

VETERINARY FEED DIRECTIVE Q&A



This Q&A covers questions submitted during a Veterinary Feed Directive (VFD) webinar sponsored by Zoetis. The questions were answered by the webinar presenters and edited for clarity. To view the webinar, please visit ResponsibleAntibioticUse.com/VFD.

GENERAL VFD: QUESTIONS ABOUT THE RULE AND VCPR

Q: HOW WILL THE FOOD AND DRUG ADMINISTRATION (FDA) AND OTHER ORGANIZATIONS DETERMINE WHETHER THIS NEW APPROACH HAS BEEN SUCCESSFUL? WILL THEY BE LOOKING AT, SAY, TONS OF ANTIBIOTICS USED VERSUS INCIDENCE OF RESISTANCE, OR ARE THERE OTHER WAYS THE POULTRY AND LIVESTOCK INDUSTRIES CAN MEASURE THEIR SUCCESS?

A: The FDA is still developing their metrics.

Q: SINCE THE VETERINARIAN-CLIENT-PATIENT RELATIONSHIP (VCPR) DIDN'T GET PUBLISHED AT THE TIME THE FINAL RULE DID, DOES ANYONE KNOW A TIMELINE FOR WHEN IT WILL BE PUBLISHED?

A: The definition of VCPR already exists in regulation (21 CFR 530) and many states have adopted the concepts from this regulation into state practice acts.

Q: AFTER THE VETERINARIAN HAS SUBMITTED A VFD, CAN THE MEDICATED FEED BE DELIVERED TO THE FARM FOR USE, OR DOES THE VFD HAVE TO BE APPROVED?

A: A VFD is similar to a prescription. Once a veterinarian writes it, the VFD is active and needs to be on file.

Q: IS THERE ANY INDICATION OF MINOR USE OR MINOR SPECIES ALLOWANCE FOR SOME OF THESE MEDICALLY IMPORTANT ANTIBIOTICS IN SMALL RUMINANTS, LIKE SHEEP AND GOATS?

A: There is no allowance for minor use or use in minor species at this time. Follow all label directions for combination uses in minor species if they are listed on the label for a product.

Q: I'VE READ THE NEW VFD RULES BECOME EFFECTIVE 120 DAYS FROM WHEN IT WAS PUBLISHED. THAT WOULD BE OCTOBER 2015, SO WHAT ACTUALLY GOES INTO EFFECT AT THAT TIME?

A: The new rule of the VFD regulation will go into effect in October 2015. This is a tool to allow the government to implement Guidance #213, which is the movement of all the medicated feed additives from over-the-counter to VFD status if they contain a medically important antibacterial drug. Any product that already requires a VFD will need to follow the new regulation as of October 2015. All products that have yet to be transformed will do so in December 2016 and will continue to be used as they are currently labeled up until that time.

Q: WILL THE FDA KNOW EXACTLY WHERE MEDICATED FEED ADDITIVES (MFAS) HAVE BEEN USED?

A: At the current time, in the new regulation there is no stipulation on recording of amounts or locations. The sponsors of veterinary pharmaceuticals have the requirement to report overall sales of all product to the agency every year. Currently, within the VFD there is no stipulation for recording of amounts sold and to which location.

Q: IN THIS GUIDANCE, IT WAS STATED THE VCPR FOR EACH STATE WILL BE PUBLISHED AT THE SAME TIME THE FINAL RULE IS PUBLISHED. HOWEVER, I HAVE NOT SEEN THAT PUBLISHED ON THE SITE WHERE THE RULE IS. HAS IT BEEN PUBLISHED? SOME COMPANIES — SUCH AS A COMPANY FARM — WOULD LIKE TO CONSULT WITH ONE VETERINARIAN TO COVER SEVERAL STATES IN WHICH THEY RAISE ANIMALS.

A: It is our understanding that the FDA will publish on their website a list of states that have adequate VCPR in their state practice act. By elimination, this will let you know which state will default to the federal definition of the VCPR. To answer the second part of the question, the veterinarian must be licensed where the animals are fed.

Q: AS AN INTEGRATOR, DOES THIS MEAN SEPARATE VFDs EVERY SIX MONTHS FOR EACH LOCATION, OR CAN I ISSUE ONE VFD TO OUR MILL, LISTING AN APPROXIMATE NUMBER OF TOTAL ANIMALS I EXPECT TO TREAT OVER THAT PERIOD OF TIME, AS REQUIRED BY THE REGULATION FOR THE ENTIRE COMPLEX, AND THEN A LIST OF ALL OF OUR PREMISES (NAME, ADDRESS, PHONE NUMBER OF THE CLIENT) THAT THE VFD COVERS?

A: The FDA has made a change with the VFD rule to allow veterinarians to list multiple premises. However, the premises will need to have shared health status or disease challenges, in order to issue one VFD.

Q: WILL THE VFD FORM HAVE A PLACE FOR THE VETERINARIAN TO INDICATE GENERIC SUBSTITUTION — FOR EXAMPLE, TILMODIL OR PULMOTIL — OR WILL THE FORM BE SPECIFICALLY FOR ONLY ONE BRAND?

A: The answer to that is, it depends. If you have a generic that's a single-use product that will have an identical label to the pioneer, then it could be replaced and it is at the veterinarian's discretion. Please note that there are pioneer products that have combination approvals that some generics do not. So if a veterinarian wants to prescribe a combination of products, and the comparable generic product is not approved for combination, the veterinarian will need to prescribe the pioneer product. The product labels do not list approved combinations; the veterinarian will have to specify within the VFD what is to be used and then what combinations will be allowed. All of them must be on-label.

Q: WHAT WILL HAPPEN TO EXISTING INVENTORY WITH OLD LABELS IN THE FIELD AFTER JAN. 1, 2017?

A: The sponsors or manufacturers of the Type A medicated articles and medicated feed are working with the industry to make sure product continues to be available. We will not have to remove product with old labels from the market. We are potentially looking at transition labels or labels that will move over to VFD at the end of 2016 and the beginning of 2017. We do know the VFD rule will go into effect even if product has an old label on it. You will need to have a VFD to use those products, but if you have product in your inventory or warehouse or on the farm that has the old label, you will not have to dispose of or destroy it.

AFFECTED PRODUCTS: QUESTIONS REGARDING SPECIFIC PRODUCTS UNDER THE NEW RULE

Q: WHERE ARE LISTS AVAILABLE FOR ALL VFD AND NON-VFD DRUGS?

A: The [FDA website](#) and the Zoetis website at ResponsibleAntibioticUse.com.

Q: WHERE DO THE PLEUROMUTILINS STAND IN THE CLASSIFICATION?

A: They are not medically important, according to the FDA.

Q: IS CARBADOX A MEDICALLY IMPORTANT ANTIBIOTIC?

A: Carbadox isn't considered medically important and is not affected by Guidance #213.

Q: WHERE CAN I FIND A LIST OF THE INGREDIENTS THAT WILL REQUIRE A VFD, AS WELL AS A LIST OF INGREDIENTS THAT WILL NOT REQUIRE A VFD?

A: Please see the [FDA's website](#), or [ResponsibleAntibioticUse.com](#) or talk with your Zoetis representative.

Q: WE ARE A LOCAL FEED MILL AND SELL CHLORTETRACYCLINE (CTC) 10 GRAMS AND 50 GRAMS. WHAT WILL BE THE PROPER PROCEDURE WHEN I HAVE A PRODUCER NEEDING 60 POUNDS OF CTC 10 TO TOP DRESS WITH? CAN I SELL THEM THE SECOND BAG OR ONLY THE 10 POUNDS?

A: A VFD is required for location, group of animals and indication. There is no requirement for an amount (pounds or bags).

Q: WHAT ABOUT RUMENSIN® (MONENSIN)? ANY REQUIREMENTS FOR IT IN THE FEED BUNK OR MINERAL?

A: Ionophores do not require a VFD, but if Rumensin is combined with a medically important antibiotic, it will require a VFD for use in combination with a medically important antibiotic.

Q: HOW WILL THIS FINAL RULING AFFECT MEDICATIONS ADDED TO MILK REPLACERS?

A: If they are medically important, they will require a VFD.

Q: AS A FEED MILL AND RETAILER, WE CURRENTLY SELL 50-POUND BAGS OF AUREOMYCIN® 90 (CHLORTETRACYCLINE) TO CUSTOMERS. WILL WE STILL BE ABLE TO DO THIS? WILL THEY NEED A VFD?

A: The feed mill and retailer will need a letter of distribution. The customer/producer will need to provide a valid VFD in order to purchase the product from the retailer. The retailer must maintain records for two years.

Q: WILL WATER-SOLUBLE ANTIMICROBIALS ADDED TO MILK REPLACER, OR MILK FOR DAIRY CALVES, BE ADMINISTERED UNDER VETERINARY DRUG PRESCRIPTION RULES OR VFD RULES?

A: Check with your veterinarian for more information about the use of water-soluble antimicrobials in milk replacers or milk.

Q: DURING THE WEBINAR, IT WAS MENTIONED THAT ANY MEDICALLY IMPORTANT WATER-SOLUBLE ANTIBIOTICS WOULD BECOME PRESCRIPTION. DOES THIS INCLUDE INJECTABLE ANTIBIOTICS, SUCH AS GENERIC PENICILLIN, OR ARE YOU TALKING ABOUT ANTIBIOTICS ADDED TO THE DRINKING WATER, SUCH AS SULFATES?

A: Yes, a prescription, not a VFD, will be necessary for medically important water-soluble antibiotics in drinking water. Injectable antibiotics that are currently over the counter will remain over the counter.

Q: WILL MEDICATED MILK REPLACERS OR TETRACYCLINES THAT CONTAIN NEOMYCIN BE ABLE TO BE USED FOR AN EXTENDED TIME OR AT ANTIBIOTIC LEVEL?

A: The answer is no. That is an extra-label use for these products, and milk replacers are considered feed, so it would be illegal. The products have to be labeled for a certain number of days and then they can be used. Medicated milk replacers with the low levels that are intended to be fed continuously will probably become unavailable. The main answer is, it needs to be on the label, and if it isn't, then it will be illegal.

CLAIMS AND LABELS: QUESTIONS AROUND PACKAGE LABELS AND PRODUCT CLAIMS

Q: WHAT HAPPENS TO PRODUCTS PRODUCED AND LABELED UNDER THE OLD REGULATIONS BUT REMAINING IN THE MARKET CHANNEL AFTER DECEMBER 2016?

A: The current labeled product will still be saleable, but there will be a transition period. However, use of this product will require a VFD and fall under the new VFD claim structure. Some claims and inclusion rates listed on the label may no longer be allowed.

Q: FOR A DRUG WITH MULTIPLE CLAIMS FOR A SINGLE LEVEL (E.G., 40 G/TON TYLOSIN), WILL THE VFD HAVE TO SPECIFY ONE CLAIM, AND WILL THE FEED TAG ALSO HAVE TO INCLUDE JUST THAT CLAIM?

A: Yes, the VFD will specify one claim. The feed tag may have all claims.

Q: DO YOU EXPECT VETERINARIANS AND FEED DISTRIBUTORS TO CHARGE A FEE TO WRITE AND HANDLE THE PAPERWORK FOR A VFD?

A: Whether a fee is charged is at the discretion of the veterinarian and feed distributor.

Q: HOW WILL THE VFD BE HANDLED FOR ANTIBIOTICS FED DAILY FOR DISEASE CONTROL, SUCH AS LIVER ABSCESS CONTROL IN FEEDER CATTLE?

A: No different than any other VFD.

Q: DOES ZOETIS HAVE ANY PRODUCTS THAT ARE CURRENTLY LABELED FOR CONSTANT/NONDEFINED DURATION OF USE FOR PREVENTION/CONTROL CLAIMS?

A: Zoetis and other sponsors have products that are fed continuously or not for a short defined period, such as products to control anaplasmosis and liver abscesses. Feeding for these products will not change under GFI #213.

Q: IF WE HAVE MEDICATED FEED IN OUR INVENTORY, SUCH AS CTC IN MINERAL, CAN WE STILL SELL IT AFTER DECEMBER 2016 IF IT WAS MADE BEFORE THAT DATE?

A: Yes, but it will require a VFD after Jan. 1, 2017.

Q: TYLOSIN IS USED TO PREVENT LIVER ABSCESSSES. IS THAT CONSIDERED A PREVENTIVE TREATMENT OR A GROWTH PROMOTION?

A: Tylosin has a therapeutic claim for reduction in the incidence of liver abscesses caused by *Fusobacterium necrophorum* and *Arcanobacterium (Actinomyces) pyogenes* in growing-finishing cattle fed in confinement for slaughter. That use is not growth promotion and the use of Tylosin will require a VFD.

Q: I THOUGHT I HEARD THERE WAS ONE PLACE YOU COULD USE A VFD OFF-LABEL.

A: As with the current law, extra-label use of medicated feed additives is strictly prohibited.

Q: WHAT IS THE RATIONALE FOR NOT ALLOWING EXTRA-LABEL USE IN FEEDS?

A: This extra-label restriction was previously put into law and was subsequently added to federal regulation in 21 CFR 558.6.

Q: DO NON-FOOD-PRODUCING ANIMALS, SUCH AS ANIMALS RAISED FOR FUR OR CLOTHING, NEED A VFD FOR TREATMENT?

A: Yes. This is not a food issue; it is an antibiotic use issue.

Q: WHAT IS THE ALTERNATIVE OR PLAN FOR THE CONCERN OF SPECIFIC DISEASE PREVENTION OR CONTROL MEASURES FOR ANAPLASMOSIS IN BEEF COWS? WILL ANAPLASMOSIS NEED TO BE CONFIRMED OR DIAGNOSED BEFORE THE CTC CAN BE USED?

A: Chloretracycline is the only product currently approved for control of anaplasmosis in beef cattle. That approval will continue up to the finalization of the VFD and this guidance will not change. The other part of the question is around confirmation of the diagnosis and really speaks to the heart of what the VFD is all about. It's incorporating veterinary oversight into the use of medicated feed additives for the prevention, control and treatment of diseases in livestock animals. If a veterinarian provides a presumptive diagnosis of anaplasmosis, it will allow him or her to write the VFD. There is not a specific confirmatory process a veterinarian will need to go through to confirm or substantiate the presumptive diagnosis.

Q: WILL PROPHYLACTIC TREATMENT FOR NEW ARRIVAL CATTLE BE ALLOWED WITH THE NEW VFD RULE?

A: Prophylactic treatment, the term itself, is really not part of the descriptor for how we will use medicated feed additives. Medicated feed additives are approved for prevention, control or treatment of specific diseases, which are listed on their product labels. Only the growth promotion or feed efficiency uses currently on the labels of medically important antibiotics will be removed. Under a Veterinary Feed Directive — in other words, under veterinary oversight — a person would be able to use that medicated feed additive after the VFD comes into effect Jan. 1, 2017.

Q: IN CERTAIN AREAS, IT IS WELL ACCEPTED THAT CATTLE THAT ARE NOT ON PREVENTIVE CTC MINERAL ARE HIGHLY LIKELY TO HAVE AN OUTBREAK OF SUDDEN DEATHS. DO WE AS VETERINARIANS WAIT UNTIL AN OUTBREAK WITH DEATHS OCCURS BEFORE WE CAN PRESCRIBE PREVENTION IN EPIDEMIC AREAS?

A: It is important to remember the veterinary oversight portion of this regulation. Veterinarians can use their medical judgment to determine the likelihood of disease outbreak in any group of animals. The definition of prevention does not require that any animals display clinical signs of disease.

RECORD KEEPING: QUESTIONS ABOUT THE ADMINISTRATION OF VFD RECORD KEEPING

Q: IF A FEED MILL DOES A LOT OF CUSTOM MIXES WHERE THERE IS NO TYPICAL FEED TAG, WOULD THE FEED MILL JUST STAPLE A COPY OF THE VFD TO THE INVOICE SHOWING THE CUSTOM MIX?

A: The feed mill will need to keep a record for all feed containing VFD/medically important antibiotics. All uses of these products must be on-label.

Q: WILL VFDs NEED TO BE WRITTEN STARTING IN OCTOBER OF THIS YEAR?

A: Only for products that currently require a VFD; all new VFD requirements will start Jan. 1, 2017.

Q: WILL STORING VFDs AS PDF FILES AT FEED MILLS AND WITH PRODUCERS BE CONSIDERED 21 CFR PART 11 COMPLIANT?

A: If you are storing scanned versions of signed VFDs, then this storage should be acceptable. If you are storing electronically generated and signed copies, the computer system will need to meet the requirements of 21 CFR Part 11. This is an area where the industry is seeking more input and clarity from the Center for Veterinary Medicine (CVM).

Q: WILL PRODUCTS IN THE MANUFACTURER'S ORIGINAL PACKAGING HAVE TO BE ACCOUNTED FOR IN ANY PARTICULAR MANNER — FOR EXAMPLE, BY LOT NUMBER OR BY POUND — TO AN OVERSIGHT AGENCY? WHAT HAPPENS IF THERE IS DAMAGE, SUCH AS A BAG BROKEN DURING TRANSPORTATION?

A: At this point, there is no indication of a requirement in the works for accounting for or reporting to an oversight agency. Standard record keeping practices that track drug lot numbers and quantity used on a daily basis should be used. The only requirement is a general letter of distribution.

Q: AS A DISTRIBUTOR, WILL WE BE ABLE TO SUPPLY VFD FEED PRODUCTS TO FEED MILLS (NOT THE FINAL USER) WITHOUT HAVING THE VFD BUT WITH A LETTER FROM THE FEED MILL SAYING THAT THEY ARE RESPONSIBLE FOR GETTING THE VFD?

A: Distributors and feed mills have to file a letter of distribution.

Q: WHAT EVIDENCE WILL BE REQUIRED IN DIAGNOSIS TO JUSTIFY A VFD?

A: The veterinarian can use his or her clinical experience, judgment, medical history and/or diagnostic data to justify treatment. This justification does not need to be attached or appended to the VFD.

Q: WHAT INFORMATION WILL NEED TO BE KEPT ON RECORD FOR TWO YEARS?

A: A VFD will need to include information about location of the animals, indication for use (what is being treated) and the medication prescribed. For more details, visit the [FDA's website](#) or [ResponsibleAntibioticUse.com](#).

Q: WHEN DO PRODUCERS AND PRACTITIONERS FIND OUT HOW (AND TO WHOM) THE VFD WILL ACTUALLY BE SUBMITTED? WILL THE VFD BE SUBMITTED TO A CENTRAL WEBSITE, A STATE WEBSITE OR SIMPLY TO THE MEDICATED FEED SUPPLIER? WHEN DO PRODUCERS AND PRACTITIONERS LEARN ABOUT THE ACTUAL LOGISTICS OF IMPLEMENTING A VFD?

A: A VFD can be fulfilled through multiple channels. There will be training from the FDA and industry in the next 18 months. Be sure to check [ResponsibleAntibioticUse.com](#) for updates.

SPECIFIC SCENARIOS: SPECIFIC QUESTIONS ABOUT A LOCATION OR OPERATION TYPE

Q: HOW WILL THIS BE IMPLEMENTED WITH SMALL-SCALE PRODUCERS IN THE VARIOUS SPECIES?

A: All producers — no matter the size of their operations — will need a VFD from a veterinarian to use feed that includes medically important antibiotics.

Q: HOW IS THIS GOING TO AFFECT MY BACKYARD PRODUCERS AND 4-H/FFA SHOW ANIMALS?

A: All producers — no matter the size of their operations — will need a VFD from a veterinarian to use feed that includes medically important antibiotics.

Q: IN THE CASE OF A LARGE DISCREPANCY IN THE NUMBER OF ANIMALS LISTED ON THE VFD AND THE ACTUAL NUMBER OF ANIMALS GIVEN THE MEDICATED FEED, DOES THE VFD NEED TO BE AMENDED? ALSO, IS IT BETTER TO UNDER- OR OVERESTIMATE THE NUMBER OF ANIMALS?

A: All efforts must be made to estimate the number of treated animals as accurately as possible. The CVM will be looking for gross overuse of antibiotics compared with what is specified in the VFD. The CVM likely will issue more guidance in the future.

Q: TO CLARIFY A SITUATION WHERE THE FEED MILL IS IN A DIFFERENT STATE THAN THE ANIMALS BEING FED, DOES THE VETERINARIAN NEED TO BE LICENSED IN THE STATE WHERE THE FEED IS MANUFACTURED OR ONLY IN THE LOCATION OF THE ANIMALS THAT WILL BE GIVEN THE MEDICATED FEED?

A: The veterinarian must be licensed where the animals are fed.

Q: WILL THE VFD BE APPLICABLE TO BACKYARD ANIMALS AND FLOCKS AT ANY NUMBER? WILL THERE BE A CHARGE FOR THE VFD?

A: VFDs will be required for use of all medically important feed products. Charges will be determined by your veterinary provider.

Q: WILL A VETERINARIAN ON STAFF OF A FEED COMPANY BE ABLE TO WRITE VFDs FOR THE CLIENTS OF THE FEED COMPANY?

A: Yes, if and only if they are properly licensed and satisfy the VCPR requirements.

Q: DOES A PRODUCER NEED TO REQUEST A NEW PRESCRIPTION FOR EACH NEW LOAD OF CALVES PURCHASED, EVEN IF THE FEED AND LEVEL OF ANTIBIOTIC IS THE SAME? ARE PRESCRIPTION REFILLS ALLOWED?

A: Each VFD is tied to a group of animals, indication and time period. Multiple groups of animals are allowed on one VFD. Refills are still being clarified with the FDA.

Q: WILL A FEED MILL BE ABLE TO INVENTORY FLOOR-STOCK FEED PRODUCTS CONTAINING ANTIBIOTICS?

A: Yes, they will with a letter of distribution. If a feed mill sells directly to a producer, the producer/customer will need to provide a valid VFD to purchase those feed products.

Q: ARE ON-FARM MIXERS CONSIDERED A FEED MANUFACTURER?

A: Yes, and a VFD will be required if they are mixing final feed for animal consumption.

Q: WHAT IS THE NEW “DISTRIBUTOR FEED MILL” REGISTRATION ABOUT? IS THIS REQUIRED OF ALL MILLS FEEDING VFD FEEDS?

A: A feed mill will need to provide the FDA with a letter of distribution if they sell retail. The feed mill/retailer will need a valid VFD from a customer in order to sell any Type A medicated article or Type B and C medicated feed containing medically important products. The feed mill/retailer must maintain records for two years on each VFD.

Q: CAN A FEED BE FLOOR-STOCKED AT A FEED PLANT WITH A CERTAIN ANTIBIOTIC (E.G., AUREO S 700® (CHLORTETRACYCLINE/SULFAMETHAZINE)) AFTER A SINGLE VFD IS RECEIVED, BUT IF THE PLANT ANTICIPATES MANY MORE VFDs FOR THE SAME PRODUCT AND DRUG LEVEL (LIKE A RECEIVING CATTLE PROGRAM)?

A: With a letter of distribution, feed mills can floor stock feeds containing AUREO S 700. The customers will need to provide a VFD in order to purchase the product from the feed mill.

Q: WE ARE A PRE-MIX MANUFACTURER THAT PRIMARILY SERVICES OTHER FEED COMPANIES AS A REGISTERED FDA FEED MILL. WILL WE NEED TO MAINTAIN THE VFD PAPERWORK IF WE ARE NOT SELLING TO THE END USER?

A: The people who will have to maintain the VFD are those who are supplying the final product where the feed is being fed.

If you have additional questions regarding the VFD, consult your veterinarian or Zoetis representative or visit ResponsibleAntibioticUse.com/VFD.