



2005 Market Street, Suite 1700 215.575.9050 Phone
Philadelphia, PA 19103-7077 215.575.4939 Fax

901 E Street NW, 10th Floor 202.552.2000 Phone
Washington, DC 20004 202.552.2299 Fax
www.pewtrusts.org

October 10, 2012

The Honorable Margaret A. Hamburg, M.D.
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; Advance Notice of Proposed Rulemaking “Antimicrobial Animal Drug Sales and Distribution Reporting”

Dear Commissioner Hamburg:

On behalf of The Pew Charitable Trusts (Pew), we are writing to urge the U.S. Food and Drug Administration (FDA) to strengthen regulations pertaining to record-keeping and public reporting of antibiotic use in food animal production. We commend FDA for soliciting public comments on improving data collection and dissemination in order to better monitor the dangerous and growing health threat of antibiotic resistance. Collecting and reporting of additional information as recommended by a 2011 Government Accountability Office (GAO) reportⁱ will support FDA’s strategy for promoting the judicious use of medically important antibiotics in food-producing animals. Additional information on livestock and poultry antibiotic sales and use is critical in order for FDA, food animal producers, health professionals, and the general public to determine whether the agency’s voluntary guidance approach is achieving desired public health outcomes and to move toward more comprehensive antimicrobial resistance monitoring.ⁱⁱ

ⁱGAO 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>.

ⁱⁱSee Federal Register Volume 77, Number 72 (Friday, April 13, 2012). Department of Health and Human Services, Food and Drug Administration. [Docket No. FDA-2010-D-0094] Guidance 209, “The Judicious Use of Medically Important Antimicrobial Drugs in Food-Producing Animals; Guidance 209,” and [Docket No. FDA-2011-D-0889] Guidance 213, “Draft Guidance for Industry on New Animal Drugs and New Animal Drug Combination Products Administered in or on Medicated Feed or Drinking Water of Food-Producing Animals: Recommendations for Drug Sponsors for Voluntarily Aligning Product Use Conditions With GFI 209; Guidance 213.”

Section 105 of the Animal Drug User Fee Amendments (ADUFA) of 2008 required first-ever collection and public reporting of certain data regarding the sales and distribution of approved antimicrobial new animal drugs intended for use in food-producing animals (codified at 21 U.S.C. §360b(1)(3)). While a helpful first step in making antibiotic use in livestock production more transparent to the American people, additional information—both in and out of the purview of ADUFA—is needed to develop appropriate responses to antibiotic resistance. We have grouped recommendations in the three areas in which FDA has specifically requested comments.

A. Sales and Distribution Data by Species

FDA should amend ADUFA rules to require that drug sponsors disclose an estimate of the total amount of each approved active ingredient sold or distributed for each food producing species. Currently, if a drug is approved and labeled for use in more than one species, manufacturers only need to report total sales and do not need to report sales by species. This means that it is impossible to determine changes within and among food animal sectors.

B. Annual Summary Report Improvements

Under the existing ADUFA requirements, FDA does not have to publish additional helpful information on antibiotic sales that is being reported by drug sponsors. Adding three elements (that industry already reports) to the publicly-available annual summary report would strengthen it and provide useful information as antimicrobial resistance trends are analyzed.

1. Report the **dosage form** (i.e., route of administration, such as by injection, in feed or water, etc.) of antibiotics both in total and by drug class. Route of administration is not necessarily a surrogate marker for the indication or end use of the drug, but it tends to separate individual from group drug purposes and may be important in resistance models. This information was made public from the 2009 data at the request of Congresswoman Louise Slaughter. This should become a standard element of the annual summary.
2. Medically important drug classes not individually reported should be **aggregated and reported separately** from those that are not medically important. Medically important drugs are those that are used in human medicine as well as in food animals. In past annual summary reports FDA has lumped medically important and non-medically important drugs in the heterogeneous groups “Not Independently Reported” (NIR) and “Not Independently Reported Exports” (NIRE) when sold by fewer than three drug sponsors. There would not be a violation of any confidential business information restrictions if FDA were to divide NIR and NIRE drug classes by their relevance to human medicine.
3. Report antibiotic sales **by month**. The results may only indicate seasonal fluctuations of buying habits, but they also may provide useful information on use and ultimately on antibiotic resistance. Adding this data to the summary report would also indicate FDA’s willingness to be more transparent to the public.

C. Alternative Methods for Obtaining Antimicrobial Use Data

FDA should require annual reporting of **Veterinary Feed Directive (VFD) data** by veterinarians and feed mills in a standardized format and should aggregate that information into a publicly available registry. Current regulations require that feed mills and veterinarians retain copies of VFDs (veterinary orders for antibiotics mixed in animal feed) that include the name of the drug, the targeted species and production class of animals, the approximate number of animals to be fed, and the indication for which the VFD was issued. FDA's newly proposed textual changes to the VFDⁱⁱⁱ that would allow for electronic requests and record keeping would likely increase the number of drugs and feed mills affected by VFDs and would give FDA additional data on intended drug usage. Although VFD data would not capture antibiotics mixed into water or given to individual animals (such as by injection), a registry with data on drugs mixed into feeds would encompass the majority of antibiotic use in food animals, thereby enabling much more meaningful analysis of factors related to the development and spread of antimicrobial resistance in connection with the use of medically important antibiotics in animal agriculture.

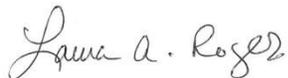
FDA should also increase **collaboration with the U.S. Department of Agriculture (USDA)** Agricultural Research Service and USDA Veterinary Services to expand collection of on-farm (pre-harvest) antibiotic use data. Both agencies have embraced the One Health approach, which states that diseases that adversely impact the health of humans, animals, and the environment can only be solved through improved communication, cooperation, and collaboration across disciplines and institutions. USDA does periodic antibiotic use surveys in different meat producing sectors, but there is no ongoing surveillance or verification of self-reports. A collaborative pilot project of USDA and FDA to determine the amount of antibiotics and the reasons for use by one of the major food animal sectors would help both agencies in their efforts to achieve the One Health goals.

ⁱⁱⁱSee Federal Register Volume 77, Number 72 (Friday, April 13, 2012). Department of Health and Human Services, Food and Drug Administration. 21 CFR Part 558 [Docket No. FDA-2010-N-0155] "Veterinary Feed Directive; Draft Text for Proposed Regulation."

We believe the recommendations suggested above will improve the amount and quality of data about antibiotics used in food animal production. It is important for us to note that these recommendations are made assuming that FDA must operate within its current statutory authorities with respect to collection of data in this realm. We believe that in addition to adopting the recommendations in these comments, FDA should seek Congressional authorization to expand its data collection authorities so that the agency and the public will have access to a full picture of the extent and precise uses of antimicrobials in animal agriculture. Publicly available, standardized user-friendly information on drug use is crucial to manage antibiotic resistance by enabling stakeholders, including producers and local public health officials, to understand and respond to continued areas of concern. Protecting human health should supersede the continued approval of medically important drugs for uses that enable over-crowding and inadequate husbandry practices in large-scale farming. Coordinated and successful strategies to preserve the effectiveness of antibiotics depend on reliable data. Further, Pew urges FDA to continue to move forward with additional steps as necessary to exercise its authority to issue formal and binding regulations barring non-therapeutic uses of medically important antibiotics in food animal production.

Thank you for your consideration.

Sincerely,



Laura Rogers
Project Director
Pew Campaign on Human Health and Industrial Farming
The Pew Charitable Trusts



Gail R. Hansen, MPH, DVM
Senior Officer, Pew Health Group
The Pew Charitable Trusts