November 20, 2017

VFD Answers from FDA

The responses below are from the FDA Center for Veterinary Medicine (CVM)

Question 1:

If a firm that raises calves develops a medicated fee protocol for the treatment of pneumonia with their veterinarian. (i.e. when weather conditions and/or stress cause bacterial pneumonia symptoms in a pen of calves then they can be fed medicated feed containing Chlortetracycline) Can the veterinarian write a VFD for the firm to manufacture medicated feed with the Type A Chlortetracycline to be fed to a pen of calves any time bacterial pneumonia symptoms are observed until the expiration date?

The VFD can be written by the veterinarian to cover all of the potential animals that may be fed the VFD at the premises prior to the expiration date of the VFD. 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.

Question 2:

Can a veterinarian write a VFD for cattle to be treated with neomycin-oxytetracycline for the prevention and treatment of early stages of whipping fever complex to be fed when the predetermined conditions exist, possibly multiple times before the VFD expires?

See the answer to #1 above regarding the approximate number of animals.

A veterinarian cannot issue a VFD that authorizes a duration of use that is inconsistent with the directions for use described on the approved product labeling. For example, when the approval limits the treatment to 14 days, the VFD can only authorize that approved duration. Issuing a VFD that authorized 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.

Question 3:

When a veterinarian has diagnosed swine respiratory disease at a swine producer client location can he/she write a VFD with the feeding instructions: "Feed continuously as the sole ration for 21 days beginning approximately 7 days before an expected outbreak of swine respiratory disease."

Can the feeding of this medicated feed be repeated when there is an expected outbreak of swine respiratory disease at the location listed on the VFD until the VFD expires?

The client is responsible for feeding the VFD according to the authorization and approval – which means completing the authorized duration by the expiration date. For some approvals there are discrete expiration and duration of use time periods where it can easily be determined whether completion of treatment would be able to finish by the expiration date. A client may use the VFD to obtain VFD feed during any time prior to the expiration period; however, they may not feed that feed after the authorization (VFD expiration) date. If a VFD will expire prior to the completion of a course of treatment, the client must obtain a new VFD from the veterinarian to authorize use of the feed for the full course of treatment prior to the expiration date on the new VFD.

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.

The veterinarian should report treatments that were not clinically effective, or any adverse reactions to FDA within 10 days of occurrence by visiting FDA's webpage entitled "How to Report Animal Drug Side Effects and Product Problems" at: http://www.fda.gov/AnimalVeterinary/SafetyHealth/ReportaProblem/ucm055305.htm.

Question 4:

There are no livestock drugs that require a VFD to manufacture medicated feed that are allowed refills. If a producer places a second or third order of medicated feed under the same VFD that has not expired, is that considered a refill?

If not, then what is considered a refill?

A refill or reorder is meant to apply to situations 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.

Question 5:

LETTER OF INTENT

Are farms that manufacture VFD feed onsite required to send FDA a "one time VFD Notice of Intent to Distribute" if they are only going to be feeding the animals that they manage or own?

Some clients manufacture their own medicated feed directly from Type A articles. In this situation, the client may purchase Type A medicated articles without the VFD, but we would expect that the client has a VFD authorizing the use of a VFD feed to be fed to their animals prior to mixing any VFD feed. We recognize it may be important to have drugs in inventory to manufacture medicated feed quickly in order to provide animals with timely treatment. However, the inventory should be appropriate to the expected amount of VFD feed that may be authorized by the veterinarian based on the approximate number of animals. It would not be appropriate to obtain excessive amounts of VFD Type A medicated article or VFD Type B or C feed. As a reminder, any VFD feed must be fed under a valid VFD and the use of the VFD feed must be done consistent with the authorization on the VFD. In addition, it must be manufactured in compliance with the Current Good Manufacturing Practice for Medicated Feeds requirements applicable in 21 CFR 225.

In 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." A producer manufacturing feed for their own animals does not meet the definition of distributor unless they will also be distributing feed to another person and they should not become a distributor unless they are doing so.

Question 6:

WATER TREATMENT PRESCRIPTION DRUG

If neomycin is approved federally for use in water or milk but the drug label states for use in water, can the vet write a prescription for a client to treat calves that the client owns or manages for scours?

Can the producer make this "on farm" for the calves that they manage?

This would be extra-label use for the drug label but within the scope of the federal approval.

On January 1, 2017, certain antimicrobial drugs of human medical importance changed marketing status from OTC to either VFD status for drugs administered through feed or Rx status for drugs administered through water. Those uses in young animals that were initially approved OTC as a Type A medicated article, or Type B or C medicated feed in 21 CFR 558 (e.g., milk replacers) have transitioned to VFD status, while those uses that

were initially approved OTC to be added to drinking water or milk in 21 CFR 520 (e.g., as soluble powder) transitioned to Rx status.

The following website provides a list of all the approved animal drug applications affected by the OTC to VFD (or Rx) transition as part of the implementation of GFI #213: http://www.fda.gov/AnimalVeterinary/SafetyHealth/AntimicrobialResistance/JudiciousUseofAntimicrobials/ucm390429.htm.

Milk is identified as an acceptable medium for delivery of a few approved oral dosage form drugs. In such cases, the administration of the drug via milk is not considered a medicated feed. An oral dosage form could be added to milk only if such use is specified on the approved labeling of the product. Therefore, please consult the label for a specific approved new animal drug to determine whether the drug can be legally added to milk. For example, 21 CFR 520.1484 for neomycin states “add to drinking water or milk”, while 21 CFR 520.88d states administer by “drench or in milk.” Please note that milk replacer is not considered to be milk in this context.

If milk is not on the label of an oral dosage form as an approved medium for delivery, use of that oral dosage form in milk would be considered an extralabel use in medicated feed, which is not permitted. Therefore, a lawful prescription, VFD, or extralabel use order cannot be written for use of such oral dosage form in milk.

Question 7:

If a producer has a valid VFD Order are the manufacturers responsible for only allowing a certain tonnage of the VFD feed to purchased?

As stated in the preamble to the VFD final rule, we expect 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. (80 FR 31708 at 31723, June 3, 2015). Distributors should retain the necessary records to document the amount of feed that was manufactured and distributed under the VFD, and make such records available for inspection and copying by FDA upon request.

Since the VFD specifies the number of animals that will be fed and not the exact amount of feed that can be manufactured, feed mills 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. In the preamble to the final rule, when discussing the change from the requirement to include amount of feed to be manufactured on the VFD to the requirement to instead include the approximate number of animals to be treated, we stated we expect 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 to be treated under the VFD. (80 FR 31708 at 31722, June 3, 2015). We anticipate that, as part of our inspectional activities, we will consider such factors as whether the amount of feed distributed is reasonable relative to the approximate number of animals specified in the VFD.

If we encounter a situation where there has been a violation in the authorization, distribution, or use of a VFD drug or feed, we intend to hold the party who committed the violation responsible. For example, if a feed mill appropriately fills a valid VFD for an approximate number of animals based on reasonable consumption information provided by the client, but the client uses the VFD feed in a manner inconsistent with the terms of the VFD as issued by the veterinarian, we would conduct a follow-up investigation. Based on the results of this investigation, we would consider whether to pursue enforcement against the individual or individuals responsible for any improper activity.

Hope you find this information helpful.

Sincerely,

AskCVM

Center for Veterinary Medicine

U.S. Food and Drug Administration