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August 12, 2015

The Honorable Stephen Ostroff, M.D.
Acting Commissioner
c/o Division of Dockets Management (HFA-305)
U.S. Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, MD 20852

ATTN: Comment Docket No. FDA-2012-N-0447; Notice of Proposed Rulemaking,
“Antimicrobial Animal Drug Sales and Distribution Reporting”

Dear Acting Commissioner Ostroff:

The Pew Charitable Trusts (Pew) commends the U.S. Food and Drug Administration (FDA) for proposing to expand collection and reporting of data pertaining to antibiotics sold for use in food animal production, to include estimates on sales by species of animal. We support FDA’s proposal, and urge rapid finalization.

Under the Animal Drug User Fee Act (ADUFA) reporting provisions, FDA proposes to require drug sponsors to report antimicrobial sales estimates by species (beef, pork, chicken, and turkey). While these data would not be precisely equivalent to on-farm usage data, they would nevertheless contribute to the overall understanding by FDA and other stakeholders of how these vitally important products are used. For example, such data would likely reflect recent changes in poultry production with a number of major producers shifting away from routine antibiotic use. This additional information would help FDA, food animal producers, and other interested stakeholders follow trends in demand as Guidance for Industry #213 and the Veterinary Feed Directive rule changes are implemented. The Government Accountability Office in 2011 reported that species-specific antibiotic use data—as well as information on the purpose of their use—are necessary “to examine trends and understand the relationship between use and resistance.”¹

We are also encouraged that the proposed rule would require that FDA publish summaries of ADUFA data by December 31st of the following year, offering more reliable timeliness to publicly-available information of importance to public health.

¹GAO Report (GAO-11-801). “Antibiotic Resistance: Agencies Have Made Limited Progress Addressing Antibiotic Use in Animals,” September 7, 2011. <http://www.gao.gov/products/GAO-11-801> <accessed August 2012>.

Even with the changes proposed in this rule, sales data will not provide a complete picture of antibiotic use. For example, still missing from current ADUFA data reports is a useful measure of the purpose of antimicrobial sales (i.e., growth promotion, disease treatment, control or prevention). Understanding *why* antibiotics are being used is crucial to identifying the opportunities for reducing avoidable antibiotic use.

Thus, in addition to finalizing the species-specific sales data rule, Pew urges FDA to quickly take additional steps, in conjunction with the U.S. Department of Agriculture, producers, veterinarians, public health experts, and other stakeholders, to develop new, more robust approaches for collecting antimicrobial usage data. Pew appreciates FDA's commitment to working with USDA and CDC to obtain on-farm antibiotic use data and looks forward to continuing to work with all government and private stakeholders to identify and support best paths forward.

Thank you for your consideration. Should you or your staff have questions, please contact Shannon Heyck-Williams at sheyck-williams@pewtrusts.org, or (202) 887-8801.

Best regards,

A handwritten signature in blue ink, appearing to read 'Kathryn Talkington', is positioned above the typed name and title.

Kathryn Talkington
Director, Antibiotic Resistance Project