

Update on Antibiotics in Food Animals 2018

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Risk Assessment Approach

- World Health Organization- 2014- Antimicrobial Resistance Global
- Report on Surveillance
- 114 countries, 7 bacteria that cause systemic disease
- Superbugs, Carbapenum resistance Enterobacter
- N. gonorrhoea, MRSA, Strep. Pneumonia, Malaria's Resistance
- TB

Action plan

- Slow the emergence of resistant bacteria and spread of infections
- 2 Strengthen one health surveillance
- 3. Find diagnostic test for bacteria
- 4. Basic and applied research for alternate therapy, vaccines and new antibiotics.
- 5. International collaboration

Expected Outcomes

- 1. Eliminate growth promotions
- 2. Upgrade antibiotic stewardship in healthcare facilities
- 3. Money- attached to research.
- 4. Metrics recommended
- 5. National One Health Surveillance
- NARMS program as well the NAH system(USDA)
- Strengthen internal laboratory diagnostics and pathogens

VFD- January 1, 2017

- A VFD is similar to a veterinary prescription for producers to obtain and use medically important antibiotics in feed in accordance with the FDA-approved directions for use.
- Across animal agriculture, there are many in-feed antibiotics that will be affected by this guidance.
- 20 months into the program. Reviewing the success.

VCPR

- Helping you know what to expect
- A VFD can only be issued from a licensed veterinarian, based on a valid veterinarian-client-patient relationship (VCPR), and include all information, shown at right, before a producer may use feeds containing antibiotics that are medically important (including complete feeds, medicated supplements and crumbles) to human health.

Began Jan. 1, 2017:
 This product will require a veterinary feed directive issued by a licensed veterinarian and will be subject to the following restriction:
 *Caution: Federal law restricts medicated feed containing this veterinary feed directive (VFD) drug to use by or on the order of a licensed veterinarian.**
 This product will no longer be approved for the indication of: increased rate of weight gain and improved feed efficiency, which means the use of this product for these purposes will no longer be legal after that date.
 *21 CFR 555.6 (Transition Label)

SUGGESTED STEPS FOR A SUCCESSFUL TRANSITION
 1. Assign a VFD administrator within your operation or feed mill to learn about the details of the new VFD regulation.
 2. Immediately establish a VCPR, as required by state regulation.
 3. Start reviewing your current list of medications to see what might be affected.
 4. Contact your veterinarian, feed supplier or nutritionist to discuss ways for your operation to comply.
 5. Add a step in your current record-keeping procedures for recording and filing VFD documentation.

Labeling- critical

Final labeling implemented after Jan. 1, 2017. As shown below, it will state that this product will require a VFD and use in an extra-label manner is not permitted.
 Final label example:
 Caution: Federal law restricts medicated feed containing this veterinary feed directive (VFD) drug to use by or on the order of a licensed veterinarian.
 Use of feed containing this veterinary feed directive (VFD) drug in a manner other than as directed on the labeling (extra-label use) is not permitted
 Also, new drugs have a NADA number and generic have an ANADA number. This shows the veterinarian what is a legal approved drug.

Documentation

- If you did not document, it was not done, it is not traceable or retrievable. Mandatory requirement
- Veterinarian, producer and the vendor or manufacturer has to keep records and animal numbers of all antimicrobials used for 2 years.
- FDA- did not make a template, left to manufacturers and veterinarians. AVMA has an example of a VFD directive, most of the companies will have one for their products.

Documentation

Three important facts to remember:

VFD 6 Months
 VFD 2 year-record keeping- veterinarian- producer-manufacturer or feed mill
 Extra-label use not allowed- EXCEPT FOR MINOR SPECIES

December 2016 Minor Species Extra-label Use

"Minor species" are all animals other than humans that are not one of the major species. They include animals such as zoo animals, ornamental fish, parrots, ferrets, and guinea pigs. Some animals of agricultural importance are also minor species. These include sheep, goats, catfish, guinea birds, and honey bees among others.

Honey bees require a VFD with a VCP, a visit to the farm, diagnostics through the state diagnostic labs if need antibiotics. Work with the honey bee inspectors.

Oxytetracycline, Chlorotetracycline, Tylosin, Lincomycin are commonly used products.

There needs to be a diagnosis and follow the exact directions to administer in the hives. The veterinarian must work with the bee inspectors for a smooth transition of treatment.

21 CFR Part 530, states many species may use extra-label feed additives if necessary by the veterinarians VFD. The 2 most prevalent diseases are American Foulbrood and the European Foulbrood.

The American Foulbrood (Paenibacillus larvae) AF8, and the hive must be burned and buried. If diagnosed in the hives. These are spore forming. If the surrounding hives are found to be free of AF8, then control can be prescribed by the veterinarian with a VCP and VFD. All directions and withdrawal times must be followed. FARAD may be consulted.

European Foulbrood - Melissococcus plutus (EF8) is non-spore forming and treatable. Destroy equipment, get new cones, sterile all areas.

• <http://www.fda.gov/oc/ohrt/2016/12/20161201.html>



draft: Guidance for Industry for Labeling Honey and Honey Products.
<https://www.fda.gov/food/guidanceregulation/guidancedocumentsregulatoryinformation/labelingnutrition/ucm389501.htm>

FDA guidelines

- May use antibiotics with a labeled method for poultry, ducks, chickens, turkeys.
- Use of antibiotics under a veterinarian is permitted, therefore this will be used written by a veterinarian, and administered by the labeled dose and the withdrawal time for safe removal of any antibiotic residual in the birds.

Antibiotics that are still OTC

- Bacitracin (BMD)
 - Bambermycin (Flavomycin)
 - Carbadox (Mecadox)
 - Tiamulin (Denagard)
 - Narasin (Skycis)
- Ionophores
Injectable drugs such as PPG, LA 200.

E. Coli - secondary to viral infection

- Treat these chickens, then they cannot be marketed as never using antibiotics because used an ionophores.

EDUCATION PROGRAMS

- Strengthen programs in medical professional schools, veterinary profession, food animal producers and the public.
- Sponsoring programs
- Outreach programs are vital, and the veterinary microbiology scientist are vital to this education.

•VFD REQUIRED WITH A VCPR

- Chlortetracycline (Aureomycin, CLTC, Pennchlor)
- Chlortetracycline + Sulfamethazine (Aureo S 700)
- Neomycin + Oxytetracycline (Neo-Terramycin, Neo-Oxy)
- Oxytetracycline (Terramycin, Pennox)
- Tylosin (Tylan)
- Tilmicosin (Pulmotil)
- Virginiamycin (V-Max)

VFD information

- The animals or approximate number of animals to be treated prior to the expiration date.
- Indication of drug use, level of drug in the VFD feed, and length of therapy. Withdrawal time, specific instructions, any cautionary statements.
- Refills, number of refills authorized, if permitted by the drug approval, approved condition or index listed. If not on the label, then do not write for refills.

Swine - AASAP-

- Closed system- biosecurity-and
- Preventive - husbandry, vaccines, differential diagnosis.
- Global vet link, producers, electric VFD .
- Antibiotic- key tool for health and welfare, must have reliable diagnostics, and better evidence based medicine.
- China- 1/10 diagnostic structure, but we have world class state diagnostic labs. Veterinarians use the state diagnostic lab. Prevention and relief of animal suffering with a valid diagnosis
- Immune enhancing products as alternatives

Beef Quality Assurance Program

- Producer VFD Preparation Steps
- Develop a Valid Veterinarian Client Patient Relationship ([VCPR Form \(pdf\)](#))
- Develop a Herd Health Plan (Vaccination and Treatment Protocols)
- Herd Health Observation and Diagnosis
- Follow Treatment Protocols
- Obtain Proper VFD for Feed Grade Antibiotics with Valid Veterinarian's Signature ([AVMA VFD Example Form \(pdf\)](#)) go to the website
- Feed as Directed on FDA Approved Label and VFD
- Maintain VFD for 2 Years

European Antimicrobial Resistance Program

- European Medicines Agency Science Medicine Health
- 2015
- Risk associated with antimicrobial resistance due to use of antimicrobials in food animals.
- Source World for Animal Health.
- Looked at a Risk Assessment
- Concentrating on food borne pathogens

New Drugs - Banamine TD-order chart

<https://www.merck-animal-health-usa.com/banamine-td/how-to-use>

- Banamine Transdermal- Relief of Pain and Fever in Beed and Dairy Cattle over 20 months and 8 day deferral.
- Pre-calibrated by weight in pounds at a dose of 3mls/ 100lbs on dry skin. Pour down the midline of the back from withers to tail head.



Chicken medications

- 8.18- Zoetis- Avatec and Lincomix (lasalocid Type A and lincomycin Type A medicated feed) to be used to manufacture Type C medication feed
- 5.5.18 Zoetis Zoamix and Lincomix - Zoalene and lincomycin- Type A medicated feed. Label NADA- coccidiostat and antimicrobial
- Broiler chickens- Label- NADA Prevention of coccidiosis and necrotic enteritis caused by Clostridium spp or other organisms sensitive to lincomycin.

Broiler Chickens

- Integrity- Elanco Avilamycin Type A medication feed-
- Label change from 10 days to 18 days.
- Integrity and Bio-Cox (Avilamycin and salinomycin Type A medicated article- NADA- Prevention of mortality caused by necrotic enteritis associated with CI. Perfringes and prevention of coccidiosis caused by *Eimeria tenella*, *E. necatrix*, *E. acervulina*, *E. maxima*, *E. brunetti*, and *E. mivati* in broiler chickens.
- Maxiban 72- Elanco Narasin and nicrbazin Type A medicated feed
- Changes withdrawal time from 4ppm to 52 ppm and reduces withdrawal from 5 days to zero days.

Swine

- Enroflox 100 Injection for Swine- generic Norbrook
- The effect of the supplement provides for the addition of the use of the drug via intramuscular injection in swine, the addition of two pathogens, *Bordetella bronchiseptica* and *Mycoplasma hyopneumoniae*, to the swine respiratory disease (SRD) treatment and control indications and the addition of indications for the control of colibacillosis in groups or pens of weaned pigs where colibacillosis associated with *Escherichia coli* has been diagnosed.

Lactating dairy and beef cows

- NADA Merial Cystorelin an added indication * For the use with cloprostenol sodium for estrus synchronization to allow for fixed time artificial insemination (FTAI).

Beef and non-lactating cattle

- Nuflor Intervet NADA label safety studies were performed to address the food safety. Complete

Beef cattle and swine

- Tylovet 40 Type A medicated feed- generic by Huvepharma Food

Chicken Medications-cont

- ANADA CocciAid amprolium 9.6% Oral Solutions- coccidiosis in growing chickens, turkeys and laying Hens by Aurora.
- Make sure it is diluted properly, prepared fresh
- Zero withdrawal .

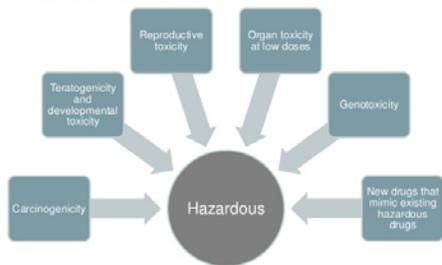
USP 800 Handling of Hazardous Drugs

- Antivirals and some Antibiotics are on the Hazardous Drug List due to Allergy
- Penicillin's and Tetracycline on the list (allergies)
- Train your employees, producers with protective gloves.

SCOPE of USP 800

- To discuss the current regulations for safe handling of medications.
- To improve healthcare worker involvement in protection from hazardous chemicals as well as protect the patient.
- To describe practice and quality standards for handling HD's

WHAT MAKES A DRUG HAZARDOUS?



USP Chapter 800

- References NIOSH List of Antineoplastic and Other Hazardous Drugs in Healthcare Settings. This is the source of the most common HD's, rather than creating more list, one location source.
- In addition, create and maintain own list of HD's
- Reviewed with each new drug or dosage form, and at least annually of all drugs for changes.
- Risk assessment of other dosage forms.

Handling of HD's- May result in exposure through skin contact, inhalation, ingestion or injection

- Handled under conditions that promote patient safety, worker safety, environmentation protection and infection prevention.
- HD areas must be restricted and distinguishable.
- Designated facilities and areas for Receipt and unpacking, storage, non-sterile compounding.
- Counting tables from bulk containers, pouring oral liquids, mixing topical, weighing or mixing components, reconstituting powders or lyophilized HDs. Withdrawal of injectable, Expelling air from syringes filled with HD, and expelling HDs from a syringe.

What does this mean?

- Have an SOP, have MOCK spills, or other problems that you think you may encounter and go over these with you staff.
- Make sure that all women and men of child bearing age understand the risk of handling hazardous drugs.
- They need to sign a waiver that they have been trained in protection and understand the risks.

Closed systems- Very important

- E.g. Spiros/ChemoClave, Genie CSTD Vial, Universal Vented Vial, Equishield.
- Drug manipulation in plastic sleeves, not the best.
- Need to be closed from the original vial all the way to the patient.

Personal Protective Equipment (PPE)

- Head/Hair Covers- appropriate- Also, mask may be replaced with shields.
Gowns: Polyethylene-coated, polypropylene gowns or other laminate material. Long sleeved, closed back, closed cuffs (elastic or knit) Changed every 2-3 hours or after contamination.
- Shoe covers- 2nd pair donned before entering buffer room and removed before exiting
- Gloves- ASTM standard D6978/ powder-free/ Changed every 30 min or when damaged or contaminated, over cuffs.

Summary

- VFD- follow strict paperwork guidelines for 2 years
- Make sure you have the VCPR
- Make sure the withdrawal times are correct
- For minor species, call FARAD for the correct withdrawal times.
- Make sure you have vaccinations for your staff such as rabies and tetanus.
- Document training of safety for HD and all infections.
