

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

SMB

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[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.

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**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 *[insert date 30 days after date of publication in the Federal Register]*.

**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:

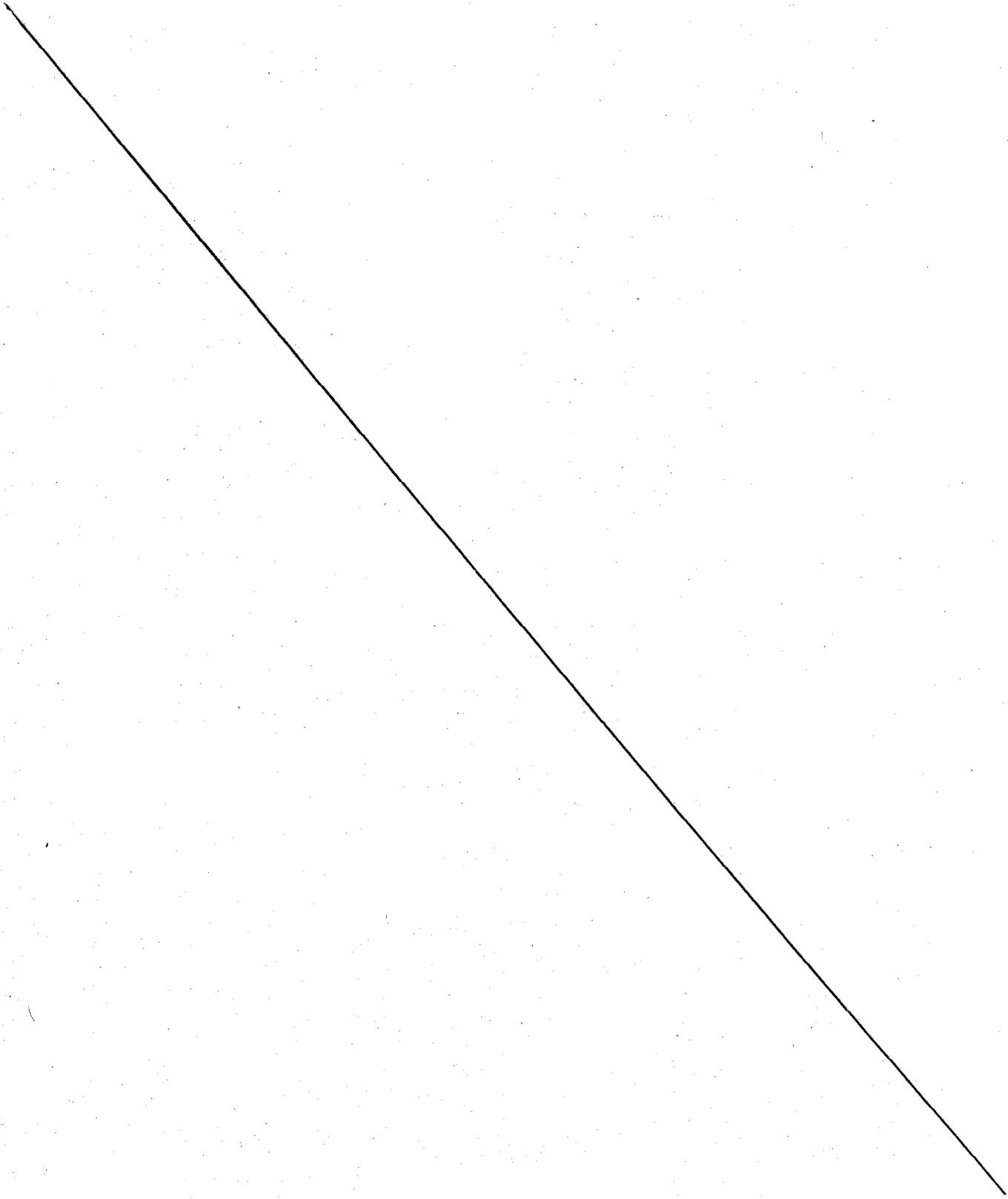
TABLE 1.—ESTIMATED ANNUAL RECORDKEEPING BURDEN<sup>1</sup>

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

<sup>1</sup> There are no capital costs or operating and maintenance costs associated with this collection of information.

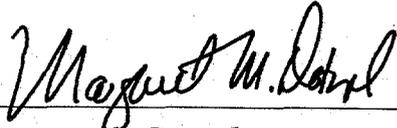
The recordkeeping requirement burden is based on the following formula: Approximately 2,000 IRBs review FDA-regulated research involving human subjects annually. The burden for each of the paragraphs under § 56.115 has been considered as one for the purpose of estimating the burden. Each paragraph cannot 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: 6/18/01  
June 18, 2001.



Margaret M. Dotzel,  
Associate Commissioner for Policy.

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