November 7, 2016

Division of Dockets Management (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Rm. 1061
Rockville, Maryland 20852

Re: FDA-2016-N-1896 "Category Definitions for Minor Species"

To Whom It May Concern:

I am writing on behalf of Trust for America's Health (TFAH) to provide comments in response to the Food and Drug Administration (FDA) final rule revising the definition of two categories of new animal drugs in medicated feeds[1]. TFAH is a non-profit, non-partisan organization dedicated to saving lives by protecting the health of every community and working to make disease prevention a national priority.

We believe that judicious antibiotic use for animal agriculture has significant implications on human health.[2] We commend efforts to promote more responsible use of new drugs in the animal industry thereby preserving effective antibiotic response to microbial pathogens. Because antibiotic resistance is a serious threat to our health system[3], stewardship of these drugs is essential within the regulatory context. Therefore, we urge FDA to carefully consider the degree to which the current classification scheme for the production of medicated feed fully accounts for the risks associated with antibiotic resistance.

Our specific comments are detailed below.

Consistent with Executive Order 13676 and the National Action Plan for Combatting Antibiotic Resistance, TFAH considers antibiotic use in animal agriculture and resulting resistance of critical importance to human health

In the United States at least 23,000 people die from infection by a "superbug" annually, amounting to $20 billion in direct costs[4]. It is important to consider whether the current classification scheme, as originally conceived to exclusively control the contaminant risk of antimicrobial residues in animal food

[1] Food and Drug Administration. *New Animal Drugs for Use in Animal Feed; Category Definitions* (2016). Available at https://www.federalregister.gov/documents/2016/08/24/2016-20148/new-animal-drugs-for-use-in-animal-feed-category-definitions
[2] Centers for Disease Control and Prevention. Antibiotic Use in Food-Producing Animals (2016). Available at http://www.cdc.gov/narms/animals.html
[3] Centers for Disease Control and Prevention. Antibiotic Resistance from Farm to Table (last updated, 2015). Available at http://www.cdc.gov/foodsafety/challenges/from-farm-to-table.html
[4] Trust for America's Health. *Blueprint for a Healthier America 2016: Policy and Priorities for the Next Administration and Congress* (2016). Available at http://tfah.org/report/129/

products, should be re-evaluated to account for the well-documented human health risks posed by increased antibiotic resistance (especially important in light of data indicating that medically important antibiotics sold for food-producing animals increased from 2009-2014).[5] Classification criteria for feed production in a licensed mill must be explicitly risk-based and the FDA should therefore update its classification scheme to comprehensively address other risks to human health associated with the use of medicated feed in livestock, including the potential for inducing resistance to medically important antibiotic classes. The use of medically-important antibiotics in agriculture poses grave risks to human health, and the classification system for medicated feed should strive to ensure stricter oversight over such products.

TFAH supports a comprehensive review of the current feed classification scheme and urges FDA to announce a timeline for updating the agency's criteria to better protect the public's health

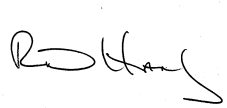
FDA should develop and announce a timeline to evaluate the appropriate classification scheme for feed mixtures that includes antimicrobial drugs which may pose an antibiotic resistance risk if given to livestock. In doing so, FDA can ensure that animal producers are able to continue to access and utilize medicated feeds when appropriate, but that the agency effectively controls the production of medicated feeds that may contribute to antibiotic resistance as a whole. Additionally, it is important to continuously reexamine the impact of these measures over time, enhancing our ability to prevent and rapidly respond to human disease caused by resistant organisms.

Conclusion

Thank you for the opportunity to comment on this final rule. We commend FDA's steps to promote more increasingly responsible use of antibiotics.

If you have any questions, please feel free to contact Dara Lieberman, TFAH's Senior Government Relations Manager, at (202) 864-5941 or dlieberman@tfah.org.

Sincerely,



Richard Hamburg
Interim President & CEO

[5] Food and Drug Administration, 2014 Summary Report on Antimicrobials Sold or Distributed for Use in Food-Producing Animals (December 2015), http://www.fda.gov/downloads/ForIndustry/UserFees/AnimalDrugUserFeeActADUFA/UCM476258.pdf.