

June 13, 2008

The Honorable John D. Dingell  
Chairman  
Committee on Energy and Commerce  
U.S. House  
Washington, DC

The Honorable Joe Barton  
Ranking Member  
Committee on Energy and Commerce  
U.S. House  
Washington, DC

Members  
Committee on Energy and Commerce  
U.S. House  
Washington, DC

**Re: The Animal Drug User Fee Act**

Dear Chairman Dingell, Ranking Member Barton, and Members of the House Committee on Energy and Commerce:

We write to urge that the reauthorization of the Animal Drug User Fee Act (ADUFA) include provisions that will ensure public health and drug safety *after the animal drug is on the market*, along with the substantial incentives for approving new animal drugs.

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, we are particularly concerned about the relatively neglected area of food animal production, where enormous, often inappropriate, use of antibiotics is commonplace.

Antimicrobial resistance is the greatest public health risk related to the use of veterinary drugs in animals under current regulatory regimes (World Health Organization. Joint FAO/OIE/WHO Expert Workshop on Non-Human Antimicrobial Usage and Antimicrobial Resistance: Scientific Assessment Geneva, December 1–5, 2003). Therefore **the long-term management of antibiotic resistance is the most critical issue facing the Food and Drug Administration (FDA) in assuring the post-market safety of veterinary antimicrobials.**

Antimicrobials (including antibiotics) are different from most other drugs in that resistance to them results from exposure and worsens over time. This means that in order to avoid the consequences of resistance—more virulent diseases, higher medical costs, and increased human suffering—the agency must be in a position to manage resistance after drugs are approved.

We urge that ADUFA, when it is passed, include provisions like those in the Preservation of Antibiotics for Medical Treatment Act (H.R. 962) that address the ongoing resistance issues associated with approved antibiotics, including:

- 1) Initiate the immediate review of safety with regard to antibiotic resistance of existing antimicrobial compounds in drug classes that are used both in human and animal medicine. Unless the drug sponsors are able to provide data showing that the nontherapeutic use of an antibiotic in food-producing animals does not generate a health risk in humans, such uses of the antibiotic would be phased out in animal agriculture, and

- 2) Require the collection of veterinary drug use data essential to the assessment and management of antimicrobial risks represented by approved antimicrobial drugs.

For both of these areas of post-market drug safety, ADUFA should set reasonable performance goals.

When the Prescription Drug User Fee Act (PDUFA) was reauthorized as part of the FDA Amendments Act of 2007, increased fees to provide for post-market human drug safety were included. 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, in part because the infusion of fees coming from drug companies through ADUFA failed to identify and fund post-market safety goals. Congress should not make the same mistake in this reauthorization.

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 antimicrobials is the evolution of resistant organisms. Congress should assist FDA in fulfilling its mission by assuring through the steps outlined above that antimicrobial drugs approved by the agency both in the past and in the future are safe with regard to antimicrobial resistance.

If you have any questions or would like to discuss this matter in detail, please contact Margaret Mellon at 202-223-6133 or email [mmellon@ucsusa.org](mailto:mmellon@ucsusa.org). Thank you for considering our views.

Sincerely,

Academy of Medicine of Toledo and Lucas County  
Adrian Dominican Sisters  
American Academy of Ambulatory Care Nursing  
American Academy of Neurology Professional Association  
American Nurses Association  
Western Nebraska Resources Council  
Catholic Charities, Diocese of Sioux City  
Catholic Health Association of the United States  
Catholic Healthcare West  
Center for Food Safety  
Citizens for Pennsylvania's Future (PennFuture)  
Department of the Planet Earth  
Buckeye Environmental Network  
Endangered Habitats League  
Park County Environmental Council  
Georgia AIDS Coalition  
Grassroots Environmental Education  
Healthy Schools Network  
Henry A. Wallace Center for Agriculture and Environmental Policy, Winrock International  
Huntington Breast Cancer Action Coalition  
Illinois Stewardship Alliance  
Izaak Walton League of America  
Leukemia and Lymphoma Society  
Maine Organic Farmers and Gardeners Association

Mankato Area Environmentalists  
Minnesota COACT (Citizens Organized ACTing Together)  
Minnesota Medical Association  
Missouri Coalition for the Environment  
Naturesource Communications  
New Mexico Environmental Law Center  
Northeast Organic Farming Association - Massachusetts  
Northeast Organic Farming Association - Vermont  
Northwest Environmental Advocates  
Ohio AIDS Coalition  
Ohio Environmental Council  
Ohio Nurses Association  
Ohio Osteopathic Association  
Oklahoma Nurses Association  
Organic Consumers Association  
Organic Trade Association  
PCC Farmland Trust  
PCC Natural Markets  
Simply Living  
South Carolina Nurses Association  
Stonyfield Farm, Inc.