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. 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.