# Federal Register: Agency Information Collection Activities; Proposed Collection; Comment Request; Postmarket Surveillance

FDA (The Center for Devices and Radiological Health)

[Federal Register: February 5, 2010 (Volume 75, Number 24)] [Notices] [Page 6036-6037] From the Federal Register Online via GPO Access [wais.access.gpo.gov] [DOCID:fr05fe10-85] ---------- DEPARTMENT OF HEALTH AND HUMAN SERVICES Food and Drug Administration [Docket No. FDA-2010-N-0033] Agency Information Collection Activities; Proposed Collection; Comment Request; Postmarket Surveillance 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 information collection requirements for Postmarket Surveillance. DATES: Submit written or electronic comments on the collection of information by April 6, 2010. ADDRESSES: Submit electronic comments on the collection of information to http://www.regulations.gov [1]. 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 (HFA-710), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-796-5156, Daniel.Gittleson@fda.hhs.gov [2]. 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. Postmarket Surveillance--21 CFR Part 822 (OMB Control Number 0910- 0449)--Extension Section 522(a) of the Federal Food, Drug and Cosmetic Act (the act) (21 U.S.C. 360l) authorizes FDA to require manufacturers to conduct postmarket surveillance (PS) of any device that meets the criteria set forth in the statute. The PS regulation establishes procedures that FDA uses to approve and disapprove PS plans. The regulation provides instructions to manufacturers so they know what information is required in a PS plan submission. FDA reviews PS plan submissions in accordance with part 822 (21 CFR part 822) in Sec. Sec. 822.15 to 822.19 of the regulation, which describe the grounds for approving or disapproving a PS plan. In addition, the PS regulation provides instructions to manufacturers to submit interim and final reports in accordance with Sec. 822.38. Respondents to this collection of information are those manufacturers who require postmarket surveillance of their products. FDA estimates the burden of this collection of information as follows: Table 1.--Estimated Annual Reporting Burden1 ---------- No. of Annual Frequency Total Annual Hours per 21 CFR Section Respondents per Response Responses Response Total Hours ---------- 822.9, 21 1 21 120 2,520 822.10 ---------- 822.21 (supplements) 5 1 5 40 200 ---------- 822.28 (stop marketing) 5 1 5 8 40 ---------- 822.29 (request waiver) 1 1 1 40 40 ---------- 822.30 (request exemption) 1 1 1 40 40 ---------- 822.38 (reports) 40 1 40 40 1,600 ---------- Total 4,440 ---------- 1 There are no capital costs or operating and maintenance costs associated with this collection of information. Table 2.--Estimated Annual Recordkeeping Burden1 ---------- No. of Annual Frequency Total Annual Hours per 21 CFR Section Recordkeepers per Recordkeeping Record Records Total Hours ---------- 822.31 21 1 21 20 420 ---------- 822.32 63 1 63 10 630 ---------- Total 1,050 ---------- 1 There are no capital costs or operating and maintenance costs associated with this collection of information. Explanation of Reporting Burden Estimate The burden captured in table 1 for this document for each of these responses is based on the data available in FDA's internal tracking system for 2009. There was not an internal tracking system prior

to 2009. Sections 822.26, 822.27, and 822.34 do not constitute information collection subject to review under the PRA because ``it entails no burden other than that necessary to identify the respondent, the date, the respondent's address, and the nature of the instrument.'' (5 CFR 1320.3(h)(1)). Explanation of Recordkeeping Burden Estimate FDA expects that at least some of the manufacturers will be able to satisfy the PS requirement using information or data they already have. For purposes of calculating burden, however, FDA has assumed that each PS order can only be satisfied by a 3-year clinically-based surveillance plan, using three investigators. These estimates are based on FDA's knowledge and experience with limited implementation of section 522 under the Safe Medical Devices Act. Therefore, FDA would expect that the recordkeeping requirements would apply to a maximum of 21 manufacturers (3 to 4 added each year) and 30 investigators (3 per surveillance plan). After 3 years, FDA would expect these numbers to remain level as the surveillance plans conducted under the earliest orders reach completion and new orders are issued. Dated: January 27, 2010. David Dorsey, Acting Deputy Commissioner for Policy, Planning and Budget. [FR Doc. 2010-2458 Filed 2-4-10; 8:45 am] BILLING CODE 4160-01-S

SOURCE [3]



**Links:**
[1] http://frwebgate.access.gpo.gov/cgi-bin/leaving.cgi?from=leavingFR.html&log=linklog&to=http://www.regulations.gov
[2] mailto://edocket.access.gpo.gov/2010/Daniel.Gittleson@fda.hhs.gov
[3] http://edocket.access.gpo.gov/2010/2010-2458.htm