

Feedstuffs

Preparing to Implement Veterinary Feed Directives Webinar - Follow-up Q&A

Significant changes to the U.S. Food & Drug Administration's Veterinary Feed Directive (VFD) regulation are ahead. With the January 1, 2017, implementation date fast approaching, now is the time for producers, feed mills and veterinarians to ensure they are armed with the knowledge necessary to effectively implement VFDs.

To help the industry with this transition and to better understand the guidelines that FDA has put forward, Feedstuffs and Elanco Animal Health brought together the nation's leading experts on the new rules for a webinar on July 14. Included on the distinguished panel were Michael Murphy, D.V.M., J.D., Ph.D., Veterinary Medical Officer, FDA; Kerry Keffaber, D.V.M., Elanco Animal Health; Mike Apley, D.V.M., Ph.D., DACVCP, Kansas State University College of Veterinary Medicine, and Angela Mills, Southern States Cooperative.

A number of questions were fielded by the panelists following their formal webinar comments. [Click here to view an archived version of the webinar.](#)

In addition, though, FDA kindly agreed to assist in seeking answers to some of the remaining questions. Those questions and answers appear below. They have been grouped under various subheads for your convenience. For more information the VFD rule, visit [VFD Central](#) on www.Feedstuffs.com

If a caretaker (not owner) of an animal gets a VFD, does a copy of the VFD have to be sent to the owner of the animal?

21 CFR 558.6 identifies the three parties – veterinarian, producer (client), and the VFD feed distributor, as the parties that are required to keep the record of a VFD order.

In the situation described, for the purposes of the VCPR (veterinarian-client-patient relationship) and VFD it may be that the caretaker will be considered the client because it appears that is the person who is responsible for feeding the animals the VFD feed.

The preamble to the final rule and the definition for a veterinary feed directive describe the client as the "owner of the animals or other caretaker." Response 26 in the preamble states that 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."

FEED COMING FROM MULTIPLE FEED MILLS

How do I write a VFD when feed for a client may be coming from multiple mills?

The distributor that the veterinarian or client gives the VFD to should be the only distributor filling the entire order.

In special circumstances (e.g., if a mill runs out of a VFD drug and the client needs VFD feed immediately to adhere to the treatment regimen or if a feed mill goes down unexpectedly), there may be a need for two mills to fill the entire order. If that is the case, the client and distributors should all keep records

documenting the situation so that it is clear that the animals received only the treatment authorized by the VFD.

It is unclear from the question whether the different feedmills are different locations for one distributor, as multiple feedmill locations could be considered one distributor if owned by the same corporation. A distributor is defined as "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." (21 CFR 558.3(b)(9)). A person is defined in 201(e) of the FD&C Act "The term "person" includes individual, partnership, corporation, and association." (21 USC 321(3)). One distributor may have multiple locations and it is acceptable for that distributor to fill a VFD from any of its locations.

In the preamble to the final rule we discussed how VFDs may be written for groups of animals with a similar age, weight range, etc., that are managed in a similar manner but housed at multiple premises. In the preamble, we said "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)." The same principle would apply to groups of animals housed at the same facility, but receiving feed from separate mills. We would expect a separate VFD for the VFD feed received from each mill.

Many feedyards "bid" a supplement for 30 days. If a veterinarian writes a script for 6 months but the "bid" changes between feed mills every 30 days, how does FDA handle that?

The VFD regulation requires the veterinarian to 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. (558.6(b)(8)). The distributor that the veterinarian or client gives the VFD to should be the only distributor filling the entire order.

In special circumstances (e.g., if a mill runs out of a VFD drug and the client needs VFD feed immediately to adhere to the treatment regimen), there may be a need for two mills to fill the entire order. If that is the case the client and distributors should all keep records documenting the situation so that it is clear that the animals received only the treatment authorized by the VFD.

If the veterinarian provides the client with a hardcopy to take to the distributor, the client can go to the distributor of their choice. When the veterinarian is issuing the VFD directly to the distributor (i.e., the client won't be taking a hard copy to the distributor), the client should tell the veterinarian which distributor to send the VFD to. If the client is unsure of where they would like to get the VFD feed, they should get a hard copy from the veterinarian so they can provide it to the distributor of their choice. If the veterinarian has sent the VFD to a distributor and the client decides they would like to get the VFD feed from a different distributor, they should contact the veterinarian to have them revoke the VFD from the original distributor and resend it to the new distributor.

Follow-up to previous question: Pulmotil is to be fed for 21 continuous days. The first seven days is Phase 1 and is fed by Mill A. The last 14 days is fed in Phase 2 by Mill B. How should the VFD be written? Can two mills be put on the same VFD?

The VFD includes information about the drug as approved for the indication. The VFD does not include information about the nutritional ingredients in the ration of the VFD feed. It is acceptable to feed several rations under a single VFD so long as each of those rations is consistent with the VFD and the drug approval.

ELECTRONIC STORAGE OF VFDs

Has the electronic storing of VFDs been clarified? Can a veterinarian store an electronic VFD on their own hard drive?

Electronic VFD (e-VFD) orders issued by veterinarians may be stored either electronically or in hard copy by distributors and clients (see 21 CFR 558.6(a)(4)).

Although the electronic storage of e-VFD orders by distributors and clients must be compliant with 21 CFR Part 11, FDA has published its intent to exercise enforcement discretion with regard to certain Part 11 requirements in guidance the Agency issued in August 2003 entitled, "Part 11, Electronic Records; Electronic Signatures—Scope and Application." The record retention portion of this guidance indicates that the Agency intends to exercise enforcement discretion with regard to the Part 11 requirements for the protection of records to enable their accurate and ready retrieval throughout the records retention period (§ 11.10 (c) and any corresponding requirement in §11.30). The guidance also states with respect to records retention that FDA does not intend to object if you decide to archive required records in electronic format to a standard electronic file format (examples of such formats include, but are not limited to, PDF, XML, or SGML).

Where can a government-approved, electronic signature be obtained, or who needs to be contacted to determine if a current e-signature is approved?

The requirements for electronic records and signatures are found in 21 CFR part 11, subpart B and C. A link to those requirements is located at:

<http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcr/CFRSearch.cfm?CFRPart=11>

In addition, FDA has published guidance regarding the part 11 requirements. This guidance is located at: <http://www.fda.gov/RegulatoryInformation/Guidances/ucm125067.htm>

What are the VFD documentation retention requirements? Can VFDs be stored on a backed up secure server?

The feed mill or any distributor is required to keep records of the receipt and distribution of all medicated feed containing a VFD drug for two years. (§ 558.6(c)(3)), and retain records of VFD manufacturing for 1 year in accordance with 21 CFR part 225 and make such records available for inspection and copying by FDA upon request.

VFD orders issued by veterinarians may be stored electronically or in hard copy by distributors and clients, 21 CFR 558.6(a)(4).

21 CFR part 11 applies to records in electronic form that are created, modified, maintained, archived, retrieved, or transmitted under any FDA records requirements (e.g., recordkeeping requirements in 21 CFR parts 225 and 558). Therefore, the maintenance in electronic form of the VFD by distributors and clients must comply with 21 CFR Part 11. Although part 11 applies in this context, FDA has published its intent to exercise enforcement discretion with regard to certain Part 11 requirements in a guidance for industry issued in August 2003 entitled, "Part 11, Electronic Records; Electronic Signatures—Scope and Application." The record retention portion of this guidance indicates that the Agency intends to exercise enforcement discretion with regard to the Part 11 requirements for the protection of records to enable their accurate and ready retrieval throughout the records retention period (§ 11.10 (c) and any corresponding requirement in §11.30). The guidance further states with respect to records retention that FDA does not intend to object if you decide to archive required records in electronic format to a standard electronic file format (examples of such formats include, but are not limited to, PDF, XML, or SGML).

ON-FARM MILLING

What about a farmer who makes his own feed for his own use? Are they a distributor? If not, can they still purchase the medication with a VFD?

A distributor is defined as “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.” (21 CFR 558.3(b)(9)). If an on-farm feed mill is not distributing VFD feed to another person, they are not considered a distributor and do not have to provide a one-time distributor notification to FDA.

Some animal producers manufacture their own medicated feed directly from Type A articles. In this situation, the producer may purchase Type A medicated articles from a sponsor without the VFD, but the producer is required to have a VFD authorizing the use of a VFD feed to be fed to their animals prior to mixing any VFD feed. Some producers manufacture their own medicated feed from a Type B or C medicated feed. In these situations, the producer would need a VFD to obtain a Type B or C medicated feed from a distributor. (Section 504(a)(3) of the FD&C Act (21 U.S.C 354(a)(3))).

We recognize that for producers who manufacture their own medicated feed it may be important to maintain some Type A medicated articles or medicated feed in inventory to manufacture medicated feed quickly in order to provide animals with timely treatment after receiving VFD authorization from their veterinarian. However, the inventory should be appropriate to the expected amount of VFD feed that would be needed to treat that producer’s animals. As a reminder, any VFD feed must be fed under a valid VFD issued by a licensed veterinarian and the use of the VFD feed must be done consistent with the conditions of use as set out in the VFD, including expiration dates.

Would a farmer need to send an acknowledgement letter to CVM before purchasing a Type A medicated article or Type B medicated feed if they intend to manufacture the VFD feed at their farm. The farmer does have a VFD from a vet.

The FD&C Act only requires a VFD or acknowledgment letter for the receipt and distribution or use of a VFD medicated feed. The FD&C Act does not require a VFD or acknowledgment letter for receipt Type A medicated article. However, the animal producer must have a VFD on hand prior to using the Type A medicated article in a VFD feed.

A distributor is defined as “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.” (21 CFR 558.3(b)(9)). If an on-farm feed mill is not distributing VFD feed to another person, they are not considered a distributor and do not have to provide a one-time distributor notification to FDA.

If the producer is not a distributor, they must have a VFD to receive a Type B or C VFD medicated feed. If the producer is also a distributor (because they will ship feed to another person as defined in 21 CFR 558.3(b)(9)) they can provide either an acknowledgment letter or VFD to their distributor to receive a Type B or C VFD medicated feed. If the producer is obtaining a Type A medicated article that is not a VFD feed, the producer does not need to provide an acknowledgment letter or VFD to receive the Type A medicated article. The producer will need a VFD prior to feeding any resulting Type C medicated feed that they mix from the Type A medicated article.

If a customer buys a 50 lb. bag of CTC 50 to mix his own feed, does he need a VFD to purchase the bag and then need a VFD for the Type C feed that he makes from the CTC 50?

Some animal producers manufacture their own medicated feed directly from Type A articles. In this situation, the producer may purchase Type A medicated articles from a sponsor without the VFD, but the producer is required to have a VFD authorizing the use of a VFD feed to be fed to their animals prior to mixing any VFD feed. Some producers manufacture their own medicated feed from a Type B or C

medicated feed. In these situations, the producer would need a VFD to obtain a Type B or C medicated feed from a distributor. (Section 504(a)(3) of the FD&C Act (21 U.S.C 354(a)(3))).

We recognize that for producers who manufacture their own medicated feed it may be important to maintain some Type A medicated articles or medicated feed in inventory to manufacture medicated feed quickly in order to provide animals with timely treatment after receiving VFD authorization from their veterinarian. However, the inventory should be appropriate to the expected amount of VFD feed that would be needed to treat that producer's animals. As a reminder, any VFD feed must be fed under a valid VFD issued by a licensed veterinarian and the use of the VFD feed must be done consistent with the conditions of use as set out in the VFD, including expiration dates.

If there is leftover feed at one site with a VFD can it be transported to another site or group? If so, what documentation would be needed?

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). The veterinarian would also need to be authorizing the same use for all of the animals covered under the VFD (e.g., the indications, species, age range, etc.)

If the end user has some VFD product left over; how do they dispose of it or can it be left on hand until needed again?

On January 1, 2017, all products with approvals that have transitioned from OTC to VFD must be used in compliance with the VFD regulations, even if the product has the old OTC labeling. At the time of transitioning from OTC to VFD marketing status, these products will fall under the 2015 VFD rule that went into effect on October 1, 2015.

On January 1, 2017, the client must have a VFD to authorize the feeding of any VFD feed. If the client already has VFD feed on site, they must receive a VFD authorizing the use of the VFD feed prior to feeding that VFD feed. If they have Type A medicated articles on site they must have a VFD prior to feeding any of the resulting VFD feed mixed from that Type A medicated article.

Disposal of feed should be in a manner that is in accordance with state or local requirements for medicated feeds.

For producers milling their own feed on the farm, do they have to a "distributor" if they own the pigs but deliver to a contract site that takes care of their pigs?

Whether or not the producer is considered a distributor depends on whether the same person (individual or business entity) is (1) distributing the VFD feed; and (2) acting as the client in the context of the veterinarian-client-patient relationship that the VFD has been authorized under. If the same person is doing both of these activities, then the person is not distributing VFD feed to another person and is not a distributor. If different people are doing both of these things, then the person distributing the VFD feed is distributing VFD feed to another person and is therefore a distributor within the context of the VFD rule.

The final rule (558.3(b)(9)) states that "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.

The preamble to the final rule and the definition for a veterinary feed directive describe the client as the "owner of the animals or other caretaker." Response 26 in the preamble states that 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 the situation described, for the purposes of the VCPR and VFD it appears that contract grower is the person who is responsible for feeding the animals the VFD feed, and they would likely be considered the “client.”

If the contract grower is the “client” as previously described, and it is their name on the VFD from a veterinarian, the producer would then be distributing VFD feed to another person, and therefore would be considered a “Distributor” and would need to meet the Distributor requirements in the VFD Final rule.

If the producer is, in fact, the “client” for the purposes of the VCPR and the VFD, they would then be both the distributing the VFD feed and acting as the client. Therefore the producer would not be distributing a VFD feed to another person and would not be considered a distributor under the VFD Final Rule.

FEED MILL ENFORCEMENT

What should be done with any leftover VFD drug on the farm?

On January 1, 2017, the client must have a VFD to authorize the feeding of any VFD feed. If the client already has VFD feed on site, they must receive a VFD authorizing the use of the VFD feed prior to feeding that VFD feed. If they have Type A medicated articles on site they must have a VFD prior to feeding any of the resulting VFD feed mixed from that Type A medicated article.

How long will retailers have to sell their existing stocks of the drugs that are coming under the VFD rule?

On January 1, 2017, all products with approvals that have transitioned from OTC to VFD must be used in compliance with the VFD regulations, even if the product has the old OTC labeling. At the time of transitioning from OTC to VFD marketing status, these products will become subject to the requirements in the VFD rule that went into effect on October 1, 2015.

A lawful VFD is required to obtain and use medicated feed containing a VFD drug (VFD feed). Beginning January 1, 2017, FDA intends to initiate surveillance and compliance activities to ensure that the products making this transition are being used in compliance with the applicable VFD requirements.

FDA recommends that parties involved in the production and/or distribution of the affected VFD products proactively manage product inventories to limit the amount of OTC-labeled product that will remain on shelves when these products are transitioned to VFD status on January 1, 2017.

This was also addressed in FDA's letter to potential distributors (retailers) regarding implementation of Guidance for Industry (GFI) 213:

<http://www.fda.gov/AnimalVeterinary/SafetyHealth/AntimicrobialResistance/JudiciousUseofAntimicrobials/ucm507353.htm>

Does the feed mill have to monitor the quantity of a VFD feed a customer buys or only that there is a VFD that has not expired?

The original VFD rule required that the veterinarian fill out the VFD with the amount of feed to be manufactured/distributed. The new VFD rule requires the veterinarian to fill out the VFD with the approximate number of animals to be treated. 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 order. 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.

It is the distributor's responsibility to fill a VFD order only if the VFD contains all required information (21 CFR 558.6(b)(3)). VFD requirements for Distributors can be found at the following link:

Veterinary Feed Directive Requirements for Distributors (Who Manufacture VFD Feed):
<http://www.fda.gov/AnimalVeterinary/DevelopmentApprovalProcess/ucm455414.htm>

Will all VFDs state the amount feed a mill can sell a client holding a valid VFD within the stated expiration timeframe? Is the feed mill solely responsible for enforcement?

The original VFD rule required that the veterinarian fill out the VFD with the amount of feed to be manufactured/distributed. The new VFD rule requires the veterinarian to fill out the VFD with the approximate number of animals to be treated. 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 order. 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.

All 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. The veterinarian must meet certain requirements (i.e. be licensed to practice veterinary medicine) to issue a lawful VFD. And clients must only feed animal feed containing a VFD drug to animals based on a VFD issued by a licensed veterinarian.

It is the distributor's responsibility to fill a VFD order only if the VFD contains all required information (21 CFR 558.6(b)(3)). VFD requirements for Distributors can be found at the following link:

Veterinary Feed Directive Requirements for Distributors (Who Manufacture VFD Feed):
<http://www.fda.gov/AnimalVeterinary/DevelopmentApprovalProcess/ucm455414.htm>

If the VFD does not contain all of the required information, the distributor must not fulfill the VFD and we recommend that the distributor notify the veterinarian that the order cannot be filled until all the necessary information on the VFD is provided. If the feed mill has reason to believe that the information on the VFD is incorrect or untruthful, we would expect that they not fill the VFD and notify their local FDA district office so that we can follow-up.

CLARIFYING DEFINITION OF A DISTRIBUTOR AND DOCUMENTATION NEEDED

Is a client that has leftover Type A antibiotic on their location a distributor? Clients that have on-farm feed mills will inevitably have CTC, OTC, Tylan or other antibiotics.

A distributor is defined as "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." (21 CFR 558.3(b)(9)). If an on-farm feed mill is not distributing VFD feed to another person, they are not considered a distributor and do not have to provide a one-time distributor notification to FDA.

Some animal producers manufacture their own medicated feed directly from Type A articles. In this situation, the producer may purchase Type A medicated articles from a sponsor without the VFD, but the producer is required to have a VFD authorizing the use of a VFD feed to be fed to their animals prior to mixing any VFD feed. Some producers manufacture their own medicated feed from a Type B or C medicated feed. In these situations, the producer would need a VFD to obtain a Type B or C medicated feed from a distributor. (Section 504(a)(3) of the FD&C Act (21 U.S.C 354(a)(3))).

We recognize that for producers who manufacture their own medicated feed it may be important to maintain some Type A medicated articles or medicated feed in inventory to manufacture medicated feed quickly in order to provide animals with timely treatment after receiving VFD authorization from their veterinarian. However, the inventory should be appropriate to the expected amount of VFD feed that would be needed to treat that producer's animals. As a reminder, any VFD feed must be fed under a valid VFD issued by a licensed veterinarian and the use of the VFD feed must be done consistent with the conditions of use as set out in the VFD, including expiration dates.

If I am a manufacturer that makes a VFD feed, but it is distributed by someone else, do I have to get the VFD in hand to manufacture?

The FD&C Act only requires a VFD or acknowledgment letter for the receipt and distribution or use of a VFD medicated feed. Before a distributor ships an animal feed containing a VFD drug (VFD feed) to another distributor (the dealer), the distributor must obtain a VFD or an acknowledgement letter from the distributor receiving the VFD feed (Section 504(a)(3) of the FD&C Act (21 U.S.C. 354(a)(3))). A description of what the acknowledgment letter must include can be found at 21 CFR 558.3(b)(11).

A distributor is defined as "... 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." (21 CFR 558.3(b)(9)).

Clarify the broker scenario: If a veterinarian sells a mineral w/ CTC to a client but the client picks up the mineral at the feed mill but the vet handles the financial transaction is the vet a distributor?

A distributor is defined as "... 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." (21 CFR 558.3(b)(9)).

In this situation, you are distributing the VFD feed directly to the client even though the order is coming through another distributor. The statute requires that any person involved in the distribution or use of a VFD feed maintain a copy of the VFD for that feed. The only exception in the statute is when the distributor is distributing the VFD feed to another person for further distribution (another distributor). (Section 504(a)(3) of the FD&C Act (21 U.S.C. 354(a)(3))). Therefore, even though your business relationship is with another distributor, you are distributing the VFD feed directly to the client who is not a distributor. Therefore, you must have a VFD for the feed you are distributing. The dealer should also retain a copy of the VFD.

LABELING/TRANSITION LABELS

Can feed in inventory January 1, 2017, without a transition label be re-labeled with a sticker or new label with the VFD statements?

On January 1, 2017, all products with approvals that have transitioned from OTC to VFD must be used in compliance with the VFD regulations, even if the product has the old OTC labeling. At the time of transitioning from OTC to VFD marketing status, these products will become subject to the requirements in the VFD rule that went into effect on October 1, 2015.

A lawful VFD is required to obtain and use medicated feed containing a VFD drug (VFD feed). Beginning January 1, 2017, FDA intends to initiate surveillance and compliance activities to ensure that the products making this transition are being used in compliance with the applicable VFD requirements.

FDA recommends that parties involved in the production and/or distribution of the affected VFD products proactively manage product inventories to limit the amount of OTC-labeled product that will remain on shelves when these products are transitioned to VFD status on January 1, 2017.

This was also addressed in FDA's letter to potential distributors (retailers) regarding implementation of Guidance for Industry (GFI) 213:

<http://www.fda.gov/AnimalVeterinary/SafetyHealth/AntimicrobialResistance/JudiciousUseofAntimicrobials/ucm507353.htm>

What is the premise definition? Is it the actual pasture the animals are in or can the main office/headquarters address be listed for the premise address.

The regulation requires the VFD order to provide the client's name, business or home address, and telephone number. It also requires the premises at which the animals are located be provided on the VFD. In response to the requirement to enter information describing the premises where the animals are located, we expect that 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 as a global positioning system (GPS) coordinate may be appropriate if a street address does not exist.

Is milk replacer considered a VFD or RX?

On January 1, 2017, we expect that certain antimicrobial drugs of human medical importance will change marketing status from over-the-counter (OTC) to Veterinary Feed Directive (VFD) for drugs administered through feed or to prescription (Rx) status for drugs administered through water.

Those uses in young animals that are presently approved OTC as a Type A medicated article, or Type B or C medicated feed in 21 CFR 558 (e.g., milk replacers) will become VFD, while those uses that are presently approved OTC to be added to drinking water or milk in 21 CFR 520 (e.g., as soluble powder) will become Rx.

The following website provides a list of all the approved animal drug applications affected by the GFI #213/209 OTC to VFD (or Rx) transition:

<http://www.fda.gov/AnimalVeterinary/SafetyHealth/AntimicrobialResistance/JudiciousUseofAntimicrobials/ucm390429.htm>

List of drugs transitioning from over-the-counter (OTC) to prescription (Rx) status:

<http://www.fda.gov/AnimalVeterinary/DevelopmentApprovalProcess/ucm482106.htm>

List of drugs transitioning from over-the-counter (OTC) to veterinary feed directive (VFD) status:

<http://www.fda.gov/AnimalVeterinary/DevelopmentApprovalProcess/ucm482107.htm>

If we make a form for veterinarians to fill out for our clients, can we submit that to the FDA and they can approve that we have all the fields that we need to have in order to be compliant? Then, if they approve it, can we use that form, since there won't be a standardized one?

1) We will not be able to review your form, however, Draft CVM GFI #233: Veterinary Feed Directive Common Format Questions and Answers, was published in December 2015. This guidance recommends

a common format for the information to be included on the VFD, provides guidance concerning the required elements of the VFD, and includes examples of how a common format might appear.

<http://www.fda.gov/downloads/AnimalVeterinary/GuidanceComplianceEnforcement/GuidanceforIndustry/UCM474640.pdf>

We anticipate finalizing this draft guidance this year; please check our website to ensure you have the most recent version. CVM Guidance for Industry draft and final documents can be found at:

<http://www.fda.gov/AnimalVeterinary/GuidanceComplianceEnforcement/GuidanceforIndustry/ucm042450.htm>

Additionally, FDA regulations require that an animal drug sponsor who is seeking approval of a drug for use in or on feed as a VFD drug must submit copies of a VFD for review by FDA's Center for Veterinary Medicine. Once the sponsor's drug is approved, the VFD form provided by the sponsor will be made available for use by veterinarians when authorizing their client to obtain and use medicated feed containing the VFD drug. You may contact drug sponsors of approved products regarding copies of VFD forms for their specific products; many sponsors may also make VFD forms available online.

2) The veterinarian may choose to work together with a feed distributor when preparing the VFD. However, it is ultimately the veterinarian's responsibility to issue the VFD and ensure that it is complete and in accordance with the approval, conditional approval, or index listing.

The VFD final rule states that the veterinarian is responsible for ensuring the VFD is complete and in accordance with the conditions for use in the relevant approval, conditional approval, or index listing (558.6(b)(2) and (3)). In order for the VFD to be complete, it must include all of the required information elements listed in the VFD regulation (21 CFR 558.6(b)(3)) and may also include the optional information elements (21 CFR 558.6(b)(4)). In draft guidance we recently issued to recommend a common format for VFDs (CVM GFI #233 Veterinary Feed Directive Common Format Questions and Answers (PDF - 921KB)), we encourage sponsors of VFD drugs to provide for use by veterinarians a fillable VFD form that is pre-populated with the relevant approved, conditionally approved, or indexed information to assist the veterinarian in issuing a complete and accurate VFD.

In regard to the scenario with the customer who orders more feed than their VFD order is for and we deliver the 3 ton but only have a 1 1/2 ton VFD is there a timeline for them to get the revised VFD to the feed mill?

The original VFD rule required that the veterinarian fill out the VFD with the amount of feed to be manufactured/distributed. The new VFD rule requires the veterinarian to fill out the VFD with the approximate number of animals to be treated. 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 order. 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.

What should happen to the distributor copy of a VFD order in the scenario that a producer has leftover medicated feed after the VFD expires? Or if the producer has VFD containing feed on his premises on January 1, 2017?

The distributor must keep records of the receipt and distribution of all medicated animal feed containing a VFD drug for 2 years.

On January 1, 2017, all products with approvals that have transitioned from OTC to VFD must be used in compliance with the VFD regulations, even if the product has the old OTC labeling. At the time of transitioning from OTC to VFD marketing status, these products will fall under the 2015 VFD rule that went into effect on October 1, 2015.

On January 1, 2017, the client must have a VFD to authorize the feeding of any VFD feed. If the client already has VFD feed on site, they must receive a VFD authorizing the use of the VFD feed prior to feeding that VFD feed. If they have Type A medicated articles on site they must have a VFD prior to feeding any of the resulting VFD feed mixed from that Type A medicated article.

For more information on the VFD regulations, visit <http://feedstuffs.com/vfd.aspx>