

which may in turn affect their dietary choices. Results of the study will not be used to develop population estimates.

To help design and refine the questionnaire, FDA plans to conduct cognitive interviews by screening 72 panelists in order to obtain 9 participants in the interviews. Each screening is expected to take 5 minutes (0.083 hour) and each cognitive interview is expected to take 1 hour. The total for cognitive interview

activities is 15 hours (6 hours + 9 hours). Subsequently, we plan to conduct pretests of the questionnaire before it is administered in the study. We expect that 1,600 invitations, each taking 2 minutes (0.033 hour), will need to be sent to panelists to have 200 of them complete a 15-minute (0.25 hour) pretest. The total for the pretest activities is 103 hours (53 hours + 50 hours). For the survey, we estimate that 80,000 invitations, each taking 2

minutes (0.033 hour) to complete, will need to be sent to the consumer panel to have 10,000 of its members complete a 15-minute (0.25 hour) questionnaire. The total for the survey activities is 5,140 hours (2,640 hours + 2,500 hours). Thus, the total estimated burden is 5,258 hours. FDA's burden estimate is based on prior experience with research that is similar to this proposed study.

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

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN<sup>1</sup>

Activity	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response (in hours) <sup>2</sup>	Total hours
Cognitive interview screener .....	72	1	72	5/60	6
Cognitive interview .....	9	1	9	1	9
Pretest invitation .....	1,600	1	1,600	2/60	53
Pretest .....	200	1	200	15/60	50
Survey invitation .....	80,000	1	80,000	2/60	2,640
Survey .....	10,000	1	10,000	15/60	2,500
Total .....					5,258

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

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

## II. References

The following references are on display in the Division of Dockets Management (see **ADDRESSES**) and may be seen by interested persons between 9 a.m. and 4 p.m., Monday through Friday.

- Levy, A.S., Fein, S.B., and Schucker, R.E. "Nutrition Labeling Formats: Performance and Preference," *Food Technology*, 45: 116–121, 1991.
- Levy, A.S., Fein, S.B., and Schucker, R.E. "More Effective Nutrition Label Formats Are Not Necessarily Preferred," *Journal of the American Dietetic Association*, 92: 1230–1234, 1992.
- Levy, A.S., Fein, S.B., and Schucker, R.E. "Performance Characteristics of Seven Nutrition Label Formats," *Journal of Public Policy and Marketing*, 15: 1–15, 1996.
- Lando, A.M. and Labiner-Wolfe, J. "Helping Consumers to Make More Healthful Food Choices: Consumer Views on Modifying Food Labels and Providing Point-of-Purchase Nutrition Information at Quick-Service Restaurants," *Journal of Nutrition Education and Behavior*, 39: 157–163, 2007.
- U.S. Food and Drug Administration. *Calories Count: Report of the Working Group on Obesity*, 2004, available at <http://www.fda.gov/Food/LabelingNutrition/ReportsResearch/ucm081696.htm>.
- U.S. Food and Drug Administration. "2008 Health and Diet Survey—Preliminary Topline Frequencies (Weighted)," 2010, available at <http://www.fda.gov/Food/ScienceResearch/ResearchAreas/ConsumerResearch/ucm193895.htm>.

- Li, F., Miniard, P.W., and Barone, M.J. "The Facilitating Influence of Consumer Knowledge on the Effectiveness of Daily Value Reference Information," *Journal of the Academy of Marketing Science*, 28: 425–436, 2000.
- Levy, L., Patterson, R.E., Kristal, A.R., and Li, S.S. "How Well Do Consumers Understand Percentage Daily Value on Food Labels?" *American Journal of Health Promotion*, 14: 157–160, 2000.
- Institute of Medicine. *Dietary Reference Intakes: Guiding Principles for Nutrition Labeling and Fortification*. Washington, DC: National Academies Press, 2003.

Dated: May 16, 2011.

**Leslie Kux,**

*Acting Assistant Commissioner for Policy.*

[FR Doc. 2011–12556 Filed 5–20–11; 8:45 am]

**BILLING CODE 4160–01–P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. FDA–2010–N–0640]

#### Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Data To Support Food and Nutrition Product Communications, as Used by the Food and Drug Administration

**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 [oira\\_submission@omb.eop.gov](mailto:oira_submission@omb.eop.gov). All comments should be identified with the OMB control number 0910–NEW and title "Data to Support Food and Nutrition Product Communications, as Used by the Food and Drug Administration." Also include the FDA docket number found in brackets in the heading of this document.

**FOR FURTHER INFORMATION CONTACT:** Denver Presley, Jr., Office of Information Management, Food and Drug Administration, 1350 Piccard Dr., PI50–400B, Rockville, MD 20850, 301–796–3793.

**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.

**Data To Support Food and Nutrition Product Communications, as Used by the Food and Drug Administration—(OMB Control Number 0910–NEW)**

FDA plans to use the data collected under this generic clearance to inform its nutrition and foods communications campaigns. FDA expects the data to guide the formulation of its food and nutrition communication objectives. FDA also plans to use the data to help tailor print, broadcast, and use electronic media communications in order for them to have powerful and desired impacts on target audiences. The data will not be used for the purposes of making policy or regulatory decisions.

The information collected will serve two major purposes. First, as formative research, it will provide the critical knowledge needed about target audiences. FDA must explore audiences' beliefs, perceptions, and decisionmaking processes about nutrition and food consumption in order to formulate the basic objectives of its risk communication campaigns. Such

knowledge will provide the needed target audience understanding to design effective communication strategies, messages, and product labels. These communications will aim to improve public understanding of the risks and benefits of consuming certain foods or nutritional products by providing users with a better context in which to place risk information more completely.

Second, as initial testing, it will give FDA some information about the potential effectiveness of messages and materials in reaching and successfully communicating with their intended audiences. Testing messages with a sample of the target audience will allow FDA to refine messages while still in the developmental stage. Respondents may be asked to give their reaction to the messages in individual or group settings.

FDA's Center of Food Safety and Applied Nutrition, Office of the Commissioner, and other Centers or Offices will use this mechanism to test messages about regulated food and nutrition products on a variety of subjects related to consumer, patient, or

health care professional perceptions and use of foods and related materials, including but not limited to, food advertising, food and nutrition labeling, emerging risk communications, online sales of food products, and consumer and professional education. The data will not be used for the purposes of making policy or regulatory decisions.

In the **Federal Register** of December 29, 2010 (75 FR 82030), FDA published a 60-day notice requesting public comment on the proposed collection of information. FDA received one comment. It complimented the data collection tools that FDA proposed to use within this clearance and suggested use of newer technologies to improve data collection. It also noted that automated survey data collection (audio computer-assisted self interview, for example) does not reduce respondent burden, which FDA acknowledges. The other parts of the comment were beyond the scope of the questions asked in the 60-day **Federal Register** notice.

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

**TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN<sup>1</sup>**

	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response (in hours) <sup>2</sup>	Total hours
Individual indepth interviews .....	360	1	360	45/60	270
General public focus group interviews .....	144	1	144	1 30/60	216
Intercept interviews:					
Central location .....	600	1	600	15/60	150
Intercept interviews:					
Telephone .....	10,000 <sup>3</sup>	1	10,000	5/60	800
Self-Administered surveys .....	2,400	1	2,400	15/60	600
Gatekeeper reviews .....	400	1	400	30/60	200
Omnibus surveys .....	2,400	1	2,400	10/60	408
Total (General public) .....	16,304	.....	16,304	.....	2,644
Total Physician focus group interviews .....	144	1	144	1 30/60	216
Total (Overall) .....	.....	.....	.....	.....	2,860

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

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

<sup>3</sup> Brief interviews with callers to test messages, concepts, and strategies following their call-in request to an FDA Center 1–800 number.

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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**BILLING CODE 4160-01-P**

## 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](mailto: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](mailto: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: