

Annually, FDA projects about 30 communication studies using the variety of test methods listed in table 1. FDA is requesting this burden so as not to restrict the Agency's ability to gather information on public sentiment for its proposals in its regulatory and communications programs.

Dated: May 17, 2011.

Leslie Kux,

Acting Assistant Commissioner for Policy.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2010-N-0307]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Antiparasitic Resistance and Combination New Animal Drugs Survey

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 (the PRA).

DATES: Fax written comments on the collection of information by June 22, 2011.

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 e-mailed to oir_submission@omb.eop.gov. All comments should be identified with the OMB control number 0910-NEW and title "Antiparasitic Resistance and Combination New Animal Drugs Survey." Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Juanmanuel Vilela, Office of Information Management, Food and Drug Administration, 1350 Piccard Dr., PI50-400B, Rockville, MD 20850, 301-796-7651, juanmanuel.vilela@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.

Antiparasitic Resistance and Combination New Animal Drugs Survey—(OMB Control Number 0910-NEW)

Resistance of parasites to one or more of the major classes of FDA approved antiparasitic drugs is a documented problem in cattle, horses, sheep, and goats in the United States. Further, FDA is aware that there are differing scientific opinions on the impact of the use of multiple antiparasitic drugs at the same time on the development of resistance to these drugs. The results from this survey will assist FDA in regulating antiparasitic drugs. FDA will also share their results with the veterinary parasitology community.

FDA plans to survey scientists and veterinarians with expertise in veterinary parasitology using a Web-based tool. The questions in the survey are designed to elicit expert opinions and clarify areas of agreement and disagreement within the veterinary parasitology community. The survey will query subjects on topics such as: (1) Concurrent use of multiple antiparasitic drug products, (2) recommended tests to detect and monitor for antiparasitic resistance, (3) characteristics of combination antiparasitic drug products that may either slow or enhance the selection for multidrug resistant parasites, and (4) regulatory considerations regarding combination antiparasitic drugs.

In the **Federal Register** of July 13, 2010 (75 FR 39948), FDA published a 60-day notice requesting public comment on the proposed collection of information. FDA received five comments (all from the same source).

(Comment 1) The first comment stated that any conclusions drawn from a survey that includes a diversity of opinion and conjecture would not be appropriate or adequate to develop the Agency's position with respect to the regulation of antiparasitic drugs. The Agency should instead consult with appropriate experts in the field to develop an appropriate science-based strategy.

(Center for Veterinary Medicine's (CVM's) Response) The proposed information collection is only one part of a strategy to compile scientific data on the subject of antiparasitic resistance and combinations. It is not the sole method by which the Agency will make any regulatory decisions. The other parts of the strategy include gathering information from scientific meetings,

consultation with outside experts, and a comprehensive literature search and evaluation. The information collection allows the Agency to gauge the awareness of the issues and affords a broader audience with an opportunity to provide scientific information to the Agency about the current state of antiparasitic resistance, the use patterns of combinations of antiparasitic drugs, and measures being employed in the field to detect and curtail antiparasitic resistance.

(Comment 2) The second comment requested that FDA publish the survey questions in the **Federal Register** for comment prior to finalizing them for the pretest and the actual survey.

(CVM's Response) In accordance with the PRA and the requirements of OMB, FDA will publish the survey questions as part of a 30-day notice in the **Federal Register**, and the public will have the opportunity to comment.

(Comment 3) The third comment requested that FDA comment on how FDA will decide who to survey.

(CVM's Response) FDA will offer the Web-based survey to scientists and veterinarians with parasitology experience. Professional organizations that FDA will notify of the availability of the survey include the American Veterinary Medical Association, American Academy of Veterinary Pharmacology and Therapeutics, American College of Veterinary Internal Medicine, American Association of Veterinary Parasitologists, World Association for the Advancement of Veterinary Parasitology, American Association of Bovine Practitioners, American Association of Equine Practitioners, American Association of Small Ruminant Practitioners, and the Veterinary Information Network. Additional organizations may be invited as appropriate.

(Comment 4) The fourth comment requested that FDA comment on who will review and compile the survey results.

(CVM's Response) Veterinarians and other scientists from CVM will review and compile the survey results.

(Comment 5) The fifth comment requested that FDA comment on how FDA plans to publish the results and how they will be made public.

(CVM's Response) FDA plans to present a summary of the information collection at a scientific forum widely available to the veterinary parasitology community.

FDA estimates the burden of this collection of information as follows:

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN ¹

Portion of study	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response (in hours) ²	Total hours
Pretest	5	1	5	20/60	1.65
Survey	100	1	100	20/60	33
Total					34.65

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

² Burden estimates of less than 1 hour are expressed as a fraction of an hour in the format “[number of minutes per response]/60”.

FDA calculated the total annual responses by multiplying the number of respondents by the annual frequency. FDA calculated the total hours by multiplying the estimated hours per response (20 minutes = 0.33 hours) by the number of respondents.

Dated: May 12, 2011.

Leslie Kux,
Acting Assistant Commissioner for Policy.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2011-N-0327]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Generic Clearance for the Collection of Qualitative Feedback on Agency Service Delivery

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 22, 2011.

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 e-mailed to oir_submission@omb.eop.gov. All comments should be identified with the OMB control number 0910-New and title “Generic Clearance for the Collection of Qualitative Feedback on Agency Service Delivery.” Also include

the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT:

Jonna Capezzuto, Office of Information Management, Food and Drug Administration, 1350 Piccard Dr., PI50-400B, Rockville, MD 20850, 301-796-3794,
Jonnalynn.Capezzuto@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.

Generic Clearance for the Collection of Qualitative Feedback on Agency Service Delivery—(OMB Control Number 0910—NEW)

The proposed information collection activity provides a means to garner qualitative customer and stakeholder feedback in an efficient, timely manner, in accordance with the Administration's commitment to improving service delivery.

By qualitative feedback, we mean information that provides useful insights on perceptions and opinions, but are not statistical surveys that yield quantitative results that can be generalized to the population of study. This feedback will provide insights into customer or stakeholder perceptions, experiences, and expectations, provide an early warning of issues with service, or focus attention on areas where communication, training, or changes in operations might improve delivery of products or services. These collections will allow for ongoing, collaborative, and actionable communications between the Agency and its customers and stakeholders. It will also allow feedback to contribute directly to the improvement of program management.

The solicitation of feedback will target areas such as: Timeliness, appropriateness, accuracy of information, courtesy, efficiency of service delivery, and resolution of issues with service delivery. Responses will be assessed to plan and inform

efforts to improve or maintain the quality of service offered to the public. If this information is not collected, vital feedback from customers and stakeholders on the Agency's services will be unavailable.

The Agency will only submit a collection for approval under this generic clearance if it meets the following conditions:

- The collections are voluntary;
- The collections are low burden for respondents (based on considerations of total burden hours, total number of respondents, or burden hours per respondent) and are low cost for both the respondents and the Federal Government;
- The collections are noncontroversial and do not raise issues of concern to other Federal Agencies;
- Any collection is targeted to the solicitation of opinions from respondents who have experience with the program or may have experience with the program in the near future;
- Personally identifiable information (PII) is collected only to the extent necessary and is not retained;
- Information gathered is intended to be used only internally for general service improvement and program management purposes and is not intended for release outside of the Agency (if released, the Agency must indicate the qualitative nature of the information);
- Information gathered will not be used for the purpose of substantially informing influential policy decisions; and
- Information gathered will yield qualitative information; the collections will not be designed or expected to yield statistically reliable results or used as though the results are generalizable to the population of study.

Feedback collected under this generic clearance provides useful information, but it does not yield data that can be generalized to the overall population. This type of generic clearance for qualitative information will not be used for quantitative information collections that are designed to yield reliably