4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2016-N-0832]

Phibro Animal Health Corp.; Carbadox in Medicated Swine Feed; Withdrawal of Notice of Opportunity for Hearing

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of opportunity for hearing; withdrawal.

SUMMARY: The Food and Drug Administration (FDA), Center for Veterinary Medicine (CVM), is announcing the withdrawal of a notice of opportunity for a hearing (NOOH), which proposed to withdraw the approved uses of carbadox, a carcinogenic animal drug intended for use in feeds for swine. FDA is publishing a proposed order that, if finalized, will revoke the current approved method for carbadox because it does not satisfy the statutory requirement that there be a method to ensure that no residue of carcinogenic concern remains in the edible tissues of treated swine. If that order is finalized, we intend to publish in the *Federal Register* an NOOH proposing to withdraw approval of all new animal drug applications for use of carbadox.

DATES: The NOOH is withdrawn as of [INSERT DATE OF PUBLICATION IN THE *FEDERAL REGISTER*].

ADDRESSES: For access to the docket to read background documents or comments received, go to https://www.regulations.gov and insert the docket number found in brackets in the heading of this document into the "Search" box and follow the prompts, and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852, 240-402-7500.

FOR FURTHER INFORMATION CONTACT: Diane Heinz, Center for Veterinary Medicine (HFV-6), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 240-402-5692, diane.heinz@fda.hhs.gov.

SUPPLEMENTARY INFORMATION: In an NOOH published in the *Federal Register* of April 12, 2016 (81 FR 21559; correction 81 FR 23499), we proposed to withdraw approval of the new animal drug applications (NADAs) for carbadox. That proposed action was based on two grounds. First, new evidence demonstrates that the Delaney Clause in section 512(d)(1)(I) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 360b(d)(1)(I)), which requires that no residue of a carcinogenic drug can be found in any edible portion of the animal after slaughter, applies because the Diethylstilbestrol (DES) Proviso exception is no longer met. The DES Proviso exception allows such an animal drug to be approved if, among other things, no residue of such drug will be found by methods of examination prescribed or approved by the Secretary of Health and Human Services by regulations, in any edible portion of such animal after slaughter or in any food yielded by or derived from the living animals. Second, new evidence demonstrates that carbadox is not shown to be safe under the General Safety Clause (section 512(e)(1)(B) of the FD&C Act). FDA has reviewed information submitted by the drug sponsor, including some studies submitted in response to the April 2016 NOOH, and determined that the current approved method for detecting residues of carcinogenic concern does not meet the requirements of part 500, subpart E (21 CFR part 500, subpart E), to demonstrate that there is "no residue" of carbadox in any food derived by treated animals as required by section 512(d)(1)(I) of the FD&C Act.

FDA is withdrawing the April 2016 NOOH, which proposed to withdraw the approved uses of carbadox. Elsewhere in this issue of the *Federal Register*, FDA is publishing a proposed

order that, if finalized, will revoke the current approved method for carbadox that measures quinoxaline-2-carboxylic acid as the marker residue for carbadox. The proposed order is based on the inadequacy of the current approved method to monitor residue of carcinogenic concern in compliance with FDA's operational definition of "no residue" in part 500, subpart E, and the requirements in section 512(d)(1)(I) of the FD&C Act. If the proposed order to revoke the current approved method is finalized and the approved analytical method is revoked, we intend to publish in the *Federal Register* an NOOH proposing to withdraw all new animal drug applications for use of carbadox based on the lack of an approved method to demonstrate compliance with part 500, subpart E, and section 512(d)(1)(I) of the FD&C Act.

Dated: July 9, 2020.

Lowell J. Schiller,

Principal Associate Commissioner for Policy.

[FR Doc. 2020-15245 Filed: 7/17/2020 8:45 am; Publication Date: 7/20/2020]