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October 25, 2019

Dr. Steven Solomon
Director, Center for Veterinary Medicine
U.S. Food and Drug Administration
5630 Fisher Lane, Rm. 1061
Rockville, MD 20852

RE: Docket No. FDA-2019-D-3614: Recommendations for Drug Sponsors for Voluntarily Bringing Under Veterinary Oversight All Medically Important Antimicrobial Drugs Approved for Use in Animals that Continue to be Available as Over-the-Counter Products

Dear Dr. Solomon:

The Pew Charitable Trusts (Pew) appreciates this opportunity to comment on the U.S. Food and Drug Administration's (FDA) Draft Guidance for Industry (GFI) #263,¹ which proposes to bring all medically important antibiotics that remain available over-the-counter (OTC) under veterinary oversight. Veterinary oversight of these remaining products is central to combatting antibiotic resistance (AMR), especially given the potential recent shift towards increased use of injectable antibiotics suggested by the 2017 ADUFA sales data.² We are encouraged by FDA's initiative to bring all medically important antibiotics under veterinary oversight, which will serve to bolster judicious use practices in animal agriculture. Given the urgency of combatting AMR, Pew offers the following comments to assist FDA in ensuring the swift and smooth implementation of GFI #263.

Shorten the implementation timeline for GFI #263 to reflect the urgency of the AMR threat

Pew strongly urges FDA to expeditiously finalize this guidance. We applaud FDA's action to bring all medically important antibiotics under veterinary oversight, as it demonstrates the agency's commitment to making meaningful progress in the fight against AMR. However, every day that this guidance is not finalized further delays appropriate veterinary oversight and is a missed opportunity to make strides in reducing AMR. While there are relatively few medically important antibiotics that remain available OTC, some of them are critically important to human medicine. Swift implementation of veterinary oversight is key to preserving the efficacy of these lifesaving drugs. For these reasons, we recommend a phase-in period not exceeding 12 months from the date of the guidance's finalization.

Take all necessary action to ensure drug sponsors quickly and fully implement GFI #263

FDA's decision to request early, binding notification by sponsors of their intention to comply with GFI #263 is encouraging. To ensure the expeditious implementation of this policy, FDA should make these notifications public and regularly report progress in the shift of each product's dispensing status from OTC to Rx. Voluntary compliance proved successful in the implementation of GFIs #209 and #213 and is a reasonable approach in the case of GFI #263.



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However, should drugs sponsors fail to expeditiously and fully implement the policy, FDA should take all necessary measures to ensure appropriate veterinary oversight of all medically important antibiotics.

Engage key partners to ensure smooth implementation

FDA's initiatives to ensure the smooth implementation of GFI #213 were highly successful and should be replicated to the extent they are relevant.³ Specifically, FDA should make efforts to engage and partner with key stakeholders to better understand and address factors that may complicate implementation, such as logistical challenges related to accessing veterinary care or inventory management. Establishing appropriate veterinary oversight while ensuring these drugs remain accessible when needed will be an important step toward improving stewardship in animal agriculture.

As one example, certain areas of the U.S. experience veterinary shortages.⁴ Under FDA's new policy, smaller operations with infrequent veterinary interaction may be concerned about their ability to access antibiotics that will soon be unavailable OTC. There are, however, initiatives such as veterinary extension services, support for rural and remote veterinary practices, and student loan repayment programs that aim to address these gaps.^{5, 6, 7} FDA should proactively engage stakeholders to understand obstacles and develop solutions to any identified implementation challenges. For example, FDA could specifically target smaller operations and operations located in more rural areas in their outreach efforts, including by engaging directly with these producers or by developing written materials to ease smaller operations' transitions into the new policy. Additionally, the agency could, to the extent possible, support initiatives to alleviate veterinary shortages across the country.

Continue other key stewardship efforts outlined in the five-year plan

FDA's five-year plan outlines important stewardship activities that, when accomplished, will advance judicious use of antibiotics in animal agriculture. Given the urgency of the AMR threat, the agency should continue to move swiftly toward the goals laid out in the plan. Many medically important antibiotics can be given for very long or undefined durations of use or are indicated for conditions that do not align with judicious use principles. FDA should act quickly to establish science-based duration limits and ensure labels reflect judicious use guidelines for all medically important antibiotics. The agency took a helpful step toward defining duration limits in its announcement to fund two studies on durations of use of medically important antibiotics in cattle.⁸ However, further studies and action are needed. Additionally, understanding how antibiotics are used on the farm – and for what purposes – is vitally important to assessing stewardship practices and evaluating the impact of policies to reduce unnecessary use of antibiotics. FDA should improve existing data collection efforts including by enhancing the National Antimicrobial Resistance Monitoring System (NARMS) and developing a functional and efficient method to collect animal antimicrobial use data. Further, FDA should move to finalize its method for calculating animal biomass to better understand and utilize data on antibiotic use in U.S. agriculture.



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In conclusion, Pew commends FDA for publishing Draft GFI #263 and is encouraged by the agency's commitment to fighting AMR and advancing the judicious use of antibiotics in animal agriculture. However, we urge the agency to expeditiously implement the policy and to take necessary measures to ensure compliance among drug sponsors. The agency should also continue to work toward swift fulfillment of the other goals identified in its five-year plan. Pew appreciates the opportunity to comment on this key policy and looks forward to continuing to work with FDA on this important issue.

Sincerely,

Kathy Talkington, Director
Antibiotic Resistance Project
The Pew Charitable Trusts

Karin Hoelzer, Senior Officer
Antibiotic Resistance Project
The Pew Charitable Trusts

¹ Food and Drug Administration, "Recommendations for Sponsors of Medically Important Antimicrobial Drugs Approved for Use in Animals to Voluntarily Bring under Veterinary Oversight All Products That Continue to Be Available over-the-Counter," Draft Guidance for Industry #263 (2019).

² Food and Drug Administration, "2017 Summary Report on Antimicrobials Sold or Distributed for Use in Food-Producing Animals" (2018), <https://www.fda.gov/media/119332/download>.

³ Farm Foundation, "Stewardship of Medically-Important Antimicrobial Drug Use in Food Animals," accessed October 21, 2019, <https://www.farmfoundation.org/projects/stewardship-of-medically-important-antimicrobial-drug-use-in-food-animals-1927-d1/>.

⁴ United States Department of Agriculture National Institute of Food and Agriculture, "Veterinary Services Shortage Situations," accessed October 21, 2019, <https://nifa.usda.gov/vmlrp-map>.

⁵ The Pew Charitable Trusts, "Veterinarians Should Oversee All Antibiotic Use in Food Animals," accessed October 21, 2019, August 21, 2019, <https://www.pewtrusts.org/en/research-and-analysis/articles/2019/08/21/veterinarians-should-oversee-all-antibiotic-use-in-food-animals>.

⁶ United States Department of Agriculture National Institute of Food and Agriculture, "Veterinarian Shortage Situations," accessed October 21, 2019, <https://nifa.usda.gov/veterinarian-shortage-situations>.

⁷ United States Department of Agriculture National Institute of Food and Agriculture, "The Veterinary Medicine Loan Repayment Program," accessed October 21, 2019, <https://nifa.usda.gov/program/veterinary-medicine-loan-repayment-program>.



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⁸ Food and Drug Administration, “FDA Announces Funding Opportunity to Help Define Durations of Use for Certain Medically Important Antimicrobial Drugs for Food Animals,” news release, April 1st, 2019, <https://www.fda.gov/animal-veterinary/cvm-updates/fda-announces-funding-opportunity-help-define-durations-use-certain-medically-important>.