



FOOD ANIMAL CONCERNS TRUST

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Chicago, Illinois 60659

October 24, 2023

Dr. Robert M. Califf
Commissioner Food and Drug Administration
10903 New Hampshire Ave
Silver Spring, MD 20993-0002

Dear Commissioner Califf,

Please see the attached petition signatures from 2,359 individuals urging leadership from the U.S. Food and Drug Administration to swiftly ban the cancer-causing pig drug carbadox - a drug which year after year puts the public at an entirely avoidable public health risk.

For fifty years, the Food and Drug Administration (FDA) has allowed the use of a known carcinogen in the production of swine. During your previous tenure as Commissioner, the FDA proposed a formal withdrawal of approval,¹ yet a legal challenge on behalf of the drug maker Phibro prodded the FDA to pivot and follow up with a proposed revocation of the residue detection method.² In the Department of Health and Human Services own words as stated in the Federal Register proposed order to revoke the current method, “An approved method is required by the Federal Food, Drug, and Cosmetic Act (FD&C Act), as implemented by regulation, to show that no residue of carcinogenic concern from a new animal drug persists in any edible tissue or in any food derived from treated animals.” The notice goes on to say that the current method “is inadequate to monitor residue of carcinogenic concern in compliance with FDA’s operational definition of no residue.” By the FDA’s own standards, it is failing to mitigate the potential exposure of millions of people to residues of carcinogenic concern. Since this notice, over three years ago, the drug remains on the market without an adequate method to detect residues of carcinogenic concern and ensure consumer safety. This is a gross dereliction of the FDA’s duty to “protect the public health by assuring the safety of our nation’s food supply.”

Food Animal Concerns Trust recently published a report³ analyzing data from the United States Department of Agriculture (USDA) national residue program. Between 2016-2023 (the years in which data is publicly available) an average of 1% of samples were violative for carbadox residues. When considering the amount of roaster pigs slaughtered each year - about 650,000 - that is an estimated 6,500 pigs. In 2019 and 2020 the detected values of QCA were between 40.8-375.8 PPM, up to 4 orders of magnitude greater than the legal tolerance value of 0.03PPM. When we questioned USDA about these absolutely staggering values, they claimed the numbers were

¹ U.S. Food & Drug Administration |Center for Veterinary Medicine. “FDA Takes Steps to Withdraw Approval of the Swine Drug Carbadox Due to Safety Concerns.” FDA News Release. FDA, April 8, 2016. <https://www.fda.gov/news-events/press-announcements/fda-takes-steps-withdraw-approval-swinedrug-carbadox-due-safety-concerns>.

² Regulations.gov. “Docket FDA-2016-N-0832 | Phibro Animal Health Corp.; Carbadox in Medicated Swine Feed; Revocation of Approved Method,” July 19, 2020. <https://www.regulations.gov/document/FDA-2016-N-0832-0069>.

³ Kleven, Madeleine, and Roach, Steven. “Poisonous Pork: Carbadox Residue Violations in USDA Testing.” Food Animal Concerns Trust, August 23, 2023. https://www.foodanimalconcernstrust.org/s/Poisonous-Pork_USDA-violations-of-Carbadox-Report_Aug-2023_FINAL.pdf

correct. Given public health authorities throughout the world, including the International Standard setting body, Codex Alimentarius, has determined “there is no safe level of residues of carbadox or its metabolites in food that represents an acceptable risk to consumers,” these violations are truly egregious. These violations are also based on levels of QCA, a marker residue which the FDA has deemed as “inadequate” because it is based on data that was shown to be invalid after the marker was set.

Since 2003⁴ research has demonstrated that carcinogenic residues persist in pork tissue longer than previously believed. In 2009, Canadian researchers found they could detect DCBX in pig tissues where no QCA was detectable, thus concluding QCA is not a suitable marker residue for carbadox and its presence in pork tissue almost certainly means carcinogenic residues are still present.⁵ This was reaffirmed in 2022 by researchers who demonstrated, DCBX persists longer in tissue than QCA.⁶

The FDA cannot sit idly by as thousands, if not millions of people are potentially exposed to harmful carcinogenic residues. How do we intend “to mobilize a national effort to end cancer as we know it”⁷, when at least half of the pigs raised for food in the United States are administered a mutagenic and genotoxic carcinogen?⁸ It is high time the FDA withdraw carbadox from the market. In the meantime, it is the agency’s responsibility to ensure there is a method in place for determining consumer safety and identifying residues of carcinogenic concern in pork being distributed to children and adults throughout the United States.

We respectfully request a meeting to discuss this neglected public health crisis and the urgent need for your leadership on federal action. Please contact Steve Roach, sroach@foodanimalconcerns.org, to coordinate the details of that meeting. Thank you for your consideration.

Sincerely,

Steve Roach
Safe and Healthy Food Program Director
Food Animal Concerns Trust

⁴ 60th JECFA Report, FAO Food and Nutrition Paper 41/15, 2003. p. 1. <https://www.fao.org/3/y4858E/y4858E00.pdf>

⁵ xvii Boison, Joe O., Stephen C. Lee, and Ron G. Gedir. “A Determinative and Confirmatory Method for Residues of the Metabolites of Carbadox and Olaquinox in Porcine Tissues.” *Analytica Chimica Acta* 637, no. 1–2 (April 1, 2009): 128–34. <https://doi.org/10.1016/j.aca.2008.09.016>.

⁶ Zhang, Jie, Wei Qu, Zongchao Wang, and Yuanhu Pan. “Metabolism and Tissue Depletion of Carbadox in Swine, Broilers, and Rats.” *ACS Agricultural Science & Technology* 2, no. 3 (June 20, 2022): 477–85. <https://doi.org/10.1021/acscagstech.1c00260>.

⁷ The White House. “Cancer Moonshot.” The White House. Accessed October 3, 2023. <https://www.whitehouse.gov/cancermoonshot/>.

⁸ United States Department of Agriculture, and National Animal Health Monitoring System. “Antimicrobial Use and Stewardship on U.S. Swine Operations, 2017,” May 2019. https://www.aphis.usda.gov/animal_health/nahms/downloads/amu-swine-operations.pdf ment of, Animal and Plant Health Inspection