information collection is available on the Internet at *http://www.reginfo.gov/public/do/PRAMain.*

Dated: December 12, 2013.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2013–30147 Filed 12–18–13; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2008–D–0150]

Agency Information Collection Activities; Announcement of Office of Management and Budget Approval; Guidance for Industry on Hypertension Indication: Drug Labeling for Cardiovascular Outcome Claims

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a collection of information entitled ''Guidance for Industry on Hypertension Indication: Drug Labeling for Cardiovascular Outcome Claims'' has been approved by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995.

FOR FURTHER INFORMATION CONTACT: FDA PRA Staff, Office of Operations, Food and Drug Administration, 1350 Piccard Dr., PI50–400B, Rockville, MD 20850, *PRAStaff@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: On September 10, 2013, the Agency submitted a proposed collection of information entitled ''Guidance for Industry on Hypertension Indication: Drug Labeling for Cardiovascular Outcome Claims'' to OMB for review and clearance under 44 U.S.C. 3507. An Agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. OMB has now approved the information collection and has assigned OMB control number 0910–0670. The approval expires on December 31, 2016. A copy of the supporting statement for this information collection is available on the Internet at *http://www.reginfo.gov/public/do/PRAMain.*

Dated: December 12, 2013.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2013–30146 Filed 12–18–13; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2013–N–0796]

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 January 21, 2014.

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 0910–0678. 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, 1350 Piccard Dr., PI50–400B, Rockville, MD 20850, *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 Medical Devices and Radiation-Emitting Products—(OMB Control Number 0910–0678)—(Extension)

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 decision making 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). 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 9, 2013 (78 FR 41066), FDA published a 60-day notice requesting public comment on the proposed collection of information. No comments were received.

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

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]

Activity	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
Individual indepth interviews	360	1	360	0.75 (45 minutes)	270
General public focus group interviews	144	1	144	1.50 hours	216
Intercept interviews: Central location	200	1	200	0.25 (15 minutes)	50
Intercept interviews: Telephone	4,000	1	4,000	0.08 (5 minutes)	320
Self-Administered surveys	2,400	1	2,400	0.25 (15 minutes)	600
Gatekeeper reviews	400	1	400	0.50 (30 minutes)	200
Omnibus surveys	1,200	1	1,200	0.17 (10 minutes)	204
Total (general public)	8,704				1,860
Physician focus group interviews	144	1	144	1.50 hours	216
Total (physician)	144				216
Total (overall)	8,848				2,076

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

Dated: December 11, 2013.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2013–30149 Filed 12–18–13; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2013–N–0001]

Food and Drug Administration/ American Academy of Ophthalmology Workshop on Developing Novel Endpoints for Premium Intraocular Lenses; Public Workshop

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

The Food and Drug Administration (FDA) is announcing the following public workshop entitled ''FDA/ American Academy of Ophthalmology (AAO) Workshop on Developing Novel Endpoints for Premium Intraocular Lenses.'' The main topic of this workshop is the current challenges in the assessment of innovative intraocular lens (IOL) designs with a focus on endpoint methodologies used in evaluating IOL safety and effectiveness. Experts in subjects ranging from patient reported outcomes to objective measures of accommodation will give talks on the latest developments in the field. Participants will then engage in in-depth discussions of the pros and cons of various methods used to assess premium IOLs, and work to devise a plan to further promote innovation in this device area. The primary goal of the workshop is to improve the regulatory science for evaluating premium IOLs, which in turn may enhance the efficiency with which safe and effective premium IOLs get to the market. This public workshop is being rescheduled due to the government shutdown.

Date and Time: The public workshop will be held on March 28, 2014, from 8:30 a.m. to 5:30 p.m. Materials may be picked up starting at 7:30 a.m.

Location: The public workshop will be held at FDA's White Oak Campus, 10903 New Hampshire Ave., Building 31 Conference Center, the Great Room (rm. 1503), Silver Spring, MD 20993. Entrance for the public workshop participants (non-FDA employees) is through Building 1 where routine security check procedures will be performed. For parking and security information, please refer to *http://www.fda.gov/AboutFDA/WorkingatFDA/BuildingsandFacilities/WhiteOakCampusInformation/ucm241740.htm*.

Contact: Michelle Tarver, Food and Drug Administration, 10903 New Hampshire Ave., Silver Spring, MD 20993, 301–796–5620, FAX: 301–847–8126, email: *michelle.tarver@fda.hhs.gov*.

Registration: AAO will charge a registration fee to cover its share of the expenses associated with the workshop. The registration fee is $250 for Academy members and $400 for non-members. Registration is available on a first-come, first-served basis. Persons interested in attending this public workshop must register online. The deadline for online registration is March 27, 2014, at 5 p.m. EDT. There will be no onsite registration on the day of the public workshop. Early registration is recommended because facilities are limited and, therefore, FDA may limit the number of participants from each organization. To register for the public workshop, please visit the AAO Web site (*http://www.aao.org/meetings/iol_workshop.cfm*). Those interested in attending but unable to access the electronic registration site should fax the *PDF form* on the AAO Web site (*http://www.aao.org/meetings/upload/FDA_iol_workshop_reg.pdf*) to 415–561–8575. Those without Internet access should contact AAO Customer Service to register at 415–561–8540 or 866–561–8558 (toll free). Please provide complete contact information for each attendee, including name, title, affiliation, address, email, and telephone number. If there are any questions with registration, please contact the AAO administrative offices at 415–561–8540. Registrants will receive confirmation after they have been accepted. You will be notified if you are on a waiting list.

This public workshop is being rescheduled due to the government shutdown. It was originally scheduled for October 11, 2013. Those who registered for the original workshop date were contacted by AAO individually and offered either a complete refund or the option to have those monies applied to the rescheduled date registration. Any questions about this process should be addressed to AAO Customer Service at 415–561–8540 or 866–561–8558 (toll free).

Food and beverages will be available for purchase by participants during the workshop breaks.

If you need special accommodations due to a disability, please contact Ms. Susan Monahan at *susan.monahan@fda.hhs.gov* or 301–796–5661 no later than March 14, 2014.

For more information on the workshop, please see FDA's Medical Devices News & Events—Workshops & Conferences calendar at *http://*