

comments on the collection of information to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852. All comments should be identified with the docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Daniel Gittleson, Office of Information Management, Food and Drug Administration, 1350 Piccard Dr., PI50-400B, Rockville, MD 20850, 301-796-5156, daniel.gittleson@fda.hhs.gov.

SUPPLEMENTARY INFORMATION: Under the PRA (44 U.S.C. 3501-3520), Federal Agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. "Collection of information" is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes Agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA (44 U.S.C. 3506(c)(2)(A)) requires Federal Agencies to provide a 60-day notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information,

before submitting the collection to OMB for approval. To comply with this requirement, FDA is publishing notice of the proposed collection of information set forth in this document.

With respect to the following collection of information, FDA invites comments on these topics: (1) Whether the proposed collection of information is necessary for the proper performance of FDA's functions, including whether the information will have practical utility; (2) the accuracy of FDA's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology.

Medical Devices; Third-Party Review Under FDAMA—21 U.S.C. 360m (OMB Control Number 0910-0375)—Extension

Section 210 of the Food and Drug Administration Modernization Act (FDAMA) established section 523 of the Federal Food, Drug, and Cosmetic Act

(the FD&C Act) (21 U.S.C. 360m), directing FDA to accredit persons in the private sector to review certain premarket notifications (510(k)s). Participation in this third-party review program by accredited persons is entirely voluntary. A third party wishing to participate will submit a request for accreditation to FDA. Accredited third-party reviewers have the ability to review a manufacturer's 510(k) submission for selected devices. After reviewing a submission, the reviewer will forward a copy of the 510(k) submission, along with the reviewer's documented review and recommendation to FDA. Third-party reviewers should maintain records of their 510(k) reviews and a copy of the 510(k) for a reasonable period of time, usually a period of 3 years.

This information collection will allow FDA to continue to implement the accredited person review program established by FDAMA and improve the efficiency of 510(k) review for low- to moderate-risk devices.

Respondents to this information collection are businesses or other for-profit organizations.

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

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN

Activity	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
Requests for accreditation	1	1	1	24	24
510(k) reviews conducted by accredited third parties	10	26	260	40	10,400
Total					10,424

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

TABLE 2—ESTIMATED ANNUAL RECORDKEEPING BURDEN

Activity	Number of recordkeepers	Number of records per recordkeeper	Total annual records	Average burden per recordkeeping	Total hours
510(k) reviews	10	26	260	10	2,600

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

I. Reporting

510(k) Reviews Conducted by Accredited Third Parties

According to FDA's data, the number of 510(k)s submitted for third-party review is approximately 260 annually, which is 26 annual reviews per each of the 10 accredited reviewers.

II. Recordkeeping

Third-party reviewers are required to keep records of their review of each submission. According to FDA's data,

the Agency anticipates approximately 260 submissions of 510(k)s for third-party review per year.

Dated: July 2, 2013.

Leslie Kux,

Assistant Commissioner for Policy.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2013-N-0796]

Agency Information Collection Activities; Proposed Collection; 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 an opportunity for public comment on the proposed collection of certain information by the Agency. Under the Paperwork Reduction Act of 1995 (the PRA), Federal Agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, and to allow 60 days for public comment in response to the notice. This notice solicits comments on communication studies involving medical devices and radiation-emitting products regulated by FDA. This information will be used to explore concepts of interest and assist in the development and modification of communication messages and campaigns to fulfill the Agency's mission to protect the public health.

DATES: Submit either electronic or written comments on the collection of information by September 9, 2013.

ADDRESSES: Submit electronic comments on the collection of information to <http://www.regulations.gov>. Submit written comments on the collection of information to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852. All comments should be identified with the docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Daniel Gittleson, Office of Information Management, Food and Drug Administration, 1350 Piccard Dr., PI50-400B, Rockville, MD 20850, 301-796-5156, Daniel.Gittleson@fda.hhs.gov.

SUPPLEMENTARY INFORMATION: Under the PRA (44 U.S.C. 3501-3520), Federal Agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. "Collection of information" is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes Agency requests or requirements that members of the public submit reports, keep records, or

provide information to a third party. Section 3506(c)(2)(A) of the PRA (44 U.S.C. 3506(c)(2)(A)) requires Federal Agencies to provide a 60-day notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, before submitting the collection to OMB for approval. To comply with this requirement, FDA is publishing notice of the proposed collection of information set forth in this document.

With respect to the following collection of information, FDA invites comments on these topics: (1) Whether the proposed collection of information is necessary for the proper performance of FDA's functions, including whether the information will have practical utility; (2) the accuracy of FDA's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology.

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.

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

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN ¹—Continued

Activity	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
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: July 2, 2013.
Leslie Kux,
Assistant Commissioner for Policy.
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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2013-N-0370]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Export of Medical Devices; Foreign Letters of Approval

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 August 8, 2013.

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 0910-0264. Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Daniel Gittleson, Office of Information Management, Food and Drug Administration, 1350 Piccard Dr., PI50-400B, Rockville, MD 20850, 301-796-5156, *daniel.gittleson@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.

Export of Medical Devices; Foreign Letters of Approval—(OMB Control Number 0910-0264)—Extension

Section 801(e)(2) of the Federal Food, Drug, and Cosmetic Act (the FD&C Act) (21 U.S.C. 381(e)(2)) provides for the exportation of an unapproved device under certain circumstances if the exportation is not contrary to the public health and safety and it has the approval of the foreign country to which it is intended for export. Requesters communicate (either directly or through a business associate in the foreign country) with a representative of the foreign government to which they seek

exportation, and written authorization must be obtained from the appropriate office within the foreign government approving the importation of the medical device. An alternative to obtaining written authorization from the foreign government is to accept a notarized certification from a responsible company official in the United States that the product is not in conflict with the foreign country's laws. This certification must include a statement acknowledging that the responsible company official making the certification is subject to the provisions of 18 U.S.C. 1001. This statutory provision makes it a criminal offense to knowingly and willingly make a false or fraudulent statement, or make or use a false document, in any manner within the jurisdiction of a department or agency of the United States. The respondents to this collection of information are companies that seek to export medical devices. FDA's estimate of the reporting burden is based on the experience of FDA's medical device program personnel.

In the **Federal Register** of April 5, 2013 (78 FR 20660), 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/section of FD&C Act	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours	Total operating & maintenance costs
Foreign letter of approval—§ 801(e)(2)	38	1	38	3	114	\$9,500

¹ There are no capital costs associated with this collection of information.