400B, Rockville, MD 20850, 301–796–7726, *Ila.Mizrachi@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.

Draft Guidance for Industry on and Food and Drug Administration Staff on Dear Health Care Provider Letters: Improving Communication of Important Safety Information—(OMB Control Number 0910–New)

This draft guidance provides recommendations on when to use a Dear Health Care Provider (DHCP) Letter, the types of information to include in a DHCP letter, how to organize that information, and formatting techniques to make the information more accessible. The draft guidance is intended to improve the quality of DHCP letters to make them more effective communication tools for new information about marketed products.

In the **Federal Register** of November 12, 2010 (75 FR 69449), FDA published a 60-day notice requesting public comment on the draft version of this guidance. Eleven public comments were received during the comment period and in nine of the letters the following two issues were raised. However, the other two comments did not address the information collection.

(Comment 1) Section V of the draft guidance states that the target audience should be all health care providers who could not only prescribe the drug, but who could also dispense or administer the drugs. The comments call this an expansion of the target audience, which would require manufacturers to send DHCP letters to physicians, nurses, pharmacists, and other prescribing and non-prescribing providers. Manufacturers would also need to seek out lists of such non-prescribing health care providers proactively and disseminate the letters more broadly than to just physicians. A recommendation was made to limit the letters to prescribers only.

(Response) The regulation requires manufacturers and distributors to mail important information to ''physicians and others responsible for patient care''. (See 21 CFR 200.5) To the extent this includes non-prescribing health care professionals responsible for patient care, the manufacturers should send letters to relevant personnel. This is not an expansion of the scope of the letters, merely a clarification of the regulation and a reflection of the health care system today, which has a variety of practitioners involved in patient care.

(Comment 2) In Section VI of the draft guidance, FDA recommends that companies conduct an evaluation of the extent to which the target audience received the DHCP letter and is aware of the information that was communicated in the letter. It also asked manufacturers to assess the impact of DHCP letters and their impact on patient behavior. Comments found this overly burdensome, beyond the Agency's statutory authority, and an unnecessary increase in correspondence, thereby potentially diluting the impact of the DHCP letters.

(Response) We agree with the comments. The final guidance has been modified to suggest that manufacturers conduct an evaluation, *for their own use,* of the utility of the letters and their success in reaching the target audiences.

Based on a review of MedWatch Safety Alerts for 2008 and 2009, we identified each Dear Health Care Provider Letter sent and the identity of each sponsor sending out a Dear Health Care Provider Letter for each year. We estimate that we will receive approximately 30 Dear Health Care Provider Letters annually from approximately 25 application holders. FDA professionals familiar with Dear Health Care Provider Letters and with the recommendations in the draft guidance estimate that it should take an application holder approximately 100 hours to prepare and send Dear Health Care Provider Letters in accordance with the draft guidance. Therefore we estimate the annual reporting burden as follows:

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]

	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
Annual Average	25	1.20	30	100	3,000

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

In the draft guidance, we refer to an earlier guidance for industry entitled ''Using Electronic Means to Distribute Certain Product Information'' (71 FR 26102; May 3, 2006). That guidance referred to previously approved collections of information found in FDA regulations that are subject to review by OMB. The collections of information in that guidance have been approved under OMB control number 0910–0249.

Dated: July 2, 2013.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2013–16445 Filed 7–8–13; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2013–N–0795]

Agency Information Collection Activities; Proposed Collection; Comment Request; Medical Devices; Third-Party Review Under the Food and Drug Administration Modernization Act

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 the information collection associated with medical devices third-party review under the Food and Drug Administration Modernization Act of 1997 (FDAMA).

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.

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.

[FR Doc. 2013–16402 Filed 7–8–13; 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; Proposed Collection; Comment Request; Testing Communications on Medical Devices and Radiation-Emitting Products

AGENCY: Food and Drug Administration, HHS.