March 19, 2012

Division of Dockets Management (HFA-305)
Docket No. FDA-2012-N-0032
Food and Drug Administration
5630 Fishers Lane, Rm. 1061
Rockville, MD 20852

RE: Agency Information Collection Activities; Proposed Collection; Comment Request; Antimicrobial Animal Drug Distribution Reports Under Section 105 of the Animal Drug User Fee Amendments of 2008 [January 17, 2012]

The Center for Science in the Public Interest (CSPI)\(^1\) appreciates the opportunity to comment on the significant issue of veterinary drug use in food-producing animals. CSPI has been monitoring this issue closely, and believes that antibiotic use in food production poses a significant hazard for consumers and the public health. Food and Drug Administration (FDA) is collecting some important data to understand and quantify the amounts of antimicrobials consumed and sold for use in food-producing animals, including via electronic forms by sponsors of new antimicrobial veterinary drugs. This information—including details on the amounts of each antimicrobial active ingredient, quantities distributed domestically and internationally, and the target animals, among other information—will allow FDA to more effectively address safety concerns related to the misuse and overuse of antibiotics in animal agriculture that have contributed to the rise and spread of antibiotic-resistant pathogens in the environment and in the food supply.

However, CSPI has some concerns regarding aspects of the data collection. First, the regulation requires that only new animal drug sponsors complete the electronic form – leading to a serious gap if this form is not utilized by companies that supply existing animal drugs. Access to information on antimicrobials in both existing veterinary drugs and new drugs is necessary to create a complete picture of antimicrobial use in animal agriculture.

CSPI also recommends that the form include a section for noting the purpose(s) of the medication – specifically stating whether the drug is for therapeutic and/or non-therapeutic purposes. The non-therapeutic use of veterinary drugs is one of the leading contributors to antimicrobial resistance, in part due to the administration of these drugs in low doses in animal feed and water. Consumer groups, including CSPI, have publicly called for limits on non-therapeutic uses of these drugs, and the collection of information regarding their intended use is central to monitoring rates of compliance.

Finally, CSPI recommends that the FDA require companies to indicate whether the active antimicrobial ingredients are ranked as critically important, highly important, or important to human medicine as stated in the FDA Guidance for Industry #152 document.\(^2\) Regardless of whether the federal government is already aware of that designation, each company should be cognizant of its contribution to antimicrobial resistance, and demonstrate its knowledge of the responsibility they carry for judicious use of these important drugs.

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\(^1\) CSPI is a non-profit consumer advocacy and education organization that focuses largely on food safety and nutrition issues. It is supported principally by the 900,000 subscribers to its *Nutrition Action Healthletter* and by foundation grants.

\(^2\) Regardless of whether the federal government is already aware of that designation, each company should be cognizant of its contribution to antimicrobial resistance, and demonstrate its knowledge of the responsibility they carry for judicious use of these important drugs.
Knowledge of the relative importance of each drug to the human population can help companies build their own judicious use policies and protocols.

All information gathered as a result of this collection should be available for public review, and should be maintained in a transparent and searchable database so that interested parties can analyze usage patterns of these important drugs.

CSPI recognizes that the agency has a duty to balance the economic burdens to industry associated with annually providing a report to the FDA on the antimicrobial agents used in animal production. We strongly believe that such burdens are nearly inconsequential when compared to the burden on society from drug-resistant pathogens and resulting infections that are difficult and sometimes impossible to treat. On March 8, 2012, Dr. James Johnson, a practicing physician specializing in infectious disease, presented at a CSPI-sponsored briefing on Capitol Hill. His presentation emphasized that drug-resistant infections increase the costs of treatment (29% increase in cost per case due to higher mortality and longer hospital stays compared to non-drug-resistant infections) and the national burden of drug-resistant infections is between $21 and 34 billion annually. Consumers are relying on the FDA to take strong and decisive steps to protect the public health from the injudicious use of these drugs. Collecting adequate and measurable information on how the drugs are being administered is simply part of the agency’s duty to American consumers.

The importance of monitoring veterinary drug usage is a central message of global public health organizations. In September of 2001, the World Health Organization convened a meeting with twenty-four countries to discuss the monitoring of antimicrobial usage in food animals for the protection of human health. As stated in the resulting WHO consultation report, “The meeting underlined the importance of monitoring antimicrobial resistance from farm-to-table, and the importance of prudent use of antimicrobials as a risk management tool at primary production level for the containment of antimicrobial resistance.”

Sincerely,

Sarah Klein
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Center for Science in the Public Interest

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