



# DAIRY VETERINARY NEWSLETTER

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## FDA's New Draft Guidance, "The Judicious Use of Medically Important Antimicrobial Drugs in Food-Producing Animals" - Comment Process and a Summary of the Document

The FDA is inviting comments on its new Draft Guidance, "The Judicious Use of Medically Important Antimicrobial Drugs in Food-Producing Animals". Below is a summary of some points covered in the 31-page document. Comments are due by 8/30/10. [The link for viewing the entire document and making comments is:](http://www.regulations.gov/search/Regs/home.html#docketDetail?R=FDA-2010-D-0094)

### What is an FDA Draft Guidance, and what authority does it convey?

According to the document itself, "This draft guidance is intended to inform the public of FDA's current thinking on the use of medically important antimicrobial drugs in food-producing animals. This guidance document is being distributed for comment purposes only. FDA's guidance documents, including this guidance, do not establish legally enforceable responsibilities. Instead, guidances describe the Agency's current thinking on a topic and should be viewed only as recommendations, unless specific regulatory or statutory requirements are cited. This draft guidance, when finalized, will represent the Food and Drug Administration's (FDA) current thinking on this topic. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. You can use an alternative approach if the approach satisfies the requirements of the applicable statutes and regulations. If you want to discuss an alternative approach, contact the FDA staff responsible for implementing this guidance." (Contact information for William T. Flynn, source of further information, will be provided near the end of this article.)

### An issue raised for many years

One of the documents on the FDA website is a 1969 report prepared in the United Kingdom, "Joint Committee on the use of Antibiotics in Animal Husbandry and Veterinary Medicine". In part, the report says, "From our consideration of the written and oral evidence presented to us, we have concluded that the administration of antibiotics to farm livestock, particularly at sub-therapeutic levels, poses certain hazards to human and animal health. We are satisfied that these hazards can largely be avoided and should not therefore be allowed to continue." The report goes on to recommend many specific limitations on the use of antibiotics in farm animals. However, the 1969 report also says, "We see no purpose in seeking to limit the number or type of antibiotics which the veterinary profession may prescribe. We recommend that no changes should be made in the law which allows the supply of antibiotics on veterinary prescription."

## **“Medically important antimicrobial drugs” and the focus of the FDA document**

The new FDA document attempts to define the term “medically important antimicrobial drugs”, but still uses the term “important” in the definition, not really spelling out what the term means. It does make clear that the phrase means “antimicrobial drugs that are important for therapeutic use in humans”. Presumably this term means “drugs with activity against a variety of microorganisms including bacteria, viruses, fungi, and parasites” that are of the greatest effectiveness, probably measured by curative response rather than just antimicrobial susceptibility and resistance testing, against infectious diseases in humans. It probably also includes the context that some of these drugs may be considered among the few remaining drugs available showing effectiveness against increasingly drug-resistant pathogens infecting people. However, while the document does mention the development of antimicrobial resistance frequently, it does not address whether this has to do with what is considered a “medically important” drug.

The draft guidance does say, “ - - this document 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 this document, 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.”

The document chronicles many different recommendations made by various groups over the years since the 1969 report mentioned earlier, including recommendations by numerous groups such as the GAO and Codex Alimentarius Commission in recent years.

## **“Strategies for controlling antimicrobial resistance”**

The above term is taken directly from the draft guidance, which continues, “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. It is imperative that strategies for controlling antimicrobial resistance include a consideration of how - - to address those uses that are injudicious in nature.”

After a general description of FDA authority regarding approval and regulation of drugs used in food-producing animals, it continues, “the administration of medically important antimicrobial drugs to entire herds or flocks of food-producing animals (e.g., for production purposes) would represent a use that poses a qualitatively higher risk to public health than the administration of such drugs to individual animals or targeted groups of animals (e.g., to prevent, control, or treat specific diseases). - - the guidance also considers such factors as the properties of the drug in question including mechanism(s) of action and - - resistance; the prevalence of zoonotic foodborne bacteria in the food-producing animal species for which the drug is intended, and the importance of the drug in question as a therapy in humans. Risk mitigating factors that are considered include - - restricting use of the drug to use by or on the order of a veterinarian.”

## **FDA will soon seek further input, and does not imply a plan to remove numerous livestock drugs from the market**

The document later says, “ - - FDA recognizes that some aspects - - (e.g., the ranking of drugs as to importance to human health) may now need to be updated to reflect the most current and relevant information. In the near future, FDA intends to seek input from experts and the public on updating the guidance.

- - The continued availability of effective antimicrobial drugs is critically important for combating infectious disease in both humans and animals. This includes the continued availability of feed and water uses of such drugs for

managing disease in animal agriculture. Therefore, it is in the interest of both human and animal health that we take a more proactive approach to considering how antimicrobial drugs are being used, and take steps to assure that such - drugs [are used as] as judiciously as possible - -.”

### **FDA’s two new recommended principles**

“FDA recognizes the need to collaborate with the animal health and animal producer communities on strategies for phasing in these recommendations.”

First principle: *“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.”*

“ - - 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. Production uses are not directed at any specifically identified disease, but rather are expressly indicated and used for the purpose of enhancing the production of animal-derived products. 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. - - FDA believes that some prevention indications are necessary and judicious. Veterinary involvement in the decision-making process associated with the use of medically important antimicrobial drugs is an important aspect of assuring appropriate use, including judicious preventive use.”

“Important factors to consider - - include whether there is: (1) evidence of effectiveness, (2) evidence that such a preventive 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.”

Second principle: *“The use of medically important antimicrobial drugs in food-producing animals should be limited to those uses that include veterinary oversight or consultation.”*

“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). - - FDA - - believes it is important to phase-in the practice of including veterinary oversight or consultation in the use of these drugs.

FDA recognizes that - - there are limited numbers of large animal veterinarians, which can make consultation or oversight challenging in certain situations. In some cases, veterinarians may be directly diagnosing and administering therapies, while in other cases they are visiting and consulting with producers periodically to establish customized disease management protocols for that producer’s herd or flock. - - increasing veterinary involvement in the use of antimicrobial drugs has significant practical implications for animal producers, veterinary practitioners, and the veterinary profession as whole. Therefore, FDA is particularly interested in receiving comments on strategies for effectively phasing-in such a change.”

### **FDA’s interest in your comments**

“In regard to comments on this draft guidance, FDA is especially interested in hearing from the public and stakeholders on how the agency can best - - support the two principles, while minimizing adverse impacts on animal health and disruption to the animal agriculture industry.” Again, the link for making comments is:

<http://www.regulations.gov/search/Regs/home.html#docketDetail?R=FDA-2010-D-0094>

**For further information**

The FDA contact for further information is:

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