U.S. Department of Health & Human Services

U.S. Food & Drug Administration

Animal & Veterinary

Questions and Answers on FDA's Draft Guidance on the Judicious Use of Medically Important Antimicrobial Drugs in Food-Producing Animals

1. **What is the purpose of the draft guidance?**

   The purpose of the draft guidance is to:
   - Discuss FDA's public health concerns about how certain uses of medically important antimicrobial drugs in food-producing animals may impact antimicrobial resistance;
   - Summarize some of the key scientific reports on the use of antimicrobial drugs in animal agriculture; and
   - Outline FDA's recommendations on how to make sure that medically important antimicrobial drugs are used judiciously in food-producing animals and remain effective for animals and people.

2. **Why is this draft guidance important?**

   This draft guidance is important because:
   - Medically important antimicrobial drugs must remain effective for use in animals and people; and
   - Antimicrobial resistance is a growing public health concern. A number of scientific reports have raised concerns over the use of medically important antimicrobial drugs in food-producing animals.

3. **What are antimicrobial drugs?**

   "Antimicrobial drugs" includes all drugs that work against a variety of microorganisms, such as bacteria, viruses, fungi, and parasites. Antimicrobial drugs that work specifically against bacteria are called "antibacterial drugs" or "antibiotics." In the draft guidance, the broader term "antimicrobial drugs" is used interchangeably with the terms "antibacterial drugs" and "antibiotics."

4. **What are medically important antimicrobial drugs?**

   "Medically important antimicrobial drugs" are antimicrobial drugs that are important for treating infectious diseases in people, particularly infections caused by bacteria.

5. **What is judicious use?**

   Judicious use is using an antimicrobial drug only when necessary and appropriate.

6. **What is antimicrobial resistance?**

   Antimicrobial resistance is when bacteria are no longer susceptible to an antimicrobial drug, meaning that the drug, and similar drugs, will no longer work against those bacteria. Antimicrobial resistance occurs after bacteria are exposed to an antimicrobial drug and continue to survive in the drug's presence. Once bacteria become resistant to a drug, the continued use of that drug may increase the number of resistant bacteria. Public health may be affected if resistant bacteria enter the food supply.
   The use of any antimicrobial drug can add to antimicrobial resistance. Using the drugs only when necessary and appropriate in animals and people will slow down the development of antimicrobial resistance.

7. **How are antimicrobial drugs normally used in food-producing animals?**

   Antimicrobial drugs that are FDA-approved for use in food-producing animals are normally used to:
   - Treat or control an on-going infectious disease;
   - Prevent an infectious disease before an outbreak occurs; or
   - Increase production by making the animal gain weight faster (increased rate of weight gain) and by improving the animal's ability to convert the food it eats into growth (improved feed efficiency). Typically, no disease is present and no outbreak is anticipated to occur. Rather, these drugs are given to animals to enhance the production of animal-derived food products.

8. **Is using medically important antimicrobial drugs to increase production in food-producing animals a judicious use?**

   No. FDA thinks that using medically important antimicrobial drugs to increase production in food-producing animals is not a judicious use.

9. **What is FDA's current approach to evaluate antimicrobial resistance associated with the use of antimicrobial drugs in food-producing animals?**

   FDA's current approach to evaluate antimicrobial resistance associated with the use of antimicrobial drugs in food-producing animals is outlined in Guidance for Industry (GFI) #152, "Evaluating the Safety of Antimicrobial New Animal Drugs with Regard to Their Microbiological Effects on Bacteria of Human Health Concern." The basic principle of GFI #152, which was published in 2003, is that the more bacteria are exposed to antimicrobial drugs, the higher the risk that antimicrobial resistance will develop to those drugs. GFI #152 recommends several measures to reduce such risk.

   For antimicrobial drugs for use in food-producing animals that were approved after 2003, the labels include "use instructions" that are consistent with the risk-reducing measures recommended in GFI #152. If these "use instructions" are followed properly, the degree to

which the drug will add to antimicrobial resistance is greatly reduced.

10. **What antimicrobial drugs used in food-producing animals concern FDA the most?**

    FDA is most concerned about medically important antimicrobial drugs that:
    - Were approved before 2003, before the approach in GFI #152 was implemented;
    - Are used in food-producing animals to increase production;
    - Are available over-the-counter (OTC), and therefore, can be given without a veterinarian's involvement; and
    - Are given continuously through the feed or water to entire herds or flocks of animals.

11. **What are FDA's recommendations for judicious use?**

    FDA recommends that all antimicrobial drugs for animals and people be used only when necessary and appropriate. Based on a thorough review of the available scientific information, FDA recommends that the use of medically important antimicrobial drugs in food-producing animals be limited to situations where:
    the use of medically important antimicrobial drugs is necessary for assuring animal health; and the use of medically important antimicrobial drugs includes veterinary oversight or consultation.

12. **Why is the involvement of a veterinarian important?**

    Most of the antimicrobial drugs approved for use in food-producing animals in feed or water are over-the-counter products. FDA thinks that including veterinary oversight or consultation when these drugs are used in food-producing animals is an important way to ensure judicious use. Veterinarians play a critical role in the diagnosis of animal disease and in deciding how to treat, control, and prevent animal disease. FDA understands that veterinary oversight or consultation varies due to many factors, such as geographic location of the farm and different animal production methods. Sometimes, veterinarians directly diagnose and treat animals, while other times, they periodically visit and consult with an animal producer to customize a disease management protocol for that producer's herd or flock.

13. **How will FDA implement the recommendations for judicious use?**

    To implement the recommendations for judicious use, FDA will actively work with drug companies; the veterinary, public health, and animal agriculture communities; and other stakeholders. FDA wants the recommendations to be implemented in a way that protects the health of animals and people. FDA does not want the recommendations to negatively impact animal health or disrupt the animal agriculture industry.

14. **How can I comment on the draft guidance?**

    FDA invites the public to comment on the draft guidance. Submit written comments on the draft guidance to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments to http://www.regulations.gov[1]. For more information on submitting comments see the Notice of Availability[2].

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1. http://www.regulations.gov/
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