Be operating in the course of the veterinarian's professional practice and in compliance with all applicable veterinary licensing and practice requirements, including issuing the VFD in the context of a veterinarian-client-patient relationship (VCPR) as defined by the State. If applicable VCPR requirements as defined by such State do not include the key elements of a valid VCPR as defined in § 530.3(i) of this chapter, the veterinarian must issue the VFD in the context of a valid VCPR as defined in § 530.3(i) of this chapter.

(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 or combination VFD drug.

(3) The veterinarian must ensure 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, business or home address, and telephone number;

(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 must not 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 must not exceed 6 months after the date of issuance;

(vi) The name of the VFD drug(s);

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

(viii) The approximate number of animals to be fed the VFD feed by the expiration date of the VFD. The approximate number of animals is the potential number of animals of the species and production class identified on the VFD that will be fed the VFD feed or combination VFD feed at the specified premises by the expiration date of the VFD;

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

(x) The level of VFD drug in the VFD 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. In cases where reorders (refills) are not specified on the labeling for an approved, conditionally approved, or index listed VFD drug, reorders (refills) are not permitted;

(xiii) The statement: ''Use of feed containing this veterinary feed directive (VFD) drug in a manner other than as directed on the labeling (extralabel use) is not permitted.'';

(xiv) An affirmation of intent for combination VFD drugs as described in paragraph (6) of this section; 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 VFD 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) of this section for each VFD drug in the combination.

(6) The veterinarian may restrict VFD authorization to only include the VFD drug(s) cited on the VFD or may expand such authorization 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) ''This VFD only authorizes the use of the VFD drug(s) cited in this order and is not intended to authorize the use of such drug(s) in combination with any other animal drugs.''

(ii) ''This VFD authorizes the use of the VFD drug(s) cited in this order in the following FDA-approved, conditionally approved, or indexed combination(s) in medicated feed that contains the VFD drug(s) as a component.'' [List specific approved, conditionally approved, or indexed combination medicated feeds following this statement.]

(iii) ''This VFD authorizes the use of the VFD drug(s) cited in this order in any FDA-approved, conditionally approved, or indexed combination(s) in medicated feed that contains the VFD drug(s) as a component.''

(7) The veterinarian must issue a written (nonverbal) VFD.

(8) The veterinarian must send a copy of the VFD to the distributor via hardcopy, facsimile (fax), or electronically. If in hardcopy, the veterinarian must send the copy of the VFD to the distributor either directly or through the client.

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

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

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

(2) The distributor is permitted to distribute an animal feed containing a VFD drug or combination VFD drug only if it 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) The distributor must keep records of the receipt and distribution of all medicated animal feed containing a VFD drug for 2 years.

(4) In addition to other applicable recordkeeping requirements found in this section, if the distributor manufactures the animal feed bearing or containing the VFD drug, 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.

(5) A distributor of animal feed containing a VFD drug must notify FDA prior to the first time it distributes animal feed containing a VFD drug. 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.

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

(7) The notifications cited in paragraphs (c)(5) and (c)(6) 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.

(8) A distributor is permitted to distribute a VFD feed to another distributor only 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 2 years.

Dated: May 28, 2015.

Leslie Kux,

Associate Commissioner for Policy.

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