

4. Minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, e.g., permitting electronic submissions of responses.

5. Assess information collection costs.

Proposed Project

National Survey of Community-Based Survey of Supports for Healthy Eating and Active Living (CBS HEAL)—New—National Center for Chronic Disease Prevention and Health Promotion (NCCDPHP), Centers for Disease Control and Prevention (CDC).

Background and Brief Description

Currently, little is known about the environmental and policy supports for healthful diets and regular physical activity within a community across the U.S., and how these supports are changing across time. As a result, CDC plans to conduct a survey to address this gap in knowledge. The survey will be administered to a nationally representative sample of 4,417

communities. Respondents will be city planners/managers in these communities. Information will be collected about the following topics: Communitywide planning efforts for healthy eating and active living, the built environment and policies that support physical activity, zoning that supports healthy eating and active living, public transportation policies that support healthy eating and active living, other policies and practices that support access to healthy food and healthy eating, and policies that support employee breastfeeding. Data will be collected using a secure, web-based survey data collection system, with telephone and mail follow-up for non-response.

The proposed survey content and data collection procedures incorporate lessons learned during an initial pilot study (OMB No. 0920–0934, “Pilot Study of Community-Based Surveillance and Supports for Healthy Eating/Active Living”, expiration 5/31/2013), as well as the 2014 baseline study (OMB control number 0920–1007, “National Survey of Community Based Policy and Environmental Supports for

Healthy Eating and Active Living”, expiration 1/1/2015).

Assessment of policy and environmental supports for healthful eating and physical activity will serve multiple uses. First, the collected data will describe the characteristics of communities that have specific policy and practice supports favorable for healthy diets and regular physical activity and progress since 2014. Second, the collected data will help identify the extent to which communities implement strategies consistent with current national recommendations. Third, local agencies may use the data collected to consider how they compare nationally or with other municipalities of a similar geography, population size, or urban status. Finally, this information can help guide communities and researchers in local efforts to implement and evaluate policies and practices that support healthy behaviors and choices.

CDC requests OMB approval for an estimated 1,693 burden hours annually. Participation is voluntary and there are no costs to respondents other than their time.

ESTIMATED ANNUALIZED BURDEN HOURS

Type of respondents	Form name	Number of respondents	Number of responses per respondent	Average burden per response (in hours)	Total burden hours
City or Town Planner or Manager.	National Survey of Community-Based Policy and Environmental Supports for Healthy Eating and Active Living.	2,650	1	30/60	1,325
	Telephone Non-response Follow-up Contact Script.	4,417	1	5/60	368
Total	1,693

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Office of Scientific Integrity, Office of Science,
Centers for Disease Control and Prevention.
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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 July 15, 2020.

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.

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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; Revocation of Approved Method

AGENCY: Food and Drug Administration, HHS.

ACTION: Proposed order.

SUMMARY: The Food and Drug Administration (FDA), Center for Veterinary Medicine (CVM), is proposing an order to revoke the approved method for detecting residues of carbadox, a carcinogenic new animal drug used in swine feed. 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 currently approved method measures quinoxaline-2-carboxylic acid (QCA) as a marker residue to detect the presence of any residue of carcinogenic concern. CVM is proposing to revoke the approved method for carbadox based on our determination that it is inadequate to monitor residue of carcinogenic concern in compliance with FDA’s operational definition of no residue because there is no established relationship between QCA measured by the approved method and the residue of carcinogenic concern.

DATES: Submit either electronic or written comments on the proposed order by September 18, 2020.

ADDRESSES: You may submit comments as follows. Please note that late, untimely filed comments will not be considered. Electronic comments must be submitted on or before September 18, 2020. The <https://www.regulations.gov> electronic filing system will accept comments until 11:59 p.m. Eastern Time at the end of September 18, 2020. Comments received by mail/hand delivery/courier (for written/paper submissions) will be considered timely if they are postmarked or the delivery service acceptance receipt is on or before that date.

Electronic Submissions

Submit electronic comments in the following way:

- **Federal eRulemaking Portal:** <https://www.regulations.gov>. Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to <https://www.regulations.gov> will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else’s Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on <https://www.regulations.gov>.

- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see “Written/Paper Submissions” and “Instructions”).

Written/Paper Submissions

Submit written/paper submissions as follows:

- **Mail/Hand Delivery/Courier (for written/paper submissions):** Dockets Management Staff (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

- For written/paper comments submitted to the Dockets Management Staff, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified as confidential, if submitted as detailed in “Instructions.”

Instructions: All submissions received must include the Docket No. FDA–2016–N–0832 for “Phibro Animal Health Corp.; Carbadox in Medicated Swine Feed; Revocation of Approved Method.” Received comments, those filed in a timely manner (see **ADDRESSES**), will be placed in the docket and, except for those submitted as “Confidential Submissions,” publicly viewable at <https://www.regulations.gov> or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday, 240–402–7500.

- **Confidential Submissions—**To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the