



## AMERICAN FARM BUREAU FEDERATION®

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April 6, 1999

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

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"

Docket Number 98D-1146.

Dear Sirs,

The following comments are presented on behalf of the American Farm Bureau Federation (AFBF). AFBF is the nation's largest general farm organization with over 4.9 million members nationwide. Our membership includes the majority of the nation's livestock producers, so the issues being discussed impact them both as producers and consumers.

The development of resistance to antibiotics by bacteria is a concern to the medical community for it limits treatment options when people become ill. Over time many of the drugs used to treat illnesses and infections have lost their effectiveness as a significant portion of the bacteria population have developed immunity to a variety of antibiotics. At the present time there are a limited number of effective products available for use by the medical profession and apparently few new products in the approval pipeline. This does make it important to maintain the effectiveness of existing products as long as possible.

It is generally accepted that the over prescription of antibiotics by physicians and the misuse of prescriptions by patients have contributed to the emergence of resistant bacteria. More recently concern has focused on the contribution that may have come from antibiotic use in animals, particularly sub-therapeutic use for growth promotion.

In July 1998, the National Research Council (NRC) and the Institute of Medicine of the National Academy of Science issued a joint report titled "The Use of Drugs in Food Animals: Benefits and Risks". The report did acknowledge a link between the use of antibiotics in food animals and the development of bacterial resistance to these drugs and human disease, but they also noted that the incidence of such disease is very low. They concluded that "the use of drugs in the food-animal production industry is not without some problems and concerns but that it does not appear to constitute an immediate public health concern; additional data might alter this

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conclusion.” They acknowledged that substantial information gaps exist and contribute to the difficulty of assessing the effect of antibiotic use in food animals on human health. Several of their recommendations focused on filling these information gaps.

It should be noted that while concerns exist over the potential for antimicrobial resistance to be passed from animals to humans, no known outbreaks have been traced to such an occurrence. It is important that we continue to monitor the situation and that we learn more about the development of antibiotic resistance, as well as its ability to pass between organisms, but it currently appears to be more an area for study rather than drastic action.

Animals, just as humans, can have bacterial infections or diseases that require treatment. To properly care for their animals, producers need access to effective antimicrobials that can be used in a therapeutic manner to address these situations. As in human medicine there are a very limited number of products available for use by veterinarians and producers. Animal agriculture also needs to maintain the effectiveness of existing products as they await the development of new products or technologies.

In addition to therapeutic use, researchers found that feeding low levels of antibiotics to various classes of animals can improve their productivity. This may come from increased feed efficiency, elimination of some minor disease problem, or some other mechanism. In any case, this use allows producers to provide consumers with a better quality product at a lower price.

What is agriculture doing to address the concerns? The NRC report indicated the need for more data and information. One effort to do this that is broadly supported by the industry, is the National Antimicrobial Resistance Monitoring System (NARMS). NARMS is a joint effort of the Center for Disease Control and Prevention (CDC), the U.S. Food and Drug Administration and the U. S. Department of Agriculture (USDA). There are both human and animal components to the study, with CDC taking the lead on the human side and USDA on the animal side. In both cases data is being collected to monitor trends in the prevalence and antibiotic resistance of 17 specific organisms. While annual summaries have been done of both human and animal information, data is still limited on both sides. It is not yet feasible to draw conclusions from the information available. This effort needs to be continued and expanded in the future. Similar data collection is taking place in other nations as well. Given the global nature of food production, efforts must continue to draw all of the data together to provide us with a perspective on our total food supply.

In addition to support for the monitoring program, producers and producer groups are taking additional steps to prevent, to the greatest extent possible, any problems from occurring. The American Veterinary Medical Association (AVMA) has taken leadership in the development of “prudent use” guidelines. Producers, as well as the pharmaceutical industry support development and use of these guidelines. In addition, all livestock species have developed and put into use, quality assurance programs that address antibiotic use. A major focus of these efforts has been the elimination of antibiotic residues from the food supply. While this has been the focus of the programs, they also emphasize proper animal drug use.

The proposed Framework for evaluating antimicrobial new animal drugs will contain few specifics as acknowledged by the word "Framework." However, it must be noted that this leaves a significant degree of concern on the part of industry that may be regulated as the specific details are developed. The proposed Framework provides only a limited indication of how the necessary standards will be determined. We strongly encourage as open a process as possible, that uses the best science and expertise available to arrive at these details. We do see the general concepts of placing the highest priority for safeguards on products that are of greatest need in human medicine. True risk analysis of factors contributing to human exposure certainly has merit.

We would also offer the following comments relative to specific questions asked in the Framework document. The Framework acknowledges that much remains to be learned relative to the development of antibiotic resistance, the relative level in humans and animals, as well as many other associated issues. We encourage the agency to keep this lack of knowledge in mind and not to impose additional regulations based on supposition, but rather work to assure that the needed knowledge becomes available for the decision making process.

One of the questions dealt with the appropriateness of the human exposure factors identified in the Framework. On the surface they appear to have merit, but we are unaware of any studies that would validate them. Unless such work exists, efforts should be expended to assure that the needed research is done to evaluate their appropriateness.

Relative to setting resistance thresholds on human data, animal data or both, we would strongly encourage the use of both sets of data. The use of human only data would present many problems as the potential certainly exists for the development of resistance to develop as a result of human cross-contamination, from foreign travel or consumption of imported food. Likewise if only animal data were used it is uncertain what if any direct implications the development of antibiotic resistance in the animal population has on human health. Efforts must also be made to validate linkages that may exist between the human and animal data. The use of genetic "fingerprinting" could be valuable in this effort.

A question is also asked relative to the concepts for assessing and assuring the safety of proposed Category I drugs. We support the expansion and enhancement of NARMS as a monitoring tool. Other initiatives require a good deal of further clarification. There are many factors that need to be considered and defined before the process moves forward. There is a need to continue the evaluation of products for their safety and efficacy in their approval process. The agency needs to look at the possibility of obtaining the additional information that is needed in the current data collection process. We also encourage continued evaluation and input in the process by appropriate experts from academia, human and animal health.

Antibiotic resistance is a concern to consumers and producers alike. Producers want to continue to assure both domestic and international consumers of the safety of our food supply. They also need to maintain access to effective animal health products to properly care for their animals. In order to do this an effective monitoring and surveillance system is needed. The industry also needs the development of new products or technologies that can help to reduce any risk that might exist and identification of cost effective technologies that can be used to reduce the

potential pathogen load at the farm or ranch. When identified, these technologies will be incorporated into producer quality assurance programs. In the mean time producers, veterinarians and the medical community need to work together to assure that antibiotics are used properly in both the human and animal populations to minimize any risk to human health.

A framework is by definition vague. Many questions remain to be worked out relative to the Framework that has been proposed. We strongly encourage open, ongoing dialogue with all parties to address these questions prior to considering any move to more extensive regulations. AFBF looks forward to being a part of this important process.

Sincerely,



Richard W. Newpher  
Executive Director  
Washington Office

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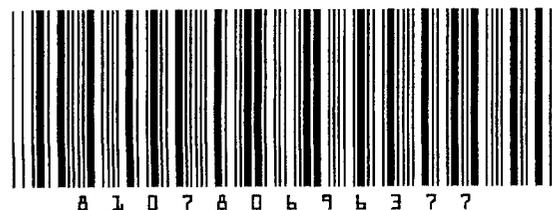
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