

August 17, 2015

The Honorable Stephen Ostroff, M.D.
Acting Commissioner
U.S. Food and Drug Administration
10903 New Hampshire Ave.
Silver Spring, MD 20993

**RE: Docket No. FDA-2012-N-0447, "Antimicrobial Animal Drug Sales and Distribution Reporting,"
Proposed rule**

Dear Acting Commissioner Ostroff:

The undersigned public health, medical, veterinary, animal welfare, environmental, and consumer organizations write in support of FDA's proposed rule to revise its collection and reporting of antibiotic sales information from animal drug companies. The rule revises a regulation first put forward in July 2012 to implement the Animal Drug User Fee Act (ADUFA).

Importantly, the proposed rule would require drug companies to estimate how their antibiotic sales break down by species. Because most antibiotics are approved for use in more than one species, understanding differing demand for antibiotics among the major food animals — chickens, cows, pigs, and turkeys — is an important window into how antibiotics may be used. We urge the agency to publicly report as much species-level information as possible while protecting business confidentiality. We also appreciate FDA's proposal to set a deadline for annual reporting of sales data summaries, so that the public can have more reliable access to information.

We applaud FDA's efforts in recent years to expand public reporting of ADUFA sales data to include additional elements needed to analyze antibiotic sales trends: medical importance, route of administration (via feed, water, or other), and whether the drug needs to be prescribed by a veterinarian. While reports also now summarize indications of use, we encourage the agency to consider other means to collect and report more meaningful information on why antibiotics are used (i.e., growth promotion vs. disease prevention vs. control vs. treatment).

Though sales data reporting has improved, and would further improve under the proposed rule, sales data is inherently limited in its ability to depict animal health and prescribing trends, and does not represent actual use. FDA has acknowledged these limitations to sales data, and has announced plans to work with USDA and CDC to find additional avenues for data collection to provide a better picture of antibiotic use, including the reasons why antibiotics are used in food animal production. It is important that FDA work with these agencies and with all stakeholders to swiftly pursue methods to collect quantitative data about how antibiotics are used in food production. Usage data will help stakeholders

identify trends in antibiotic effectiveness in treating animal health conditions and assess the success of alternative management practices. In addition, usage data would enable FDA to monitor sector use and measure the impacts of its growth-promotion withdrawal policy, Guidance for Industry #213, which is set to take effect in less than two years. In particular, we urge the FDA to strengthen its data collection approach by announcing a framework to collect and publish antimicrobial sales and distribution data by species, production class, and purpose of use from manufacturers of medicated feeds. This could include collection of data from associated veterinary feed directive (VFD) orders to provide additional information on the purpose of use for feed antimicrobials.

Thank you for your consideration and for the agency's continued commitment to addressing the public health threat of antibiotic resistance. We urge you to finalize this rule as quickly as possible, and to work expeditiously with USDA and CDC to develop methods for better understanding how and why antibiotics are used in practice.

Sincerely,

Alliance for the Prudent Use of Antibiotics
American College of Preventive Medicine
American Public Health Association
Antibiotic Resistance Action Center at the Milken Institute School of Public Health, The George Washington University
Association for Professionals in Infection Control and Epidemiology
Center for Foodborne Illness Research and Prevention
Center for Food Safety
Center for Science in the Public Interest
Food & Water Watch
Food Animal Concerns Trust
Keep Antibiotics Working
Health Care Without Harm
The Humane Society of the United States
Humane Society Veterinary Medical Association
Johns Hopkins Center for a Livable Future
Natural Resources Defense Council
Pediatric Infectious Diseases Society
The Pew Charitable Trusts
Sharing Antimicrobial Reports for Pediatric Stewardship
Society of Infectious Disease Pharmacists
Trust for America's Health
U.S. PIRG