



September 6, 2016

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Dear Dr. Rademacher:

Thank you for submitting questions from the 2016 World Pork Expo to the Center for Veterinary Medicine (CVM) regarding the 2015 Veterinary Feed Directive rule and CVM's antimicrobial resistance policies as published in Guidances for Industry (GFIs) #209 and #213. Please find below the answers to your questions.

1. **This is a common scenario: Producer A wants to feed 2 pulses of Chlortetracycline (CTC) in the nursery phase (8 week duration of growth). In a single group of a 1,000 pigs, they get 2 weeks of CTC at the beginning (weeks 0-2 at 15 lbs. of weight) and again the last 2 weeks of the group (weeks 7-8 at 60 lbs. of weight). How many VFD's are required for this group?**

A veterinarian cannot issue a VFD that authorizes a duration of use that is inconsistent with the directions for use described on the product labeling. In the example provided, if the approval limits the treatment to 14 days, the VFD can only authorize that approved duration. Issuing a VFD that authorizes a 14-day course to be repeated for the same animals would be considered an illegal extralabel use.

However, if the veterinarian reassesses the animals involved after a single course of therapy (i.e., drug administered according to the labeled dose and duration), the veterinarian may decide that additional therapy is warranted. In such case, a new VFD is needed.

2. **Producers buy some products from one mill, and other diets/products from a second mill. Do they need a VFD for each mill, or can they write one VFD with all of the products on it?**

The distributor to which the veterinarian or client gives the VFD 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 feed mills are different locations for one distributor, as multiple feed mill 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 these locations.

However, it is the distributor's responsibility to comply with the applicable requirements in 21 CFR 558.6(a) and (c), including the requirement to distribute a VFD only if they comply with the terms of the VFD and the requirement to keep records of receipt and distribution of all VFD feed for 2 years. Therefore, we would expect a distributor filling a VFD from multiple locations would have required manufacturing records under 21 CFR 225 and VFD distribution records under 21 CFR 558.6(c) to support that these requirements have been met.

During an inspection we will review VFD orders and compare them to manufacturing records. We would expect that the amount of medicated feed produced to fill that VFD, whether in one or several batches, would be commensurate with the amount of feed necessary for the approximate number of animals the VFD authorizes to be fed.

- 3. The producer batch farrows. He will put Pulmotil in the lactation feed for 21 days at 181 grams per ton. Next month he will batch farrow again and want to put Pulmotil in his lactation feed. My VFD only says to feed it for 21 days at 181 grams/ton. There are no stipulations on the VFD of when the 21 day period is, so does he need another VFD each month?**

A veterinarian must include the approximate number of animals that need to be treated on 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. This number can include animals that are expected to be acquired by the client as part of the normal animal production operation prior to the expiration date of the VFD. CVM expects that the veterinarian issuing the VFD will have knowledge of the capacity and normal animal turnover of the facility and the prevalence of illnesses when issuing a VFD that would include animals that the client will acquire during the time the VFD is valid. This provision is not meant to allow the retreatment of animals.

- 4. What about the producer buying and producing his own feed for his own site? Do they need a VFD to purchase product? Do they need acknowledgement/distributor letters? What is the process?**

If the producer is not a distributor, they must have a VFD to receive a Type B or C VFD 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 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.

The statute states that "Any persons involved in the distribution or use of animal feed bearing or containing a veterinary feed directive drug and the licensed veterinarian issuing the veterinary feed directive shall maintain a copy of the veterinary feed directive applicable to each such feed, except in the case of a person distributing such feed to another person for further distribution. Such person distributing the feed shall maintain a written acknowledgment from the person to whom the feed is shipped stating that that person shall not ship or move such feed to an animal production facility without a veterinary feed directive or ship such feed to another person for further distribution unless that person has provided the same written acknowledgment to its immediate supplier." (Section 504(a)(3) of the FD&C Act (21 USC 354(a)(3)).

**5. Will my veterinarian have to visit every site I have to do a VFD?**

In order for a veterinarian to write a lawful VFD, the veterinarian issuing the VFD must 1) be licensed to practice veterinary medicine, and 2) be operating within 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 21 CFR 530.3(i), the veterinarian must issue the VFD in the context of a valid VCPR as defined in 21 CFR 530.3(i) (21 CFR 558.6(b)(1)).

Refer to this link to determine if the State or Federal VCPR definition applies to a lawful VFD in your State: <http://www.fda.gov/AnimalVeterinary/DevelopmentApprovalProcess/ucm460406.htm>

A veterinarian would need to meet these requirements for all of the animal locations in order to issue a lawful VFD.

**6. How are feed delivery records going to be tied back to the VFD? Generally the feed mill has these records, but are the producers and the veterinarians going to have to have the feed delivery records as well?**

During an inspection we will review VFD orders and compare them to manufacturing records. We would expect that the amount of medicated feed produced to fill that VFD, whether in one or several batches, would be commensurate with the amount of feed necessary for the approximate number of animals the VFD authorizes to be fed. The client and veterinarian are required to maintain the VFD record, but are not required to maintain feed delivery records under the final VFD rule.

7. **Are there special provisions (secure servers, etc.) for how to store VFD or feed delivery records electronically for producers or veterinarians? Does it need to be stored in an approved electronic storage system? Can a producer have the feed mill electronically store the feed delivery records that can be retrieved during an FDA audit?**

Electronic records, such as an electronic VFD that meets the requirements of 21 CFR part 11 (part 11), may be used in lieu of a paper VFD. As we have previously stated in GFI #120, part 11 applies to records in electronic form that are created, modified, maintained, archived, retrieved, or transmitted under any FDA records requirements. 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.).

The VFD is required to be signed by the veterinarian. If the veterinarian chooses to sign the VFD electronically, the electronic signature needs to be part 11 compliant. We recommend that users check with Global Vet Link, or any other electronic VFD service provider, to confirm that the software system is part 11 compliant. If a veterinarian signs a paper copy and scans the VFD to distribute a copy to the client/distributor, that is not considered an electronic signature.

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" (<http://www.fda.gov/downloads/RegulatoryInformation/Guidances/ucm125125.pdf>).

8. **Will there be a transition label for WSPs (Water Soluble Products)?**

We have communicated the expectations for labeling to sponsors in a letter: <http://www.fda.gov/downloads/AnimalVeterinary/SafetyHealth/AntimicrobialResistance/JudiciousUseofAntimicrobials/UCM482139.pdf>.

As stated in the letter, CVM will review applications as they are received and, in general, will work toward coordinated approval dates for all similar applications by the end of December 2016. Our goal is to meet the January 1, 2017, implementation date.

Our primary goal is that on January 1, 2017, all affected products are being used in the market in accordance with the principles outlined in GFIs #209 and #213. Our expectation is that after January 1, 2017, product in distribution channels (i.e., no longer in the sponsor's control) either is 1) labeled with "new" final printed label, 2) has a sticker affixed to the product that includes the "new" final label language, or 3) is labeled with "transitional label" statement(s).

Recognizing the complexity and scale of this effort, CVM intends to exercise as much flexibility as possible in relation to this transition period. However, we ask that affected drug sponsors exercise due diligence to transition to the new labeling in an expedient manner.

**9. How accurate do vets need to be on their pig numbers (approximate number of animals) on VFDs?**

A veterinarian must include the approximate number of animals that need to be treated on 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. This number can include animals that are expected to be acquired by the client as part of the normal animal production operation prior to the expiration date of the VFD.

CVM expects that the veterinarian issuing the VFD will have knowledge of the capacity and normal animal turnover of the facility and the prevalence of illnesses when issuing a VFD that would include animals that the client will acquire during the time the VFD is valid. This provision is not meant to allow the retreatment of animals.

During an inspection we will review VFD orders and compare them to manufacturing records. We would expect that the amount of medicated feed produced to fill that VFD, whether in one or several batches, would be commensurate with the amount of feed necessary for the approximate number of animals the VFD authorizes to be fed.

**10. Clarify the producer owned feed mill situation. Does a producer need a distributor letter or a VFD? Does it matter if all of the pigs are on the mill site? Does it matter if the producer owns sites away from his farm or if those sites are contract finisher sites even though he owns all of the pigs?**

21 CFR 558.3(b)(9) states that "For the purposes of this part [558], 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." Based on this definition, if the same company is manufacturing and distributing the VFD feed and also feeding VFD feed to the animals (client), they would not be considered a distributor, because they are not distributing the VFD drug to another person. If the company is manufacturing and distributing the VFD, but another person (individual or business entity) is feeding the animals and thus the client, the company would be considered a distributor because they are distributing VFD feed to another person.

If a distributor is distributing VFD feeds, they must meet all of the requirements in 21 CFR part 558 that are applicable to a distributor, including distributor notification. To distribute VFD feed, the distributor must first receive either (1) an acknowledgment letter (if distributing the feed to another distributor); or (2) a VFD (if distributing the feed to the client).

Additional information on requirements for VFD distributors can be found at the following websites:

Veterinary Feed Directive (VFD):

<http://www.fda.gov/AnimalVeterinary/DevelopmentApprovalProcess/ucm071807.htm>

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

In the case of transfers within the same corporate entity, we would not consider the corporate entity to be distributing to another person. Therefore, an acknowledgment letter would not be required for transfers within the same corporate entity.

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)). An acknowledgment letter is provided to another distributor to obtain VFD feed instead of a VFD order. In the case of a person distributing such feed to another person for further distribution, such person distributing the feed shall maintain a written acknowledgment from the person to whom the feed is shipped stating that that person shall not ship or move such feed to an animal production facility without a veterinary feed directive or ship such feed to another person for further distribution unless that person has provided the same written acknowledgment to its immediate supplier. (Section 504(a)(3) of the FD&C Act (21 USC 354(a)(3))).

A person is defined in the FD&C Act: "The term 'person' includes individual, partnership, corporation, and association." (201(e) (21 USC 321(3))).

**11. For a producer who mills their own feed for their owned sites, do they need a VFD to purchase the bulk product from an animal health company? What is their procedure to bring products in?**

Some animal producers manufacture their own medicated feed directly from Type A medicated 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 consistent with the conditions of use as set out in the VFD, including expiration dates.

**12. Next year if a youth exhibitor is showing a pig at a Jackpot show (just a 1-2 day pig show, not terminal, and pigs will go back home) will the exhibitor have to have a copy of their VFD or prescription in their possession at the show if a FDA person asked for it or do they have time to produce it a later date?**

The VFD final rule requires that "All involved parties must make the VFD and any other records specified in this section available for inspection and copying by FDA upon request." (21 CFR 558.6(a)(5)). Therefore, we would recommend that the exhibitor's copy of a VFD or prescription be readily available.

**13. Confusion regarding the "One Time" Distributor Notification and the "Acknowledgement Letter". What is the difference and when does each come into play?**

A distributor needs to have provided a one-time notification to FDA of the distributor's intent to distribute prior to the first time they distribute a VFD feed. For each VFD feed the distributor distributes, the distributor needs to receive either a VFD from any client purchasing the VFD product, or an acknowledgment letter from any distributor purchasing the VFD product. 21 CFR part 558 provides specific items that must be included in the distributor notification and the acknowledgment letter.

Distributor Notification

21 CFR 558.6(c)(5) explains what is required for distributor notification. The notification (we suggest using a letter format, and addressing it to "VFD Distributor Notification") simply needs to say that the firm intends to distribute animal food that contains a VFD drug. The notification also needs to contain:

1. The complete name and address of the distributor's company,
2. The name and signature of the distributor or distributor's authorized agent, and
3. The date the notification was signed.

If there is a change in ownership, and/or name or address of the business, FDA must be notified within 30 days. This notification must be mailed or sent by FAX to Food and Drug Administration, Center for Veterinary Medicine, Division of Animal Feeds (HFV-220), 7519 Standish Pl., Rockville, MD 20855, FAX: 240-453-6882.

The only listing requirement is for those feed mills that are considered 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)). 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.

Acknowledgment Letter

An acknowledgement letter is a letter that a distributor obtains from a consignee distributor (the distributor receiving the VFD feed) when the distributor ships an animal feed containing

a VFD drug in the absence of a valid VFD. The distributor receiving the VFD feed signs and sends the acknowledgment letter. 21 CFR 558.3(b)(11) contains a description of what the acknowledgment letter must affirm.

The acknowledgment letter must be provided either in hardcopy or through electronic media and must affirm:

1. That the distributor will not ship such VFD feed to an animal production facility that does not have a VFD.
2. That the distributor will not ship such VFD feed to another distributor without receiving a similar written acknowledgment letter, and
3. That the distributor has complied with the distributor notification requirements of § 558.6(c)(5).

In addition to the affirmation above, we would also expect to see the name of the distributor who is receiving the VFD feed and to whom they are providing the acknowledgment letter.

Additional information on the VFD Final Rule is available at the following links:

Veterinary Feed Directive:

<http://www.fda.gov/AnimalVeterinary/DevelopmentApprovalProcess/ucm071807.htm>

GFI #120:

<http://www.fda.gov/downloads/AnimalVeterinary/GuidanceComplianceEnforcement/GuidanceforIndustry/UCM052660.pdf>

**14. I'm not sure where distributors who plan to inventory/sell VFD feed grade antibiotics in bulk fit into this VFD process? Can distributors sell directly to the farm if the producer has a current valid VFD?**

If you are distributing Type B or C VFD feed to another person, you are considered a distributor. The distributor must be in compliance with all of the applicable requirements in § 558.6, with special attention to the requirements applicable to everyone in § 558.6(a) and those specific to distributors in § 558.6(c). If the distributor is also manufacturing the VFD feed, they will also need to meet the manufacturing requirements.

If you are distributing VFD feed (Type B or C) to another distributor you need to receive either a VFD or acknowledgment letter from that distributor. If you are distributing VFD feed (Type B or C) to a client then you need to receive a VFD from the client.

If you are distributing Type A medicated article, that is not considered a VFD feed and you do not need to receive an acknowledgment letter or VFD prior to distribution.



**15. Do veterinarians need to do anything different to purchase bulk feed-grade antibiotics for resale?**

If you are the veterinarian and the distributor of a Type B or C VFD feed, to distribute the VFD feed you would need to follow the distributor requirements, including sending a one-time notification to FDA that you are a distributor. If you are distributing VFD feed (Type B or C) to another distributor, you need to receive either a VFD or acknowledgment letter from that distributor. If you are distributing VFD feed (Type B or C) to a client, then you need to receive a VFD from the client.

If you are distributing Type A medicated article, that is not a VFD feed and you do not need to receive an acknowledgment letter or VFD prior to distribution.

All involved parties (veterinarian, client, distributor) must retain a copy of the VFD order for 2 years. The veterinarian is required to keep the VFD order in its original format. The distributor and client copies may be kept as an electronic copy or hardcopy. If you are both the veterinarian and the distributor, keeping the original is sufficient.

**16. During our discussion the question came up about duration of treatment for a VFD. What I mean by this is Pulmotil needs to be fed for 21 days no longer or shorter per label. Are the new VFDs of the current feed labeled drugs going to allow a window of treatment length or are they all specified days. Also how big of deal is it to run short 1 day i.e. pigs ate the feed faster than thought so they had an appropriate drug amount but it was consumed faster?**

The client/producer is authorized to use (feed) the medicated feed for the number of days specified on the VFD order. In order to be lawful, the VFD order must authorize the duration of use on the FDA approved application. Many, but not all, new animal drugs with VFD marketing status have a fixed number of days for the duration of dosing. For example, you mentioned tilmicosin in swine has an approved duration of 21 days. However, the avilamycin approved application states: "... as the sole ration for 21 consecutive days. The veterinarian may direct feeding for up to a total of 42 consecutive days, based on the clinical assessment." In this case, the VFD feed should be fed at least 21 days, but the veterinarian has the discretion to direct feeding for additional days up to 42. The client/producer will need to follow the duration of dosing the veterinarian indicates on the VFD order.

**17. The farm ordered 12 ton of feed and only 10 ton would fit in the bin. What can I do with that medicated feed? Normally it gets delivered to another related site in the general vicinity of the original site.**

The VFD order authorizes the client to obtain and use the medicated feed. One requirement is that the veterinarian must indicate on the VFD order the premises at which the animals to be feed the VFD feed are located. Generally speaking, delivery of the authorized medicated feed to one or more bins on the premises specified on the VFD order is acceptable, provided the

total amount of VFD feed delivered is commensurate with the number of animals listed on the VFD order.

The VFD final rule requires the veterinarian to list the "approximate number of animals" to be fed the VFD feed by the expiration date of the VFD. (21 CFR 558.6(b)(3)(viii)). In the preamble to the final rule, we encourage the feed mill and client to work together in determining the amount of feed that would be commensurate with the approximate number of animals to be given the VFD feed. The feed mill and client should take into account the feed storage capacity at the farm in determining whether the entire amount commensurate with the number of animals listed on the VFD should be manufactured and delivered at once, or over multiple deliveries.

**18. Will each packet of product require an Rx label to be applied by the distributor or will one Rx label on the bucket or box be sufficient?**

The answer depends on whether the use is "on-label" or "extralabel".

On-label:

For prescription (Rx) new animal drugs, including prescription medically important antimicrobial new animal drugs used in the water of food-producing animals, CVM reviews the label and labeling (including a shipping label) in the approved application provided by the drug sponsor. The FDA-approved label and labeling essentially "defines" the "on-label" use of a particular prescription drug.

State authority may also require a label on prescription drugs; this label is normally added by the veterinarian in such a way that it does not obscure the FDA-approved label or labeling. Please refer to the state board of veterinary medicine, board of pharmacy, or other appropriate authority for the state requirements for this label/labeling for on-label use of the prescription drug(s).

Extralabel:

As a result of amendments made to the Federal Food, Drug, and Cosmetic Act by the Animal Medicinal Drug Use Clarification Act of 1994 (the AMDUCA) (Pub. L. 103-396), veterinarians may legally prescribe the use of approved drugs in animals in an "extra-label" manner under certain conditions other than for use in or on animal feed. The Federal regulatory requirements for extralabel use of approved drugs in animals are published in FDA's regulations at 21 CFR part 530. Drugs prescribed and dispensed for extralabel use under the lawful order of a veterinarian must bear or be accompanied by labeling as described in 21 CFR 530.12. Each individual package does not have to have the § 530.12 information; however, the extralabel use labeling must accompany the product.

**19. Is there a difference in the label when the recommendation is to "feed for...days" vs "feed up to...days"?**

The veterinarian is required to include on the VFD the level of VFD drug in the VFD feed and the duration of use. (21 CFR 558.6(b)(3)(x)). In addition, the veterinarian must issue a VFD that is in compliance with the conditions of use approved, conditionally approved, or indexed for the VFD drug or combination VFD drug.

Durations of use may be reflected in different ways in the approval, conditional approval, or index listing and on the corresponding labeling. For example, a label that states "feed for X days" indicates that the VFD feed must be fed for the exact number of days specified on the label and does not provide discretion for the veterinarian to authorize use for a different number of days. In contrast, a label that states "feed up to X days" indicates that the veterinarian has some discretion in selecting any number of days up to the X day when writing the duration of use on the VFD.

The client/producer is authorized to use (feed) the medicated feed in compliance with the terms of a lawful VFD order that is issued by a licensed veterinarian.

**20. Can a vet write a VFD for CTC in combination with Denagard followed immediately by CTC without Denagard ?**

The veterinarian must only issue a VFD that is in compliance with the conditions of use approved, conditionally approved, or indexed for the VFD drug or combination VFD drug. The active ingredient in Denagard is tiamulin. Tiamulin is approved for use in feed with CTC (Chlortetracycline hydrochloride). After the expected changes on January 1, 2017, resulting from implementation of FDA's GFI #213, CTC will become a VFD drug and the combination of tiamulin with CTC will be a combination VFD drug. Currently, the indication for the combination drug is "For treatment of swine bacterial enteritis caused by *Escherichia coli* and *Salmonella choleraesuis* and bacterial pneumonia caused by *Pasteurella multocida* sensitive to chlortetracycline, and control of swine dysentery associated with *Brachyspira* (formerly *Serpulina* or *Treponema*) *hyodysenteriae* sensitiveto tiamulin."

The limitations applicable to the combination drug as described in 21 CFR 558.612 are: "Feed continuously as sole ration for 14 days. Use as only source of chlortetracycline. Withdraw 2 days before slaughter. As chlortetracycline calcium complex, Type A medicated articles containing the equivalent of 50 to 100 grams per pound of chlortetracycline hydrochloride provided by 054771 and 069254 in 510.600(c) of this chapter. Use as only source of tiamulin."

CTC is also separately approved for use in swine for:

1. Treatment of bacterial enteritis caused by *Escherichia. coli* and *Salmonella choleraesuis* and bacterial pneumonia caused by *Pasteurella multocida* susceptible to chlortetracycline; and
2. Control of porcine proliferative enteropathies (ileitis) caused by *Lawsonia intracellularis* susceptible to chlortetracycline.

Once a veterinarian has authorized and the client has fed a course of CTC and tiamulin therapy in compliance with the approved, conditionally approved, or indexed conditions of use, a veterinarian may use his or her medical judgment to determine that an additional course of CTC is indicated. In this case, because the CTC would be a VFD drug, the veterinarian would need to issue a new VFD to authorize this additional treatment.

**21. A producer has a VCPR with a veterinary clinic with 5 veterinarians. Can any of the veterinarians write a VFD?**

In order for a VFD to be lawful, the veterinarian issuing the VFD must be operating in the course of the veterinarian's professional practice and in compliance with 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 no applicable and appropriate State VCPR requirements exist, the veterinarian must issue the VFD in the context of a valid VCPR as defined in Federal regulations at 21 CFR 530.3(i). (see 21 CFR 558.6(b)(1)(ii)).

The Federal VCPR definition at 21 CFR 530.3(i) states:

(i) A valid veterinarian-client-patient relationship is one in which:

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

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

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

The Federal VCPR definition refers only to the individual veterinarian and not to the veterinary clinic. Therefore, in those instances in which the Federal VCPR definition applies, it is not permissible to have any of the veterinarians at a clinic with multiple veterinarians write the VFD unless they also have an individual VCPR with the client. In those instances in which Federal VCPR requirements do not directly apply, please refer to the applicable VCPR requirements as defined by the State.

Refer to the link below to determine if the State or Federal VCPR definition applies to a veterinarian writing a lawful VFD in your state:

<http://www.fda.gov/AnimalVeterinary/DevelopmentApprovalProcess/ucm460406.htm>

**22. Are on-farm feed mixture operations (grind and mix, or feeder wagon) going to be required to obtain class C production licenses? This is regarding small operations that mix their feed on premise, and do not purchase the final product from a feed mill.**

We are unsure what you mean by "class C production license." This response discusses the situations in which an operation may need a medicated feed mill license under the Federal medicated feed regulatory requirements. States may have additional requirements.

An on-farm mixer could obtain the Type A medicated article or the Type B medicated feed to manufacture the final Type C medicated feed to be fed to his/her animals. If the Type A medicated article the manufacturer will use to make the Type C medicated feed is a Category II drug, the manufacturer must have a medicated feed mill license. If the Type A medicated article is a Category I drug, or if the on-farm mixer obtains Type B medicated feed (whether Category I or II) for use in making the Type C medicated feed, a feed mill license is not required.

Thank you for your interest in helping to address this important public and animal health issue.

Sincerely,



William T. Flynn, DVM, MS  
Deputy Director for Science Policy  
Center for Veterinary Medicine

*This communication does not constitute a written advisory opinion under Title 21 CFR 10.85, but rather is an informal communication under Title 21 CFR 10.85(k) which represents the best judgment of the employee providing it. This information does not necessarily represent the formal position of FDA, and does not bind or otherwise obligate or commit the agency to the views expressed.*

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