Veterinary Feed Directive (VFD) Overview

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American Feed Industry Association

AFIA members include:
- Ingredient Suppliers
- Feed Manufacturers
- Associations
- Industry Support
- Pet Food Manufacturers
- Educational Institutions
- Pharmaceuticals
- Equipment Manufacturers
- Media

Represents 75% of the feed (173 million tons) in the U.S.A. and 70% of the non-grain ingredients

Over 600 members

Founded in 1909

Based in Arlington, VA
The Feed Industry at a Glance

6.8 billion bushels of grain and...

1/2 billion tons of agriculture commodities make feed for...

9.5 billion livestock animals

&

70 million dogs

and

74 million cats
Animal Feed

WHAT IS FEED?

- Distillers Grains
- Minerals
- Soybean Meal
- Medications
- Forage
- Sorghum
- Animal Protein
- Corn
- Vegetable
- Barley
- Oats
- Vitamins
- Fruits
- Wheat
Veterinary Feed Directive (VFD)

President Clinton signed the Animal Drug Availability Act into law in October, 1996

It created a new category of animal drugs – VFD drugs – that can be used for animals with a veterinarian's order.
Veterinary Feed Directive (VFD)

• VFD offered as alternative to Rx feed
  – But it is not a Rx under federal or state law
• First drug was approved in 1996 for swine
• Then there were three with five uses
  – Florfenicol (aquaculture and swine)
  – Tilmicosin (beef and swine)
  – Avilamycin (swine)
• Basically, requires more documentation for control/use of drugs in feed
Why Make Changes?

Growing concern over antimicrobial resistance

**President signs order to fight superbugs**

By Saundra Young, CNN
Updated 9:29 PM ET, Thu September 18, 2014

17 photos: Antibiotic-resistant bacteria
Carbapenem-resistant enterobacteriaceae (CRE)

**Story highlights**

- Obama administration steps up efforts to combat problem of antibiotic resistance
- Antibiotic-resistant bacteria is a serious challenge to public health and national security
- President establishes inter-agency task force and advisory council

The rise in antibiotic-resistant bacteria could lead to a future full of untreatable infections, experts have warned for years.

Now the Obama administration is stepping up its efforts to combat the growing problem of antibiotic resistance.

The President signed an executive order Thursday establishing a new inter-agency task force charged with developing a national strategy to combat antibiotic-resistant bacteria.

Dr. John Ulzheimer, director of the White House Office of Science and Technology Policy and assistant to the President, said the task force will work to accelerate the development of new drugs and vaccines.

As more bacterial strains become antibiotic resistant, stopping the spread of "superbugs" is a top public health priority for agencies all over the world. Here's a look at how the growing problem of antibiotic resistance developed and some steps you can take to help.

**The rise of superbugs: How antibiotic resistance develops and how you can help stop it**

By Published August 26, 2015 | Hardwald

Even the man who discovered penicillin in the 1940s knew that one day antibiotics could become useless if used improperly.

Sir Alexander Fleming warned about the misuse of antibiotics leading to resistance, and now experts say that's exactly what's happening. The Centers for Disease Control and Prevention (CDC) estimates that each year, 2 million adults become infected with antibiotic-resistant bacteria, and about 23,000 die from them.

The spread of antibiotic-resistant bacteria is fueled mainly by three things: doctors prescribing antibiotics when they aren't needed, patients not finishing antibiotic prescriptions when they are needed and the routine antibiotic treatment of livestock that eventually become food.

According to a 2013 CDC report on antibiotic resistance, "up to half of antibiotic use in humans and much of antibiotic use in animals is unnecessary and inappropriate, and makes everyone less safe. Stopping even some of the inappropriate and unnecessary use of antibiotics in people and animals would help greatly in slowing down the spread of resistant bacteria."

Drug-Resistant Bugs a Global Threat, WHO Says - NBC News

APR 30 2014, 8:07 PM ET

Germs that defy antibiotics are now a major global health threat, causing near-un treatable cases of diarrhea, septis, pneumonia and gonorrhea, the World Health Organization said Wednesday.

Overuse and misuse of antibiotics are to blame, and the WHO's been warning about the problem for years but it keeps worsening, says Dr. Keiji Fukuda, WHO's Assistant Director-General for Health Security.

"We are really seeing the emergence of this all over the world," Fukuda told a news conference.

"What it means is that all of us, all our family members...when we are most vulnerable and in need of these medicines there is simply the chance that they are not available," he added.

"Unless we take significant actions to improve efforts to prevent infections..."
VFD: What is all changing?

What documents are out there?

1. Guidance for Industry 209
   • April 2012 – Judicious Use Strategy

2. Guidance for Industry 213
   • December 2013 - use of medically important antibiotics in food and water will be limited to therapeutic purposes only by January 2017

3. Veterinary Feed Directive, Final Rule
   • June 2015 – Changes VFD form and process

4. Draft Guidance for Industry 233
   • Provides a common format for a fillable form and Describes the requirements for sponsor submission of a VFD to FDA
VFD: Goals for Changes

(Jan 2017)

• Supervision of licensed veterinarians
• Remove production purposes (i.e., growth promotion and feed efficiency)

“Judicious use of medically important antimicrobials in food-producing animals”
Animal Drugs Expected to be VFD Drugs

Apramycin (not marketed)
Avilamycin (new VFD)
Chlortetracycline
Erythromycin (not marketed)
Florfenicol (already VFD)
Hygromycin B
Lincomycin
Neomycin
Oleandomycin (not marketed)

Oxytetracycline
Penicillin
Sulfadimethoxine:Ormetoprim
Tilmicosin (already VFD)
Tylosin
Sulfamerazine
Sulfamethazine
Virginiamycin

*Bambermycin, ionophores, and dewormers are not included in this list.*

List of affected products:
http://www.fda.gov/AnimalVeterinary/SafetyHealth/AntimicrobialResistance/JudiciousUseofAntimicrobials/ucm390429.htm
VFD: The Process

• Simple process; involves veterinarian
• Lawful VFD form is required from veterinarian → producer → feed distributor before medicated feed can be delivered to a producer
• Purchases of drug premix from supplier triggers “use” letter to FDA and an “acknowledgement” letter to supplier about agreeing to comply with requirements
VFD: The Process

- Veterinarian (retains original)
- Producer
- Feed Distributor
- FDA
- Drug Supplier

- Sends one time “intent to distribute letter”
- Sends “acknowledgement letter”
VFD: The Process

Who can classified as be a distributor?

- The Feed Mill
- The Retail Establishment
- The Producer??

Why is it important who is classified as the distributor?

- The major paperwork and records requirements falls on the distributor
VFD: The Process

What are the paperwork and records requirements for the distributor?

- Maintain all VFD forms in files for two years post-distribution
- Send one-time "Intent to Distribute" letter to FDA stating intent to distribute a VFD medicated feed
- Send one-time "Acknowledgement Letter" to the supplier of the VFD medicated feed stating the recipient will abide by the rules and not provide the drug to any firm without a lawful VFD or similar letter of acknowledgement
VFD: The Process

• VFD form has three parts; all which must be maintained for two years post-distribution
• Original part for vet; one for producer and one is for the feed distributor
• A VFD form is specific for the species, class, group of animals, drug levels and indications for use
• NO deviations from legal levels, indications, species or age class are allowed, even by the vet
  – Would constitute a violation
VFD: The Process

The **manufacturer** of the VFD medicated feed (Feed Mill) is responsible for the following:

- Make sure the VFD medicated feed is a legal use level and/or legal drug combination
- Make sure the VFD medicated feed has a legal medicated feed label
- Send the one-time **"Intent to Distribute"** letter to **FDA** stating intent to distribute a VFD medicated feed **only** if they are **selling directly to a producer**
- Maintain VFD Form in file for 2-years if **selling directly to producer**
- Send the one-time **"Acknowledgement Letter"** to **the supplier of the VFD Type A medicated feed article** stating they will abide by the rules and not provide the drug to any firm without a lawful VFD or similar letter of acknowledgement
VFD: The Process

• The VFD form must contain (some are pre-printed):
  • Drug name
  • Amount
  • Indications for use
  • Location
  • Number and kind of animals
  • Name/address/phone of veterinarian
  • Treatment date
  • VFD date
  • Feeding instructions
  • Withdrawal time
  • Warning and/or cautionary statements
  • Veterinarian’s signature
  • Affirmation Statement
VFD: Affirmation Statements

Veterinarian must mark one of the following on each VFD form:

- Drug cannot be used in combination with other drugs
- Drug can be used with the following FDA-approved combinations [list allowed combinations]
- Drug can be used with any FDA-approved combination
VFD: Practical Issues

• Original VFD form is retained by the veterinarian and copies to the producer and feed distributor
• Faxes and limited electronic VFDs are allowed
• Phone-in VFDs are not allowed
• Feed distributors can deliver smaller amounts than on VFD and save rest for later
• Delivering a VFD medicated feed to the farm before the producer has a VFD form is not permitted
VFD: Current Challenges

• Feed companies police the veterinary profession by reviewing the form and making sure the drug use is legal
  – However, FDA has clearly stated vets are responsible for the accuracy of the VFD

• Failure to return the original VFD forms by vets for faxes and electronic VFDs was common and left the feed mill vulnerable for violations
  – This will no longer be an issue with the changes
  – Now may have difficulty reading triplicate form...
VFD: Current Challenges (cont’d.)

• More VFD approvals increases the paperwork load and review times for feed distributors
• Feed distributors could be put at a disadvantage when producer customer cannot be served appropriately due to incorrect forms
• Storing VFD medicated feeds prior to use and prior to receiving the VFD form could present problems for producers
VFD: The Future Challenges

• How will this happen: overnight, phase-in???
• Will drug sponsors save these changes and release all the new drugs at once?
• Will FDA require training for vets?
• Will there be a list of trained vets?
• Will there be enough vets?
• Will there be FDA enforcement with vets?
• Will there be FDA enforcement at the distributor level?
VFD: The Future Challenges

• AFIA is addressing these issues with FDA
• We hope FDA is agreeable to an orderly phase-in period
• FDA will likely require “stickering” of old premix bags to note that use of these premixes after 2017 will require a VFD
• We hope FDA will allow supplies to be exhausted
VFD: Timeline

- The new VFD form should now be implemented
- Summer/Fall 2016, drug sponsors should contact feed companies with label changes
- January 1, 2017, must cease all growth promotion and feed efficiency claims
  - can still use old premixes but must have a valid VFD
- Will likely allow some time exhaust supplies:
  - AFIA is doing a survey to help with decisions
VFD: The Premix Survey

• Survey will go out to medicated feed facilities soon asking about amount and $ volume of premixes made and on-hand
• This is to build a baseline and determine how much will remain in December 2016
• Another survey will go out in Nov. 2016 and again in July 2017, if needed
• The survey results will be the basis for asking FDA for extension of time to exhaust supplies
VFD: Resources

- [http://feedstuffs.com/vfd.aspx](http://feedstuffs.com/vfd.aspx)

We partnered with feedstuffs on a VFD webinar

FDA is a always another resource