

July 12, 2012

The Honorable Margaret A. Hamburg, M.D.
Commissioner
C/o Division of Dockets Management (HFA-305)
U.S. Food and Drug Administration
5630 Fishers Lane
Room 1061
Rockville, MD 20852

RE: Comment Docket No. FDA-2011-D-0889, "Draft Guidance for Industry on New Animal Drugs and New Animal Drug Combination Products Administered in or on Medicated Feed or Drinking Water of Food-Producing Animals: Recommendations for Drug Sponsors for Voluntarily Aligning Product Use Conditions With GFI 209"; Guidance 213

Dear Commissioner Hamburg:

We, the undersigned organizations, respectfully request that the federal government accelerate and expand actions to curtail the overuse and misuse of antibiotics in food animal production. Despite overwhelming scientific evidence that these practices threaten human health, the routine administration of antibiotics in industrial meat and poultry operations continues unabated, putting the health of all Americans at risk for dangerous antibiotic-resistant infections.

Four decades ago, experts began sounding an alarm about the use of antibiotic drugs in food animal production, warning that concerted action is needed to ensure that antibiotics are preserved as the vital, life-saving medicine we depend upon to treat common but dangerous infections. In addition, the U.S. Food and Drug Administration (FDA), U.S. Department of Agriculture and the Centers for Disease Control and Prevention (CDC) have all testified before Congress that there is a definitive link between the routine, non-therapeutic uses of antibiotics on industrial farms and the crisis of antibiotic resistance in humans.

Yet almost no action has been taken by the United States – even as a mountain of scientific evidence has been presented by the CDC, the World Health Organization, the National Research Council and scores of public health organizations showing the link between antibiotic resistance and overuse of antibiotics in agriculture.

The call for action, grounded in science, has been largely ignored and the crisis of antibiotic resistance has grown. Data compiled by the FDA demonstrates that 80 percent of all antibiotics sold in the United States is for food animal production, the vast majority to promote faster growth and compensate for the effects of unsanitary and crowded conditions.

It is time for the FDA and other federal agencies to act in the interest of public health and the American people. FDA should protect public health from resistant organisms as a result of using antibiotics in animal agriculture for growth promotion and routine disease prevention. Recent rulings by a federal court in New York have directed the agency to move forward with withdrawal proceedings for penicillin and tetracyclines, as well as evaluate the safety risks of other medically important antibiotics and make a finding about whether the use of these drugs in animal feed is shown to be safe. FDA should move

ahead with this important process irrespective of the status of any appeal, since public health requires strong action to preserve the effectiveness of these critical, life-preserving drugs.

In addition, we note FDA's recent issuance of Guidance for Industry numbers 209 and 213, as well its Veterinary Feed Directive (VFD). [Guidance 209, Docket No. FDA-2010-D-0094 Draft Guidance 213, Docket No. FDA-2011-D-0889; and Veterinary Feed Directive Draft Text for Proposed Regulation, Docket No. FDA-2010-N-0155] Together, these initiatives have the potential to be a useful parallel framework for eliminating non-therapeutic uses of antibiotics and ensuring more rigorous veterinary oversight in the use of antibiotics in food animal production. To succeed, these voluntary initiatives will require concerted and good faith implementation by industry to curtail misuse and overuse of antibiotics. They will also require significant improvements.

We call on FDA to act quickly and vigorously to:

- Move forward with complying with the court's orders.
- Clarify that routinely administering low doses of medically important antibiotics at a herd-wide or flock-wide level is not appropriate preventive use.
- Make clear that using antibiotics in lieu of addressing inappropriate diets, overcrowding and poor sanitation is not judicious use.
- Establish the baseline data and monitoring system required to verify that antibiotic use in food animal production is reduced in a measurable and meaningful fashion.
- Verify and demonstrate that drug companies change labels and marketing to eliminate references to growth promotion as an approved use.
- Verify that veterinarians are providing proper oversight in the dispensing of medically important drugs only for therapeutic purposes.
- Clearly communicate progress, or lack thereof, to the American people in a timely and regular fashion.
- Withdraw the proposal in Guidance 213 to create a weaker alternative method for evaluating the safety of antibiotics used in food producing animals.

The ingenuity and hard work of a few scientists prior to World War II led to the creation of antibiotics, which have been called "miracle" drugs. Similar dedication is required now by all Americans – from patients to consumers, the public to the private sector – to ensure that we preserve these pillars of public health. With leadership from the FDA, we have the potential to help save lives, and reduce human suffering.

Sincerely,

The Alliance for the Prudent Use of Antibiotics
American Academy of Pediatrics
American College of Preventive Medicine
American Grassfed Association
American Osteopathic Association
American Public Health Association
Association of State and Territorial Health Officials
Association for Professionals in Infection Control and Epidemiology
The American Society for Clinical Laboratory Science
Boston Public Health Commission
Breast Cancer Action

Breast Cancer Fund
Center for Foodborne Illness Research & Prevention
Center for Food Safety
Center for Science in the Public Interest
Citizens Action Coalition
Children's Health Fund
Colorado Mountain College Culinary Institute
Consumers Union
Cumberland Countians for Peace & Justice
Endangered Habitats League
Environmental Working Group
FamilyFarmed.org
Farm Sanctuary
Food Animal Concerns Trust
Food Democracy Now!
Food and Water Watch
Friends of Toppenish Creek
Health Care Without Harm
Humane Farming Association
Humane Society of the United States
Humane Society Veterinary Medical Association
Immunization Action Coalition
Institute for Agriculture and Trade Policy
Johns Hopkins Center for a Livable Future
Keep Antibiotics Working
Klamath Forest Alliance
League of United Latin American Citizens
March of Dimes
Michigan Antibiotic Resistance Reduction (MARR) Coalition
National Association of County and City Health Officials
National Center for Disaster Preparedness at Columbia University Mailman School of Public Health
National Research Center for Women & Families
Natural Resources Defense Council
Network for Environmental & Economic Responsibility of the United Church of Christ
Ohio Public Health Association
Organic Consumers Association
Pediatric Infectious Diseases Society
The Pew Charitable Trusts
Spottswode Estate Vineyard & Winery
St. Joseph Health
STOP Foodborne Illness
Trust for America's Health
Union of Concerned Scientists
Washington Physicians for Social Responsibility
Waterkeeper Alliance
Waterkeepers Carolina
Western Nebraska Resources Council