4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2010-N-0420]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Testing Communications on Food and Drug Administration-Regulated Products Used in Animals

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 [INSERT DATE 30 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER].

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 0910-0689. Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: FDA PRA Staff, Office of Operations, Food and Drug Administration, 8455 Colesville Rd.; COLE-14526, Silver Spring, MD 20993-0002 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.

Testing Communications on FDA/Center for Veterinary Medicine (CVM)-Regulated Products Used In Animals (21 U.S.C. 393 (d)(2)(D))--OMB Control Number 0910-0689--Reinstatement

FDA is authorized by section 1003(d)(2)(D) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 393(d)(2)(D)) to conduct educational and public information programs relating to the safety of CVM-regulated products. FDA must conduct needed research to ensure that such programs have the highest likelihood of being effective. FDA expects that improving communications about the safety of regulated animal drugs, feed, food additives, and devices will involve many research methods, including individual indepth interviews, mall-intercept interviews, focus groups, self-administered surveys, gatekeeper reviews, and omnibus telephone surveys.

The information collected will serve three major purposes. First, as formative research it will provide critical knowledge needed about target audiences to develop messages and campaigns about the use of FDA-regulated products for use in animals. Knowledge of consumer and veterinary professional decision-making processes will provide the better understanding of target audiences that FDA needs to design effective communication strategies, messages, labels, and labeling. These communications will aim to improve public understanding of the risks and benefits of using regulated animal drugs, feed, food additives, and devices by providing users with a better context in which to place risk information more completely.

Second, as initial testing, it will allow FDA to assess 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 will be asked to give their reaction to the messages in either individual or group settings.

Third, as evaluative research, it will allow FDA to ascertain the effectiveness of the messages and the distribution method of these messages in achieving the objectives of the message campaign. Evaluation of campaigns is a vital link in continuous improvement of communications at FDA.

In the Federal Register of June 16, 2014 (79 FR 34312) FDA published a 60-day notice requesting public comment on the proposed collection of information. One comment was submitted; however, it was not responsive to the four collection of information topics solicited and therefore is not discussed in this document.

FDA estimates the burden of this collection of information based on recent prior experience with the various types of data collection methods described in this document:

Table 1.--Estimated Annual Reporting Burden[1]

21 U.S.C. 393(d)(2)(D)	No. of Respondents	No. of Responses per Respondent	Total Annual Responses	Average Burden Per Response	Total Hours
Individual Indepth Interviews	360	1	360	0.75	270
General Public Focus Group Interviews	288	1	288	1.5	432
Intercept Interviews: Central Location	600	1	600	0.25	150
Intercept Interviews: Telephone	10,000[2]	1	10,000	0.08	800
Self-Administered Surveys	2,400	1	2,400	0.25	600
Gatekeeper Reviews	400	1	400	0.50	200
Omnibus Surveys	2,400	1	2,400	0.17	408
Total (General Public)	16,448		16,448		2,860
Veterinarian/Scientific Expert Focus Group Interviews	288	1	288	0.75	216
Total (Veterinarians/Scientific Experts)	288	1	288		216
Total (Overall)	16,736	1	16,736		3,076

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

[2] These are brief interviews with callers to test message concepts and strategies following their call-in request to an FDA Center 1-800 number.

Annually, FDA projects about 30 studies with 16,736 respondents, using a variety of research methods and lasting an average of 0.17 hours each (varying from 0.08-1.5 hours).

Dated: October 28, 2014.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2014-26141 Filed 11/03/2014 at 8:45 am; Publication Date: 11/04/2014]