

**DEPARTMENT OF HEALTH AND HUMAN SERVICES****Food and Drug Administration**

[Docket No. 03N-0187]

**Agency Information Collection Activities; Proposed Collection; Comment Request; Postmarket Surveillance of Medical Devices****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 information collection, and to allow 60 days for public comment in response to the notice. This notice solicits comments on information collection requirements for postmarket surveillance (PS) of medical devices.

**DATES:** Submit written or electronic comments on the collection of information by July 14, 2003.

**ADDRESSES:** Submit electronic comments on the collection of information to <http://www.accessdata.fda.gov/scripts/oc/dockets/edockethome.cfm>. Submit written comments on the collection of information to the Dockets Management Branch (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:**

Peggy Robbins, Office of Information Resources Management (HFA-250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-827-1223.

**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: (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 of Medical Devices—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(a)) authorizes the FDA to require manufacturers to conduct PS of any device that meets the criteria set forth in the statute.

The PS regulation in part 822 (21 CFR part 822) establishes procedures that FDA uses to approve and disapprove PS plans. The regulation provides specific, clear, and flexible instructions to manufacturers so they know what information is required in a PS plan submission. FDA reviews submissions in accordance with §§ 822.15 through 822.18 (which describe the grounds for approving or disapproving a PS plan). If this information is not collected, FDA cannot ensure that the PS will result in the collection of useful data that can reveal unforeseen adverse events or other information necessary to protect the public health.

Respondents to this collection of information are those manufacturers who require PS of their products. As previously stated, the collection of data and information under these regulations is conducted on a very infrequent basis and only as necessary.

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

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN<sup>1</sup>

21 CFR Section	No. of Respondents	Total Annual Responses	No. of Responses	Hours per Response	Total Hours
822.9 and 822.10	5	1	5	120	600
822.21	2	1	2	40	80
822.26	1	1	1	8	8
822.27	1	1	1	40	40
822.28	1	1	1	40	40
822.29	1	1	1	120	120
822.30	1	1	1	40	40
822.34	1	1	1	20	20
822.38	23	2	46	80	3,680