May 26, 2022

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

RE: Docket ID. FDA-2021-N-1326 "Scientific Data and Information Related to the Residue of Carcinogenic Concern for the New Animal Drug Carbadox; Public Hearing; Request for Comments"

Dear Commissioner Sharpless,

The National Pork Producers Council (NPPC) appreciates the opportunity to comment on the FDA proposed action to revoke the approved method for detecting residues of carbadox.

NPPC conducts public policy advocacy on behalf of U.S. hog farmers and 42 affiliated state pork producer associations. Our producers' mission is two-fold: provide a growing world population with safe, nutritious and affordable pork; and ensure that animals receive the highest degree of care. Key to this effort is antibiotic stewardship, including the judicious use of antibiotics to treat, control or prevent disease in animals.

Pork producers work closely with veterinarians to develop herd health programs, including responsible use of antibiotics essential to proper animal care. A top priority of the swine industry is to preserve the use of medically important antibiotics for conditions that cannot be effectively treated with production practices, vaccinations and/or non-medically important antibiotics. Carbadox is not used in human medicine, so it has the important benefit of not contributing to antimicrobial resistance in humans.

Enteric diseases such as swine dysentery and salmonella are difficult to effectively control with vaccination or antibiotics other than carbadox. If carbadox is taken off the market, hog farmers will be forced to treat their pigs with antibiotics that are important to fighting human infections, such as amino glycosides neomycin and gentamicin.

Enteric disease in the nursery (housing for pigs aged three weeks to approximately 11 weeks) is among the leading health challenges we face. Carbadox has been effectively used by most pork producers for decades to support animal health, while adhering to the 42-day withdrawal period. Since carbadox is mainly used for pigs at the nursery stage, the 42-day withdrawal period is likely extended to 60 days or more, resulting in an additional safety buffer against residues. Pork producers prioritize the avoidance of violative residues of all animal health products, as evidenced by the high level of participation in the industry's Pork Quality Assurance Plus certification program and the extremely low level of all violative residues in market swine tested

by the USDA's Food Safety Inspection Service. Several key trading partners use a variety of methods to test for carbadox residues and, to our knowledge, have not found measurable residues which would result in the rejection of imported pork shipments.

If carbadox is removed from the market, it is estimated that the total cost to the U.S. pork industry in the first year could be as high as $500 million dollars, driven by the higher level of disease and death losses. This could drive further pork production consolidation and force more independent producers out of the industry.

In 2020, a survey was conducted to better understand the impacts we could expect with the removal of carbadox. Respondents included veterinarians who participated in the health decisions of more than 94 million pigs, and said that removal of carbadox from the market would have "disastrous" impacts on the health of pigs in the United States. Veterinarians estimate that removal of carbadox would result each year in up to 53.5 million otherwise healthy pigs becoming ill. All survey respondents said that use of medically important antibiotics would increase if carbadox was removed from the market. Treatment of this additional illness burden would not be optional—it would be essential to maintain animal health and welfare.

These same survey respondents indicated that if carbadox is not available, the estimated cost to the U.S. swine industry over the next 10 years would be $5.3 billion. The three major drivers of this cost will be increased incidence of salmonella, E. coli and brachyspira in pigs. Even more concerning than the economic costs are the inevitable negative animal welfare impacts due to increases in morbidity. Delaying treatment in known cases of swine dysentery may result in a high rate of mortality — 10-30% above normal, and as high as 50% in some experimental models. Early treatment with carbadox can prevent unnecessary suffering or even death. In addition, over 60% of the veterinarians surveyed said there would be increased food safety concerns. The expectation is that salmonella and brachyspira would make their way into slaughterhouses, potentially resulting in lower meat quality and increased contamination with these zoonotic pathogens.

Again, the removal of carbadox from the marketplace would inevitably increase the use of other antibiotics and increase the likelihood of difficult-to-control antimicrobial resistance in important bacterial pathogens. We believe this to be in direct conflict with the objectives of FDA's Guidance for Industry 213 and the goals outlined in FDA's 2018 five-year plan, including aligning antimicrobial drug product use with the principles of antimicrobial stewardship and fostering stewardship of antimicrobials in veterinary settings.

We would also like to note our concerns with the evolution of this process. In 2016, FDA issued a Notice of Opportunity for a Hearing (NOOH) to withdraw carbadox approvals. FDA's Center for Veterinary Medicine (CVM) agreed that the sponsor was entitled to a hearing on the NOOH

and, in 2017, recommended that the Commissioner grant one. Nonetheless, in a surprising move, in July 2020, FDA withdrew the NOOH. Instead, FDA published the Order to which these comments address, proposing to revoke the "regulatory method" that is part of the drug's approval. FDA explained that if it finalizes this Order, it will then issue a new NOOH based on the fact that there is no longer a "regulatory method" because FDA just revoked it. In other words, FDA is proposing to withdraw its carbadox regulations that contain the testing method for carbadox and then to withdraw approval of the drug on the ground that no such regulatory method exists.

NPPC objects to the clear bureaucratic maneuvering exhibited by FDA. If FDA has concerns about the method it uses to test carbadox residue, NPPC believes **the agency should work with the sponsor to develop and approve a new regulatory method** rather than remove this very effective, non-medically important antibiotic.

We are alarmed by FDA's actions regarding this long-used drug and the negative consequences for the animals in our care. These concerns are magnified by the severe financial and emotional toll exacted recently on hog farmers by the COVID-19 pandemic. We ask that FDA reconsider this action in light of the devastating impact it would have on hog farmers, animal welfare, the food supply, and antimicrobial stewardship.

Thank you for your consideration.

Sincerely,

Terry Wolters
President
National Pork Producers Council