

Policy Pennings by Daryll E. Ray & Harwood D. Schaffer

## Guidance document provides FDA's current thinking on use of antibiotics in food animals

In June of 2010, the US Food and Drug Administration, Center for Veterinary Medicine, issued draft guidance #209 on "The Judicious Use of Medically Important Antimicrobial Drugs in Food-Producing Animals" (<http://www.fda.gov/downloads/AnimalVeterinary/GuidanceComplianceEnforcement/GuidanceforIndustry/UCM216936.pdf>). According to the FDA, the "draft guidance is intended to inform the public of FDA's current thinking on the use of medically important antimicrobial drugs in food-producing animals" and was "distributed for comment purposes only."

While the term antimicrobial can be used in a generic sense to refer to "broadly to drugs with activity against a variety of microorganisms including bacteria, viruses, fungi, and parasites," in the FDA draft guidance #209, the word antimicrobial is used in a more restricted sense referring only to drugs that are antibiotic or antibacterial.

According to the FDA, "Antimicrobial resistance, and the resulting failure of antimicrobial therapies in humans, is a mounting public health problem of global significance. This phenomenon is driven by many factors including the use of antimicrobial drugs in both humans and animals.

"In regard to animal use, [draft guidance # 209] addresses the use of medically important antimicrobial drugs in food-producing animals for production or growth-enhancing purposes. These uses, referred to as production uses in [#209], are often also referred to as "nontherapeutic" or "subtherapeutic" uses. Such uses are typically administered through the feed or water on a herd- or flock-wide basis and are approved for such uses as increasing rate of weight gain or improving feed efficiency.

"Unlike other uses of these drugs in animals (e.g., for the treatment, control, and prevention of disease), these "production uses" are not directed at any identified disease, but rather are expressly indicated and used for the purpose of enhancing the production of animal-derived products (e.g. increasing rate of weight gain or improving feed efficiency)."

Draft guidance # 209 then reviews 15 papers produced over the last 40 years-examining the connection between the widespread use of antibiotics in meat production and the "development of...antimicrobial-resistant pathogens that could produce human disease."

The "FDA has reviewed the recommendations

provided by the various published reports and, based on this review, believes the overall weight of evidence available to date supports the conclusion that using medically important antimicrobial drugs for production purposes is not in the interest of protecting and promoting the public health."

"The scientific community generally agrees that antimicrobial drug use is a key driver for the emergence of antimicrobial-resistant bacteria. Since all uses of antimicrobial drugs, including use in both humans and animals, are collectively contributing to the selection pressures that drive antimicrobial resistance development, these drugs must be used judiciously in both humans and animals."

While recognizing the role of the use of antibiotics in humans, draft guidance #209 focuses on the use of antibiotics in food animals, particularly as a growth enhancer. As a result the FDA established two principles. First, "The use of medically important antimicrobial drugs in food-producing animals should be limited to those uses that are considered necessary for assuring animal health."

"In light of the risk that antimicrobial resistance poses to public health, FDA believes the use of medically important antimicrobial drugs in food-producing animals for production purposes (e.g., to promote growth or improve feed efficiency) represents an injudicious use of these important drugs."

"In contrast, FDA considers uses that are associated with the treatment, control, or prevention of specific diseases, including administration through feed and water, to be uses that are necessary for assuring the health of food-producing animals." Thus the FDA continues to allow the preventative use of antibiotics to ensure herd health and prevent specific diseases.

The FDA writes, "important factors to consider when determining the appropriateness of a preventative use include whether there is: (1) evidence of effectiveness, (2) evidence that such a preventative use is consistent with accepted veterinary practice, (3) evidence that the use is linked to a specific etiologic agent, (4) evidence that the use is appropriately targeted, and (5) evidence that no reasonable alternatives for intervention exist."

The second principle states, "The use of medically important antimicrobial drugs in food-producing

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ing animals should be limited to those uses that include veterinary oversight or consultation." At present, "most of the feed-use antimicrobial drugs are currently approved for over-the-counter use in food-producing animals for purposes that include the treatment, control, and prevention of disease as well as for production purposes (i.e., for growth promotion uses such as increased rate of weight gain).

"In addition to instituting measures that would limit use of medically important antimicrobial drugs in food-producing animals to uses that are considered necessary to assure the animals' health, FDA also believes it is important to phase-in the practice of including veterinary oversight or consultation in the use of these drugs."

Draft guidance #209 concludes by saying, "In order to minimize the development of antimicrobial resistance, FDA believes that steps need to be taken to ensure the judicious use of medically important antimicrobial drugs in animal agriculture. Such steps should include phased-in measures that would limit medically important antimicrobial drugs to uses in food-producing animals that are considered necessary

for assuring animal health and that include veterinary oversight or consultation. Such limitations would reduce overall medically important antimicrobial drug use levels, thereby reducing antimicrobial resistance selection pressure, while still maintaining the availability of these drugs for appropriate use."

The 60 day time period for submitting comments has passed and the timeframe for releasing the final guidelines has not been released. Guidelines, in contrast to regulations, cannot be legally enforced, but are provided as recommendations. Given the long history of concern over the issue of the widespread use of antibiotics in meat production and the development of antibiotic-resistant pathogens that could endanger human health, it seems safe to conclude these guidelines will not be the last word on the issue.

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