# Consumer Federation of America

November 13, 2017

Dockets Management Staff
HFA-305
Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, MD 20852

**Re: FDA-2017-N-1197: FDA's Proposed Method for Adjusting Data on Antimicrobials Sold or Distributed for Use in Food-Producing Animals, Using a Biomass Denominator**

To whom it may concern:

Consumer Federation of America appreciates the opportunity to submit these comments on the above-referenced FDA proposal. For the reasons explained in our joint comments with other members of the Keep Antibiotics Working (KAW), we commend FDA for moving forward with a methodology to improve pharmaceutical companies' reporting of antibiotic sales for animal use. The proposed method will help to better characterize antibiotic use, inform public policy, and increase transparency. FDA should therefore proceed with expediency to implement the method, taking care to fully disclose sources of uncertainty and potential bias and correct for them where possible. At the same time, as we noted in our joint comments, FDA must pursue strategies to collect more reliable data, and to achieve measurable reductions in animal antibiotic use. CFA writes separately here to emphasize the unique role that FDA plays in protecting consumers from antibiotic resistance.

Sound science shows that reducing animal antibiotic consumption will greatly benefit public health. Just last week, the World Health Organization issued new guidelines on animal antibiotics that recommend curtailing the use of medically important antibiotics in food animals for both growth promotion and disease prevention. The guidelines further recommend policies to prevent any use in animals of the antibiotics most important to human medicine, unless other antibiotics fail to effectively treat a condition.[1] WHO explained that its recommendations "aim to help preserve the effectiveness of antibiotics that are important for human medicine by reducing their unnecessary use in animals," and it based them on "decades of expert reports and evaluations of the role of agricultural antibiotic use in the increasing threat of antibiotic resistance."[2]

---

[1] *See* WHO guidelines on use of medically important antimicrobials in food-producing animals. Geneva: World Health Organization; 2017. Licence: CC BY-NC-SA 3.0 IGO, at 14-15 ["WHO Guidelines"]. In some respects, this condition is less stringent than current U.S. policy, which, for example, absolutely prohibits any use of fluoroquinolones in poultry. *See* FDA. "Extralabel Use and Antimicrobials," https://www.fda.gov/AnimalVeterinary/SafetyHealth/AntimicrobialResistance/ucm421527.htm.

[2] WHO. Press Release, "Stop using antibiotics in healthy animals to prevent the spread of antibiotic resistance." Nov. 7, 2017 http://who.int/mediacentre/news/releases/2017/antibiotics-animals-effectiveness/en/

The last time that WHO issued comprehensive recommendations on the use of antibiotics in food animals was in 2000, when it recommended eliminating the practice of giving antibiotics to animals for growth promotion. This January, nearly 17 years later, FDA implemented that recommendation, relying on the voluntary action of pharmaceutical companies to remove labeling indications for growth promotion. The agency should similarly adopt the latest WHO recommendations, but much more quickly.

The WHO guidelines cite hundreds of peer-reviewed studies, which examined a wide variety of antibiotic uses and their impacts on resistance. The studies make clear that: giving animals antibiotics gives rise to more resistant bacteria;[3] these resistant bacteria colonize humans through food and environmental channels, increasing the risk of drug-resistant infections, and;[4] limitations on antibiotics in animal agriculture have not significantly affected production in other countries that are leading on this issue and providing a model for the rest of the world.[5] We are perplexed by the USDA Chief Scientist's assessment that the WHO's guidelines "are not supported by sound science" because they "erroneously conflate disease prevention with growth promotion in animals."[6] Nevertheless, we note that USDA "agrees that we need more data to assess progress on antimicrobial use and resistance," and we reiterate our call for FDA to put forward a plan for collecting that data.

Sales data can only tell us so much. According to the latest estimates, food animals consume over 70% of medically important antibiotics in the United States.[7] At the same time, antibiotic resistant infections are killing over 23,000 people each year.[8] FDA's "judicious use" policy is rooted in a recognition that we need to reduce "misuse and overuse of antimicrobial drugs,"[9] but the lack of precision in the sales data supplied by pharmaceutical companies allows industry players to shirk responsibility. As we point out in our joint comments, FDA still has no plans to systematically collect on-farm antibiotic use data, despite recommendations from a slew of taskforces and advisory boards

---

[3] WHO Guidelines at 14 (describing a review of 179 studies, including 80 that showed "reduction in prevalence of antimicrobial resistance in bacteria isolated from animals following restriction of antimicrobial use . . . from 0-39%").

[4] *Id.* (referencing 21 studies that "described antimicrobial resistance outcomes in humans (19 of which also reported antimicrobial resistance in bacteria isolated from animals)," and noting that "the pooled prevalence of antimicrobial resistance was 24% lower in intervention groups (where interventions to reduce antimicrobial use in food-producing animals were implemented) compared to comparator groups.").

[5] *Id.* ("Finally, another review found that any adverse consequences of restricting antimicrobial use in food-producing animals appear to be limited and temporary.").

[6] USDA. Release No. 0146.17 (Nov. 7, 2017), https://www.usda.gov/media/press-releases/2017/11/07/usda-chief-scientist-statement-who-guidelines-antibiotics. The basis for this critique is unclear. The guidelines reference economic studies that estimate the impact of growth promotion bans on European livestock producers, but they also cite several studies indicating that further restrictions on antibiotic use have had negligible costs or even resulted in savings. *See* Web Annex A at 323 ("Other studies"). In any event, authority for regulating animal antibiotic drugs lies with FDA, not USDA, whose dual mandate to promote and regulate U.S. food products poses an inherent conflict of interest. *See* Safe Food Act of 2015, S.287 — 114th Congress (2015-2016) (proposing to establish "an independent agency to administer and enforce food safety laws.").

[7] Landers TF, Cohen B, Wittum TE, Larson EL. A review of antibiotic use in food animals: perspective, policy, and potential. *Public Health Rep* 2012;127:4-22, https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3234384/

[8] CDC, Antibiotic Resistance Threats in the United States (2013), https://www.cdc.gov/drugresistance/pdf/ar-threats-2013-508.pdf.

[9] FDA. Guidance for Industry #209, "The Judicious Use of Medically Important Antimicrobial Drugs in Food-Producing Animals" (Apr. 13, 2012), https://www.fda.gov/downloads/AnimalVeterinary/GuidanceComplianceEnforcement/GuidanceforIndustry/UCM216936.pdf

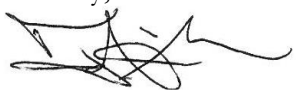
going back to 2001. Nor has FDA proposed establishing a baseline by which to measure antibiotic use, or established goals for reducing use, a strategy that has helped to sharply drive down animal antibiotics use in countries like the Netherlands and Germany.

By doing more to protect the public from overuse of antibiotics in animals, FDA will help to level the playing field for companies and food purchasers that are already adopting responsible antibiotics use policies. Already, two major poultry processors—Perdue and Tyson—have committed to phasing out routine antibiotic use in their chicken production,[10] and earlier this year, Cargill's Shady Brook Farms brand became the first line of turkey products to earn the Certified Responsible Antibiotic Use (CRAU) designation, which prohibits routine antibiotic use.[11] Large restaurant chains, like Subway and McDonalds, have pledged to only purchase chicken raised without antibiotics, and chains like Chipotle and Panera are serving beef and pork raised without antibiotics.[12] Finally, school districts, hospitals, and city departments are adopting procurement policies that favor meat and poultry raised without antibiotics.[13]

By setting the foundation for more comprehensive action on animal antibiotic use, FDA will encourage more companies and institutions to adopt responsible antibiotic policies. Conversely, if the agency refuses to take action to dissuade industry laggards, they will undercut their more virtuous competitors with practices that externalize production costs onto the public and consumer.

Thank you for considering these comments.

Sincerely,



Thomas Gremillion
Director of Food Policy
Consumer Federation of America

[10] Perdue Farms, "*Antibiotics Position Statement,"* 2016, available at: https://www.perduefarms.com/news/statements/antibiotics-position-statement/; Tyson Foods, Inc., "*Antibiotic Use*," 2016, http://www.tysonfoods.com/Media/Position-Statements/Antibiotic-Use.aspx.

[11] Cargill. https://www.cargill.com/2017/shady-brook-farms-becomes-first-turkey-brand-to-meet-crau

[12] *See* Chain Reaction III (2017), https://foe.org/projects/food-and-technology/good-food-healthy-planet/chain-reaction/

[13] *See* Consumer Federation of America. Going Local: Initiatives to Reduce Antibiotics in the Food Supply. (Oct. 5, 2017), http://consumerfed.org/reports/going-local-initiatives-reduce-antibiotics-food-supply/