

VFD : On Farm Changes

Chris J. Rademacher, DVM

ISU Swine Extension Veterinarian

cjrdvm@iastate.edu

Twitter: @cjrdvm

Summary of FDA Guidance 209/213

1. Limits “medically important” antibiotics to therapeutic purposes (to protect animal health and well-being).
 - Therapeutic Purposes
 - Treatment
 - Control
 - Prevention
2. Non-therapeutic uses of “medically important” antibiotics are no longer permitted.
 - Improved growth and feed conversion

Summary of FDA Guidance 209/213

3. Also states the importance of **veterinary oversight** into all on-farm antibiotic decisions.
- **Veterinary oversight** will now guide all antibiotic decisions on the farm.
 - All “medically important” antibiotics used in mass medication (feed/water) will have to be scripted (Rx) in their use.
 - Eliminates “Over the Counter” usage of medically important antibiotics used in mass medication (Feed and/or Water).
 - No longer be able to purchase “medically important” antibiotics (feed/water) without a prescription (Rx) from a licensed veterinarian.



How do you determine if an antibiotic is “medically” important?

- FDA Guidance #152 (2003)
- Risk assessment for veterinary drugs creating “**potential**” resistance issues for human medicine.
 - **All scientific assessments done to date have demonstrated that the risk is negligible.**
- Classified all antibiotics into 2 classes:
 - Medically Important for Human Use
 - Non-medically Important for Human Use



Antibiotics **NOT** affected by Guidance 209/213

- Antibiotics that are already VFD or Rx based:
 - avilamycin, florfenicol, tilmicosin; or Rx - Tylosin.
- Antibiotics that are not medically important:
 - Ionophores (monensin, lasalocid, narasin (Skycis, etc.)
 - Bacitracin (BMD, bacitracin zinc)
 - Bambermycins (Flavomycin)
 - Carbadox (Mecadox)
 - Tiamulin (Denagard)
- Other drugs (that are not antibiotics), including:
 - Anthelmintics: Coumaphos, Fenbendazole, Ivermectin
 - Beta agonists: Ractopamine, Zilpaterol
 - Coccidiostats: Clopidol, Decoquinate, Diclazuril

Producer Responsibilities

- Establish VCPR with your veterinarian
- Ensure VFD is valid
- Retain VFD copy for 2 years

VCPR: Federal

- Valid veterinarian-client-patient relationship:
 - Vet has assumed responsibility for making medical judgments regarding health of animal(s) and need for medical treatment. Client (owner or caretaker) has agreed to follow instructions of vet
 - Sufficient knowledge of animal(s) by the vet to initiate at least a general or preliminary diagnosis of medical condition of the animal(s)

VCPR: Federal

- Valid veterinarian-client-patient relationship:
 - Practicing vet is readily available for followup in case of adverse reactions or failure of regimen of therapy. Such a relationship can exist only when **vet has recently seen and is personally acquainted with the keeping and care of animal(s)** by virtue of examination of animal(s), and/or by medically appropriate and **timely visits to premises** where animal(s) are kept.

VCPR: AVMA

- A VCPR is present when all of the federal requirements are met, as well as:
 - The vet provides oversight of treatment, compliance, and outcome.
 - The producer agrees to follow the instructions provided by the veterinarian.
 - Protocols
 - Patient records are maintained.
 - Patient records are VITAL
 - Document any VFD feed being fed on your site

VFD Scope

- One vet
 - not clinic, individual veterinary signature
- One client
 - person responsible for the care and feeding of the animals receiving the VFD feed
- One feed distributor
 - Individual, partnership, corporation, or association
 - May have multiple locations & fill from any of them
- One or more animal production sites (new)
 - Can have multiple sites as long as they are managed the same and fed from the same feed mill.
- One medication (+/- legal combinations)

VFD Process

- VFD must be signed by vet
 - Electronic signature and transmittal not only acceptable, but encouraged by FDA!
- Vet distributes VFD to both distributor and client (owner) via digital, fax, email or mail
 - Telephone VFDs will still not be allowed
- **Producer, vet and distributor must save copy for 2 years**
 - **Distributor must retain all feed deliveries tied to the VFD.**
 - **Producer/Site should keep a copy as well.**

Potential Inspection Questions

- Questions specific to producers/clients:
 - Does the client keep copies of VFD orders for at least 2 years?
 - Did the client feed the VFD feed to the authorized number of animals on the VFD order?
 - Did the client feed the VFD feed for the identified duration on the VFD order?
 - Did the client stop feeding the VFD feed prior to the expiration date on the VFD order?
 - Did the client follow the withdrawal period for the VFD feed, if any?

What about “Pulse Dosing”?

Pulse dosing

- Defined as using the same antibiotic on the same group of animals at 2 different times
 - Refill?
 - Treatment failure?
- Current recommendation from FDA-CVM
 - Write 2 different VFD’s
 - One for each pulse.
 - Veterinary documentation on why you need the second pulse.

What format can I use to store my VFD?

- It depends!
 - Veterinarian – must store in original format, generated electronically it must be electronic
 - Producer/client – any format
 - Feed distributor – any format

A producer gets feed from a cooperative all underneath the same ownership, but may be milled out of 3 different physical plants. Will they need to get a different VFD from each of the mills?

- NO
 - Since all the mills are technically under the same ownership structure, you would only need 1 VFD.

How close does the client have to be to the intended duration of feeding (number of days fed)?

- VERY CLOSE
 - Must be fed according to the duration listed on the label
 - Aureo: “For not more than 14 days”
 - Pulmotil: “shall not be fed to pigs for more than 21 days
 - Linco/Tylan: “..feed for disease X for 21 days at 100 grams and then at 40 grams to market....”
 - Regulator comments indicate they expect it to be close to duration stated on VFD (i.e. within 1-2 days)

My veterinarian works in a veterinary clinic with 5 other veterinarians. Can any of the vets write me a VFD?

- NO
 - A valid VCPR is with one veterinarian, not a veterinary clinic

Resources

- Iowa Pork Industry Center
 - <https://www.ipic.iastate.edu/>
 - Go to Diseases and Health tab
- FDA website
 - Questions: AskCVM@fda.hhs.gov
- Veterinary and industry trade associations
 - Pork.org/antibiotics resource center
- GlobalVetLINK website
 - VFD, Script and OTC drug list
 - Paper vs electronic VFD process
 - Questions: info@globalvetlink.com

The screenshot displays the Iowa Pork Industry Center website. At the top, it features the Iowa State University logo and the text 'College of Agriculture and Life Sciences | College of Veterinary Medicine'. Below this is a navigation bar with 'IOWA STATE UNIVERSITY' and 'Iowa Pork Industry Center'. A search bar is located in the top right corner. The main content area is divided into a left sidebar with a menu and a main content area. The sidebar menu includes: IPIC Homepage, Animal Welfare/Handling, Breeding and Reproduction, Diseases and Health (highlighted), Economics and Marketing, Employee Training and Managing, Environment, Facilities, Niche Production, Nutrition, Pork Quality/Safety, Swine Exhibition and Youth Projects. The main content area is titled 'Diseases and Health' and contains several sections: 'Antibiotic Use' with links to 'IPIC Veterinary Feed Directive Information', 'Farm Foundation Regional Meetings Questions and Answers', 'New Antibiotic Rules Jan. 1, 2017: Plan Ahead fact sheet', and 'Use of Antibiotics in Livestock Production in Light of New FDA Guidelines of VFD questions and scenarios with FDA responses'; 'Biosecurity' with links to 'Biosecurity 101', 'Center for Food Safety and Public Health Swine Biologic at Risk Management', 'Pork Information Gateway - Biosecurity of Pigs and Farm Security', and 'Truck wash facilities and information'; and 'Disease' with a link to 'Foot and mouth disease (FMD) - FMD fact sheet'. On the right side of the page, there is a 'Check out' section with links to 'Hot topics', 'Calendar of events', 'Certification information', 'Current publications', 'IPIC programs and projects', 'Presentations', and 'Software and other decision tools'. Below this is an 'ISU links' section with links to 'Agricultural and Biosystems Engineering', 'Animal Science', 'Economics', 'ISU Extension and Outreach', and 'Veterinary Diagnostic and Production Animal Medicine'. At the bottom right, there is a 'Partner links' section with logos for 'IOWA PORK PRODUCERS ASSOCIATION' and 'pork checkoff'.