

# Congress of the United States

Washington, DC 20515

June 24, 2011

The Honorable Margaret A. Hamburg, M.D.  
Commissioner  
Food and Drug Administration  
10903 New Hampshire Avenue  
Silver Spring, MD 20903

Dear Dr. Hamburg:

We write regarding the Food and Drug Administration's ("FDA" or the "Agency"), June 10, 2011 response (the Reponse) to our letter of April 12, 2011 on FDA's possible ban of extralabel use of cephalosporin. As we explained to you in our letter, this possible ban raises significant concerns among our nation's producers, veterinarians and consumers because of its impact on food safety and animal health. Despite this significant concern, FDA refused to answer our questions on the possible ban and its scientific basis.

These concern results from FDA's use of sound science (of lack thereof) in regulatory decision-making. From the 2008 order prohibiting the extralabel use of cephalosporin antimicrobial drugs in food-producing animals (Federal Register, Docket No. FDA-2008-N-0326) to the recent debate during House passage of the Fiscal Year 2012 Agriculture Appropriations Bill (H.R. 2112), many have questioned whether FDA uses sound science. The reason for these continued questions appears to be, in part, due to FDA's refusal to adequately address important questions related to its use of sound science.

Because of its refusal to answer our questions in its July 10, 2011 Response, we again ask the Agency to address the following questions:

- 1) How will the restrictions placed on the utilization of these antimicrobial drugs by veterinarians to treat disease affect animal welfare, food safety and public health? Is it possible that the ban will create more food safety issues than it solves? Has the FDA considered the possible consequences of the ban on increased drug residues in food? In answering this question, please describe and provide the risk assessment conducted by FDA of the possible negative outcomes.
- 2) What is the scientific basis for FDA's ban of extralabel use? In answering this question, please describe and provide all studies, reports and data forming the scientific basis of the action.
- 3) What alternatives, short of a banning extralabel use, did the Agency consider using and why were those alternatives not pursued?

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- 4) Based on comments on the original Order, there appear to be extralabel uses of cephalosporin, including some in dairy, that have neither appropriate nor efficacious alternative treatments. How has this concern been addressed by the Agency?

We request that you brief our staff within one week on the aforementioned questions. Please contact Mark Ratto of the Committee on Small Business Committee, John Goldberg of the Committee on Agriculture and Clay Alspach of the Committee on Energy and Commerce to schedule the briefing.

Sincerely,



Sam Graves  
Chairman  
Committee on Small Business



Fred Upton  
Chairman  
Committee on Energy and  
Commerce



Frank Lucas  
Chairman  
Committee on Agriculture

cc: The Honorable Nydia Velasquez, Ranking Member  
Committee on Small Business

The Honorable Henry A. Waxman, Ranking Member  
Committee on Energy and Commerce

The Honorable Collin C. Peterson, Ranking Member  
Committee on Agriculture