March 15, 2013

President Barack Obama
The White House
1600 Pennsylvania Avenue, NW
Washington, DC 20500

Dear President Obama:

As organizations committed to protecting public health, animal health, and food safety, the undersigned groups seek your continued leadership in addressing the urgent and growing epidemic of antibiotic resistance. Specifically, we ask that you move forward with stalled U.S. Food and Drug Administration (FDA) actions to reduce the overuse and misuse of antibiotics in food animal production, including strengthening and finalizing voluntary guidelines and moving forward with mandatory withdrawals of unsafe uses of antibiotics. We also ask you to support improvements to reporting requirements for livestock antibiotic sales in legislation currently before Congress.

According to the Infectious Diseases Society of America, nearly two million Americans each year develop hospital-acquired infections, resulting in 99,000 deaths—with a steadily increasing number due to antibacterial-resistant infections. The Director General of the World Health Organization last year warned that, “[t]hings as common as strep throat or a child’s scratched knee could once again kill. . . . A post-antibiotic era means, in effect, an end to modern medicine as we know it.”1 Currently, medically important antibiotics sold for food animal use constitute more than 70 percent of total reported sales of medically important antibiotics in the United States.

We were dismayed in 2011 when the FDA formally declined to use its regulatory authority to withdraw approvals for certain uses of penicillins and tetracyclines in animal feed—something it first proposed to do in 1977 after finding that these uses threaten public health by contributing to the crisis of antibiotic resistance. Given the rapid rate at which many antibiotics are becoming ineffective for treating human disease and the limited number of new antibiotics in development, the FDA should take bold steps to rein in overuse and misuse. We ask you to ensure that FDA moves immediately to use its regulatory authority to withdraw approvals for the non-therapeutic use (i.e., use of antibiotics for purposes other than disease treatment and disease control) of all medically-important antibiotics from food animal production, thus preserving their use for treating sick animals and people.

The FDA has instead issued voluntary draft guidance for the pharmaceutical industry (Guidance for Industry #213) that establishes guidelines by which it is encouraging the phase-out of growth-promoting uses of antibiotics in livestock and poultry, an economic use designed to speed animal growth and reduce feed costs. While the guidance cannot replace a regulatory path that would

guarantee an end to these and other non-medically necessary uses of antibiotics in food animals, it could be improved to be more helpful, and we have shared with FDA our two primary concerns to be addressed in the final Guidance #213:

1) it must clearly limit the use of antibiotics for “disease prevention” in animals. “Disease prevention” is often a catch-all term covering many uses in the absence of clinical disease. The Guidance should provide a more restrictive definition to ensure appropriate use of antibiotics; and

2) it should include a plan to monitor progress in reducing antibiotic use and antibiotic resistance. Data collection on antibiotic use is virtually non-existent, and data on antibiotic sales is insufficient to measure the effectiveness of the guidance program.

We seek your help in strengthening and then advancing these policies quickly. We recommend that by the start of the summer the FDA issue a finalized and strengthened Guidance #213 that limits routine use of antibiotics for disease prevention and establishes tracking mechanisms so the public health community, pharmaceutical companies, and the public in general have the fullest picture of how your Administration plans to address the agricultural contribution to the antibiotic resistance crisis.

Finally, we ask that you support stronger reporting requirements for agricultural antibiotic sales and distribution as part of this year’s reauthorization of the Animal Drug User Fee Act (ADUFA), which can help illustrate current use patterns, explain resistance trends, and monitor progress in assuring responsible animal antibiotic use. The American people need your help to ensure that these essential medicines will be effective in protecting our children into the future.

We are eager to help in any way we can. Thank you for your consideration.

Sincerely,

Alliance for the Prudent Use of Antibiotics
American Academy of Pediatrics
American College of Preventive Medicine
American Nurses Association
American Public Health Association
Applegate
Assateague COASTKEEPER
Association for Politics and the Life Sciences
American Society for the Prevention of Cruelty to Animals
Bon Appetit Management Company
Brown's Ranch
Center for Foodborne Illness Research and Prevention
Center for Food Safety
Consumers Union
Dignity Health
Environmental Working Group
FamilyFarmed.org
First Focus Campaign for Children
Food Animal Concerns Trust
Food and Water Watch
Fresh Direct
Health Care Without Harm
Heritage Foods, LLC
Humane Society Veterinary Medical Association
Infectious Diseases Society of America
Institute for a Sustainable Future
Institute for Agriculture and Trade Policy
Johns Hopkins Center for a Livable Future
Keep Antibiotics Working
March of Dimes
Michigan Antibiotic Resistance Reduction (MARR) Coalition
National Research Center for Women & Families
National Consumers League
Natural Resources Defense Council
Organic Consumers Association
Ozark Mountain Pork Cooperative
Niman Ranch Pork Co.
Pediatric Infectious Diseases Society
Pitman Farms
School Food FOCUS National Office
Society of Infectious Diseases Pharmacists
STOP Foodborne Illness
The Humane Society of the United States
The Pew Charitable Trusts
Trust for America’s Health
Union of Concerned Scientists
Waccamaw RIVERKEEPER
WATERKEEPER Alliance
Yadkin RIVERKEEPER

Cc: The Honorable Kathleen Sebelius, Secretary, Department of Health and Human Services
    The Honorable Tom Vilsack, Secretary, Department of Agriculture
    The Honorable Margaret Hamburg, Commissioner, Food and Drug Administration