EXHIBIT U

TO DECLARATION OF
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FDA Website (Public Health Focus)

U.S. Food and Drug Administration

News & Events

Antimicrobial Resistance

Antimicrobial drugs have been widely used in human and veterinary medicine for more than 50 years, with tremendous benefits to both human and animal health. The development of resistance to this important class of drugs, and the resulting loss of their effectiveness as antimicrobial therapies, poses a serious public health threat. Misuse and overuse of antimicrobial drugs create selective evolutionary pressure that enables antimicrobial resistant bacteria to increase in numbers more rapidly than antimicrobial susceptible bacteria and thus increase the opportunity for individuals to become infected by resistant bacteria. Because antimicrobial drug use contributes to the emergence of drug resistant organisms, these important drugs must be used judiciously in both animal and human medicine to slow the development of resistance.

- Dr. Sharfstein Testimony [1]
- Dr. Woodcock Testimony [2]

Humans

Antibiotics are drugs used for treating infections caused by bacteria. Also known as antimicrobial drugs, antibiotics have saved countless lives. Antibiotic resistance in humans and animals is a growing public health concern worldwide. When a person or animal is infected with an antibiotic-resistant bacterium, treatment becomes more difficult because standard antibiotic therapies become less effective or may not work at all. In an effort to combat antibiotic resistance, FDA has formed a task force to address the issue of antimicrobial resistance that combines the talents of experts from around the agency. Leaders from within FDA have also answered the call, including Dr. Joshua Sharfstein, Principal Deputy Commissioner and Dr. Janet Woodcock, Director for the Center for Drug Evaluation and Research, who have been raising awareness about antibiotic resistance in animals and people with the American public.

When antibiotics don't work it may mean longer or more complicated illnesses, frequent doctor or veterinary visits, the use of stronger and more expensive drugs with potentially serious side effects, and more deaths related to bacterial infections.

In cooperation with other government agencies, FDA has started several initiatives to address antibiotic resistance and has issued drug labeling regulations emphasizing the prudent use of antibiotics, as well as implemented regulations for human use of antibiotics that encourage health care professionals to prescribe the drugs only when clinically necessary.

To ensure optimal use, FDA recommends the following:

- Don’t skip doses and do take your medicine as prescribed. Antibiotics are most effective when taken as prescribed.
- Don’t save antibiotics. The drug is meant for a particular infection at that time. Don’t use leftover medicine. Taking the wron drug can delay the appropriate treatment and your infection might get worse.
- Don’t take antibiotics prescribed for others. Only a health care professional can determine the right treatment for your infection. [3]

- More on antibiotics [4]
- Combating Antibiotic Resistance [5]
- Resources for You: Antibiotics and Antibiotic Resistance [6]

- Information by Drug Class: Antimicrobial Resistance [7]
- Public Health Focus: Antibiotic Resistance Podcast [8]
- Get Smart: Online Features, Podcasts, E-cards [9]

Use of Antimicrobials in Veterinary Medicine

Antimicrobial use in animals can contribute to the emergence of antimicrobial resistance which may be transferred to humans, thereby reducing the effectiveness of antimicrobial drugs for treating human disease. CVM Antimicrobial Resistance [10] FDA believes it is critically important that antimicrobial drugs be used as judiciously as possible in an effort to minimize resistance development. Therefore, FDA has implemented a number of measures related to antimicrobial use in animals and is continuing to develop strategies for addressing this public health issue. These activities include:

Judicious Use

FDA has worked collaboratively with veterinary and animal producer organizations to develop and distribute information to support the judicious use of antimicrobial drugs in food-producing animals. Copies of these brochures are available at Judicious use of antimicrobial drugs in food-producing animals brochures [11]

In addition, FDA has developed a framework for policy regarding the judicious use of medically important antimicrobial drugs in food-producing animals. This framework includes phasing in such measures as 1) limiting medically important antimicrobial drugs to uses in food-producing animals that are considered necessary for assuring animal health; and 2) limiting such drugs to uses in food-producing animals that include veterinary oversight or consultation. Collaboration involving the public, the public health, animal health, and animal agriculture communities on the development and implementation of such strategies is needed. Draft guidance is available at Judicious use of medically important antimicrobial drugs in food-producing animals (PDF - 76KB) [12]

Pre-Approval Assessment of Antimicrobial Drugs

In 2003,FDA developed and implemented guidance for the animal drug industry for evaluating, as part of the animal drug approval process, the potential development of antimicrobial resistance resulting from the use of antimicrobial new animal drugs in food-producing animals. This FDA guidance is available at Guidance for animal drug industry (PDF - 131KB) [13]

National Antimicrobial Resistance Monitoring System (NARMS)

FDA coordinates the NARMS program, a surveillance system that tracks antibiotic resistance in foodborne bacteria. The NARMS program was established in 1996 as a partnership between the U.S. Food and Drug Administration (FDA), the Centers for Disease Control and Prevention (CDC), and the U.S. Department of Agriculture (USDA).

NARMS monitors antimicrobial susceptibility among enteric bacteria from humans, retail meats, and food animals. Detailed information regarding the NARMS program, including comprehensive annual reports, is available at National Antimicrobial Resistanc Monitoring System [14].

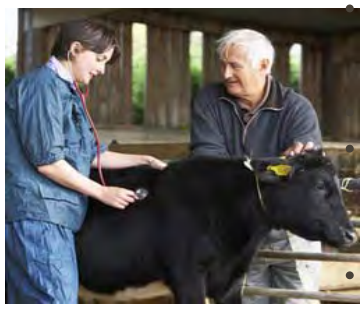
Antimicrobial Drug Sales/Distribution Summary Data

The Animal Drug User Fee Act of 2003 (ADUFA), amended the Federal Food, Drug, and Cosmetic Act (FFDCA) to require antimicrobia drug sponsors to annually report to FDA the amount of antimicrobial active ingredient in their drugs that have been sold or distributed for use in food-producing animals. ADUFA also requires FDA to summarize the sales and distribution information received from drug sponsors each year to provide the summary report to the public. The first annual report (for 2009) is available at Antimicrobial Drug Sales/Distribution Summary Data (PDF - 75KB) [15]

FDA has also completed a report, Estimates of Antibacterial Drug Sales in Human Medicine [16], on antibacterial drug sales in human medicine.

Additional Resources

- National Antimicrobial Resistance Monitoring System [17]



- Judicious Use of Medically Important Antimicrobials in Food Producing Animals [18]
- FDA 101:Animal Feed [19]
- CVM Reports on Antimicrobials Sold or Distributed for Food-Producing Animals [20]
- Report on Antimicrobials Sold or Distributed for Food-Producing Animals (PDF - 75KB) [21]

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6. /Drugs/ResourcesForYou/Consumers/BuyingUsingMedicineSafely/AntibioticsandAntibioticResistance/default.htm
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9. http://www.cdc.gov/getsmart/campaign-materials/online-materials.html%0A%20%20%20%20
10. /AnimalVeterinary/SafetyHealth/AntimicrobialResistance/ucm2006489.htm
11. /AnimalVeterinary/SafetyHealth/AntimicrobialResistance/JudiciousUseofAntimicrobials/ucm2007130.htm
12. /downloads/AnimalVeterinary/GuidanceComplianceEnforcement/GuidanceforIndustry/UCM216936.pdf
13. /downloads/AnimalVeterinary/GuidanceComplianceEnforcement/GuidanceforIndustry/UCM052519.pdf
14. /AnimalVeterinary/SafetyHealth/AntimicrobialResistance/NationalAntimicrobialResistanceMonitoringSystem/ucm2006490.htm
15. /downloads/ForIndustry/UserFees/AnimalDrugUserFeeActADUFA/UCM231851.pdf
16. /Drugs/DrugSafety/InformationbyDrugClass/ucm261160.htm
17. /AnimalVeterinary/SafetyHealth/AntimicrobialResistance/NationalAntimicrobialResistanceMonitoringSystem/default.htm
18. /AnimalVeterinary/SafetyHealth/AntimicrobialResistance/JudiciousUseofAntimicrobials/default.htm
19. /ForConsumers/ConsumerUpdates/ucm164473.htm
20. /AnimalVeterinary/NewsEvents/CVMUpdates/ucm236143.htm
21. /downloads/ForIndustry/UserFees/AnimalDrugUserFeeActADUFA/UCM231851.pdf