Federal Register: Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Medical Devices; Third Party Review Program...(2)

U.S. Food & Drug Administration

[Federal Register: December 28, 2010 (Volume 75, Number 248)] [Notices] [Page 81616-81617] From the Federal Register Online via GPO Access [wais.access.gpo.gov] [DOCID:fr28de10-116]
---------- DEPARTMENT OF HEALTH AND HUMAN SERVICES Food and Drug Administration [Docket No. FDA-2010-N-0447] Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Medical Devices; Third Party Review Program 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 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 (the PRA). DATES: Fax written comments on the collection of information by January 27, 2011. 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 e-mailed to oira_submission@omb.eop.gov [1]. All comments should be identified with the OMB control number 0910-0375. 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, e-mail: Daniel.Gittleson@fda.hhs.gov [2]. 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. Medical Devices; Third Party Review Program Under the Food and Drug Administration Modernization Act--(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) of the FD&C Act (21 U.S.C. 360) 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. I. Reporting 510(k) Reviews Conducted by Accredited Third Parties According to FDA's data in 2009, the Agency has experienced that 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 in 2009, the Agency anticipates approximately 260 submissions of 510(k)s for third-party review per year. In the Federal Register of September 22, 2010 (75 FR 57801), FDA published a 60-day notice requesting public comment on the proposed collection of information. FDA received one comment; however, it was not PRA related. FDA estimates the burden of this collection of information as follows: Table 1--Estimated Annual Reporting Burden
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Annual Section 523 of the FD&C Act No. of frequency per Total annual Hours per Total hours respondents response responses response
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Requests for accreditation..... 1 1 1 24 24 510(k) reviews conducted by 10 26 260 40 10,400 accredited third parties..... Total..... 10,424
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There are no capital costs or operating and maintenance costs associated with this collection of information. Table 2--Estimated Annual Recordkeeping Burden \1---------
---------- Annual Section 523 of the FD&C Act No. of frequency per Total annual Hours per Total hours recordkeepers recordkeeping records record ----------
---------- 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. Dated: December 21, 2010. Leslie Kux, Acting Assistant Commissioner for Policy. [FR Doc. 2010-32603 Filed 12-27-10; 8:45 am] BILLING CODE 4160-01-P

SOURCE [3]

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http://www.mdtmag.com/news/2010/12/federal-register-agency-information-collection-activities-submission-office-management-and-budget-review-comment-request-medical-devices-third-party-review-program2?qt-recent_content=0

Links:
[1] mailto://edocket.access.gpo.gov/2010/oira_submission@omb.eop.gov
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