EXHIBIT E

TO THE DECLARATION OF MITCHELL S. BERNARD

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Division of Dockets Management (HFV12)
Center for Veterinary Medicine
Food and Drug Administration
7519 Standish Pl.
Rockville, MD 20855

Re: Draft Guidance 209 – The Judicious Use of Medically Important Antimicrobial Drugs in Food-Producing Animals
(Docket No. FDA2010D0094)

Dear Sir or Madam:

The American Farm Bureau Federation (AFBF) submits these comments in response to the notice of availability of a draft guidance (#209) on the use of medically important antimicrobial drugs in food-producing animals, published by the Food and Drug Administration (FDA) in the June 29, 2010 *Federal Register*. AFBF is the nation's largest agriculture organization. Our members encompass every type of livestock and poultry production across the country.

The availability of antibiotics for the livestock industry is critical. Farm Bureau shares FDA's interest in ensuring that all animal health products, including antibiotics, continue to be safe and effective. Furthermore, we agree that human antibiotic resistance is a growing healthcare problem. The development of bacterial resistance to certain antibiotics poses a serious public health threat.

Developing strategies for reducing antimicrobial resistance is important for protecting both public and animal health. However, it is imperative that any new policy relative to antibiotics be grounded in data and reflect the reality of modern animal agriculture production. In repeated comments and conversations with FDA, particularly over the last 14 months, Farm Bureau has expressed serious concern about the detrimental impact of eliminating approved animal health products and uses.

Further limiting or eliminating animal antibiotic use for livestock will have negative economic and animal health consequences. Therefore, we oppose restricting antibiotic use for the livestock and dairy industries that is not based on peer-reviewed, scientific information.

Current Practice and Procedures

While Guidance 209 is not a statement about the safety of current products, a review of historical and modern safeguards is appropriate. Antimicrobial drugs are critical to address the health needs of animals. They have been widely used in human and veterinary medicine for

more than 50 years with benefits to both public and animal health. Published, scientific work over the past decade has demonstrated the role healthy food animals play in producing meat, milk and eggs that are free from bacteria that cause human illness. The judicious use of antibiotics approved by FDA plays an important role in food safety by keeping animals healthy.

Antibiotics in livestock are used carefully by producers in a process that is highly regulated by FDA. Veterinary medicines are approved by FDA. They are held to the same strict standards for safety and efficacy as human medicines and are assessed for safety to people who consume animal-derived food. In 2003, FDA implemented an additional safety measure that consists of a comprehensive, evidence-based approach to prevent antimicrobial resistance that may result from the use of antimicrobial drugs in animals.

There are also post-market monitoring programs, such as the National Antimicrobial Resistance Monitoring System (NARMS), which is conducted jointly by the Centers for Disease Control and Prevention (CDC), FDA and the Department of Agriculture (USDA). NARMS data show that resistance in animal products has been steady or declining in recent years.

Farm Bureau has long supported efforts to promote the judicious use of antibiotics. Each livestock and poultry species has quality production/assurance programs, most FDA-reviewed, that educate producers about the responsible use of antibiotics. We expect our members to participate in these industry programs and adhere to the guidelines instituted for the judicious use of antimicrobial drugs. Antibiotics are given to livestock strategically, when animals are sick, susceptible or exposed to illness. They are an integral part of comprehensive management plans that provide animals with an environment designed to keep them safe, healthy and comfortable.

FDA has the authority to review every animal health product, including antibiotics, prior to approval and at periodic intervals after the product is on the market. FDA can and will deny or limit products that are shown to produce resistance in either animals or people. Layers of regulatory and industry protections are based on years of data collection. Products available to livestock caretakers today have gone through rigorous and continuous scientific testing.

Facts About Antibiotic Use and Resistance

We are concerned by recent FDA actions that appear to indicate the agency is basing complex animal health policies on theory rather than sound scientific studies. Guidance 209 appears to propose action without fully evaluating the resulting benefits and consequences. This has the potential for a tremendous negative impact on animal health and, ultimately, food safety. Healthy animals produce safe food, and every available tool is needed to protect animal health.

There are no peer-reviewed scientific studies that establish that judicious use of antibiotics in livestock increases antibiotic resistance in human infections. Consequently, it is notable that the actions proposed in Guidance 209 are not based on demonstrated safety risk. Additionally, there are no data to indicate that limiting antibiotic use in livestock decreases human health problems with antibiotic resistance. The Danish experience, which many

proponents of restricting antibiotic use in livestock cite as a "success," does not show any improvement in the antibiotic resistance concerns in humans.

On the contrary, peer-reviewed studies have shown that antibiotic use on farms does not significantly increase resistant bacteria in humans. Since antibiotics have been used in livestock for half a century, resistance related to antibiotic use in agriculture would have occurred by now. The fact that it has not means that antibiotic use in animals is not a major risk to human health.

Top scientists with the CDC and the National Institutes of Health (NIH) told a congressional committee earlier this year that there is no scientific study linking antibiotic use in food animal production with antibiotic resistance. At an April 28 hearing, CDC Director Dr. Thomas Frieden stated, "I am not aware of evidence in this country that has documented the spread from animals to humans, feed animals to humans." Similarly, when asked by a congressional subcommittee on July 14 to identify the scientific studies that indicate a public health benefit of removing antibiotics approved for growth promotion, USDA could not cite any peer-reviewed U.S. research. At the same hearing last month, Congress inquired of FDA what decreases in the level of human antibiotic resistance are expected to result from Guidance 209 as currently proposed. The agency responded that it had not quantified the intended human health impact. The data cited to verify any reduction in human resistance was a 2003 report from the Institute of Medicine which was not a study, but rather a literature review of multiple opinions on the topic.

It is important to calculate both the benefits and costs of proposed action before implementation.

Issues in Guidance 209

Despite the FDA's own scientific data and rigorous safety testing and approval procedures already in place, Guidance 209 indicates the FDA intends to take two actions to decrease antibiotic use in livestock:

1) Eliminate growth promotion as an acceptable antibiotic use in livestock production.
2) Require antibiotics to be used under the oversight of, or in consultation with, a veterinarian.

Guidance 209 calls for antibiotics that are "medically important" to humans to be used in animals only when necessary to assure their health. It also says those antibiotics should be administered with veterinary "oversight or consultation." These key terms are not fully defined. An overly-broad interpretation could eliminate certain antibiotics that are extremely important to livestock health, animal welfare, and food safety.

We support veterinary oversight, defined as a working relationship with a licensed veterinarian. The medical importance to humans of antibiotics must be evaluated on a specific case-by-case basis, using thorough risk assessments. All steps in the causal pathway should be quantified, examining the relationship of a livestock antibiotic first to the development of resistance in the animal and subsequently the transfer of that specific resistant bacteria through the food chain to a consumer who seeks treatments for symptoms from the bacteria and receives

the antibiotic initially given to the animal. Given the demonstrated complexity of this chain of events, the risk assessment process is not easy but it is the only way to determine true risk as opposed to unsubstantiated concern. To simplify the number of necessary risk assessments, antibiotics or other animal health products not used in human medicine should not be classified as medically important, alleviating the need for costly and time-consuming comprehensive assessment of antimicrobials utilized solely for animal health.

It appears that antibiotics currently used for growth promotion but not currently labeled for the other three approved claims (preventing, treating or controlling diseases) could continue to be used if, after undergoing a second rigorous FDA approval process, one of those label claims is proved. But the approval process typically takes seven to 10 years and can cost millions of dollars.

We recognize the public health importance of issues concerning all antibiotic use, whether human or livestock, and strongly encourage FDA to base future policy and regulatory decisions regarding such use on objective, substantive scientific evidence obtained through valid research. As a general farm organization, we do not claim to be scientific experts in the field of veterinary medicine or epidemiology. However, we do understand the daily practicalities of raising healthy animals in a manner which respects the welfare of the animals, the safety of the workers, and the impact on the overall environment. Ultimately, our goal is to continue providing safe, high-quality, abundant, affordable meat, milk, and eggs for a growing population. In order to achieve that goal, we must have the full use and range of animal health and herd/flock management tools.

Role of Veterinarians and the Veterinary Feed Directive (VFD)

The animal agriculture industry relies on the veterinary community to assist witih and oversee animal health. Our members work closely with their veterinarians on a range of management issues. Producers utilize veterinary expertise to develop animal health plans that include the judicious use of antibiotics. We support veterinarian oversight of the administration of antibiotics, rather than limitations on or elimination of these critical animal health and food safety protection tools.

Requiring that all antibiotics be accompanied by feed directives would be problematic given the country's severe shortage of large animal veterinarians. Currently approved VFD drugs have a record of safe use in animals under this process. However, we are concerned that the VFD process – even if improved dramatically – may be ill-suited to serve as a vehicle for providing increased veterinary oversight for a larger number of currently approved antimicrobials. We question whether the VFD can be expanded to apply to the number of antimicrobials previously approved by FDA for feed use, as envisioned by the agency under draft Guidance 209.

Farm Bureau recommends that the agency undertake significant discussions with stakeholders in the animal feed, animal health, veterinary, and producer sectors to determine whether the VFD process can be improved to the extent necessary to be workable for these

currently approved, non-VFD animal health products. The current system would have to be substantively altered if it is to be applied to a large number of products, and we question whether this is the most efficient approach given the other influencing factors with which to contend.

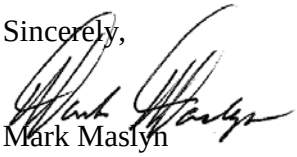
The Animal Drug Availability Act of 1996, which established the VFD category, states that a VFD is not a prescription under state or federal law. Were this not the case, feed mills handling and/or dispensing "prescription" medicated feeds would need a veterinarian or pharmacist on staff, and to comply with other state pharmacy board requirements. This is significant given the staffing issues prevalent in the food animal industry today.

Farm Bureau and other animal health, livestock and poultry organizations have documented the severe shortage of veterinarians in many geographic areas. A study commissioned by the American Veterinary Medical Association (AVMA) last year indicates that the demand for food supply veterinarians will increase by about 13 percent over the next several years, while the supply will have a short fall of about 4-5 percent annually. Meanwhile, the number of veterinary school graduates entering food supply medicine remains stagnant. Although we are pursuing all avenues to increase veterinary capacity, the situation will not be corrected easily or quickly.

This shortage would create a significant hindrance if FDA were to attempt to expand the list of currently approved animal drugs whose distribution and use in food-producing animals is subjected to the VFD process. The issue of an insufficient supply of veterinarians must be recognized as FDA contemplates possible changes to the regulatory requirements for medicated feeds containing VFD drugs. It would be counterproductive to the health of animals and the safety of the food supply to make drastic, fundamental changes to a 14 year-old functioning system, including replacing it with a new system requiring a substantially larger veterinarian force when those professionals are currently unavailable.

We appreciate FDA's consideration of our comments. Farm Bureau believes stakeholder collaboration is critical and welcomes a constructive discussion of production practices, including the use of antibiotics in livestock. We look forward to continuing our long-standing partnership to protect and improve animal health.

Sincerely,



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