FOR FURTHER INFORMATION CONTACT: Margaret R. Schlosburg, Office of Information Resources Management (HFA–250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–1223.

SUPPLEMENTARY INFORMATION: In compliance with section 3507 of the PRA (44 U.S.C. 3507), FDA has submitted the following proposed collection of information to OMB for review and clearance.

Premarket Notification Submission 510(k), Subpart E—(OMB Control Number 0910–0120—Reinstatement)

Section 510(k) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 360(k)) and the implementing regulation, 21 CFR 807.81, require a person/manufacturer who intends to market a medical device to submit a premarket notification submission to FDA at least 90 days before proposing to begin the introduction, or delivery for introduction into interstate commerce, for commercial distribution of a device intended for human use.

Section 510(k) of the act allows for exemptions to the 510(k) submissions, i.e., a premarket notification submission would not be required if FDA determines that premarket notification is not necessary for the protection of the public health, and they are specifically exempted through the regulatory process. Under 21 CFR 807.85, ''Exemption from premarket notification,'' a device is exempt from premarket notification if the device intended for introduction into commercial distribution is not generally available in finished form for purchase and is not offered through labeling or advertising by the manufacturer, importer, or distributor for commercial distribution. In addition, the device must meet one of the following conditions: (1) It is intended for use by a patient named in order of the physician or dentist (or other specially qualified persons), or (2) it is intended solely for use by a physician or dentist and is not generally available to other physicians or dentists.

A commercial distributor who places a device into commercial distribution for the first time under their own name and a repackager who places their own name on a device and does not change any other labeling or otherwise affect the device, shall be exempted from premarket notification if the device was legally in commercial distribution before May 28, 1976, or a premarket notification was submitted by another person.

The information collected in a premarket notification is used by the medical, scientific, and engineering staffs of FDA in making determinations as to whether or not devices can be allowed to enter the U.S. market. The premarket notification review process allows for scientific and/or medical review of devices, subject to section 510(k) of the act, to confirm that the new devices are as safe and as effective as legally marketed predicate devices. This review process, therefore, prevents potentially unsafe and/or ineffective devices, including those with fraudulent claims, from entering the U.S. market. This information will allow FDA to collect data to ensure that the use of the device will not present an unreasonable risk for the subject and will not violate the subject's rights. The respondents to this information collection will primarily be medical device manufacturers and businesses.

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

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN[1]

21 CFR Section	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
807.81 and 807.87	5,000	1	5,000	80	400,000

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

TABLE 2.—ESTIMATED ANNUAL RECORDKEEPING BURDEN[1]

21 CFR Section	No. of Recordkeepers	Annual Frequency per Recordkeeping	Total Annual Records	Hours per Recordkeeper	Total Hours
807.93	2,000	10	20,000	0.5	10,000

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

FDA has based these estimates on conversations with industry and trade association representatives, and from internal review of the documents listed in Tables 1 and 2 of this document. Based on the trend in the past 3 years, an estimated 5,000 submissions are expected each year. FDA's administrative and technical staff, who are familiar with the requirements for submission of premarket notifications, estimate that an average of 80 hours are required to prepare a submission (exclusive of preparing clinical data, research, etc.). FDA, therefore, estimates that a total of 400,000 hours of effort is required for the 5,000 submissions. It is also estimated that the respondents will receive requests for an average of 20,000 documents. At an estimated one-half hour to process these documents, an additional 10,000 recordkeeping hours are expected for this program.

Dated: August 24, 1998.

William K. Hubbard,

Associate Commissioner for Policy Coordination.

[FR Doc. 98–23402 Filed 8–31–98; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 98N–0357]

Agency Information Collection Activities; Announcement of OMB Approval; Medical Devices; Current Good Manufacturing Practice (CGMP) Quality System (QS)

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing

that a collection of information entitled ''Medical Devices; Current Good Manufacturing Practice (CGMP) Quality System (QS)'' has been approved by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (the PRA).

FOR FURTHER INFORMATION CONTACT: Margaret R. Schlosburg, Office of Information Resources Management (HFA–250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–1223.

SUPPLEMENTARY INFORMATION: In the **Federal Register** of June 15, 1998 (63 FR 32667), the agency announced that the proposed information collection had been submitted to OMB for review and clearance under section 3507 of the PRA (44 U.S.C. 3507). An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. OMB has now approved the information collection and has assigned OMB control number 0910–0073. The approval expires on July 31, 2001.

Dated: August 20, 1998.

William K. Hubbard,

Associate Commissioner for Policy Coordination.

[FR Doc. 98–23403 Filed 8–31–98; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 97N–0385]

Agency Information Collection Activities; Submission for OMB Review; Comment Request

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that the proposed collection of information listed below 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: Submit written comments on the collection of information by October 1, 1998.

ADDRESSES: Submit written comments on the collection of information to the Office of Information and Regulatory Affairs, OMB, New Executive Office Bldg., 725 17th St. NW., rm. 10235, Washington, DC 20503, Attn: Desk Officer for FDA.

FOR FURTHER INFORMATION CONTACT: Margaret R. Schlosburg, Office of Information Resources Management (HFA–250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–1223.

SUPPLEMENTARY INFORMATION: In compliance with section 3507 of the PRA (44 U.S.C. 3507), FDA has submitted the following proposed collection of information to OMB for review and clearance.

Supplements to Premarket Approval Applications for Medical Devices

The Food and Drug Administration Modernization Act of 1997 (FDAMA) (Pub. L. 105–115) added section 515(d)(6) to the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 360e(d)(6)), modifying FDA's statutory authority regarding premarket approval of medical devices. This new section provides for an alternate form of notice to the agency for certain types of changes to a device for which the manufacturer has an approved premarket approval application (PMA). Under section 515(d)(6) of the act, PMA supplements are required for all changes that affect safety and effectiveness, unless such changes involve modifications to manufacturing procedures or the method of manufacture. For those types of manufacturing changes, the manufacturer may submit to the agency an alternate form of notice in the form of a 30-day notice, or where FDA finds such notice inadequate, a 135-day PMA supplement. The 30-day notice must: (1) Describe the change the manufacturer intends to make, (2) summarize the data or information supporting the change, and (3) state that the change has been made in accordance with the requirements of 21 CFR part 820.

The manufacturer may distribute the device 30 days after FDA receives the notice, unless FDA notifies the applicant, within that 30-day period, that the notice is inadequate. If the notice is inadequate, FDA will inform the manufacturer that a 135-day supplement is required and will describe what additional information or action is necessary for FDA to approve the change. The rule would incorporate the provisions for a 30-day notice and 135-day supplements into FDA's regulations in § 814.39 (21 CFR 814.39) to reflect the changes made by FDAMA.

Description of Respondents: Businesses or other for profit organizations.

The information collection for § 814.39 has been approved by OMB until September 30, 1998, under Premarket Approval of Medical Devices (OMB control number 0910–0231) for a total of 36,063 hours. FDA believes that the submission of 30-day notices in lieu of PMA supplements will result in approximately a 10 percent reduction in the total number of hours needed to comply with § 814.39. As a result, FDA estimates that the new total number of hours needed to comply with the information collection requirements in § 814.39 is 32,612 for a reduction of 3,451 hours.

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

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN[1]

21 CFR Section	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
814.39	493	1	493	66.15	32,612

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