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 enrolled in the study and will not violate the subject's rights.

The likely respondents to this information collection will primarily be medical device manufacturers, investigators, hospitals, health maintenance organizations, and businesses.

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

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN

21 CFR Section	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
812.10 (waiver requests)	0.0	0.0	0.0	0.50[1]	0.1[2]
812.20, 812.25, and 812.27 (original application)	500	0.428	214	80	17,120
812.35 and 812.150 (amendments and supplements)	500	6.86	3,430	6	20,580
Total					37,700

There are no capital costs or operating and maintenance costs associated with this collection of information.
[1] FDA's best estimate given the fact that no waiver request has ever been submitted.
[2] FDA's best estimate given the fact that no sponsor has submitted such a request between fiscal years 1991 and 1995.

Based on past conversations with manufacturers, industry and trade association representatives, and businesses, FDA has estimated that the annual reporting burden for one IDE original application takes approximately 80 hours to complete, and the annual reporting burden for one IDE amendment and supplement takes approximately 6 hours to complete. The number of respondents who annually respond to this collection of information has decreased from 700 to 500, due to multiple applications received from each respondent.

Based on an average of IDE's submitted from fiscal years 1991 through 1995, approximately 500 respondents submit IDE applications (originals and supplements) annually. Based on data from fiscal years 1991 to 1995, an average of 214 original IDE applications are submitted annually.

The reporting burden for nonsignificant risk device studies is negligible. Normally, nonsignificant risk device studies are not reported to FDA unless a problem is reported such as an unanticipated adverse device reaction, failure to obtain informed consent, withdrawal of IRB approval, or a recall of a device. In the past, an average of 10 incidences or less annually have been reported to FDA.

TABLE 2.—ESTIMATED ANNUAL RECORDKEEPING BURDEN

21 CFR Section	No. of Recordkeepers	Annual Frequency per Recordkeeping	Total Annual Records	Hours per Recordkeeper	Total Hours
812.140 (original and supplement)	500	0.428	214	10	2,140
		6.86	3,430	1	3,430
812.140 (nonsignificant)	500	1	500	6	3,000
Total					8,570

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

Over the past several years, in conversations with manufacturers, industry trade association groups, and businesses, FDA has estimated that the recordkeeping burden for preparing an original IDE submission averages 10 hours for each original IDE submission. Similarly, through the same conversations mentioned above, FDA has estimated recordkeeping for each supplement requires 1 hour.

The recordkeeping burden for nonsignificant risk device investigations is difficult to estimate because nonsignificant risk device investigations are not required to be submitted to FDA. The IDE staff estimates that the number of nonsignificant risk device investigations is equal to the number of active significant risk device investigations. The recordkeeping burden, however, is reduced for nonsignificant risk device studies.

Dated: July 7, 1997.

William K. Hubbard,

Associate Commissioner for Policy Coordination.

[FR Doc. 97–18593 Filed 7-15-97; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 97N–0264]

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 August 15, 1997.

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: Judith V. Bigelow, Office of Information Resources Management (HFA–250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–1479.

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.

Information Required in a Premarket Notification Submission (21 CFR 807.87, 807.92, and 807.93) (OMB Control Number 0910–0281—Reinstatement)

Under section 510(k) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360(k)), a premarket notification must be filed before the introduction or delivery for introduction of a device intended for human use. Under § 807.87 (21 CFR 807.87), premarket notifications are required to contain certain information, including the device name, establishment registration number, class of the device, the device's proposed labeling, action taken by the person required to register to comply with performance standards, and a 510(k) summary as described in § 807.92 (21 CFR 807.92) or a 510(k) statement as described in § 807.93 (21 CFR 807.93). In addition, § 807.87(i) requires that those filing premarket notification who claim substantial equivalence to certain devices as described in § 807.87(i), that are classified into class III, must submit to FDA a summary of safety and effectiveness problems and a citation to the information upon which the summary is based. The premarket notification submitter must also furnish FDA with a certification that a reasonable search has been conducted of all known information.

The information collected in the premarket notification is necessary to enhance FDA's ability to ensure that only premarket notification submissions for devices that are as safe and as effective as legally marketed predicate devices are cleared for marketing. In addition, FDA makes publicly available this information concerning devices for which a marketing order has been issued, in order to provide to the public the agency's basis for equivalence determinations.

Respondents to this collection of information are medical device manufacturers and distributors.

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

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN

21 CFR Section	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
807.87(h) and 807.92 (simple 510(k) summaries)	2,592	1	2,592	8	20,736
807.87(h) and 807.92 (complex 510(k) summaries)	247	1	247	12	2,964
807.87(h) and 807.93 (510(k) statements)	2,896	1	2,896	1	2,896
807.87(i) and 807.94 (certifications)	208	1	208	40	8,320
Total					34,916

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

FDA bases these estimates on conversations with industry and trade association representatives, and from internal review of the documents listed in the table above.

Under § 807.93, anyone submitting a 510(k) statement must make that information available to anyone who requests it.

TABLE 2.—ESTIMATED ANNUAL RECORDKEEPING BURDEN

21 CFR Section	No. of Recordkeepers	Annual Frequency per Recordkeeping	Total Annual Records	Hours per Recordkeeper	Total Hours
807.93	2,896	10	28,960	0.5	14,480
Total					14,480

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

Dated: July 7, 1997.

William K. Hubbard,

Associate Commissioner for Policy Coordination.

[FR Doc. 97–18595 Filed 7-15-97; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 97N–0129]

Agency Information Collection Activities; Announcement of OMB Approval

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a collection of information entitled ''FDA Safety Alert/Public Health Advisory Readership Survey'' has been approved by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995.

FOR FURTHER INFORMATION CONTACT: Margaret R. Wolff, 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 April 21, 1997 (62 FR 19323), the agency announced that the proposed information collection had been submitted to OMB for review and clearance under section 3507 of the Paperwork Reduction Act of 1995 (44 U.S.C. 3507). OMB has now approved the information collection and has assigned OMB control number 0910–