

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2010-N-0344]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Testing Communications on Medical Devices and Radiation-Emitting Products

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 [oir\\_submission@omb.eop.gov](mailto:oir_submission@omb.eop.gov). All comments should be identified with the OMB control number 0910-NEW and the title "Testing Communications on Medical Devices and Radiation-Emitting Products." Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT:

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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 Medical Devices and Radiation-Emitting Products--(OMB Control Number 0910-NEW)

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 regulated medical devices and radiation-emitting products. FDA must conduct needed research to ensure that such programs have the highest likelihood of being effective. Improving communications about medical devices and radiation-emitting products 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 medical device and radiation-emitting product use. Knowledge of consumer and health care professional decisionmaking processes will provide the better understanding of target audiences that FDA needs to design effective

communication strategies, messages, and labels. These communications will aim to improve public understanding of the risks and benefits of using medical devices and radiation-emitting products 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.

Annually, FDA projects about 30 studies using a variety of research methods and lasting an average of 0.17 hours each (varying from 0.08-1.5 hours). The operating and maintenance costs include contractor expenses for designing and conducting information collection activities, specifically, drawing samples, training interviewers, collecting and analyzing information, and reporting and disseminating findings. FDA estimates the burden of this collection of information based on prior recent experience with the various types of data collection methods described earlier. 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.

In the Federal Register of July 13, 2010 (75 FR 39952), FDA published a 60-day notice requesting public comment on the proposed collection of information. FDA received one comment, however it was not related to the collection of information.

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

Anticipated Data Collection Methods	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
Individual indepth interviews	360	1	360	.75	270
General public focus group interviews	144	1	144	1.5	216
Intercept interviews: central location	600	1	600	.25	150
Intercept interviews: telephone	10,000 <sup>2</sup>	1	10,000	.08	800
Self-administered surveys	2,400	1	2,400	.25	600
Gatekeeper reviews	400	1	400	.50	200
Omnibus surveys	2,400	1	2,400	.17	408
Total (general public)	16,304		16,304		2,644
Physician focus group interviews	144	1	144	1.5	216
Total (physician)	144		144		216
Total (overall)	16,448		16,448		2,860

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

<sup>2</sup>Brief interviews with callers to test message concepts and strategies following their call-in request to an FDA Center 1-800 number.

Dated: October 13, 2010.

Leslie Kux,

Acting Assistant Commissioner for Policy.

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