

July 17, 2012

The Honorable Margaret Hamburg, M.D.
Commissioner, Food and Drug Administration
10903 New Hampshire Ave
Silver Spring, MD 20993-0002

Dear Commissioner Hamburg:

We, the undersigned groups, write to urge the FDA to not appeal the June decision by federal district court ordering the agency to reconsider its denial of 7-year old and 13-year old citizen's petitions asking the FDA to move to withdraw its approvals for nontherapeutic uses in food animals of medically important antibiotics.

The FDA has already appealed an earlier March 2012 court decision ordering it to withdraw feed additive approvals of penicillin and tetracyclines unless drug makers were able to show them to be safe. The new decision covers more medically important antibiotics in animal feed than just penicillins and tetracyclines, and more uses of them. Other antibiotics approved for animal feed include, for example, streptogramins, sulfas, aminoglycosides and macrolides.

We note that an FDA decision to NOT appeal the latest court decision need not interfere with the Agency's ongoing work under Guidance 209 and draft Guidance 213 to encourage pharmaceutical companies to voluntarily withdraw from the market their FDA-approved products for food animals. It is our belief, in fact, that threat of further legal action could aid in persuading companies to participate in a purely voluntary program.

FDA delays on this critically important health issue date back three and half decades. With 29 million pounds of animal antibiotics sold every year, and the fact that overall use is an important driver of antibiotic resistance, the public health crisis has continued to worsen. We are on the cusp of a post-antibiotic era, where bacterial infections once easily cured will no longer respond to the antibiotics at hand.

With antibiotic resistant infections costing society an estimated \$35 billion in total costs, and many tens of thousands of lives per year, we can ill afford further delay.

We urge the FDA to not appeal the court's decision, and to move forward expeditiously with withdrawal proceedings.

Sincerely,

Institute for Agriculture and Trade Policy
Johns Hopkins Center for a Livable Future
Food and Water Watch
The Alliance for the Prudent Use of Antibiotics
Center for Food Safety
STOP Foodborne Illness
Humane Society of the United States
Humane Society Veterinary Medical Association

cc: Bernadette M. Dunham, D.V.M., Ph.D., Director, Center for Veterinary Medicine

Michael R. Taylor, J.D., Deputy Commissioner for Foods, Food and Drug Administration
Linda R. Tollefson, DVM, MPH, Associate Commissioner for Foods & Veterinary Medicine