Congress of the United States
Washington, DC 20515

July 12, 2012

Division of Dockets Management, HFA–305
Food and Drug Administration, HHS
5630 Fishers Lane, rm. 1061
Rockville, MD 20852

To Whom It May Concern:

RE: Federal Register Docket No. FDA–2011–D–0889
Draft Guidance for Industry on New Animal Drugs and New Animal Drug Combination Products Administered in or on Medicated Feed or Drinking Water of Food-Producing Animals: Recommendations for Drug Sponsors for Voluntarily Aligning Product Use Conditions with GFI #209

We appreciate this opportunity to comment on the Food and Drug Administration's (FDA) Draft Guidance for Industry #213 (Guidance 213), which proposes voluntary guidelines to reduce the use of antibiotics in food-animal production in order to lessen the growing public health threat of antibiotic resistance. Specifically, Guidance 213 recommends the drug industry voluntarily remove indications for use for "production purposes" (e.g., growth promotion) from antibiotics currently approved for use in food-animals and change the marketing statuses of these drugs to require veterinary oversight.

While Guidance 213 is a step in the right direction, as a voluntary measure limited in scope, it does not do enough to protect the American people. Research has clearly shown that feeding low doses of antibiotics to healthy animals contributes to the rise of antibiotic-resistant bacteria. Guidance 213 addresses antibiotic use for the purposes of growth promotion, but not disease prevention. Both of these types of use can lead to antibiotic resistance. We are concerned that in the absence of stronger definitions of inappropriate use, the underlying problem of drug resistance will not be fully addressed.

We also question the effectiveness of FDA's non-binding approach to the problem given that it is not in the economic interest of drug manufacturers, veterinarians, and livestock producers to reduce sales or use of antibiotics. Furthermore, without effective surveillance and monitoring measures in place, FDA will not be able to determine whether on-farm antibiotic use or antibiotic resistance declines as a result of Guidance 213 implementation.

Given these concerns, we would like to make the following recommendations:

1) **Guidance 213 should address antibiotics used for disease prevention as well as production purposes.**

The language of Draft Guidance 213 creates a loophole by allowing the chronic use of antibiotics for disease prevention purposes. Scientific research has clearly shown that feeding low doses of antibiotics to healthy animals contributes to the rise in antibiotic resistant bacteria. Given that antimicrobial use for disease prevention results in the same problems with antibiotic resistance as do using antibiotics for growth promotion/production purposes we ask that Guidance 213 address both of these uses. Antibiotics should only be used to treat sick animals. Drug labels should reflect this principle.

2) **Guidance 213 should recommend the current method, Guidance for Industry #152 (Guidance 152), which addresses safety issues related to antimicrobial resistance in food-animals, rather than recommend a new method for evaluating the safety of antimicrobial drugs.**

Compared to Guidance 152, Draft Guidance 213 creates a highly simplified approach for addressing safety issues related to antimicrobial resistance and weakens controls on use. Rather than require a complete, qualitative, microbial food safety risk assessment, Draft Guidance 213 instead asks sponsors to provide information without any qualification of what data should be provided, how transparent the process should be, or recommendations on safe conditions for use. For this reason we do not think that Draft Guidance 213 provides adequate safety restrictions for evaluating antimicrobial drugs. For safety and consistency purposes, Guidance 213 should recommend that the transparent and data driven guidelines already established in Guidance 152 be followed to evaluate antimicrobial drug applications.

3) **Guidance 213 should include a plan for quarterly public reporting of implementation.**

In order to enable independent verification and assessment of the implementation of Guidance 209 and Guidance 213, we ask that FDA release quarterly public reports that include numbers of submitted and approved applications to remove production claims, add therapeutic claims, and change marketing status of antimicrobial drugs. In addition, we ask that FDA provide the number of production claims and marketing statuses that need to be changed to better assess implementation progress.

4) **Guidance 213 should include an evaluation plan that incorporates goals for anticipated reductions in antimicrobial use and levels of resistance in monitored bacteria along with potential actions to be taken if goals are not met.**

Draft Guidance 213 states that the FDA will evaluate progress on the program three years after the guidance is finalized. However, Draft Guidance 213 lacks a plan for monitoring and evaluation of guidance implementation, and provides no clear way to determine if voluntary measures result in the decline of on-farm antibiotic use or antibiotic resistance. We strongly urge FDA to design a system to assess the effectiveness of Guidance 213 policies, and to state clear goals, including reductions in antimicrobial sales and antibiotic resistance, which

should be met after the allotted time. Furthermore, we ask that FDA state what measures will be taken if sponsors do not comply with Guidance 213 recommendations and if these goals are not met.

Decades of research has clearly shown that misuse of antibiotics in food-animals contributes to the growing problem of antibiotic drug resistant bacteria. According to FDA's own data, 80 percent of all antibiotics sold in the United States are sold for use in food-animals.

FDA has stated that, "It is well established scientifically that all uses of antimicrobial drugs, in both humans and animals, contribute to the development of antimicrobial resistance, and that this is an important public health concern. Experts agree that antimicrobial drugs must be used 'judiciously' in both animal and human medicine to slow the development of resistance."

We agree with FDA's statement and support efforts to curb the rise of antimicrobial resistance. It is our hope that our recommendations will strengthen the efforts by FDA and move towards ending the misuse of antimicrobial drugs.

Sincerely,

Louise M. Slaughter
Member of Congress

Earl Blumenauer
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[i] "FDA's Strategy on Antimicrobial Resistance - Questions and Answers." U.S. Food and Drug Administration. 11 Apr. 2012. Accessed 12 Jul. 2012. <http://www.fda.gov/AnimalVeterinary/GuidanceComplianceEnforcement/GuidanceforIndustry/ucm216939.htm>.