December 15, 2017

Ms. Kristin Peck
Executive Vice President and President, U.S. Operations
Zoetis
10 Sylvan Way
Parsippany, New Jersey 07054

Dear Ms. Peck,

The undersigned consumer and public health organizations urge Zoetis to request voluntarily that the Food and Drug Administration (FDA) withdraw the approval for use in food-producing animals of Zoetis products that contain drugs in the polymyxin class. We appreciate the commitments that Zoetis has made to promote antibiotic stewardship,[1] and these requests for withdrawals represent an important opportunity to demonstrate this commitment.

The polymyxin-class antibiotics, polymyxin B and colistin, have become the drugs of last resort for treating serious multi-drug resistant gram-negative infections in humans.[2] Zoetis is the only sponsor of polymyxin-class antibiotics for use in food-producing animals in the U.S. Zoetis has an approval for colistin for injection in chickens (NADA 141-069). Zoetis has two polymyxin B approvals for use in food-producing animals, one for injection in poultry (NADA 031-944), and another as a component of an eye ointment for use in sheep and cattle (NADA 008-763). These approvals raise public health concerns because of the importance of polymyxins for treating human infections for which no other drugs work.[3] Moreover, the use of colistin in food-producing animals has recently been linked to the global spread of transferrable resistance to polymyxins.[4] The vital importance of polymyxins to human health, on the one hand, and the demonstrated link between their use in food-producing animals and resistance in humans, supports withdrawing approval.

There is no clear animal health need for the use of polymyxins in U.S. food-producing animals. An FDA report indicates that Zoetis did not market the product containing colistin in 2016, but did market one of the products containing polymyxin B.[5] Many poultry producers have moved away from using injectable antibiotics in hatcheries. For the polymyxin B eye ointment, most sources question the effectiveness and practicality of using antibiotic eye ointments in cattle[6] and

[1] Kristin Peck. "ZOETIS TAKES ACTION FOR ANTIBIOTIC STEWARDSHIP: ADVOCATE, INNOVATE AND COLLABORATE," Available from: https://www.zoetisus.com/news-and-media/zoetis-takes-action-for-antibiotic-stewardship.aspx
[2] Kaye et al. 2016. Agents of last resort: Polymyxin resistance. Infectious Disease Clinics. 30(2):391-414.
[3] Nation et al. 2015. Framework for optimisation of the clinical use of colistin and polymyxin B: the Prato polymyxin consensus. Lancet Infectious Disease 15(2):225-234.
[4] Webb et al. 2017. Illustrative examples of probable transfer of resistance determinants from food animals to humans: Streptothricins, glycopeptides, and colistin [version 1; referees: 2 approved]. F1000Research 6:1805.
[5] FDA. 2017. 2016 Summary Report On Antimicrobials Sold or Distributed for Use in Food-Producing Animals. Available from:
https://www.fda.gov/downloads/ForIndustry/UserFees/AnimalDrugUserFeeActADUFA/UCM588085.pdf
[6] Whittier et al. 2009. Pink Eye in Cattle. Virginia Cooperative Extension Publications /400/ 400-750.

sheep[7] because they require multiple daily administrations. The lack of demonstrated animal health need for all of these products, two of which are not marketed, supports withdrawal.

We hope that, as you state on your website, you will take your antibiotic stewardship "responsibility to heart". By voluntarily withdrawing approvals for the use of these critically important drugs in food-producing animals, Zoetis can help keep them available for treating sick patients who desperately need them. We look forward to your response to this letter, which you should direct to Steven Roach at sroach@foodanimalconcerns.org.

Sincerely,

Food Animal Concerns Trust
Consumer Federation of America
The Center for Foodborne Illness Research & Prevention
Antibiotic Resistance Action Center, the George Washington University
Johns Hopkins Center for a Livable Future
Center for Science in the Public Interest
Society of Infectious Diseases Pharmacists (SIDP)
Natural Resources Defense Council
Consumers Union
National Center for Health Research

[7] NADIS. 2010. Eye Diseases in Sheep. Available from: http://www.nadis.org.uk/bulletins/eye-diseases-in-sheep.aspx.