enzootic status and genetic factors affecting the disease in each location, thereby providing better inferential value than the laboratory study. Limitations of the field study are that the exposure to infective *D. immitis* larvae is assumed, but uncertain, and, in cases of dogs with positive antigen tests, the actual timing of the exposure is unknown. Additionally, the relatively short duration of the field study in relationship to the heartworm life cycle and testing limitations may not adequately evaluate the entire dosing period of the investigational new animal drug. Assurance that individual dogs were exposed to *D. immitis* larvae during the critical first few months of the study is lacking, which complicates interpretation of a negative antigen test at the end of the study. If the study is started during a time of low transmission, such as in winter, exposure is even more uncertain. Because of the delay in the ability to detect an adult heartworm infection, it is impossible to tell with certainty if infections detected between 4 and 8 months after study initiation were pre-existing infections or due to lack of effectiveness of the preventative. Obtaining false negative and false positive antigen test results are possible and, because worm counts are not performed, the false results may result in the misclassification of outcome for individual dogs.

In recognition of the limitations of the current recommended laboratory and field effectiveness studies for heartworm preventatives for use in dogs, we are interested in evaluating alternative approaches to these study designs that would mitigate the limitations of such studies while ensuring that the studies generate data to support substantial evidence of effectiveness as defined in 21 CFR 514.4.

Currently, there are gaps in knowledge and understanding that prevent us from fully evaluating alternative approaches to meeting the substantial evidence of effectiveness standard. To address these gaps, we are seeking public comment regarding the following questions:

Population level effectiveness endpoint. The design and evaluation of effectiveness studies rely on an understanding of the appropriate outcome measure. In seeking to design alternative study approaches, we would like to determine a population level effectiveness endpoint that could be used to design future studies. Currently we do not have a defined level of performance that heartworm preventatives are expected to meet when applied to the entire United States canine population. Determining a population level endpoint would allow us to explore the suitability and feasibility of alternative study designs for the evaluation of effectiveness for heartworm preventatives. Factors that may contribute to a heartworm preventative's effectiveness include the inherent potency of the drug, differences in heartworm susceptibility, and owner compliance.

1. Assuming that a product was administered according to labeled directions, what would be an acceptable rate of failure of an approved heartworm preventative in the overall United States canine population to which it is administered?

2. What would be the maximum acceptable rate of failure in a high-risk population?

3. Alternatively, if you do not have a numerical estimate, what recommendations do you have for determining what an acceptable rate of failure should be?

Exposure to infective D. immitis larvae. For humane reasons, field studies are not conducted with a negative control group that would reflect the study population's level of exposure to heartworm infection. Therefore, it is necessary to have other measures to ensure that the level of exposure to infective *D. immitis* larvae experienced in the study is sufficient to adequately test the effectiveness of the investigational new animal drug. Please provide comment on other methods that could reliably be used to ensure adequate exposure of dogs enrolled in a field study. Consider the following points:

4. Can available tests be used to determine an individual dog's exposure to infective larvae? What are the sensitivity and specificity of those tests in this application? How would the level of sensitivity and specificity of these tests impact the reliable assessment of rate of failure in the population?

5. Does the use of a heartworm preventative, even if only partially effective, have an impact on the results of these tests?

6. Could methods that consider a wider area (as opposed to an individual animal) such as mosquito testing, forecasting, or modeling be reliably used to determine the likely exposure to infective larvae of dogs at a specific study site? What information would be needed to create the methods or to verify the validity of the methods? What are the limitations to such an approach?

Outcome Assessment. Accurate assessment of the outcome endpoint (heartworm infection) is essential for field studies where necropsy worm counts will not be performed.

7. What are the most reliable ways of properly classifying the outcome in a non-terminal study?

8. Are there critical pieces of information supporting substantial evidence of effectiveness that can only be gained from a well-controlled laboratory study? Are there elements that could be added to a field study that would partially address those data gaps?

Other.

9. Are there laboratory study designs other than the traditional dose confirmation study that provide additional information or include a model that is more representative of real world exposure? For example, the use of live mosquitoes to induce infection rather than the mechanical injection of larvae.

10. How might differences in the route of administration, dosing frequency, or pharmacokinetic factors impact effectiveness? How might studies be designed to incorporate these factors? For example, a drug that demonstrates an early peak, with minimal to no drug levels in the dog for the remainder of the dosing interval versus a product with continuous drug levels in the dog for the entire dosing interval?

Dated: May 21, 2018.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2018–11132 Filed 5–23–18; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2018–N–1857]

Agency Information Collection Activities; Proposed Collection; Comment Request; Current Good Manufacturing Practice, Hazard Analysis, and Risk-Based Preventive Controls for Food for Animals

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing an opportunity for public comment on the proposed collection of certain information by the Agency. Under the Paperwork Reduction Act of 1995 (PRA), Federal Agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information,

including each proposed extension of an existing collection of information, and to allow 60 days for public comment in response to the notice. This notice solicits comments on the information collection requirements associated with current good manufacturing practice, hazard analysis, and risk-based preventive controls for animal food.

DATES: Submit either electronic or written comments on the collection of information by July 23, 2018.

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 July 23, 2018. The *https://www.regulations.gov* electronic filing system will accept comments until midnight Eastern Time at the end of July 23, 2018. 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–2018–N–1857 for ''Agency Information Collection Activities; Proposed Collection; Comment Request; Current Good Manufacturing Practice, Hazard Analysis, and Risk-Based Preventive Controls for Food for Animals.'' 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.

- 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 information you claim to be confidential with a heading or cover note that states ''THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION.'' The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on *https://www.regulations.gov.* Submit both copies to the Dockets Management Staff. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as ''confidential.'' Any information marked as ''confidential'' will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: *https://www.gpo.gov/fdsys/pkg/FR-2015-09-18/pdf/2015-23389.pdf.*

Docket: For access to the docket to read background documents or the electronic and written/paper 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.

FOR FURTHER INFORMATION CONTACT: Domini Bean, Office of Operations, Food and Drug Administration, Three White Flint North, 10A–12M, 11601 Landsdown St., North Bethesda, MD 20852, 301–796–5733, *PRAStaff@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: Under the PRA (44 U.S.C. 3501–3520), Federal Agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. ''Collection of information'' is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes Agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA (44 U.S.C. 3506(c)(2)(A)) requires Federal Agencies to provide a 60-day notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, before submitting the collection to OMB for approval. To comply with this requirement, FDA is publishing notice of the proposed collection of information set forth in this document.

With respect to the following collection of information, FDA invites comments on these topics: (1) Whether the proposed collection of information is necessary for the proper performance of FDA's functions, including whether the information will have practical utility; (2) the accuracy of FDA's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology.

Current Good Manufacturing Practice and Hazard Analysis and Risk-Based Preventive Controls for Food for Animals—21 CFR Part 507 OMB Control Number 0910–0789—Extension

The information collection supports FDA regulations. As amended by the FDA Food Safety Modernization Act (FSMA) (Pub. L. 111–353), the Federal Food, Drug, and Cosmetic Act (the FD&C Act) enables the Agency to better protect the public health by helping to ensure the safety and security of the food supply. It enables FDA to focus

more on preventing food safety problems rather than relying primarily on reacting to problems after they occur. FSMA recognizes the important role industry plays in ensuring the safety of the food supply, including the adoption of modern systems of preventive controls in food production. Specifically, section 418 (21 U.S.C. 350g) of the FD&C Act sets forth requirements for hazard analysis and risk-based preventive controls for facilities that produce food for animals. To implement these provisions, regulations were codified under 21 CFR part 507—*Current Good Manufacturing Practice, Hazard Analysis, And Risk-Based Preventive Controls For Food For Animals.* The regulations establish requirements for a written food safety plan; hazard analysis preventive controls; monitoring; corrective actions and corrections; verification; supply-chain program; recall plan; and associated records and became effective November 16, 2015. Currently, we continue to evaluate burden associated with the information collection requirements however, for purposes of extending the information collection we retain the currently approved figures as shown below.

We estimate our burden of the information collection as follows:

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN FOR OMB CONTROL NO. 0910–0789 [1]

21 CFR section; activity	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
507.7 exemption: Submit attestation of preventive controls or compliance with State and local laws (non-federal).	1,120	0.5	560	0.5 (30 minutes) ...	280
507.67, 507.69, and 507.71; submission of an appeal, including submission of a request for an informal hearing.	1	1	1	4	4
507.85(b); requests for reinstatement of exemption	1	1	1	2	2
Total	.....	.....	.....	.....	286

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.

TABLE 2—ESTIMATED ANNUAL RECORDKEEPING BURDEN [1]

21 CFR section; activity	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
Subpart A—General Provisions					
507.7(e); records attesting that the facility is a ''qualified'' facility	1,120	0.5	560	0.1 (6 minutes)	56
507.4(d); documentation of animal food safety and hygiene training.	7,469	0.75	5,579	0.05 (3 minutes) ...	279
Subpart C—Hazard Analysis and Risk-Based Preventive Controls					
507.31 through 507.55; food safety plan—including hazard analysis, preventive controls, monitoring, corrective actions, verification, validation reanalysis, modifications, and implementation records.	7,469	519	3,876,411	0.1 (6 minutes)	387,641
Subpart E—Supply-Chain Program					
507.105 through 507.175; written supply-chain program—including records documenting program.	7,469	519	3,876,411	0.1 (6 minutes)	387,641
Subpart F—Requirements Applying to Records					
507.200 through 507.215; general requirements, additional requirements applying to food safety plan, requirements for record retention, use of existing records, and special requirements applicable to written assurance.	7,469	519	3,876,411	0.1 (6 minutes)	387,641
Totals	.....	.....	11,635,372	.....	1,163,258

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.

TABLE 3—ESTIMATED ANNUAL THIRD-PARTY DISCLOSURE BURDEN [1]

21 CFR section; activity	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
507.27(b); labeling for the animal food product contains the specific information and instructions needed so the food can be safely used for the intended animal species.	330	10	3,300	0.25 (15 minutes)	825

TABLE 3—ESTIMATED ANNUAL THIRD-PARTY DISCLOSURE BURDEN [1]—Continued

21 CFR section; activity	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
507.7(e)(1); change labels on products with labels	1,526	4	6,104	1	6,104
507.7(e)(2); change address on labeling (sales documents) for qualified facilities.	1,329	1	1,329	1	1,329
507.25(a)(2); animal food, including raw materials, other ingredients, and rework, is accurately identified.	330	312	102,960	0.01 (36 seconds)	1,030
507.28(b); holding and distribution of human food byproducts for use as animal food.	40,798	2	81,596	0.25 (15 minutes)	20,399
Total					29,687

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.

These figures are based on our regulatory impact analysis in support of the final rule on Preventive Controls for Food for Animals, which published in the **Federal Register** of September 17, 2015 (80 FR 56170). Using Agency data we estimated the number of animal food facilities that we believe are subject to the regulations. We base our estimate of the time necessary for the individual reporting, recordkeeping, and third-party disclosure activities on our experience with similar information collections.

Dated: May 18, 2018.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2018–11114 Filed 5–23–18; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2011–N–0279]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Prescription Drug Marketing; Administrative Procedures, Policies, and Requirements

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a proposed collection of information has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995.

DATES: Fax written comments on the collection of information by June 25, 2018.

ADDRESSES: To ensure that comments on the information collection are received, OMB recommends that written comments be faxed to the Office of Information and Regulatory Affairs, OMB, Attn: FDA Desk Officer, Fax: 202–395–7285, or emailed to *oira_submission@omb.eop.gov.* All comments should be identified with the OMB control number 0910–0435. Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Domini Bean, Office of Operations, Food and Drug Administration, Three White Flint North, 10A–12M, 11601 Landsdown St., North Bethesda, MD 20852, 301–796–5733, *PRAStaff@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: In compliance with 44 U.S.C. 3507, FDA has submitted the following proposed collection of information to OMB for review and clearance.

Prescription Drug Marketing Act of 1987—Administrative Procedures, Policies, and Requirements

OMB Control Number 0910–0435—Extension

This information collection supports FDA regulations codified at part 203 (21 CFR part 203) implementing the Prescription Drug Marketing Act of 1987 (PDMA). The PDMA was intended to ensure safe and effective drug products and to avoid an unacceptable risk that counterfeit, adulterated, misbranded, subpotent, or expired drugs are sold to consumers. The reporting and recordkeeping requirements found in the regulations are intended to help achieve the following goals: (1) To ban the reimportation of prescription drugs produced in the United States, except when reimported by the manufacturer or under FDA authorization for emergency medical care; (2) to ban the sale, purchase, or trade, or the offer to sell, purchase, or trade, of any prescription drug sample; (3) to limit the distribution of drug samples to practitioners licensed or authorized to prescribe such drugs or to pharmacies of hospitals or other healthcare entities at the request of a licensed or authorized practitioner; (4) to require licensed or authorized practitioners to request prescription drug samples in writing; (5) to mandate storage, handling, and recordkeeping requirements for prescription drug samples; (6) to prohibit, with certain exceptions, the sale, purchase, or trade, or the offer to sell, purchase, or trade, of prescription drugs that were purchased by hospitals or other healthcare entities or that were donated or supplied at a reduced price to a charitable organization; and (7) to require unauthorized wholesale distributors to provide, prior to the wholesale distribution of a prescription drug to another wholesale distributor or retail pharmacy, a statement identifying each prior sale, purchase, or trade of the drug.

In the **Federal Register** of December 14, 2017 (82 FR 58808), we published a notice soliciting public comment of the information collection. One caller responded to the notice asking about the impact the Drug Supply Chain Security Act (DSCSA) (Title II of the Drug Quality Security Act of 2013) has on the information collection. We note that the Agency is currently proposing to amend its regulations at part 203 to reflect changes resulting from enactment of the DSCSA (RIN 0910–AH56). While we expect these changes will result in a reduction of burden associated with the information collection, current regulations and associated information collection requirements remain in effect. Upon finalization of rulemaking, we will revise the information collection accordingly.

We therefore estimate the burden for the information collection as follows: