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Division of Dockets Management (HFA-305)
U.S. Food and Drug Administration
5630 Fishers Lane, Rm. 1061
Rockville, MD 20852

Submitted electronically to:  http://www.regulations.gov

SUBJ: [Docket No. FDA-2012-N-0447] Antimicrobial Animal Drug Sales and Distribution Reporting

Dear Sir/Madam:

The Infectious Diseases Society of America (IDSA) appreciates the opportunity to provide comments on the Food and Drug Administration’s (FDA) advance notice of proposed rulemaking for antimicrobial animal drug sales and distribution reporting. IDSA represents nearly 10,000 infectious diseases physicians and scientists devoted to patient care, prevention, public health, education, and research in the area of infectious diseases. The Society’s members focus on the epidemiology, diagnosis, investigation, prevention and treatment of infectious diseases in the United States and abroad. Our members care for patients of all ages with serious and often life-threatening infections, including those caused by drug-resistant microorganisms.

There is substantial scientific evidence supporting the claim that non-judicious use of antimicrobials in both humans and food animals leads to greater degrees of antimicrobial resistance in human pathogens. Given the increasing proportion of highly-resistant pathogens that are causing human disease today, improved antimicrobial stewardship will have a significant positive impact on human health. Unless we are able to significantly change the way we use antimicrobials in both clinical practice and in agriculture, we risk entering a “post-antibiotic” era. In advance of future rulemaking on antimicrobial animal drug sales and distribution reporting, IDSA urges FDA to carefully consider three principles outlined below.

1. **FDA should ensure that U.S. experts have access to reliable, standardized data on the scope of antibiotic consumption in animals by species to effectively control the antibiotic resistance epidemic.**

The Animal Drug User Fee Act of 2008 (ADUFA) authorizes FDA to collect and publish data from pharmaceutical companies on antibiotics sold for use in food animals, but unfortunately stops short of requiring critical details that would be needed to effectively interpret trends in rates of resistance. The sales data FDA currently collects suffers from three substantial limitations: (1) it does not include
retail outlet-level sales data; (2) it does not identify species in which antibiotics are used or the purpose of their use; and (3) it is collected only at the national level. Unfortunately, standalone sales data, without additional granularity, is insufficient to effectively combat non-judicious use of antibiotics in food animals.

To effectively control the antibiotic resistance epidemic, both governmental and non-governmental animal health and infectious disease experts need ongoing access to reliable data on the scope of antibiotic consumption in animals, by species, and in a unit of measure that can be compared across species and localities. “Consumption” data includes drug use data (i.e., prescribing data) as well as manufacturers’ distribution and sales data. The current lack of adequate U.S. antibiotic consumption data impedes our understanding of geographic and temporal trends in antibiotic resistance. In the agricultural context, a more complete and accurate dataset on antibiotic consumption will make information currently collected under the National Antimicrobial Resistance Monitoring System (NARMS) more effective, because it could be used to show possible correlations between antibiotic use and the development of resistance.

2. **FDA should look to the experiences of Denmark and the European Union (EU) as it considers potential changes to regulations relating to records and reports for approved new animal drugs.**

The United States is far behind other countries in collecting, and benefiting from, antibiotic consumption data. The Danish Integrated Antimicrobial Resistance Monitoring and Research Program (DANMAP) performs continuous monitoring of both consumption data and resistance data in humans, animals, and food. Human consumption data is collected from the pharmaceutical industry and the Danish Medicines Agency, while DANMAP’s “VetStat” system collects food animal data by species from pharmacies, farms, feed mills, and veterinary practitioners.

On a Europe-wide level, the European Surveillance of Antimicrobial Consumption (ESAC) system collects human and more limited animal consumption data from 34 countries, while the European Antimicrobial Resistance Surveillance System (EARSS) collects resistance data. The inputs are largely standardized since countries must adhere to World Health Organization standards regarding measurement (“defined daily doses”) and classification of antibiotics. Despite logistical hurdles to collecting data from member nations, EU officials have recognized and emphasized the importance of gathering consumption data to evaluate the effects of risk management policies and to further understand the connection between antibiotic use in animals and resistance in humans. FDA also has recognized the importance of gathering consumption data, and IDSA urges FDA to study the EU experience and apply those lessons in the U.S.

3. **FDA should amend its regulations to require the submission of additional sales and distribution data.**

IDSA supports the recommendations set forth by the September 2011 Government Accountability Office (GAO) report titled *Antibiotic Resistance: Agencies Have Made Limited*
Progress Addressing Antibiotic Use in Animals\(^1\), which highlighted shortcomings in the current FDA regulations on antimicrobial animal drug sales and distribution reporting. IDSA urges FDA to amend these regulations under the authority established by ADUFA in order to ensure the judicious use of antibiotics in food animals. Specifically, FDA should require, to the greatest extent possible, the following:

- species-level distribution data;
- indication for use;
- route of administration (e.g., feed, water, injection, etc.);
- 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”.

Finally, when reporting distribution data for antimicrobials that have fewer than three independent sponsors (as specified and restricted by ADUFA), FDA can maximize the value of such reports and still comply with ADUFA by breaking out the data based on relationships between drug classes and by medical importance for human health. FDA summaries to date have lumped these data into an umbrella group instead of smaller groups based on drug class relationships or by medical importance. Consequently, some antimicrobials critically important to human health (e.g., fluoroquinolones) have been grouped with drugs not used in human medicine. Breaking out the data by drug class relationship and by medical importance will allow compliance with ADUFA requirements while permitting experts access to valuable data that may have implications for antimicrobial resistance and related threats to human health.

If FDA determines it does not have the authority to implement these additional requirements, IDSA urges FDA to seek clarification from Congress, and additional authority if necessary. IDSA also requests a written response explaining any legal limitations the agency identifies, so that we can effectively advocate for a legislative solution.

IDSA commends FDA for continuing to move forward with measures to ensure judicious use in animals of antimicrobials important to human health. This is a matter of great importance to the health of the U.S. public. We appreciate the opportunity to provide comment and for FDA’s ongoing efforts to eliminate non-judicious use of antimicrobials in food animals. Should you have any questions or comments, please contact John Billington, IDSA Program Officer for Health Policy, at jbillington@idsociety.org / (703) 299-0200.

Sincerely,

Thomas G. Slama, MD FIDSA
President