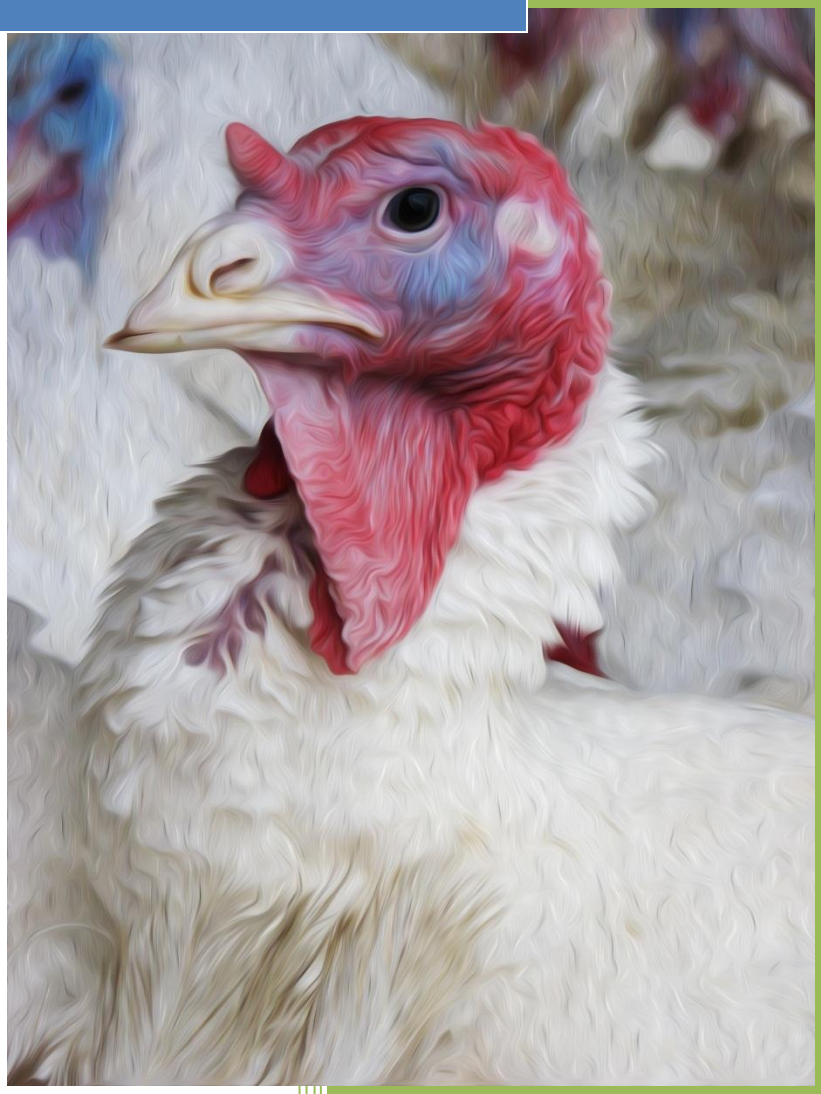
NATIONAL Turkey FEDERATION

Stewardship Manual

All those involved in turkey production work hard every day to maintain the health and welfare of our birds, to keep our environment clean, safe and sustainable and the products we produce safe, wholesome and affordable. The National Turkey Federation has worked with its members, who represent 99% of the industry, to adopt stringent standards to ensure consistency across the turkey industry. Through a variety of documents, we have worked to communicate these standards both to those involved in turkey production as well as those outside the industry who are interested in better understanding all that is done to keep the animals, food and environment safe, healthy, and sustainable.

The purpose of this document is to consolidate our stewardship information into one easy-to-use manual. Though much of the information included we will be familiar, new information is included to reflect the regulations published in 2015 regarding the Veterinary Feed Directive and the Preventive Controls for Animal Food. Given the record-keeping requirements in those rules, we have also included a section to help better understand documentation.



Acknowledgements

This manual was produced with generous financial support from USPOULTRY.

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Background

The health and welfare of turkey flocks is of the utmost importance to NTF members. The foundation of our commitment to animal health and food safety is our effort to protect the health and welfare of the turkeys. Just as in human medicine, the appropriate antibiotic use and management of that use is essential to protecting the health of turkeys and by extension, human health.

Veterinarians are limited in their use of therapeutic antimicrobials in feed based on Food and Drug Administration (FDA) regulations published in the Code of Federal Regulations (21 CFR) and veterinary feed directive drugs section of the Animal Drug Availability Act of 1996 as well as the final Veterinary Feed Directive rule published June 3, 2015. Industry also is effectively bound by various FDA "Guidance for Industry Documents" that, while technically not having the force of statutory or regulatory law, detail the agency's expectations of how animal drugs will be administered.

On December 11, 2013, the FDA finalized Guidance for Industry #213 *New Animal Drugs and New Animal Drug Combination Products Administered in or on Medicated Feed or Drinking Water of Food Producing Animals: Recommendations for Drug Sponsors for Voluntarily Aligning Product Use Conditions with GFI #209*, establishing procedures for phasing out growth promotion indications for medically important antimicrobials in alignment with Guidance for Industry #209 *The Judicious Use of Medically Important Antimicrobial Drugs on Food-Producing Animals*. FDA's Center for Veterinary Medicine (CVM) will assess progress made by drug sponsors after a 3-year period (December 2016). Until December 2016, please check labels carefully as they will be changing to reflect compliance with Guidance 209 and 213. After December 2016, production claims will have been eliminated from all labels.

The two guidance documents and the VFD regulation are integrated pieces of an FDA policy to more tightly control the use of antibiotics the agency deems "medically important" in food-producing animals. The VFD regulation mandates the rules and responsibilities of licensed veterinarians in prescribing and administering medically important antimicrobials in feed. Guidance for Industry #209 establishes two principles: use of medically important antimicrobial drugs in food-producing animals should be limited to uses considered necessary for assuring animal health and use of medically important antimicrobial drugs in food-producing animals should include veterinary oversight or consultation. Veterinarians need to be involved in decisions regarding antimicrobial use in animals by taking into consideration the health and welfare of the animals and expected treatment outcome. Use of all medicated feed articles and combinations in poultry require following the FDA-approved label completely, as extra-label drug use is not permitted in feed. Veterinarians can refer to specific disease therapeutic strategies to assess the potential benefit of approved feed-grade antimicrobials.

NTF members work to ensure comprehensive stewardship of their birds. Accordingly, this document includes information for producers about government directives as well as other actions the industry recommends to ensure the health and welfare of our birds, the environment and the product we produce.

It is important to note that there is no discussion of hormones in this document because no hormones are used in the production of turkeys.

Judicious Antibiotic Use

Veterinarians in the turkey industry take any and all medication use very seriously and follow American Veterinary Medical Association (AVMA) and American Association of Avian Pathologists (AAAP) Judicious Use Guidelines. AVMA and AAAP judicious use guidelines clearly lay out effective principles to safely use antimicrobials. Following these guidelines, producers can treat, control and prevent diseases that could have a significant impact on animal wellbeing as well as food safety. Prevention of disease is an important part of judicious use as it maintains the health and welfare of the animal in the face of disease challenges. An animal that is unhealthy is more susceptible to secondary infections, some of which could have food safety implications.

The overall goals of judicious therapeutic antibiotic use are:

1. To educate producers regarding the appropriate use of antibiotics in poultry;

2. To minimize antibiotic resistance development; and

3. Provide insight and bring awareness to producers of the global problem of antimicrobial resistance.

Residue Program

CVM is required by law to approve all antibiotic drugs for safety and efficacy. Specific regulations govern their safe use and proper withdrawal period. To ensure the meat and poultry we consume does not include illegal residues, USDA's Food Safety and Inspection Service (FSIS) monitors meat for residues of antibiotics or other medications at the time of slaughter. FSIS samples flocks of turkeys at random to test for violative residues. Animals that test positive for residues above an acceptable safe level cannot go into the food supply. Each week, FSIS publishes a "Weekly Residue Repeat Violator for Use by Livestock Markets and Establishments" so that violations are public knowledge. (http://bit.ly/FSISResidueViolation)
The turkey industry has an outstanding record of compliance.

Overview of Turkey Production Judicious Use

Antibiotics in turkey production are primarily administered through feed or water. Judicious use of antibiotic use is monitored/regulated through the VFD requirements as well as the AAAP/AVMA Judicious Use Guidelines. These rules and guidelines follow the two principals laid out in Guidance 209:

- Use of medically important antimicrobial drugs in food-producing animals should be limited to uses considered necessary for assuring animal health

- Use of medically important antimicrobial drugs in food producing animals should include veterinary oversight or consultation.

Additionally, FDA has published answers to frequently asked questions for industry regarding judicious use.

http://bit.ly/FAQJudiciousUse

Antibiotics may be administered in feed only in accordance with label instructions. Any animal feed containing a VFD drug can only be fed to animals based upon an order, called a veterinary feed directive issued by a licensed veterinarian in the course of the veterinarian's professional practice. The use of medically important antimicrobials in animals is intended for therapeutic purposes at therapeutic dosages (considered by FDA to be treatment, control and prevention) and under the supervision of a veterinarian. As noted earlier, products should be administered according to the manufacturer's labeled recommendations or based on the clinical experience of the attending veterinarian.

When multiple barns are present on the farm with disease, each flock within each barn should be evaluated individually for current disease status and risk of disease exposure. Only barns with clinically affected birds or those judged to be at definite risk should be treated. Morbidity and mortality rates should be evaluated closely to determine the treatment protocols. The least number of diseased and at-risk birds should be treated on a farm. Additionally, management, biosecurity, and vaccination programs should be reevaluated and corrective actions taken as necessary in order to mitigate any future disease challenges.

Extra-Label Uses

Licensed veterinarians can prescribe extra-label uses of Food and Drug Administration (FDA)-approved drugs in animals administered in water and injections (extra label use in feed is prohibited). Extra-label drug usage can be prescribed for therapeutic purposes only and prescription must follow the specific guidelines summarized below.

For administration via water or injection, extra-label use may be additionally permitted if the federally codified valid veterinarian-client-patient relationship is established (see below). Only after the valid veterinarian-client-patient relationship is established and flock and farm history and diagnostic procedures are performed is extra-label drug use permitted. Additionally, there must be no approved animal drug labeled available in the necessary dosage and concentration to treat the condition.

Prior to prescribing or dispensing an FDA-approved drug for extra-label use in a food-producing animal the veterinarian must:

- Make a careful diagnosis and evaluation of the conditions for which the drug is to be used;
- Establish a substantially extended withdrawal period for milk, meat, or other products supported by scientific information, if applicable;
- Institute procedures to assure that the identity of the treated animal or animals is carefully maintained; and
- Take appropriate measures to assure that assigned timeframes for withdrawal are met and no residues exist.

Veterinary Feed Directive and Veterinary-Client-Patient Relationship (VCPR)

Under the Veterinary Feed Directive Rule, antibiotic use is under the supervision of a licensed veterinarian. As such, judicious use must meet all requirements of a valid veterinarian-client-patient relationship.

1. A valid veterinarian-client-patient relationship (VCPR) has key elements including: veterinarian engagement;
2. Sufficient knowledge of the flock; and
3. The provision of any necessary follow-up evaluation or care.

In those states with VCPR requirements that include the key elements mentioned above, a veterinarian must adhere to the VCPR state requirements to issue a VFD or prescription. In states where the FDA determines that no applicable or appropriate state VCPR requirements exist, veterinarians will need to issue VFDs in compliance with federally defined VCPR requirements. All veterinarians will need to adhere to a VCPR that includes the key elements in the final rule:

1. A veterinarian has assumed the responsibility for making medical judgments regarding the health of (an) animal(s) and the need for medical treatment, and the client (the owner of the animal or animals or other caretaker) has agreed to follow the instructions of the veterinarian;
2. There is sufficient knowledge of the animal(s) by the veterinarian to initiate at least a general or preliminary diagnosis of the medical condition of the animal(s); and
3. The practicing veterinarian is readily available for follow-up in case of adverse reactions or failure of the regimen of therapy.

Such a relationship can exist only when the veterinarian has recently seen and is personally acquainted with the keeping and care of the animal(s) by virtue of examination of the animal(s), and/or by medically appropriate and timely visits to the premises where the animal(s) are kept. On a November 13, 2015, call between FDA's Center for Veterinary Medicine (CVM) officials and the

NTF Turkey Health and Welfare Committee, CVM officials said consistently they view the current veterinary oversight at vertically integrated operations of turkeys is sufficient to meet the veterinary-client-patient relationship.

The FDA set forth the following responsibilities for a veterinarian issuing a lawful VFD:

i) Be licensed to practice veterinary medicine; and

ii) Be operating in the course of the veterinarian's professional practice and In compliance with all applicable veterinary licensing and practice requirements, including issuing the VFD in the context of a veterinarian-client-patient relationship (VCPR) as defined by the State.

The supervisory veterinarian should be familiar and have working or "on-farm" knowledge of the flock before writing a VFD. FDA officials noted their desire to provide some flexibility "to adjust the specific criteria for a VCPR to appropriately align with current veterinary practice standards, technological and medical advances, and other regional considerations." (FDA's final rule on Veterinary Feed Directive, June 3, 2015) However, if you are working in a state with a state board we recommend you contact them to determine their specific state requirements.

Other items of note for a VFD:

- Each premise (individual farm) that holds animals must be listed on the VFD, rather than the individual barn;

- The VFD's expiration date must not exceed 6 months after the date of issuance;

- The veterinarian may restrict VFD authorization to only include the VFD drug(s) cited on the VFD or may expand such authorization to allow the use of the cited VFD drug(s) along with one or more over-the-counter (OTC) animal drugs in an approved, conditionally approved, or indexed combination VFD drug. The veterinarian must affirm his or her intent regarding combination VFD drugs by including one of the following statements on the VFD:

    - "This VFD only authorizes the use of the VFD drug(s) cited in this order and is not intended to authorize the use of such drug(s) in combination with any other animal drugs."
    - "This VFD authorizes the use of the VFD drug(s) cited in this order in the following FDA-approved, conditionally approved, or indexed combination(s) in medicated feed that contains the VFD drug(s) as a component." [List specific approved, conditionally approved, or indexed combination medicated feeds following this statement.]
    - "This VFD authorizes the use of the VFD drug(s) cited in this order in any FDA-approved, conditionally approved, or indexed combination(s) in medicated feed that contains the VFD drug(s) as a component."

- VFD feed should be treated like any other medicated feed in regards to storage and handling.

In regards to VFD documentation, FDA has stated that the original VFD should be maintained by the veterinarian who issued the VFD and should be maintained in the manner it was generated, either electronic or hardcopy. The client and distributor should each also have a copy of the VFD, and that copy may be electronic or hardcopy. These records must be kept for a 2-year period.

In addition to other applicable recordkeeping requirements found in this section, if the distributor manufactures the animal feed bearing or containing the VFD drug, the distributor must also keep VFD feed manufacturing records for 1 year in accordance with part 225 of this chapter. Such records must be made available for inspection and copying by FDA upon request.

Check List to Ensure Judicious Use of Antimicrobial Use[1]

The following are general guidelines to aid in making informed decisions regarding antimicrobial use:

Utilize veterinary expertise in preventative medicine and husbandry programs to prevent disease problems and minimize the use of drugs and medications.

Prescription, Veterinary Feed Directive, and extra-label use of antibiotics must meet all the requirements of a valid veterinarian-client-patient relationship.

- The VCPR should be established on a farm prior to antibiotic therapy. Veterinarians should closely monitor antibiotic use in their poultry flocks. They maintain close contact with service technicians and managers (in situations where these resources are available) related to the use of antibiotics. Antibiotics should always be used under the direction and knowledge of the company veterinarian or veterinary consultant.

Veterinarians should work with those responsible for the care of poultry to use antibiotics judiciously regardless of the distribution system through which the antibiotic was obtained.

- Poultry producers are responsible for the production of poultry on their farms; however, information provided by live production mangers (where applicable), veterinarians and/or best management practices that have been established by the National Turkey Federation should be followed. Veterinarians should work closely with producers, service technicians, service persons, and production managers to ensure responsible use of therapeutic antibiotics. A veterinarian, however, should always be responsible for the initiation and evaluation of antibiotic therapy.

All antimicrobial therapy must be used only in accordance with the Food, Drug, and Cosmetic Act and its regulations.

- Use according to labeled instructions should be considered first, if farm history, results of in vitro antimicrobial susceptibility testing, and clinical judgment warrant.

- Extra-label drug use of antimicrobials administered via drinking water or injection may be considered if labeled use of antimicrobials in the same class have failed, if farm history or in vitro antimicrobial susceptibility testing dictates, or based on clinical experience of the attending veterinarian. Extra-label drug use must be within the context of a valid veterinarian-client-patient relationship.

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[1] The information in the check list comes from: *AAAP-AVMA Guidelines for Judicious Therapeutic Use of Antimicrobials in Poultry* , American Veterinary Medical Association (https://www.avma.org/KB/Policies/Pages/AAAP-Guidelines-to-Judicious-Therapeutic-Use-of-Antimicrobials-in-Poultry.aspx*); Judicious Use of Antimicrobials for Poultry Producers*, Department of Healthy and Human Services, Public Health Service, Food and Drug Administration, Center for Veterinary Medicine) http://www.fda.gov/downloads/AnimalVeterinary/SafetyHealth/AntimicrobialResistance/JudiciousUseofAntimicrobials/UCM095590.pdf); *Judicious Use of Antimicrobials for Poultry Veterinarians,* DHHS/PHS/FDA/CVM (http://www.fda.gov/downloads/AnimalVeterinary/SafetyHealth/AntimicrobialResistance/JudiciousUseofAntimicrobials/UCM095575.pdf)

- When farm history, results of in vitro antimicrobial susceptibility testing, or clinical judgment warrants the use of highly important antimicrobials, their use should be in accordance with labeled instructions before extra-label use is considered. Antimicrobial choice should be dictated by potency and site-of-infection drug concentrations derived from pharmacokinetic and pharmacodynamic data if available, with extended withdrawal periods as appropriate.

Antibiotics considered important in treating refractory infections in human or veterinary medicine should be used in animals only after careful review and reasonable justification. Consider using other antibiotics for initial therapy.

- Poultry veterinarians and producers should recognize the importance of antibiotic resistance in both human and veterinary medicine. Important antibiotics used in both poultry and humans are to be held in reserve to minimize the rate of resistance development to these important compounds.

- Use of critically important antimicrobials should be considered as a last resort based on all appropriate information after antimicrobials classified as important or highly important have been carefully considered and all other intervention strategies have failed.

Use narrow spectrum antibiotics whenever appropriate.

- With any therapeutic regimen of important or highly important antimicrobials, use of narrow-spectrum antimicrobials is recommended to avoid overuse of broad-spectrum antimicrobials.

Utilize bacterial culture and susceptibility results to aid in the selection of antibiotics when clinically relevant.

- Bacteriostatic drugs should be considered cautiously when treating chronic infection due to decreased primary defense mechanisms in the birds. Overall effectiveness of bacteriostatic drugs in chronic infections may be decreased. Likewise, when immunosuppressive agents are involved, bacteriostatic antimicrobials may not be clinically effective.

Antimicrobial Therapeutics Administered Via Water

- Antimicrobial therapy can be administered via drinking water. Addition of ammonia to raise the pH of water may increase the solubility of some antimicrobials, such as sulfonamides Addition of organic or inorganic acid to lower water pH may increase the solubility of some classes of antimicrobials (eg, erythromycin and oxytetracycline) when used via water application. In all cases, federal and state laws must be followed. Any combination of antimicrobials would be subject to extra-label drug use rules as described in 21 CFR 530.13 (extra-label use from compounding of approved new animal and approved human drugs).

In-feed Antimicrobial Therapeutics

- Poultry veterinarians have the option to administer in-feed medications. Combinations of FDA-approved in-feed medications that have obtained cross-clearance are limited.

However, if in-feed antimicrobials are considered, the appropriate feed-grade antimicrobial must be used per the FDA-approved label indication. Extra-label drug use of in-feed antimicrobials is not permitted under any commercial conditions. The implementation of VFD classification in 2017 will further ensure strict veterinary oversight.

Injectable Antimicrobial Therapeutics

- Injectable antimicrobials are used predominately at 1 day of age or in ovo to control omphalitis in poults. In ovo administration to prevent infection when the yolk is withdrawn into the body cavity can be an important intervention strategy to control early bacterial contamination. However, appropriate egg sanitation and temperature controls must be maintained from breeder farm through the hatchery to minimize of the need for antimicrobials at 1 day of age or in ovo. Injection strategies should be used to support ongoing hatchery sanitation and proper egg collection techniques and not in lieu of these procedures. Current antimicrobials cleared for use in 1-day-old poults (as is the case with chicks) are not approved for use in ovo, and therefore, extra-label drug use regulations must be followed. The use of cephalosporins at unapproved dosages, frequencies, durations or routes of administration is prohibited; therefore, *in ovo* use in turkeys is no longer permitted since 2012.

- Injectable antimicrobials are occasionally used in an extra-label manner, except for the cephalosporin class, for acute disease outbreaks in valuable and long-lived poultry. Fowl cholera and erysipelas can be treated in this manner. Antimicrobials used in this manner include long-acting oxytetracycline, florfenicol, and tetracycline. With any such extra-label administration, extra-label drug use regulations must be followed.

Therapeutic exposure to antibiotics should be minimized by treating only for as long as needed for the desired clinical response.

- Due to the limited availability of antibiotics in poultry, producers should work with veterinarians and service technicians to closely monitor antibiotic treatments and minimize antibiotic therapeutic exposure in flocks. Producers should use antibiotics according to labeled indications that include the treatment period. Any extra-label use of antibiotics should be in accordance with a VCPR and within Animal Medicine Drug Use Clarification Act (AMDUCA). Producers should avoid prolonged use of antibiotics but should treat for a period sufficient to achieve the desired clinical outcome.
  Limit therapeutic antibiotic treatment to ill or at risk animals, treating the fewest animals indicated.

- In a poultry disease outbreak, all birds are not infected at the same time with the disease to which antibiotic therapy is warranted. A veterinarian should be consulted to determine what populations are at risk and furthermore which birds should be treated.

Regimens for therapeutic antibiotic use should be optimized using current pharmacological information and principles.

- Continuing education programs by the American Veterinary Medical Association, American Association of Avian Pathologists and technical updates from pharmaceutical technical service veterinarians, keep poultry veterinarians and managers up to date on current

information regarding antibiotic use. Producers should use these individuals as resources regarding current information on antibiotic use.

Minimize environmental contamination with antibiotics whenever possible.

- Every effort should be made to avoid environmental contamination with antibiotics. Properly dispose of unused antibiotics.

Check List for Live Production Management and Control: Good Manufacturing Procedures (GMPs)[2]

In-feed Medications and Residue Prevention

- All feed mills using medication capable of causing residues in turkey and turkey products must follow FDA Good Feed Manufacturing Practices (GMPs). The GMPs are published by FDA, and they provide specific practices for production and manufacturing of feed which will prevent residue contamination of finished feed. Sequencing, flushing and drug reconciliation records are required in the GMPs.

- Only approved medications at the approved inclusion rate are allowed and must be under the supervision of a veterinarian.

- Withdrawal time and procedures must be accurately followed.

- Feed delivery and feeding on the farm must be done so as to prevent cross contamination of medicated requiring a withdrawal period and marketer feeds.

- Maintain the feed mill grounds, facilities and, equipment in a repaired condition and protected from precipitation, moisture and contamination from outside sources including wild animals, birds and rodents.

- Maintain a list of chemicals and lubricants used and maintain a file of certificates as to the safety and non-residue potential of each.

- Electric transformers must be certified free of polychlorinated biphenyl fluids.

- Ingredient suppliers must provide a certificate of assay or residue free status of each delivery as appropriate and certification of liability and/or liability insurance. This is especially important for feed grade fats and byproducts, especially animal byproduct ingredients.

- Routine assay of finished feeds is required in the GMPs and should include assay for chlorinated hydrocarbon compounds as well as medication feeds.

- Procedures to follow for the disposition of miss-mixed feed or residue violative feed must be approved and ready when needed.

- Written procedures must be kept up to date and included in routine training sessions for employees.

Farm Site and Buildings

- Select a site with good drainage and minimal potential for toxic chemical contamination

[2] The information in the check list comes from: National Turkey Federation Chemical Residue Avoidance Program for Turkeys, NTF Chemical Residue Avoidance Subcommittee, 1992)

- Assay soil samples as needed to assure safe farm environment prior to construction or expansion

- Control rodent, wild birds and animals to minimize the need for chemical control and risk of contaminating the turkeys. Fence, screen and maintain buildings and facilities in good repair. Maintain the farm site free of spilled feed and trash and keep open areas mowed to discourage wildlife activity.

- Use protected bait stations for rodenticides and other pest poisons on the farm and especially if they are used in the building where turkeys are housed.

- Provide a safe secure storage area for all chemicals used on the farm. Maintain identification of all chemical products preferably with the original label and directions for use.

- Make a list of approved chemicals for the operation and do not allow any unapproved chemicals to be brought to the farm.

- Maintain a usage of record for pesticides and other chemicals on the farm and in the buildings.

Litter Supply

- Maintain a list of approved suppliers who have furnished a certification of liability and/or certificate of liability insurance.

- Periodically assay suppliers of litter samples for toxic chemical residues.

- Provide litter storage that is dry and well drained and free of wild animals, birds and vermin.

Wells and Water Supply System

- Test new wells for toxic chemical residues and then shock chlorinate at least annually as needed.

- Periodically test all wells on the farm for residues and shock chlorinate annually or as needed.

- Maintain a clean system free of mold, bacterial growth and toxins, including pumps, pressure tanks, lines, filters, medicators, valves, etc. Use acid cleaners and/or concentrated chlorine solutions.

- Provide check valves, back flow or vacuum beaker valves to prevent leakage between systems and cross contamination.

- Provide the capability in the system to clean and flush lines and watering equipment after medicating which will assure all of the drugs and chemicals are out of the water supply for the birds.

- Maintain and monitor chlorination equipment to prevent over use of chlorine and contamination of the turkeys with residue potential chlorinated compounds.

Water Medication and Vaccines

- Provide safe, secure temperature controlled storage areas for all vaccines and medications. They should be kept separate from any other chemicals

- Use only approved products and at approved dosage and only under the supervision of a veterinarian. Extra-label use of medication is only to be done under the oversight and direction of a veterinarian.

- Maintain inventories with proper identification in the original container with the original label and directions.

- Read and follow directions carefully

- Follow the approved withdrawal times.

- Keep accurate records of the use of all water medications and vaccines including serial numbers as appropriate and withdrawal time used on each flock.

- Utilize a "Water Medication Certification Record" or medication certificate which assures accurate dosing and medication clearance time with personnel responsibility.

- Use prepared written directions for the use of medications and vaccines and include them in routine training sessions for employees.

Poult Supply and Turkey Hatcheries

- Use only ingredients in poult injection material that will not cause chemical residues at market time.

- Obtain certification of quality control and liability insurance from the manufacturer and/or supplier of injection materials and formulations.

- Maintain accurate records of material use, including serial numbers.

Documentation

Overview

Accurate records of treatment and outcome should be used to evaluate therapeutic regimens. Record keeping is an integral part of the integrated turkey industry. Production records including medication costs, evaluation and outcome are kept and placed in the history of the farm for future reference. Producers should also maintain their own records of flock treatments (product used, date of use, duration of treatment, dosage, outcome of treatment, etc.) for future reference. Such information will largely be collected through the VFD.

FDA's authority to inspect and copy documents in animal feed and feed ingredient facilities) is limited, however, based on historical practice, they will often ask to review and copy broad categories of documents, particularly in situations like a recall. Therefore, the following lays out the authority FDA has regarding document inspection and copy. Additionally, after these facts, we provide a suggestion on a way to manage potential FDA requests.

Record Requirement and Document Review

General:

- Records must be kept relating to the manufacture, processing, packing, distribution, receipt, holding or importation of the food/feed and FDA has broad authority to inspect and copy all records relating to food/feed (and to related food that could be similarly affected) that could assist in determining whether the food is adulterated and presents a threat of serious adverse health consequences or death as long as they have "reasonable belief" that an article of food/feed is adulterated AND "presents a threat of serious adverse health consequences or death.(21 U.S.C. Section 350c(a). Note that financial, pricing, personal, research and sales (other than shipment date regarding sales) data are expressly exempt from FDA access.
    - To invoke this authority, an FDA representative must present a special written "Notice of Inspection – Request for Records" (From FDA 482c). This is not the normal "Notice of Inspection," (Form FDA 482.
- Food/feed manufacturers and distributors are required to maintain records to show the receipt of ingredients (including packaging) from their immediate suppliers and the distribution of product forward to direct consignees (commonly called "one up, one down". 21 U.S.C. Section 350c; 21 CFR Part 1, Subpart J
    - FDA only has the authority to review and copy them if FDA needs the information to address "credible threats of serious adverse health consequences or death. 21 U.SC. Section 350c(b)

Medicated Feed Mills:

- Facility holding a medicated feed mill license must maintain records according to the cGMP regulations for licensed feed mills and FDA has express statutory authority to inspect and copy all documents. 21 U.S.C. Section 360b(m)(5)(B)

- Manufacturers of VFD drugs must retain VFD orders for two years from the date of issuance.

- Feed distributers that distribute animal feeds containing VFD drugs must keep records of the receipt and distribution of animal feed containing VFD drug for a period of 2 years.

- A distributer that manufacturers a VFD animal feed must keep VFD feed manufacturing records for one year.

    - **FDA has the authority to inspect and copy VFD orders upon request.**

Preventative Controls for Animal Feed

- For those covered by the recently published FSMA Preventive Controls for Animal Feed rule, they are required record keeping for the following:

    - Records of preventive control monitoring;

    - Instances of nonconformance that is material to food safety;

    - Results of testing and other appropriate means of verification;

    - Efficacy of preventive controls and corrective actions.

    - Except for the Food Safety Plan, other preventive control records offsite so long as they can be delivered to the plant for inspection within 24 hours.

- For those covered by the sanitary transportation rules, documents must be kept and FDA has the right to inspect and copy records.

Managing FDA Review of Records

A commonly used way to handle such requests is to adopt a written company policy that the company personnel responsible for escorting an FDA investigator do not have general authority to provide documents to FDA. Instead, the FDA investigator should be asked to provide a list of documents desired in writing, so that the list can be reviewed by management and/or legal counsel as appropriate. This technique is widely used by industry and allows an inspected firm to consider and balance – on its own schedule – FDA's legal authority, the benefits of cooperating with FDA, FDA's need for the information requested, the confidentiality of the information, and other relevant factors. Reliance on a written "company policy" adopted by an appropriate company decision making body (e.g., Board of Directors, management committee) also removes a potential point of contention between the FDA investigator and the company escort, because the escort is not authorized to make a decision in the investigator's presence or to waive compliance with the company policy.

Data Collection Overview

It should be noted that there is significant interest in data collection around use that could be significantly misunderstood if it is not put in proper context. Through NTF's stewardship efforts, we aim to more effectively communicate the industry's commitment to responsible antibiotic use, animal husbandry and animal welfare. Though we are learning more and more each day, we know that the challenges of animal disease will not go away. Our ultimate goal is to incorporate practices that ensure human and animal health, which includes preserving the effectiveness of antibiotics for both humans and animals.

As FDA considers data collection regulations and the industry continues to evaluate data collection options, this section will be updated to reflect those developments.