comments and recommendations for the proposed information collection should be sent directly to the OMB desk officer designated above at the following address: Human Resources and Housing Branch, Office of Management and Budget, New Executive Office Building, Room 10235, 725 17th Street, N.W., Washington, D.C. 20503.

Comments may also be sent to Cynthia Agens Bauer, OS Reports Clearance Officer, Room 503H, Humphrey Building, 200 Independence Avenue S.W., Washington, DC, 20201. Written comments should be received within 30 days of this notice.

Dated: January 16, 1998.

Dennis P. Williams,

Deputy Assistant Secretary, Budget.

[FR Doc. 98–1845 Filed 1–26–98; 8:45 am]

BILLING CODE 4150–04–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Office of the Secretary

Notice of Interest Rate on Overdue Debts

Section 30.13 of the Department of Health and Human Services' claims collection regulations (45 CFR Part 30) provides that the Secretary shall charge an annual rate of interest as fixed by the Secretary of the Treasury after taking into consideration private consumer rates of interest prevailing on the date that HHS becomes entitled to recovery. The rate generally cannot be lower than the Department of Treasury's current value of funds rate or the applicable rate determined from the ''Schedule of Certified Interest Rates with Range of Maturities.'' This rate may be revised quarterly by the Secretary of the Treasury and shall be published quarterly by the Department of Health and Human Services in the **Federal Register**.

The Secretary of the Treasury has certified a rate of 14½% for the quarter ended December 31, 1997. This interest rate will remain in effect until such time as the Secretary of the Treasury notifies HHS of any change.

Dated: January 20, 1998.

George Strader,

Deputy Assistant Secretary, Finance.

[FR Doc. 98–1844 Filed 1–26–98; 8:45 am]

BILLING CODE 4150–04–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Committee on Vital and Health Statistics: Meeting

Pursuant to the Federal Advisory Committee Act, the Department of Health and Human Services announces the following advisory committee meeting.

Name: National Committee on Vital and Health Statistics (NCVHS), Subcommittee on Population-Specific Issues.

Times and Dates: 9:00 a.m.–5:00 p.m., February 9, 1998; 9:00 a.m.–4:00 p.m., February 10, 1998.

Place: Wyndam Metro Center Hotel, 10220 North Metro Parkway East, Phoenix, Arizona.

Status: Open.

Purpose: The Subcommittee is in the process of examining a number of data needs and issues associated with Medicaid managed care. The purpose of this site visit to Arizona is to obtain information on one State's Medicaid managed care program, with special attention to data needs, data systems, data uses and data issues. Presentations are planned involving representatives of State agencies, providers, plans, and patient advocacy groups who will describe their data needs and issues relating to Medicaid managed care. A subsequent site visit to Massachusetts also is planned.

Contact Person for more Information: Substantive program information as well as a roster of committee members may be obtained from Carolyn Rimes, lead Subcommittee staff, Health Care Financing Administration, DHHS, 7500 Security Boulevard, C–3–21–06, Baltimore, Maryland 21244–1850, telephone (410) 786–6620, or Marjorie S. Greenberg, Executive Secretary, NCVHS, NCHS, CDC, Room 1100, Presidential Building, 6525 Belcrest Road, Hyattsville, Maryland 20782, telephone 301/436–7050. Additional information about the full Committee is available on the NCVHS website, where the tentative agenda for the Subcommittee meeting will also be posted when available: http://aspe.os.dhhs.gov/ncvhs

Dated: January 20, 1998.

James Scanlon,

Director, Division of Data Policy.

[FR Doc. 98–1843 Filed 1–26–98; 8:45 am]

BILLING CODE 4151–04–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 97N–0535]

Agency Information Collection Activities: Institutional Review Boards: Proposed Collection; Comment Request

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing an opportunity for public comment on the proposed collection of certain information by the agency. Under the Paperwork Reduction Act of 1995 (the PRA), Federal agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, and to allow 60 days for public comment in response to the notice. This notice solicits comments on FDA's protection of human subjects recordkeeping and reporting requirements for institutional review boards (IRB's). IRB's are groups composed of members of varying backgrounds which are charged with reviewing the ethics and risk/benefit aspects of clinical studies involving human subjects to assure that the rights and welfare of human subjects are adequately protected.

DATES: Submit written comments on the collection of information by March 30, 1998.

ADDRESSES: Submit written comments on the collection of information to the Dockets Management Branch (HFA–305), Food and Drug Administration, 12420 Parklawn Dr., rm. 1–23, Rockville, MD 20857. All comments should be identified with the docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: JonnaLynn P. Capezzuto, Office of Information Resources Management (HFA–250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–4659.

SUPPLEMENTARY INFORMATION: Under the PRA (44 U.S.C. 3501–3520), Federal agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. ''Collection of information'' is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA (44 U.S.C. 3506(c)(2)(A)) requires Federal agencies to provide a 60-day notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, before submitting the collection to OMB for approval. To comply with this requirement, FDA is publishing notice of the proposed collection of information listed below.

With respect to the following collection of information, FDA invites comments on: (1) Whether the proposed collection of information is necessary for the proper performance of FDA's functions, including whether the information will have practical utility; (2) the accuracy of FDA's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology.

Institutional Review Boards—(21 CFR Part 56.115)—(OMB Control Number 0910–0130)—Extension

When reviewing clinical research studies regulated by FDA, IRB's are required to create and maintain records describing their operations, and make the records available for FDA inspection when requested. These records include: (1) Written procedures describing the structure and membership of the IRB and the methods which the IRB will use in performing its functions; (2) the research protocols, informed consent documents, progress reports, and reports of injuries to subjects submitted by investigators to the IRB; (3) 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; (4) records of continuing review activities; (5) copies of all correspondence between investigators and the IRB; (6) statements of significant new findings provided to subjects of the research; (7) 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 IRB's deliberations, and any employment relationship between each member and the IRB's institution. This information is used by the FDA in conducting audit inspections of IRB's to determine whether IRB's and clinical investigators are providing adequate protections to human subjects participating in clinical research.

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	10,000	65	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 IRB's review FDA-regulated research involving human subjects annually. The burden for each of the paragraphs under 21 CFR 56.115 has been considered as one for purposes of estimating the burden. Each paragraph cannot reasonably be segregated from one another because all are interrelated. FDA has about 2,000 IRB's in its inventory. The 2,000 IRB's meet on an average of 14.6 times annually. The mean number of IRB meetings per year was derived from a study conducted by the agency and published by the Office of Planning and Evaluation. 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, copies of all correspondence between the IRB and investigators, member records, and written IRB procedures which are approximately five pages per IRB.

Dated: January 20, 1998.

William K. Hubbard,

Associate Commissioner for Policy Coordination.

[FR Doc. 98–1944 Filed 1–26–98; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 96P–0316]

Determination That Minocycline Hydrochloride Tablets Were Not Withdrawn From Sale for Reasons of Safety or Effectiveness

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) has determined that minocycline hydrochloride tablets were not withdrawn from sale for reasons of safety or effectiveness. This determination will allow FDA to approve abbreviated new drug applications (ANDA's) for minocycline hydrochloride tablets.

FOR FURTHER INFORMATION CONTACT: Mary E. Catchings, Center for Drug Evaluation and Research (HFD–7), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–594–2041.

SUPPLEMENTARY INFORMATION: In 1984, Congress enacted the Drug Price Competition and Patent Term Restoration Act of 1984 (Pub. L. 98–417) (the 1984 amendments), which authorized the approval of duplicate versions of drug products approved under an ANDA procedure. ANDA sponsors must, with certain exceptions, show that the drug for which they are seeking approval contains the same active ingredient in the same strength and dosage form as the ''listed drug,'' which is a version of the drug that was previously approved under a new drug application (NDA). Sponsors of ANDA's do not have to repeat the extensive clinical testing otherwise necessary to gain approval of an NDA. The only clinical data required in an ANDA are data to show that the drug that is the subject of the ANDA is bioequivalent to the listed drug.

The 1984 amendments included what is now section 505(j)(6) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(j)(6)), which requires FDA to publish a list of all approved drugs. FDA publishes this list as part of the ''Approved Drug Products with Therapeutic Equivalence Evaluations,'' which is generally known as the ''Orange Book.'' Under FDA regulations, drugs are withdrawn from the list if the agency withdraws or suspends approval of the drug's NDA or ANDA for reasons of safety or effectiveness, or if FDA determines that the listed drug was withdrawn from sale for reasons of safety or effectiveness (21 CFR 314.162). Regulations also provide that the agency must make a determination as to