

# Judicious Use of Antibiotics- What Does This Mean for a Dairy Producer?

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The Food and Drug Administration (FDA) is implementing a new strategy to encourage the judicious use in food-producing animals of antibiotics considered important in treating human infections. “Judicious use” is using a drug appropriately and only when necessary. The development of resistance to medically important drugs, and the resulting loss of their effectiveness, poses a serious public health threat. Misuse and overuse of antimicrobial drugs allows resistant bacteria (the hard-to-kill “bad bugs”) to increase in numbers faster than susceptible bacteria (the easy-to-kill bugs) and can transfer through the food chain to humans. This increases the opportunity for people to become infected by resistant (bad bug) bacteria. FDA’s goal is to protect public health, slow the development of resistant drugs, and help to reduce the number of infections in humans that are difficult to treat. A public meeting was held at Western Kentucky University on April 9, 2013 to “provide an opportunity for public dialogue and feedback on challenges faced by the animal agriculture industry and practicing veterinarians” as FDA begins this new initiative regarding antibiotics used in medicated feed or drinking water. In this meeting, FDA’s approach was outlined which includes:

- Issuing a guidance for industry (Guidance #209), entitled “[Judicious Use of Medically Important Antimicrobials in Food Producing Animals](#),” which explains how FDA plans to phase out production uses (growth promotion and feed efficiency) and phase in veterinary oversight of the remaining uses of these drugs. This guidance for industry (GFI) was finalized on April 11, 2012 and can be found at:  
<http://www.fda.gov/downloads/AnimalVeterinary/GuidanceComplianceEnforcement/GuidanceforIndustry/UCM216936.pdf>
- Issuing a [draft guidance](#) (Guidance #213) that will help guide drug companies voluntarily change product labels to remove feed efficiency and growth promotion claims and add instead disease prevention, control, and treatment uses. This guidance document also advises companies on how to change marketing to include veterinary oversight or supervision.
- Providing [draft text for a proposed regulation](#) intended to simplify the process of obtaining a Veterinary Feed Directive (VFD) drug. These are drugs intended for use in or on animal feed which are under the professional supervision of a licensed veterinarian.

*Which drugs currently used in food animals are the focus of FDA’s strategy?*

The drugs of interest are those:

- Approved prior to October 2003, before Guidance 152, *Evaluating the Safety of Antimicrobial New Animal Drugs with Regard to Their Microbiological Effects on Bacteria of Human Health Concern* was published.
- Used in food-producing animals to increase feed efficiency and promote growth;
- Available over-the-counter (OTC), and therefore, can be given without a veterinarian’s involvement; and
- Given continuously through the feed or water to entire herds or flocks of animals.

A list of antimicrobial drugs FDA considers medically important are listed in Appendix A of [Guidance for Industry #152](#). Products used in the dairy industry affected by this proposal include chlortetracycline (CTC) and neomycin (often used in medicated milk replacer). Interestingly, we have several growth promotion products in the cattle industry that are **not** listed in Appendix A. Bacitracin, bambamycins

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(Gainpro®), laidlomycin (Cattlyst®) used in feeder cattle, and ionophores (such as Rumensin®) used in dairy and beef cattle are not affected by this GFI. The complete GFI #152 can be found at this link: <http://www.fda.gov/downloads/AnimalVeterinary/GuidanceComplianceEnforcement/GuidanceforIndustry/UCM052519.pdf>

*Why is veterinary oversight necessary?* Prior to 1993, most drugs given in feed and water were approved for over-the-counter use. At that time, the methods used by FDA to assess food safety aspects of new animal drug applications were not as rigorous as those used today, in part because less scientific data was available about antimicrobial resistance. However, as time passed and data has accumulated, all antimicrobial new animal drugs approved by the FDA Center for Veterinary Medicine (CVM) since 1993 have been labeled with prescription (Rx) or VFD marketing status (with the exception of a few generic copies of existing drugs). Based on the available scientific evidence, FDA believes that the use of medically important antimicrobial drugs should involve the scientific and clinical training of a licensed veterinarian. Veterinarians are uniquely qualified to determine which specific disease-causing organisms are likely to be present and to determine appropriately timed administration of medication relative to the disease.

*Timeline for Implementation?* Once the final version of Guidance #213 is finalized, FDA will monitor the progress of its strategy for the voluntary adoption of these changes in order to make an orderly and relatively smooth transition. After 3 years, the agency will then consider further action as needed in accordance with existing provisions of the Food, Drug, and Cosmetic (FD&C) Act for addressing matters related to the safety of approved new animal drugs.

Developing strategies for reducing antimicrobial resistance is critically important for protecting both public and animal health. Collaboration involving the public, the public health, animal health, and animal agriculture communities is needed to assure that the public health is protected while also assuring that such strategies are economically feasible to the producer and that the health needs of animals are addressed. It is critically important to remember the benefits of using antibiotics in food animal production and the adverse effects that would result from their removal. Although the convenience of buying feed grade antimicrobials at a local farm supply will be changed by adoption of these guidelines, it is important that correct and medically sound advice accompany these purchases. Unfortunately, not all employees of stores that sell health supplies (including online pharmacies) are adequately trained to give correct advice and may be unfamiliar with the potential harm if label directions are not carefully followed. FDA recognizes that it is important to work with the veterinary and animal producer communities to ensure that their concerns are taken into consideration as these changes are implemented. FDA is very interested in receiving comments on the practical implications of these changes for animal producers, particularly those with smaller operations in remote locations. The agency is also interested in receiving input on how impacts or disruptions to animal producers could be minimized and the economic effects that may result from the adoption of the practices set out in this Guidance. Submit comments on the Veterinary Oversight of Antimicrobial Use in Livestock: Impact on Stakeholders by August 5, 2013 at: <http://www.regulations.gov/#!submitComment;D=FDA-2012-N-1046-0001>. Submit written comments to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852. You should identify all comments with the docket number (Document ID FDA-2012-N1046-0001).

Additional copies of the guidance document (GFI #213) may be requested from the Communications Staff (HFV-12), Center for Veterinary Medicine, Food and Drug Administration, 7519 Standish Place, Rockville, MD 20855, and may be viewed on the Internet at either <http://www.fda.gov/AnimalVeterinary/GuidanceComplianceEnforcement/GuidanceforIndustry/default.htm> or <http://www.regulations.gov>.