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April 2, 1999

Dockets Management Branch (HFA-305)
Food and Drug Administration
Rm. 1061
5630 Fishers Lane
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"

The National Turkey Federation represents U.S. turkey growers, processors, breeders and hatchery owners as well as allied industries. NTF represents more than 95 percent of the U.S. turkey industry, and it is the only national trade association representing the turkey industry exclusively. Our members are committed to using all classes of animal drugs in a safe manner that preserves their efficacy in veterinary and human medicine. We are pleased to comment on "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."

NTF's members oppose implementation of any element of the proposed framework document prior to the completion of a comprehensive, qualitative assessment of the actual risk associated with on-farm use of antibiotics in food-producing animals. Our members believe that, absent a risk assessment, the agency will be placing a significant new regulatory burden on industry and effectively reducing the availability antimicrobials without any certainty that these actions will protect public health. In fact, there is a possibility that, by limiting the number of antimicrobials available for on-farm use, the framework actually could increase resistance. A risk assessment also would assure that any regulatory requirements for the turkey industry and animal agriculture are proportionate to the real risk of those industries contributing to increased resistance. Finally, conducting a risk assessment prior to regulating is commensurate with the 1998 recommendations of the World Health Organization and the National Research Council.

The National Turkey Federation presented these arguments in more detail on behalf of the Coalition for Animal Health during the January 25-26, 1999, meeting of FDA's Veterinary Medical Advisory Committee. A copy of those comments is attached for the record.

NTF is committed, both as an individual association and as a member of the Coalition for Animal Health, to work with the Center for Veterinary Medicine to conduct such an assessment, and we pledge to work with CVM to implement regulatory changes clearly indicated by the assessment results. We also would like to endorse in general the comments submitted by the Animal Health Institute to this docket.

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SUITE 400 ▪ 1225 NEW YORK AVENUE, NW ▪ WASHINGTON, DC 20005 ▪ TEL: (202)898-0100 ▪ FAX: (202)898-0203

We appreciate the opportunity to comment, and we would be happy to answer any questions the agency may have.

Sincerely,

Joel Brandenberger
Vice President, Legislative Affairs

Enclosure

The Coalition for Animal Health

STATEMENT

OF THE

COALITION FOR ANIMAL HEALTH

on

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

Before the

Veterinary Medical Advisory Committee

January 25, 1999

Thank you Mr. Chairman.

My name is Joel Brandenberger, and I am speaking today on behalf of the Coalition for Animal Health. The Coalition is comprised of more than a dozen organizations representing every major livestock and poultry association in the United States as well as the commercial feed industry, veterinarians and animal pharmaceutical companies. Coalition members include the American Farm Bureau Federation, American Feed Industry Association, American Sheep Industry Association, American Veterinary Medical Association, Animal Health Institute, National Cattlemen's Beef Association, National Chicken Council, National Pork Producers Council, National Turkey Federation, United Egg Association and United Egg Producers.

The Coalition was formed in the mid-1990s to promote public policies that ensure the availability of the widest possible variety of safe, effective drugs to help treat the animals in our members' care. The Coalition has worked with FDA and the Center for Veterinary Medicine (CVM) on several issues, but our most extensive experience with the agency came in 1995 and 1996 when we worked cooperatively to reach consensus on the Animal Drug Availability Act of 1996. That effort remains a model of how stakeholders and CVM can work together cooperatively to address difficult, complex policy questions. It is the Coalition's hope that we are able to enjoy a similar spirit of cooperation as we address the antimicrobial resistance issue that is before us today.

The Coalition commends CVM for bringing together this committee to discuss the scientific evidence regarding the use of antibiotics in food-producing animals and antimicrobial resistance. It is a complex issue and one that deserves this committee's attention. The Coalition is pleased to be able to comment on "A Proposed Framework for Evaluation and Assuring the Human Safety of the Microbial Effects of Antimicrobial New Animal Drugs Intended for Use in Food-Producing Animals." Many of the Coalition members are offering individual comments; these remarks are designed to highlight our areas of common concern.

Coalition members share FDA's and the public health community's concern about antibiotic resistance – whether in humans or animals. The safety of the food supply is of utmost importance to all of us, as is the continued effectiveness of antibiotics. We hope to continue working with FDA and all relevant government agencies to ensure we are providing the safest products possible to our consumers while minimizing incidence of illness and other suffering in farm animals. Healthier animals reduce risk of food-borne pathogens entering the food supply.

Need for the Framework

Our policy toward the framework needs to be clear: the Coalition for Animal Health will find it difficult to support any change in the policy for approving antibiotics in food-producing animals if that change is not preceded by a comprehensive assessment of the actual risk posed by antibiotic use in farm animals or the risk of resistant bacteria in those animals.

This position should not be misinterpreted as indifference on the part of the Coalition toward the need to address the antimicrobial resistance issue or unwillingness to work with FDA toward policy change. The Coalition shares the goal FDA stated in the recently released framework document. We are absolutely committed to protecting the public health and to ensuring the use of antimicrobial drugs in food-producing animals does not result in adverse health consequences to humans. We

also are pleased FDA agrees with the Coalition that the use of antimicrobial drugs in food-producing animals is important to promoting animal health and providing an abundant and affordable supply of meat, milk and eggs. As the National Research Council noted in a 1998 report, "(t)he benefit to human health in the proper use of antibiotics in food-producing animals is related to the ability for these drugs to combat infectious bacteria that can be transferred to humans by either direct contact with the sick animal, consumption of food contaminated with pathogens, or proliferation from the animal into the environment."

Coalition members also would agree that this is an appropriate time to examine the antimicrobial resistance issue in further detail and to contemplate potential changes in the FDA approval policy for antibiotics. We understand the seriousness of the issue as well as the need to develop appropriate measures both to protect the use of antibiotics in humans and to minimize the negative consequences to animals and the food supply. There is no doubt bacteria can develop resistance to some antibiotics, whether they are used in humans or animals, or both. However, the likelihood and extent to which antibiotic resistance occurs on the farm setting and is then transferred to humans has been neither adequately assessed or established.

This is the crux of the Coalition's concern. Neither FDA nor any credible scientific organization has conducted a comprehensive risk assessment with regard to this issue. We don't see how FDA, or any other agency, for that matter, can look at data and studies that are incomplete or contradictory and come to the conclusion that the recommendations in the proposed framework represent the best possible public policy solution to the danger of antimicrobial resistance. FDA cannot give into the temptation to regulate based on scare headlines and studies that have yet to stand the test of peer review.

We would remind FDA that three recent reports from the National Research Council (NRC), the Institute of Medicine (IOM) and the World Health Organization (WHO) do not come to the same conclusion that FDA did in this proposed framework document. All agree there is cause for close scrutiny, but all recommend additional data to determine the appropriate course of action. Indeed, the 1998 NRC report entitled, *The Use of Drugs in Food Animals: Benefits and Risks* acknowledges the possible link between antibiotic use in farm animals and the development of bacterial resistance in humans, but the report says "information gaps hinder the decision making policy process for regulatory approval and antibiotic use in food animals. A data driven-scientific consensus on the human health risk posed by antibiotic use in food animals is lacking." According to NRC, "(U)ntil more accurate data on animal antibiotic use, patterns and rates of resistance transfer to humans, occurrences of actual disease emergence, and mechanisms of resistance are available, actions aimed at regulating antibiotics cannot be implemented through a science-driven, well-validated, and justified process."

Georgetown University's Center for Food and Nutrition Policy is conducting a risk assessment to better determine the quantitative risk. This risk assessment model is a step in the right direction to determine the actual risk and subsequently develop the appropriate plan of action.

Let's look briefly at what we don't know at this point. While some animals unquestionably carry resistant bacteria, we have limited information about how many animals with such bacteria ever make it to the processing plant. We have no clear idea how much resistant bacteria actually survives all the critical control points in modern food processing and packaging. We have very little data about how much of that bacteria survives because of mishandling or undercooking of meat and

poultry products by the end consumer. And, we don't understand the potential for "reservoirs" of disease or bacteria to develop and increase both in the wild and in domestic animals if the use of antibiotics in food animals is curtailed. This too should be a part of a risk assessment.

While science is still trying to determine how many people actually get sick each year from foodborne illness, we do know that – to date – no death from foodborne illness ever has been connected to a resistant bacteria derived from the use of antibiotics in animals.

Given this dearth of information, how can we be sure the policies in the proposed framework actually will reduce the risk of antimicrobial resistance? It is far more certain these policies will reduce the availability of antimicrobials to food-animal producers, and we must remember that there also is a risk associated with narrowing the spectrum of available antibiotics. Dr. Mitchell Cohen of CDC was quoted recently as saying one of the reasons we have resistance problems today is because antibiotic development slowed in the 1980s, and fewer alternatives now are available to counter drug-resistant infections. Well, what do we think is going to happen if livestock and poultry producers have fewer and fewer antibiotics to utilize and drug companies find the regulatory cost of bringing new antibiotics to market prohibitive?

The Coalition understands it is not enough simply to say, "Do a risk assessment." So, we will work tirelessly with FDA to develop an affordable risk assessment plan that provides – in the shortest possible time – all the data needed to make science-based policy changes. And, when a consensus analysis of that data is complete, you have our pledge to work with the agency to make all changes dictated by the risk assessment.

Other Concerns

Looking now at some concerns about specific proposals in the framework, the Coalition finds it troubling that the framework appears to ignore several proactive steps already being undertaken by stakeholders.

The meat and poultry industry, for example, is in the midst of a significant effort to control pathogens in the food supply. Meat and poultry processing plants are implementing the Hazard Analysis Critical Control Point, or HACCP, inspection system to minimize exposure to foodborne pathogens. In addition, other steps are being taken, including steam pasteurization and educational campaigns to reduce the incidence of foodborne illness. All these steps must be taken into consideration when determining the actual risk associated with antibiotic use in food-producing animals.

It also is troubling that the FDA proposed framework does not seem to consider current efforts by our nation's producers and veterinarians, who have begun developing a program to ensure that antibiotics are used judiciously. At the behest of FDA and CDC, veterinarians, producers and others have spent time and resources to develop these guidelines to adequately address the concerns about the misuse of antibiotics. Instead of working with producers and the industry to ensure that these guidelines properly address the issue, FDA is proposing additional complex and potentially costly regulations less than eight months after asking us to undertake the judicious use effort.

This is even more confusing when you consider the educational approach is acceptable in human medicine. Extensive efforts are underway on the human side to educate patients, and in the case of children, their parents, on appropriate and inappropriate antibiotic therapy as well as encourage physicians to use antibiotics more judiciously. While animal and human medicine are not exactly the same, there are similarities, and the human and animal medicine approaches do not appear very consistent.

The Coalition also has great concerns about FDA's proposal to extend surveillance and monitoring to the farm. As we have noted above, the number of animals treated does not necessarily equate to human exposure to foodborne pathogens. Consumers do not typically have direct contact with the animal itself, but rather with the food product. Therefore, to get a true analysis of the actual risk to consumers, we must be sure we are testing for resistance at the right place in the food chain, and we have serious doubts about whether meaningful data is going to be gathered on the farm. We also have numerous concerns about how FDA proposes to gather the on-farm data and who would be doing the data collection.

The National Antimicrobial Resistance Monitoring System, established in conjunction with the approval of fluoroquinolones, provides one possible model for expanded resistance testing, though we again believe a comprehensive risk assessment will provide the clearest indication as to the appropriate resistance testing point in the food chain.

Summary Recommendations

Member groups participating in this Coalition have taken a number of steps to reduce and eliminate foodborne pathogens and ensure a safe food supply. In addition to those steps mentioned earlier – HACCP implementation, steam pasteurization, irradiation research and consumer education campaigns – the industry also has been working through quality assurance programs, educating producers on the principles of proper antibiotic use.

The Coalition therefore recommends that the federal government take the following steps to address appropriately the issue of antibiotic resistance:

- conduct an adequate and appropriate risk assessment;
- continue and strengthen the National Antimicrobial Resistance Monitoring System;
- work with producers and veterinarians to develop and integrate judicious use guidelines; and
- work with producers, veterinarians and the animal health industry to develop appropriate and scientifically based mitigation steps to control a problem as identified in a risk analysis process.

Everyone here agrees action is necessary to minimize the threat to humans from antibiotic resistance. The real question is whether we utilize a scientifically sound approach to the issue that produces guaranteed results or whether we give in to the temptation to create an appearance of action and hastily adopt policy that in the end produces no clear public health benefits while jeopardizing producers' ability to deliver healthy animals to market.

A T I O N A L
E R A T I O N
1225 New York Avenue, NW
ON, DC 20005

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

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