

February 28, 2022

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

Dear Commissioner Califf,

Welcome back to the Food and Drug Administration. The undersigned organizations write to urge you to immediately withdraw FDA approval of the carcinogenic swine antibiotic carbadox. Over half of U.S. pigs are administered carbadox, according to the latest USDA survey data.¹ Yet public health authorities around the world, including FDA, have long recognized that consuming pork products from swine administered carbadox raises cancer risk. FDA should stop indulging craven industry efforts to put off the inevitable, and act now to protect consumers.

FDA initiated formal action to withdraw approval of carbadox over five years ago, during your previous tenure as Commissioner.² This action itself arrived long overdue. The European Union and Canada prohibited use of carbadox in 1999 and 2006, respectively, due to concerns about residues and the safety of workers handling the drug.³ In 2014, the international standard setting body Codex Alimentarius found that there is no safe level of residues of carbadox or its metabolites in food that represents an acceptable risk to consumers, a finding that FDA cited in its 2016 proposal to withdraw approval.⁴ As FDA explained in its 2016 notice, “[c]ontinued

¹ USDA. 2019. “Antimicrobial Use and Stewardship on U.S. Swine Operations, 2017” USDA–APHIS–VS–CEAH–NAHMS. Fort Collins, CO #752.0819.

https://www.aphis.usda.gov/animal_health/nahms/amr/downloads/amu-swine.pdf.

² 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-swine-drug-carbadox-due-safety-concerns>.

³ Ungemach, Fritz R. “Carbadox (Addendum) WHO JECFA Food Additives Series.” *Internationally Peer Reviewed Chemical Safety Information* 51. Accessed January 12, 2022.

<https://inchem.org/documents/jecfa/jecmono/v51je05.htm>.

⁴ Joint FAO/WHO Food Standards Programme CODEX Alimentarius Commission. “Report of the Twenty-First Session of the CODEX Committee on Residues of Veterinary Drugs in Foods” 37 (July 14, 2014).;

U.S. Food & Drug Administration |Center for Veterinary Medicine. FDA, April 8, 2016.

approval of carbadox would expose humans to concentrations of total residues of carcinogenic concern that are approximately 30 times higher” than the levels “that would be considered safe.”⁵

Notwithstanding this clear threat to consumers, carbadox remained on the market while its manufacturer, Phibro Animal Health, launched a legal challenge to FDA’s proposed withdrawal. After more than four years, FDA followed up on its proposed withdrawal action with a proposed order to revoke the approved method for detecting residues of carbadox. Such a revocation would operate to ban carbadox because no other approved residue detection method exists. As noted in the 2020 order, Phibro failed to provide data showing that the level of carbadox residue in pork “represents no significant increase in the risk of cancer to people.”⁶ Now, over a year and half since FDA’s proposed revocation of the method of detecting carbadox residues, and nearly six years since FDA first proposed withdrawing approval of the antibiotic, the delays continue, with no relief in sight for consumers. Most recently, FDA has announced “a public hearing on scientific data and information related to the residue of carcinogenic concern for the new animal drug carbadox, a carcinogenic new animal drug used in swine feed.”⁷ This hearing, to be held March 10, 2022, will only serve to delay the inevitable.

Section 512(d)(1)(I) of the Federal Food, Drug, and Cosmetic Act—the so-called “Delaney Clause”—requires that no residue of a carcinogenic drug can be found in any edible portion of an animal after slaughter.⁸ As FDA explained in 2016, and reiterated in its 2020 order, the current approved method for detecting residues of carcinogenic concern from the use of carbadox is inadequate.⁹ No alternative residue detection method exists to validate carbadox’s safety for consumers. Were Phibro or anyone else able to come up with a way to show that

⁵ Federal Register. “Phibro Animal Health Corp.; Carbadox in Medicated Swine Feed; Opportunity for Hearing: A Notice by the Food and Drug Administration.” Federal Register, April 12, 2016. <https://www.federalregister.gov/documents/2016/04/12/2016-08327/phibro-animal-health-corp-carbadox-in-medicated-swine-feed-opportunity-for-hearing>.

⁶ 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>.

⁷ Federal Register. “Scientific Data and Information Related to the Residue of Carcinogenic Concern for the New Animal Drug Carbadox; Public Hearing; Request for Comments.” Federal Register, January 13, 2022. <https://www.federalregister.gov/documents/2022/01/13/2022-00475/scientific-data-and-information-related-to-the-residue-of-carcinogenic-concern-for-the-new-animal>.

⁸ 21 U.S.C. 360b(d)(1)(I).

⁹ Federal Register Online via the Government Publishing Office. “Federal Register, Volume 85 Issue 139 Pages 43853-43858.” www.gpo.gov, July 20, 2020. <https://www.govinfo.gov/content/pkg/FR-2020-07-20/html/2020-15246.htm>.

carbadox does not subject consumers to harmful levels of carcinogenic residues, they would have done so by now. In addition, carbadox poses allergen and genotoxicity hazards to the farm and feed mill workers who handle products containing the drug.¹⁰ Compared to these significant costs, the benefits associated with carbadox appear vanishingly small.

The approved uses of carbadox are growth promotion, the control of swine dysentery, and control of Salmonellosis caused by *Salmonella Choleraesuis*.¹¹ Swine dysentery and *Salmonella Choleraesuis* are rare in US swine herds and can be managed without antibiotics.¹² This leaves growth promotion to account for the prodigious levels of carbadox use in the U.S. The fact that other, “medically important,” antimicrobials have required a veterinarian’s order since 2017, and may not be legally administered for growth promotion, further illuminates how carbadox has become so popular.¹³ Needless to say, an imperative to make pigs grow faster, and more cheaply, should not justify exposing consumers to harmful carcinogenic residues. Nor can the industry defend carbadox as a necessity for maintaining animal health, given the experiences of successful swine farmers in Canada, the European Union, the United Kingdom, and other countries that have long banned the antibiotic.

FDA should act now to bring the United States into conformity with its industrialized trading partners and similarly protect consumers from carbadox. We call on you to finish the job started the first time you were FDA Commissioner and make sure consumers and workers are not at an increased risk of cancer from this genotoxic carcinogen used in swine production.

¹⁰ Baars, A.J. “Carbadox - An Evaluation” 97.17 (April 1997). <https://edepot.wur.nl/264615>.

¹¹ U.S. Food & Drug Administration |Center for Veterinary Medicine. “Animal Drugs @ FDA | NADA 041-061.” Accessed January 10, 2022. <https://animaldrugsatfda.fda.gov/adafda/views/#/home/previewsearch/041-061>.

¹² Iowa State University College of Veterinary Medicine. “Swine Dysentery | Swine Dysentery and Spirochaetal Colitis.” Iowa State University College of Veterinary Medicine Veterinary Diagnostic and Production Animal Medicine. Accessed January 26, 2022.

[https://vetmed.iastate.edu/vdpam/FSVD/swine/index-diseases/swine-dysentery](https://vetmed.iastate.edu/vdpam/FSVD/swine/index-diseases/swine-dysentery;);

Schwartz, Kent. “Salmonella Choleraesuis in Swine – Hogs, Pigs, and Pork.” swine.extension.org, August 28, 2019. <https://swine.extension.org/salmonella-choleraesuis-in-swine/#Treatment>.

¹³ Center for Veterinary Medicine, U.S. Food and Drug Administration. “CVM GFI #213 new animal drugs and new animal drug combination products administered in or on medicated feed or drinking water of food-producing animals: recommendations for drug sponsors for voluntarily aligning product use conditions with GFI #209.” 2013. Retrieved from <https://www.fda.gov/regulatory-information/search-fda-guidance-documents/cvm-gfi-213-new-animal-drugs-and-new-animal-drug-combination-products-administered-or-medicated-feed>

We would appreciate the opportunity to meet with you and to discuss our recommendations with you and your staff. To arrange, please respond to Steven Roach, sroach@foodanimalconcerns.org, Safe and Healthy Food Program Director, Food Animal Concerns Trust.

Sincerely,

Alliance for Natural Health USA

As You Sow

Center for Biological Diversity

Consumer Federation of America

Consumer Reports

Center for Food Safety

Door County Environmental Council, Wisconsin

Earthjustice

Environmental Working Group

Food & Water Watch

Food Animal Concerns Trust

Health Care Without Harm

Institute for Agriculture and Trade Policy

Kewaunee CARES

Lymphoma Foundation of America

South Florida Cancer Association

The Cornucopia Institute