Dated: July 7, 1997.

William K. Hubbard,

Associate Commissioner for Policy Coordination.

[FR Doc. 97–18592 Filed 7–15–97; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 97N–0265]

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, Attention: 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, rm. 16B–19, 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.

Investigational Device Exemptions Reports and Records (21 CFR Part 812) (OMB Control Number 0910–0078—Reinstatement)

This information is collected under the statutory authority of the Federal Food, Drug, and Cosmetic Act (the act) regarding investigational devices (section 520(g) (21 U.S.C. 360j(g))). An investigational device exemption (IDE) allows a device, which would otherwise be subject to provisions of the act such as premarket notification or premarket approval, to be used in investigations involving human subjects in which the safety and effectiveness of the device is being studied. The purpose of this section, as explained in part 812 (21 CFR part 812) in § 812.1, is to encourage, to the extent consistent with the protection of public health and safety and with ethical standards, the discovery and development of useful devices intended for human use. Under §§ 812.20, 812.25, and 812.27, information collected in the application includes sponsor information; a report of prior investigations including reports of all prior clinical, animal, and laboratory testing of the device, a bibliography of all publications, and a summary of all other unpublished information; an investigational plan including study, purpose, protocol, risk analysis, device description, and monitoring procedures; a description of the methods, facilities, and controls used for the manufacture, processing, packing, and storage of the device; investigator information including agreements and certifications; institutional review board (IRB) information; information on the amount to be charged for the device; device labeling; and informed consent materials.

Section 812.10, regarding waiver of IDE requirements, states that if a sponsor does not wish to comply with certain requirements of part 812, the sponsor may voluntarily submit a waiver request.

Under § 812.35, when an investigational plan changes, a sponsor is required to submit a supplemental application to FDA, and the sponsor may not begin a part of an investigation at a facility until the IRB has approved the investigation, FDA has received the certification of IRB approval, and FDA has approved the supplemental application relating to that part of the investigation.

Section 812.140 requires investigators to maintain records, including correspondence and reports concerning the study; records of receipt, use or disposition of devices; records of each subject's case history and exposure to the device; informed consent documentation; study protocol and documentation of any deviation from the protocol. Sponsors are required, under the same section, to maintain records including correspondence and reports concerning the study; records of shipment and disposition; signed investigator agreements; adverse device effects information; and, if of nonsignificant risk, an explanation of nonsignificant risk determination, records on device name and intended use, study objectives, investigator information, IRB information, and statement on the extent that good manufacturing practices will be followed.

Section 812.150 requires investigators to submit reports on unanticipated adverse device effects, withdrawal of IRB approval, progress reports, deviations from investigational plan, failure to obtain informed consent, and final report. Sponsors are required to submit reports on unanticipated adverse device effects, withdrawal of IRB approval, withdrawal of FDA approval, current investigator lists, progress reports, notification of recall and device disposition, final report, failure to obtain informed consent, and significant risk device determination.

The following parts of the IDE regulations are covered by other sections of part 812, and thus are not mentioned as separate reporting or recordkeeping burden requirements. The requirements for § 812.18, regarding import and export requirements for IDE's, are already covered under § 812.20(b)(1). Section 812.18 states that foreign companies are required to be sponsored by a U.S. agent, whose identity is required under the IDE application. This is not an additional information collection, and a separate requirement for information is not essential just because this is an imported device. Sections 812.40, 812.45, and 812.46, regarding the general responsibilities of sponsors, are described under §§ 812.20, regarding actual application and 812.150, regarding recordkeeping.

Section 812.5, regarding the labeling of investigational devices, is included under § 812.20(b)(10), where the submitter is required to enclose a copy of the label that bears information required by § 812.5 (i.e., name and place of business of manufacturer, packer, or distributor, the quantity of contents if appropriate, and the following statement: ''CAUTION—Investigational device. Limited by Federal (or United States) law to investigational use''). This label shall describe all relevant contraindications, hazards, adverse effects, interfering substances or devices, warnings, and precautions. The label will also not bear any statement that is false or misleading in any particular and shall not represent that the device is safe or effective for the purposes for which it is being investigated. If the device is being used solely for animal research, the label shall bear the following statement: ''CAUTION—Device for investigational use in laboratory animals or other tests that do not involve human subjects.'' This section's burden is required under § 812.20(b)(10), therefore a separate burden estimate is not required.

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,

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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).

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