

# United States Senate

WASHINGTON, DC 20510-1502

COMMITTEES:  
AGRICULTURE  
APPROPRIATIONS  
HEALTH, EDUCATION,  
LABOR, AND PENSIONS  
SMALL BUSINESS

April 24, 2013

The Honorable Margaret Hamburg  
Commissioner  
U.S. Food and Drug Administration  
10903 Hampshire Avenue  
Silver Spring, MD 20093

Dear Commissioner Hamburg:

We write today in order to request increased transparency in the Food and Drug Administration's publication of data regarding food-animal antimicrobial drugs, and to improve the effectiveness of the agency's veterinary medicines program.

We support your efforts in *Guidance for Industry 209* and *Draft Guidance for Industry 213*. We request that the FDA set a clear timeline to develop an antimicrobial data collection strategy based on the Advanced Notice of Proposed Rulemaking published on July 27, 2012. As part of developing this strategy, we ask that the FDA assess current data collection and dissemination, in consultation with the United States Department of Agriculture and the Centers for Disease Control & Prevention, in order to determine data needs and if additional data could be made public subject to Section 512(l) of the Food, Drug and Cosmetic Act. We would request that this needs assessment be published and presented to Congress, and that any available additional data that the agency already collects under the Animal Drug User Fee Act of 2008, such as dosage form, strength, container size, and marketing status, be published beginning with the next annual report. We expect that you will ensure policies are in place when publishing additional public data to ensure no proprietary or personal identifiable information of businesses or producers is released in violation of any applicable laws or standards. We would also request that the FDA finalize *Draft Guidance for Industry 213* as soon as possible in order to begin to eliminate injudicious uses of antimicrobial drugs, as well as a plan for evaluation of the implementation of this policy.

The steps above will provide scientists with more data to further evaluate the effectiveness of current public health programs. We look forward to working collaboratively with you in order to ensure your agency's programs and policies are effective in order to protect public health, maintain a safe food supply system, and preserve effective antimicrobial drugs for humans and animals.

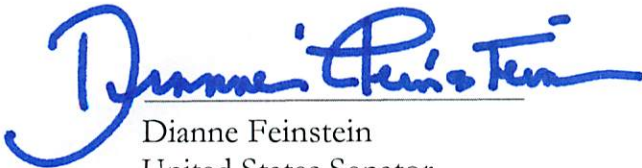
Sincerely,



Tom Harkin  
United States Senator



Lamar Alexander  
United States Senator



Dianne Feinstein  
United States Senator



Kirsten E. Gillibrand  
United States Senator



Mark Kirk  
United States Senator