

Congress of the United States
House of Representatives
Washington, DC 20515

May 11, 2012

The Honorable Margaret Hamburg
Commissioner
U.S. Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993

Dear Commissioner Hamburg:

We write out of concern that the use of antibiotics in corn-based livestock feed may be contributing to the development of antibiotic-resistant bacteria and subverting the Food and Drug Administration's (FDA) efforts to ensure the judicious use of antibiotics in food-animal production.

Misuse and overuse of antibiotics, especially in small doses not intended to treat disease, leads to the growth of bacteria that are antibiotic-resistant, endangering humans who become infected and cannot be effectively treated with routine antibiotic therapy.¹ Antibiotic resistant strains of bacteria are a grave public health threat that is growing worldwide. When a person has an antibiotic-resistant infection, not only is treatment of that patient more difficult, the antibiotic-resistant infection may spread to other people. It is estimated that between five and ten percent of all hospital patients develop an infection, and about 90,000 of these people die every year as a result of these infections, the majority of which are antibiotic-resistant.²

Currently, about 80 percent of antibiotics sold in the United States are used in animals and have the potential to make their way into our food stream. As a step to combat the growing crisis of antibiotic resistance, just last month FDA announced that it will ask drug manufacturers to voluntarily change the labels on antibiotics used in food-animals to require a veterinary prescription. This measure is expected to drastically reduce the use of antibiotics in agriculture for the purposes of animal growth promotion.

The same antibiotics that are used in animal agriculture and that are important for human medicine such as penicillin, erythromycin, virginiamycin and tylosin, are also used by ethanol producers in order to prevent bacterial growth during the corn-based ethanol fermentation process. Producers sell the byproduct of ethanol production, known

¹ Guidance for Industry: *The Judicious Use of Medically Important Antimicrobial Drugs in Food-Producing Animals*. Food and Drug Administration, April 13, 2012.
See: <http://www.fda.gov/downloads/animalveterinary/guidancecompliancencforcement/guidanceforindustry/ucm216936.pdf>

² <http://www.niaid.nih.gov/topics/antimicrobialResistance/Understanding/Pages/quickFacts.aspx>

as “distillers grains with solubles” or DGS, as livestock and poultry feed. In 2008, FDA initiated a nationwide survey of 60 distiller grains and detected antibiotic residues in more than half of tested samples.³ A later study by the FDA demonstrated that levels of certain antibiotics remaining in DGS have the potential to cause antibiotic resistant bacteria.⁴

A recent report by the Institute for Agriculture and Trade Policy (IATP),⁵ explains that there exist non-antibiotic alternatives to combat bacterial growth in ethanol plants. Furthermore, some ethanol plants opt to operate antibiotic-free in order to sell the produced DGS to the layer hen industry where DGS with antibiotic residues, particularly virginiamycin, are prohibited by the FDA. According to the FDA “when the distillers grains are used as feed or feed ingredients the antimicrobial would be considered a Food Additive and regulated by the FDA.”⁶ However, according to a recent report by the Institute for Agriculture and Trade Policy (IATP),⁷ drug companies that sell antibiotics to ethanol producers have stated that their drugs are not subject to FDA regulation because they are “Generally Recognized As Safe” or GRAS, which appears to be in direct conflict with FDA’s posture

In order to clarify this matter and to better understand the actions the FDA is taking to address this issue, we request that you respond to the following questions and provide supporting documents and other relevant information within 15 business days or by close of business on June 1, 2012.

1. Why hasn’t the FDA published the full results of the 2008 survey of antibiotic residues in DGS? Are the full results of the 2008 survey publically available? If so, where? If not, why not?
2. Did the information collected by the FDA in its surveys of antibiotic residues in DGS suggest that drug contamination may pose a risk to animals used for human consumption? Are these antibiotic residues found in meat or poultry products? Are these antibiotic residues found in milk and eggs? Please provide the full results of studies in which residues of DGS were surveyed.

³See: <http://www.fda.gov/downloads/AnimalVeterinary/Products/AnimalFoodFeeds/Contaminants/UCM151206.pdf> and National Grain and Feed Association. FDA sampling detects antibiotic residues in ethanol distillers products. *NGFA Newsletter*. 2009; 61(2):1, <http://www.ngfa.org/files/misc/News1-29-09.pdf>

⁴ Karen Blickenstaff, Faiza Benahmed, Sonya Bodeis-Jones, Marla Luther, Linda Benjamin and Mark Rasmussen, “Impact of Low Level Antimicrobial Residues in Distillers Grains,” abstract, poster session of the Symposium on Biotechnology for Fuels and Chemicals, New Orleans, LA. May 2, 2012. See abstract: <http://sim.confex.com/sim/34th/webprogrampreliminary/Paper21348.html>

⁵ *Bugs in the System: How the FDA Fails to Regulate Antibiotics in Ethanol Production*. May 2012 See: http://www.iatp.org/files/2012_05_02_AntibioticsInEthanol_JO.pdf

⁶ *Bugs in the System: How the FDA Fails to Regulate Antibiotics in Ethanol Production*. May 2012 See page 8.

⁷ *Bugs in the System: How the FDA Fails to Regulate Antibiotics in Ethanol Production*. May 2012 See: http://www.iatp.org/files/2012_05_02_AntibioticsInEthanol_JO.pdf

3. Does FDA believe that the presence of antibiotics in DGS used for livestock feed may pose a similar public health concern as the impact of directly using antibiotic drugs to promote livestock growth? Please fully document your response.
4. A report by the IATP presents FDA's position that antibiotics in DGS are considered Food Additives and are therefore subject to regulations under the Federal Food, Drug and Cosmetic Act, but that industry rejects this view. What is FDA doing to ensure that ethanol producers are complying with Food Additive Regulations? If FDA is not taking any action to ensure compliance or if FDA has changed its position regarding the need to comply with Food Additive regulations, please provide a clear explanation.
5. Why did FDA choose to ban the use of DGS contaminated with the antibiotic, virginiamycin, in laying hens, but not in other food-producing animals? Please fully document your response.

As the threat of antibiotic resistance expands, we must ensure that the unnecessary use of antibiotics in agricultural animals is minimized and FDA has the ability to limit their use if it serves to protect public health. We appreciate your timely response to these questions. Should you have any further questions, please have your staff contact Dr. Avenel Joseph of Rep. Markey's staff at 202-225-2836 or Dr. Carolyn Shore of Rep. Slaughter's staff at 202-225-3615.

Sincerely,


Edward J. Markey


Louise M. Slaughter