

May 29, 2020

Division of Dockets Management
Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, MD 20852

Re: Docket FDA-2016-P-2737 – Supplement to Citizen Petition to withdraw approval of the use of medically important antibiotics in livestock and poultry for disease-prevention purposes

The Natural Resources Defense Council (NRDC), Earthjustice, Food Animal Concerns Trust, Public Citizen, U.S. Public Interest Research Group, and California Public Interest Research Group submit this Supplement to their September 13, 2016 Petition (docket FDA-2016-P-2737) to withdraw approval of the use of medically important antibiotics in livestock and poultry for disease-prevention purposes.¹

FDA has not ruled on the Petition or referred it to hearing. Accordingly, the petitioners may supplement the Petition without Agency approval and without prejudice to resubmission. 21 C.F.R. § 10.30(g).

Since the Petition was filed, evidence supporting withdrawal of disease-prevention uses has continued to mount. The documents included in this Supplement demonstrate a broad consensus that use of medically important antibiotics in livestock and poultry for disease-prevention purposes is not safe.

The following information and documents (Tabs S1-26, included as Attachments 1-8) are hereby added to the Petition:

1. In 2017, the World Health Organization strongly recommended “complete restriction of use of all classes of medically important antimicrobials in food-

¹ FDA announced that implementation of Guidance for Industry No. 213, including withdrawal of growth promotion indications, was completed in 2017. See FDA Announces Implementation of GFI #213, Outlines Continuing Efforts to Address Antimicrobial Resistance (Jan. 3, 2017), <https://wayback.archive-it.org/7993/20190423131636/https://www.fda.gov/AnimalVeterinary/NewsEvents/CVMUpdates/ucm535154.htm>. Nonetheless, the grounds for withdrawal of approvals identified in the Petition remain valid, and, as noted in the Petition, disease prevention uses may increase under Guidance No. 213.

producing animals for prevention of infectious diseases that have not yet been clinically diagnosed.”

TAB S1. World Health Organization, WHO Guidelines on Use of Medically Important Antimicrobials in Food-Producing Animals (2017), *available at* <https://apps.who.int/iris/bitstream/handle/10665/258970/9789241550130-eng.pdf;jsessionid=AC6171DD4ECCBEF98C00F36E0024DCE2?sequence=1>

TAB S2. World Health Organization, WHO Guidelines on Use of Medically Important Antimicrobials in Food-Producing Animals, Policy Brief (Nov. 2017), *available at* <https://apps.who.int/iris/bitstream/handle/10665/259243/WHO-NMH-FOS-FZD-17.5-eng.pdf?sequence=1>

2. In 2018, the European Union adopted a ban on preventative use of antimicrobials.

TAB S3. European Commission, Fact Sheet: Questions and Answers on the new legislation on Veterinary Medicinal Products (VMP) and Medicated Feed (Nov. 2018), *available at* https://ec.europa.eu/commission/presscorner/detail/en/MEMO_18_6562

TAB S4. More, European perspectives on efforts to reduce antimicrobial usage in food animal production, Irish Veterinary Journal 73:2 (2020), DOI:10.1186/s13620-019-0154-4

3. Two states, California and Maryland, have restricted preventive use of medically important antimicrobial drugs.

TAB S5. California Senate Bill 27 (2015) (Cal. Food & Agric. Code §§ 14400-14408 (West 2020))

TAB S6. Maryland Senate Bill 471 (2019), Md. Code Ann., Agric. §§ 3-1001 - 3-1006 (West 2020)

4. In 2017, an Expert Commission on addressing the contribution of livestock to the antibiotic resistance crisis recognized that routine uses of antibiotics in livestock “en masse – even when under veterinary supervision – raise additional concerns,” and noted that “mass administration to flocks or herds ... continues to be the primary way antibiotics are administered for routine disease prevention purposes.” The

Commission recommended phasing out the routine or programmed use of medically important antibiotics. The Commission's recommendations were endorsed by 12 prominent medical and public health organizations.

TAB S7. Expert Commission on Addressing the Contribution of Livestock to the Antibiotic Resistance Crisis, Combating Antibiotic Resistance: A Policy Roadmap to Reduce Use of Medically Important Antibiotics in Livestock (2017), *available at* <http://battlesuperbugs.com/sites/battlesuperbugs.com/files/Expert%20Commission%20Report%2001.02.18.pdf>

TAB S8. List of medical and public health organizations that have endorsed Expert Commission Policy Roadmap recommendations and summary of roadmap recommendations (excerpted), *available at* <http://battlesuperbugs.com/PolicyRoadmap>

5. Despite FDA's failure to withdraw disease-prevention uses of antibiotics, the chicken industry has dramatically reduced use of medically important antibiotics to meet consumer demand. However, use remains high in beef, pork, and turkey production. In contrast, European countries have significantly reduced antibiotic use in all livestock sectors.

TAB S9. FDA, 2017 Summary Report on Antimicrobials Sold or Distributed for Use in Food-Producing Animals (Dec. 2018), *available at* <https://www.fda.gov/media/119332/download>

TAB S10. FDA, 2018 Summary Report on Antimicrobials Sold or Distributed for Use in Food-Producing Animals (Dec. 2019), *available at* <https://www.fda.gov/media/133411/download>

TAB S11. European Medicines Agency, Sales of veterinary antimicrobial agents in 31 European countries in 2017: Trends from 2010 to 2017 Ninth ESVAC report (Oct. 2019), *available at* https://www.ema.europa.eu/en/documents/report/sales-veterinary-antimicrobial-agents-31-european-countries-2017_en.pdf

- TAB S12.** European Union Health and Food Safety Directorate-General, Overview Report: Measures to Tackle Antimicrobial Resistance Through the Prudent Use of Antimicrobials in Animals. Luxembourg: Publications Office of the European Union (2018), *available at* <https://op.europa.eu/en/publication-detail/-/publication/aa676ddd-2d87-11e8-b5fe-01aa75ed71a1>
- TAB S13.** European Union Health and Food Safety Directorate-General, Final Overview Report: Measures to Tackle Antimicrobial Resistance Through the Prudent Use of Antimicrobials in Animals. Luxembourg: Publications Office of the European Union (2019), *available at* <https://op.europa.eu/en/publication-detail/-/publication/be1710ba-b1aa-11e9-9d01-01aa75ed71a1/language-en/format-PDF>
- TAB S14.** Wallinga, NRDC, Better Bacon: Why It's High Time the U.S. Pork Industry Stopped Pigging Out on Antibiotics (May 2018), *available at* <https://www.nrdc.org/resources/better-bacon-why-its-high-time-us-pork-industry-stopped-pigging-out-antibiotics>
- TAB S15.** NRDC, Issue Brief: Antibiotic Consumption in U.S. Pork, Beef, and Turkey Industries Vastly Outstrips Comparable Industries in Europe, and the U.S. Chicken Industry (Nov. 2018), *available at* <https://www.nrdc.org/sites/default/files/antibiotic-consumption-us-pork-beef-and-turkey-industries-ib.pdf>
- TAB S16.** NRDC, Issue Brief: Antibiotic Consumption in U.S. Pork, Beef, and Turkey Industries Vastly Outstrips Comparable Industries in Europe, and the U.S. Chicken Industry, Appendix (Nov. 2018), *available at* <https://www.nrdc.org/sites/default/files/antibiotic-consumption-us-pork-beef-and-turkey-industries-appendix.pdf>
- TAB S17.** Wallinga & Kar, NRDC, Very High Livestock Antibiotic Use Undercuts Effective Drugs (Dec. 2019), <https://www.nrdc.org/experts/avinash-kar/very-high-livestock-antibiotic-use-undercuts-effective-drugs>
- TAB S18.** NRDC, Intensity of Antibiotic Consumption In U.S. Livestock: 2019 Update, *available at* https://www.nrdc.org/sites/default/files/media-uploads/attachment_to_blog_v2_0.pdf

TAB S19. Alliance to Save Our Antibiotics, Supermarket antibiotics policies assessment 2019 (Jan. 2020), *available at* <http://www.saveourantibiotics.org/media/1826/supermarket-antibiotics-policies-assessment-2020-report.pdf>

TAB S20. The Poultry Site, More than half of US broilers raised without antibiotics in 2018 (May 2019), <https://thepoultrysite.com/news/2019/05/more-than-half-of-us-broilers-raised-without-antibiotics-in-2018>

TAB S21. Poultry Health Today, Nearly 60% of US broilers now raised without antibiotics, but that number may have peaked (May 2020), <https://poultryhealthtoday.com/nearly-60-of-us-broilers-now-raised-without-antibiotics-but-that-number-may-have-peaked/>

6. A growing body of science demonstrates how overuse of antibiotics in livestock production contributes to the widespread proliferation of antibiotic resistance and threatens human health.

TAB S22. Ge et al., Effects of low concentrations of erythromycin, penicillin, and virginiamycin on bacterial resistance development in vitro (Sept. 2017), Scientific Reports, 7: 11017, DOI:10.1038/s41598-017-09593-4

TAB S23. Liu et al., Escherichia coli ST131-H22 as a Foodborne Uropathogen (Aug. 2018), mBio 9:e00470-18, DOI:10.1128/mBio.00470-18

TAB S24. Tchesnokova et al., Pandemic fluoroquinolone resistant Escherichia coli clone ST1193 emerged via simultaneous homologous recombinations in 11 gene loci, Proceedings of the National Academy of Sciences of the United States of America, 116 (29) 14740-14748 (July 2019), DOI:10.1073/pnas.1903002116

TAB S25. Tchesnokova et al., Pandemic uropathogenic fluoroquinolone-resistant Escherichia coli have enhanced ability to persist in the gut and cause bacteriuria in healthy women, Clinical Infectious Diseases, Volume 70, Issue 5, 1 (Mar. 2020) 937-939, DOI:10.1093/cid/ciz547

7. The Review on Antimicrobial Resistance, chaired by Jim O'Neill, issued a final report and recommendations.

TAB S26. The Review on Antimicrobial Resistance, Tackling Drug-Resistance Infections Globally: Final Report and Recommendations (May 2016), available at https://amr-review.org/sites/default/files/160525_Final%20paper_with%20cover.pdf

Respectfully submitted,



Allison Johnson
Avinash Kar
Natural Resources Defense Council
111 Sutter Street, 21st Floor*
San Francisco, CA 94104
Phone: (415) 875-6100
aljohnson@nrdc.org
akar@nrdc.org

On behalf of Petitioners Natural Resources Defense Council, Earthjustice, Food Animal Concerns Trust, Public Citizen, U.S. Public Interest Research Group, and California Public Interest Research Group

*We are working remotely until further notice, due to COVID-19 safety concerns. We respectfully request that you send any response to the Petition or other correspondence by email or contact us by phone.