Families is soliciting public comment on the specific aspects of the information collection described above. Copies of the proposed collection of information can be obtained and comments may be forwarded by writing to the Administration for Children and Families, Office of Information Services, 370 L'Enfant Promenade, SW., Washington, DC 20447, Attn: ACF Report Clearance Officer. All requests should be identified by the title of the information collection.

The Department specifically requests comments on: (a) Whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the proposed collection of information; (c) the quality, utility, and clarity of the information to be collection; and (3) ways to minimize the burden of the collection information on respondents, including through the use of automated collection techniques or other forms of information technology. Consideration will be given to comments and suggestions within 60 days of this publication.

Dated: June 19, 2001.

Bob Sargis,

Reports Clearance Officer.

[FR Doc. 01–15802 Filed 5–22–01; 8:45 am]

BILLING CODE 4184–01–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 01D–0129]

Agency Information Collection Activities; Submission for OMB Review; Comment Request; Implementation of the Biomaterials Access Assurance Act of 1998

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.

DATES: Submit written comments on the collection of information by July 25, 2001.

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: Wendy Taylor, Desk Officer for FDA.

FOR FURTHER INFORMATION CONTACT: Peggy 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 44 U.S.C. 3507, FDA has submitted the following proposed collection of information to OMB for review and clearance.

Implementation of the Biomaterials Access Assurance Act of 1998

The Biomaterials Access Assurance Act of 1998 (BAA98) (21 U.S.C. 1601–1606) establishes a mechanism to protect biomaterial suppliers of implanted medical devices from liability in civil actions. BAA98 includes exceptions for when protection from liability is not available to suppliers. One of those exceptions is when a supplier acts as a manufacturer of the implanted device. BAA98 says that a biomaterials supplier may be considered a manufacturer of a medical device if the supplier is the subject of an FDA declaration that the supplier was required to register under section 510 of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 360) and failed to do so, or was required to list its device under section 520(j) of the act (21 U.S.C. 360(j)) and failed to do so.

BAA98 allows persons to petition FDA for a declaration that a biomaterials supplier should have registered its establishment or listed its device with FDA, and failed to do so. Petitioners are requested to include information about the prerequisites for filing a petition. This information includes the following: (1) A civil suit has been filed in State or Federal court alleging that an implant directly or indirectly caused harm; (2) the suit was filed after August 13, 1998; and (3) the manufacturer of the implant was named as a party to the civil action. Petitioners are also requested to include information to identify the following: (1) The final product and how it is intended to be used, (2) the activities the supplier performs on the device, and (3) the name as well as type of entity or person to which the supplier sends the device. These draft reporting requirements are intended to provide FDA with sufficient information to show that the prerequisites for filing the petition are met and determine whether a biomaterial supplier should have registered its establishment or listed its device with FDA, and failed to do so.

In the **Federal Register** of April 2, 2001 (66 FR 17562), the agency requested comments on the proposed collection of information. No comments were received.

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

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN[1]

No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
5	1	5	1	5

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

BAA98 became effective August 13, 1998. Up until the current date, no petitions for declaration have been filed with FDA. However, FDA believes that in future years a handful (estimated at 5) of petitioners may file with the agency. FDA estimates that respondents would take approximately 1 hour to gather the requisite information and draft a petition. The likely respondents to this collection of information are persons involved in civil actions based on harm arising from an implanted medical device.

Dated: June 18, 2001.

Margaret M. Dotzel,

Associate Commissioner for Policy.

[FR Doc. 01–15780 Filed 6–22–01; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 01N–0132]

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

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.

DATES: Submit written comments on the collection of information by July 25, 2001.

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: Wendy Taylor, Desk Officer for FDA.

FOR FURTHER INFORMATION CONTACT: Karen L. Nelson, Office of Information Resources Management (HFA–250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–1482.

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

Institutional Review Boards (OMB Control Number 0910–0130)—Extension

When reviewing clinical research studies regulated by FDA, IRBs are required to create and maintain records describing their operations, and make the records available for FDA inspection when requested. These records include: Written procedures describing the structure and membership of the IRB and the methods which the IRB will use in performing its functions; the research protocols, informed consent documents, progress reports, and reports of injuries to subjects submitted by investigators to the IRB; minutes of meetings showing attendance, votes and decisions made by the IRB, the number of votes on each decision for, against, and abstaining, the basis for requiring changes in or disapproving research; records of continuing review activities; copies of all correspondence between investigators and the IRB; statement of significant new findings provided to subjects of the research; and a list of IRB members by name, showing each member's earned degrees, representative capacity, and experience in sufficient detail to describe each member's contributions to the IRBs deliberations, and any employment relationship between each member and the IRBs institution. This information is used by FDA in conducting audit inspections of IRBs to determine whether IRBs and clinical investigators are providing adequate protections to human subjects participating in clinical research.

In the **Federal Register** of March 30, 2001 (66 FR 17427), the agency requested comments on the proposed collection of information. There were no comments received.

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

TABLE 1.—ESTIMATED ANNUAL RECORDKEEPING BURDEN[1]

21 CFR Section	No. of Recordkeepers	Annual Frequency per Recordkeeping	Total Annual Records	Hours per Recordkeeper	Total Hours
56.115	2,000	14.6	29,200	4.5	131,400
Total					131,400

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

The recordkeeping requirement burden is based on the following formula: Approximately 2,000 IRBs review FDA-regulated research involving human subjects annually. The burden for each of the paragraphs under § 56.115 has been considered as one for the purpose of estimating the burden. Each paragraph cannot reasonably be segregated from one another because all are interrelated. FDA has about 2,000 IRBs in its inventory. The 2,000 IRBs meet on an average of 14.6 times annually. The agency estimates that approximately 4.5 hours of person time per meeting are required to transcribe and type the minutes of the meeting; to maintain records of continuing review activities; and to make copies of all correspondence between the IRB and investigator's member records, and written IRB procedures which are approximately five pages per IRB.

In the **Federal Register** of June 9, 1998 (63 FR 31502), the agency requested comments on the proposed collections of information. No significant comments were received.

Dated: June 18, 2001.

Margaret M. Dotzel,

Associate Commissioner for Policy.

[FR Doc. 01–15781 Filed 6–22–01; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Substance Abuse and Mental Health Services Administration

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

Periodically, the Substance Abuse and Mental Health Services Administration (SAMHSA) will publish a list of information collection requests under OMB review, in compliance with the Paperwork Reduction Act (44 U.S.C. Chapter 35). To request a copy of these documents, call the SAMHSA Reports Clearance Officer on (301) 443–7978.

Participant Feedback on Training Under the Cooperative Agreement for Mental Health Care Provider Education in HIV/AIDS Program II (OMB No. 0930–0195, Extension)—The Substance Abuse and Mental Health Services Administration's (SAMHSA) Center for Mental Health Services (CMHS) intends to continue to conduct a multi-site assessment of its Cooperative Agreement for Mental Health Care Provider Education in HIV/AIDS Program II until the end of the sites' expenditure of Program II funds (anticipated end date of September 2002). The education programs funded under this cooperative agreement are