



The Science Source for Food,
Agricultural, and Environmental Issues

April 5, 1999

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Dockets Management Branch (HFA-305)
Food and Drug Administration
5630 Fishers Lane
Room 1061
Rockville, MD 20852

Dear Madam/Sir:

RE: "A Proposed Framework for Evaluating and Assuring the Human Safety of the Microbial Effects of Antimicrobial New Animal Drugs Intended for Use in Food-Producing Animals."

Please find attached a comment on the above topic submitted by the Council for Agricultural Science and Technology (CAST). This response was drafted by Dr. Don Beitz (Iowa State University) and was reviewed, edited, and approved by the CAST Executive Committee on behalf of CAST.

The leadership and membership of CAST appreciate the opportunity to participate in such important discussions and decisions that have an impact on the health and well-being of humans and food-producing animals. CAST trusts our comments will be useful to FDA in evaluation of the scientific evidence and regulation of antibiotic use.

Sincerely,

Richard E. Stuckey, Ph.D.
Executive Vice President

David R. Lineback, Ph.D.
President

980-1146

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Comment on Subtherapeutic Use of Antibiotics in Animal Agriculture

by the
Council for Agricultural Science and Technology
Ames, Iowa

The Council of Agricultural Science and Technology (CAST) is a nonprofit organization composed of 37 scientific societies and many individual, student, company, nonprofit, and associate society members. The mission of CAST is to identify food and fiber, environmental, and other agricultural issues and to interpret related scientific research information for legislators, regulators, and the media for use in public policy decision making. Dr. Donald C. Beitz, professor, Departments of Animal Science and Biochemistry, Biophysics, and Molecular Biology, Iowa State University, prepared this response to the document entitled “A Proposed Framework for Evaluating and Assuring the Human Safety of the Microbial Effects of Antimicrobial New Animal Drugs Intended for Use in Food-Producing Animals.” There is no docket number for this document.

Antibiotics are used widely throughout animal agriculture as therapeutic agents to treat bacterial infections that lead to losses in productivity and to animal discomfort. In addition, subtherapeutic doses of antibiotics are used to prevent or decrease the incidence of bacterial diseases and to cause improvements in productivity of food-producing animals. Many of the antibiotics used in animal agriculture also are used for treatment of human bacterial infections. Their use in animal agriculture has come under increased scrutiny because of concern over development of mutant microbes having resistance to usual microbicidal effects of antibiotics. Much of the antibiotic usage in the United States is for humans. Most of the remainder is used in food-producing animals and in pets.

Antibiotic resistance by pathogenic microorganisms is of major concern to human and animal practitioners. Resistance to antibiotics develops when a mutation occurs in microbial populations, which enables bacteria to survive in the presence of the antibiotic. The mutation may cause antibiotic resistance by enabling bacteria to (1) decrease the ability of the antibiotic to penetrate the microbe, (2) increase the conversion of the antibiotic to noninhibitory forms, and (3) cause alterations in its metabolism, such as protein synthesis, so the antibiotic no longer inhibits a specific metabolic reaction. Logically, decreasing unnecessary use of antibiotics in hospitals, doctors' offices, and on farms seems prudent to minimize the potential for development of antibiotic resistance.

Does the scientific evidence available today indicate that subtherapeutic use of antibiotics for food-producing animals should be stopped? A 1999 study entitled *The Use of Drugs in Food Animals: Benefits and Risks* was prepared by the National Research Council (NRC) and published by the National Academy Press. The National Research Council-sponsored committee concluded that the use of

drugs in the food animal production industry is not without some problems and concerns. On the basis of current scientific information, however, the subtherapeutic use of antibiotics does not seem to constitute an immediate public health concern. The committee indicated that additional data might alter this conclusion.

The NRC committee generated three major recommendations:

1. The Center for Veterinary Medicine should establish integrated national databases to support “rational, visible, science-driven decision-making process and policy development for regulatory approval and use of antibiotics in food animals.”
2. Further development and use of antibiotics in human medicine and animal agriculture should be overseen by an interdisciplinary panel of scientists from the veterinary and animal health industry, human medicine community, consumer advocacy organizations, animal production industry, and research, epidemiology, and regulatory agencies.
3. Increased research should be conducted to study effects of nutrition and management on immune function and disease resistance of food-producing animals including additional research on new vaccines, antibody production, and genetic and molecular mechanisms of disease resistance. The goal of the additional research is to markedly decrease the amount of antibiotics required for treatment of infectious diseases through alternate non-drug techniques.

CAST agrees with the conclusions of the National Research Council committee. We recognize the potential problems associated with therapeutic and subtherapeutic uses of antibiotics in animal agriculture. However, current data do not indicate antibiotic use in animal agriculture is the major culprit in increasing antibiotic resistance among microbial pathogens. We support the additional directed research recommended by the National Research Council committee. CAST recommends that action should not be taken to impose a wide-spread ban on subtherapeutic use of antibiotics in animal agriculture until more definitive information is available.