December 4, 2014

Dr. Margaret Hamburg, Commissioner
Food and Drug Administration
10903 New Hampshire Ave
Silver Spring, MD 20993-0002

Dear Commissioner Hamburg:

We, the undersigned organizations, are aware the Food and Drug Administration has a key role in implementing the upcoming National Action Plan on combating antimicrobial resistance. We also recognize that collection and public distribution of data is essential to the FDA’s success in that effort.¹

We therefore request that FDA move quickly to 1) release already-collected data on the sales of antibiotics for use in food-producing animals from 2013; 2) make public the FDA’s plans for collecting data on how antibiotics are used on farms; and 3) identify any gaps or barriers to collecting these data.

Public health agencies and experts, including advisors to the White House, recognize that to better address the catastrophic threat from antibiotic resistance, the U.S. needs to do a better job of collecting and rapidly disseminating data, monitoring and surveillance of resistance, as well as reporting antimicrobial sales and usage data. Given that a significant proportion of U.S. antibiotics are used in agricultural settings, detailed data on that usage is critical for understanding antibiotic use overall, as well as resistance trends.

We applaud the FDA for the step forward represented by its 2012 report on the sales and distribution of antimicrobials for use in food-producing animals.² This report was clearer and more comprehensive than past reports, reflecting significant work by FDA staff. Having done that hard work, we urge FDA to move forward without delay – and keeping with the timeline of prior years (FDA released its 2010 data in October 2011) – to release the already-collected data from 2013 using this new format.

While data collected and reported so far as required by the Animal Drug User Fee Act (ADUFA) have provided an important summary of the overall quantity of antibiotics sold for use in food animals, they lack some basic and critical details for meeting public health goals. In addition to these summary data, FDA should collect and report the following:

- data on the distribution of antimicrobials at least at the level of animal species (e.g., cattle, pig, chicken);
- data on the distribution of antimicrobials at the production class level;
- indications for antimicrobials (e.g., treatment, disease prevention, growth promotion);
- dosage level;
- route of administration (e.g., feed, water, injection, etc.);

¹ Collection of antimicrobial use data was recommended by the Public Health Action Plan To Combat Antimicrobial Resistance in 2000, the Science Board to the FDA in 2007, the United States Government Accountability Office in 2011, and the President’s Council of Advisors on Science and Technology in 2014, and is included in the Presidential Executive Order on Combating Antibiotic-Resistant Bacteria.

• retail outlet-level data on antibiotic sales rather than a national aggregate; and
• antimicrobial drug sales data from manufacturers of medicated animal feeds, or “animal feed mills”.

These are critical details needed to understand and monitor how antibiotic use in food-animal production changes over time, and to evaluate the impact of these changes on antimicrobial resistance. Reductions in use cannot be assessed without a baseline understanding of where and how such use currently takes place. If FDA faces challenges to collecting and releasing comprehensive data on antimicrobial use in agricultural settings, such as insufficient funding or statutory authority, the agency should identify the barriers so stakeholders and policymakers may take appropriate steps to address them.

The threat to the nation posed by antibiotic resistant bacteria is both real and serious. Collection and comprehensive reporting of sufficiently detailed and accurate data on antimicrobial use is essential for understanding, and managing, this crisis.

Thank you. We look forward to the release of the 2013 ADUFA data by the end of 2014. In doing so, the Department of Health and Human Services, now tasked with leading renewed efforts across all federal agencies to combat the march of antibiotic resistance, can signal its strong commitment to this issue. Please direct correspondence to Dwallinga@gmail.com.

Sincerely,

Alliance for the Prudent Use of Antibiotics
American Academy of Pediatrics
American College of Preventive Medicine
American Medical Association
American Public Health Association
American Society for Microbiology
Cempra
Center for Science in the Public Interest
Center for Foodborne Illness Research and Prevention
Consumers Union
Dignity Health
Food and Water Watch
Food Animal Concerns Trust
Health Care Without Harm
Health Watch USA
Healthy Food Action
Keep Antibiotics Working
Infectious Diseases Society of America
Johns Hopkins University Center for a Livable Future
MAD-ID
National Association of County and City Health Officials
Natural Resources Defense Council
National Foundation for Infectious Diseases
Pediatric Infectious Disease Society
Society of Critical Care Medicine
Society of Infectious Disease Pharmacists
Stop TB USA
Trust for America's Health