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August 18, 2015

The Honorable Stephen Ostroff, MD
Acting Commissioner
US 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 Infectious Diseases Society of America (IDSAs) appreciates the opportunity to comment on the US Food and Drug Administration's (FDA) proposed rule pertaining to the collection and reporting activities on antimicrobial animal drug sales under Section 105 of the Animal Drug User Fee Act (ADUFA). IDSAs represents over 10,000 infectious diseases physicians and scientists devoted to patient care, prevention, public health, education, and research in the field of infectious diseases. Our members care for patients of all ages with serious and often life-threatening infections, including those caused by drug-resistant microorganisms.

IDSAs strongly supports the FDA's proposal to collect species level data for swine, cattle, chickens, and turkeys. 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 commend the FDA for taking an important step forward to improve what we view as an inadequate reporting system. The addition of species-level data will enhance the public's understanding of antimicrobial resistance and provide some useful information to the public and researchers about how medically important drugs are used in food animals.

There is substantial scientific evidence supporting the claim that non-judicious use of antimicrobials in both humans and food animals advances antimicrobial resistance in human pathogens. Better information on the use of antimicrobial drugs in food animals will enable public health officials and scientists to better understand and interpret trends and variations in antimicrobial resistance. This will improve the understanding of the relationship between animal uses of these drugs and antimicrobial resistance in animals and humans, to identify agricultural sectors with challenges to judicious use of antimicrobials, and to evaluate interventions to prevent and control resistance.

The current lack of adequate US antimicrobial consumption data impedes our understanding of geographic and temporal trends in antimicrobial resistance. To effectively combat the antimicrobial resistance crisis, both governmental and non-governmental public health, animal health and infectious diseases experts need ongoing access to reliable data on the scope of antimicrobial consumption in animals, and in a unit of measure that can be assessed across time, species, and

geography. Sales data alone will not increase our knowledge about how and why antimicrobials are used in animals. Such data should be coordinated with other sources of on-farm and antimicrobial resistance data in order to yield meaningful information.

Specifically, we offer the following additional recommendations:

- ***Publish monthly sales data.*** Since 2008, the FDA has collected data from animal pharmaceutical manufacturers about the amounts sold every month. Accordingly, FDA should include a table that reports aggregate unit (i.e. container, strength, dose) sales by month for each drug class. This information may help scientists identify connections between antimicrobial use and the occurrence of specific diseases, which could help advance novel treatment or prevention approaches.
- ***Publish state- or regional-level data.*** FDA should report state-by-state data (and where informative, smaller geographic areas) on antimicrobial sales rather than a national aggregate. Such data would be useful to benchmark antimicrobial use based on the density of food-animal production in a particular state or region. The Centers for Disease Control and Prevention (CDC) has successfully used outpatient antimicrobial prescribing for humans by region.
- ***Work with the US Department of Agriculture (USDA) to improve the National Animal Health Monitoring System (NAHMS) reporting of on-farm antimicrobial use.*** NAHMS collects qualitative information on antimicrobial use in livestock production but reporting is voluntary and not comprehensive. Better information about on-farm antimicrobial usage (e.g., prophylactic vs. therapeutic use), including what factors influence livestock producers' decisions about using antimicrobials and a method to quantify use will help to target outreach and education activities related to antimicrobial use and resistance.
- ***Work with USDA and CDC to develop a public communication plan to explain the implications of collected data for human and animal health.*** It is important that farmers, ranchers, and the public understand exactly what data on antimicrobial sales and use mean in terms of threats to human and animal health. FDA should work with the USDA in advance of data publication to create a public dissemination and education plan so that confusion is minimized.

We appreciate the opportunity to provide comments and for FDA's ongoing efforts to promote judicious use of antimicrobials in food animals. Should you have any questions, please contact John Billington, IDSA Director of Health Policy, at jbillington@idsociety.org / (703) 299-0015.

Sincerely,



Stephen B. Calderwood
President, IDSA