KEEP ANTIBIOTICS WORKING
The Campaign to End Antibiotic Overuse
www.KeepAntibioticsWorking.com

July 24, 2008

Dear Senator:

Re: Animal Drug User Fee Act (ADUFA) and Preservation of Antibiotics for Medical Treatment Act (PAMTA)

Antibiotic resistance is a growing threat. Antibiotics, the miracle drugs of the last century, are in danger of being lost as a result of overuse in both human and animal medicine. While both settings deserve urgent attention, food animal production is a relatively neglected area where enormous, often inappropriate, use of antibiotics is commonplace.

We, the undersigned members of Keep Antibiotics Working, write to urge that the reauthorization of the Animal Drug User Fee Act (ADUFA), along with its substantial incentives for approving new animal drugs, include provisions that will ensure public health and drug safety *after the animal drug is on the market*. Keep Antibiotics Working is a coalition of health, environmental, agricultural, animal welfare, and science organizations with more than 10 million supporters. The coalition is dedicated to the preservation of antibiotics for use in human and animal medicine.

According to the Centers for Disease Control (CDC) and the World Health Organization, antimicrobial resistance is the greatest public health risk we face. Antimicrobials (including antibiotics) are different from most other drugs in that resistance results from exposure and worsens over time. This means that in order to avoid the consequences of resistance-increasingly virulent diseases, higher medical costs, and increased suffering-the Food and Drug Administration (FDA) must continue to address resistance after drugs are approved. Many antibiotics routinely used in animal agriculture were approved decades ago, before resistance concerns were even considered.

We urge that ADUFA, when it is passed, include provisions from Title 1 and Title 2 of the Preservation of Antibiotics for Medical Treatment Act (PAMTA, S. 549) to address the ongoing resistance issues associated with approved antibiotics. The PAMTA provisions would:

1) Initiate the immediate review of existing antibiotics, in classes that are used both in human and animal medicine, of their safety for nontherapeutic purposes with regard to antibiotic resistance, and direct the FDA to take timely action on the basis of that review.

2) Require the collection of drug use data essential to the assessment and management of resistance risks associated with approved antibiotic drugs.

For both of these areas of post-market drug safety, the FDA must move quickly.

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When the Prescription Drug User Fee Act (PDUFA) was reauthorized as part of the FDA Amendments Act of 2007, it addressed post-market safety issues in human drugs. Similarly, any reauthorization of ADUFA should address post-market animal drug safety.

Over the past five years, FDA has consistently neglected the tasks necessary for the long-term management of resistance, as it has given priority to other goals funded by fees. Congress should not allow this failure to continue. Current funding now built into the agency's base, thanks to an earlier appropriation amendment, can be applied to the reviews required by Title 1 of PAMTA.

According to its mission statement, FDA is a consumer protection agency with a mandate to provide safe drugs. The most important aspect of safety when dealing with antibiotics is the evolution of resistant organisms. Congress should assist FDA in fulfilling its mission by assuring through the steps outlined above that antibiotics approved by the agency for nontherapeutic purposes, both in the past and in the future, are safe with regard to the evolution of resistance.

We urge you not to let ADUFA go forward without the vital public health provisions of PAMTA.

Sincerely,

Richard Wood
Executive Director
Keep Antibiotics Working

The Keep Antibiotics Working Coalition

Center for Science in the Public Interest
Environmental Defense
Food Animal Concerns Trust
Global Resource Action Center for the Environment
Humane Society of the United States
Institute for Agriculture and Trade Policy
National Catholic Rural Life Conference
Natural Resources Defense Council
Physicians for Social Responsibility
Safe Tables Our Priority (S.T.O.P.)
Sierra Club
Union of Concerned Scientists
Waterkeeper Alliance

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