July 11, 2016

The Honorable Robert M. Califf, M.D., Commissioner of Food and Drugs
Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993

Re: Opportunity for Hearing

Docket Number: FDA-2016-N-0832

Dear Commissioner Califf,

The undersigned consumer, public health, and environmental organizations appreciate the opportunity to comment on the Food and Drug Administration (FDA), Center for Veterinary Medicine's (CVM) proposal to withdraw approval of all new animal drug applications (NADAs) providing for use of carbadox in medicated swine feed. We urge you to move swiftly. The evidence summarized in CVM's Notice of Opportunity for Hearing (NOOH) makes clear that the approved use of carbadox poses "an imminent hazard to the health of man" and CVM should therefore suspend approval immediately pursuant to section 512(e) of the Food, Drug, and Cosmetic Act. 21 U.S.C. 360b(e); 21 C.F.R. § 514.115. Alternatively, CVM may opt to deny Phibro Animal Health's request for a hearing and move forward expeditiously with the withdrawal of the drug's approval. Under no circumstances should CVM allow carbadox residues to continue to contaminate the food supply while Phibro contests withdrawal through a formal hearing, a process that could easily take up to a decade.

As the agency's notice indicates, Phibro has had ample opportunity to rebut the evidence of carbadox's toxic effect. Since at least 2003, research has demonstrated that approved usage of carbadox results in unsafe levels of carcinogenic residues. Indeed, the best evidence indicates these levels are at least 10 times higher, and possibly 87 times higher, than what public health authorities deem "safe." Despite lengthy consultations with CVM traversing over a decade, Phibro has failed to refute multiple lines of evidence showing that approved use of carbadox likely leads to carcinogenic residues in pork products and that these residues create an increased risk of cancer in people consuming these products. Yet during this time, treatment of swine with carbadox has continued, subjecting countless individuals to a significant increased cancer risk.

The available evidence leaves no doubt that the assumptions used in the initial safety evaluation and subsequent reviews of carbadox use in swine were unfounded. Carcinogenic residues persist well beyond 72 hours. Un-extractable residues are not all non-carcinogenic. Quinoxaline-2-carboxylic acid (QCA) is not a valid marker residue for carbadox and its metabolites. Again, the Food and Drug Administration (FDA) and Phibro Animal Health have been aware of these concerns since at least 2003, and FDA formally asked Phibro Animal Health to address them at least as early as 2006. Yet as noted in CVM's notice, "No evidence has been presented to CVM by Phibro or any other source to show that the unidentified residues are noncarcinogenic or that the residues do not otherwise present a threat to public health."

Now, Phibro has requested a hearing to provide substantial evidence addressing all of the safety concerns enumerated in the notice, including identifying a valid analytical method for residues. We see little likelihood of the company meeting this evidentiary burden in light of its past track record, and we encourage CVM to act quickly to deny the request for a hearing and finalize this withdrawal. If Phibro presents evidence that requires more lengthy review, the agency should suspend approval pursuant to 21 C.F.R. § 514.115. Allowing carbadox residues to continue to contaminate the food supply while a lengthy contested hearing drags out for years would subject the public to an unacceptable risk and be inconsistent with the agency's duty under the FD&C Act.

Sincerely,

Food Animal Concerns Trust

Food and Water Watch

Consumer Federation of America

Johns Hopkins Center for a Livable Future

Center for Science in the Public Interest