record keeping requirements in regulations including program announcements. This program announcement does not contain information collection requirements beyond those approved for ANA grant applications under the Program Narrative Statement by OMB.

J. Receipt of Applications

Applications must either be hand delivered or mailed to the address in Section F, The Application Process: Application Submission. The Administration for Native Americans cannot accommodate transmission of applications by fax or through other electronic media. Therefore, applications transmitted to ANA electronically will not be accepted regardless of date or time of submission and time of receipt. Videotapes and cassette tapes may not be included as part of a grant application for panel review.

Applications and related materials postmarked after the closing date will be classified as late.

1. Deadlines

- Mailed applications shall be considered as meeting an announced deadline if they are either received on or before the deadline date or sent on or before the deadline date and received by ACF in time for the independent review to: U.S. Department of Health and Human Services, Administration for Children and Families, Division of Discretionary Grants, 370 L'Enfant Promenade, SW., Mail Stop 6C–462, Washington, D.C. 20447.
- Applicants are cautioned to request a legibly dated U.S. Postal Service postmark or to obtain a legibly dated receipt from a commercial carrier or the U.S. Postal Service. Private metered postmarks shall not be acceptable as proof of timely mailing.
- Applications hand carried by applicants, applicant couriers, or by overnight/express mail couriers shall be considered as meeting an announced deadline if they are received on or before the deadline date or postmarked on or before the deadline date, Monday through Friday (excluding Federal holidays), between the hours of 8:00 am and 4:30 pm at: U.S. Department of Health and Human Services, Administration for Children and Families, Division of Discretionary Grants, ACF Mailroom, 2nd Floor Loading Dock, Aerospace Center, 901 D Street, S.W., Washington, D.C. 20024.

(Applicants are cautioned that express/overnight mail services do not always deliver as agreed.)

- ACF cannot accommodate transmission of applications by fax or through other electronic media. Therefore, applications transmitted to ACF electronically will not be accepted regardless of date or time of submission and time of receipt.
- No additional material will be accepted, or added to an application, unless it is postmarked by the deadline date.

2. Late Applications

Applications which do not meet the criteria above are considered late applications. ACF shall notify each late applicant that its application will not be considered in the current competition.

3. Extension of Deadlines

Administration for Children and Families may extend an application deadline for applicants affected by acts of God such as floods and hurricanes, or when there is a widespread disruption of the mails. A determination to extend or waive deadline requirements rests with the Chief Grants Management Officer.

(Catalog of Federal Domestic Assistance Program Numbers: 93.612 Native American Programs; and 93.587 Promoting the Survival and Continuing Vitality of Native American Languages)

Dated: December 31, 1997.

Gary N. Kimble,

Commissioner, Administration for Native Americans.

[FR Doc. 98–583 Filed 1–8–98; 8:45 am]

BILLING CODE 4184–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 97N–0532]

Agency Information Collection Activities: Proposed Collection; Radioactive Drug Research Committees; 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 a 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 reporting requirements related to radioactive drugs used in research.

DATES: Submit written comments on the collection of information by March 10, 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:

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: 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.

Radioactive Drugs for Certain Research Uses—(21 CFR 361.1)—(OMB Control Number 0910–0053—Extension)

Under sections 201, 505, and 701 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321, 355, and 371), FDA has the authority to issue regulations governing the use of radioactive drugs for basic informational research, Section 361.1 (21 CFR 361.1) sets forth specific regulations regarding the establishment and composition of Radioactive Drug Research Committees and their role in approving and monitoring research studies utilizing radiopharmaceuticals. No study involving any administration of a radioactive drug to research subjects is permitted without the authorization of an FDA approved Radioactive Drug Research Committee (§ 361.1(d)(7)). The type of research that may be undertaken with a radiopharmaceutical drug must be intended to obtain basic information and not to carry out a clinical trial. The types of basic research permitted are specified in the regulation, and includes studies of metabolism, human physiology, pathophysiology, or biochemistry.

Section 361.1(c)(2) requires that each Radioactive Drug Research Committee shall select a chairman, who shall sign all applications, minutes, and reports of the committee. Each committee shall meet at least once each quarter in which research activity has been authorized or conducted. Minutes shall be kept and shall include the numerical results of votes on protocols involving use in human subjects. Under § 361.1(c)(3), each Radioactive Drug Research Committee shall submit an annual report to the FDA. The annual report shall include the names and qualifications of the members of, and of any consultants used by, the Radioactive Drug Research Committee, and for each study conducted during the preceeding year, using FDA Form 2915.

Under § 361.1(d)(5), each investigator shall obtain the proper consent required under the regulations. Each female research subject of childbearing potential must state in writing that she is not pregnant, or on the basis of a pregnancy test to be confirmed are present.

Under § 361.1(d)(8), the investigator shall immediately report to the Radioactive Drug Research Committee all adverse effects associated with use of the drug, and the committee shall then report to the FDA all adverse reactions probably attributed to the use of the radioactive drug.

Section 361.1(f) sets forth labeling requirements for radioactive drugs. These requirements are not in the reporting burden estimate because they are information supplied by the Federal Government to the recipient for the purposes of disclosure to the public (5 CFR 1320.3(c)(2)). Types of research studies not permitted under this regulation are also specified, and include those ''intended for (the) immediate therapeutic, diagnostic, or similar purposes or to determine the safety and effectiveness of the drug in humans for such purposes (i.e., to carry out a clinical trial).'' These studies require filing of an investigational new drug application (IND) under 21 CFR 312.1 and the associated information collections are covered in OMB Approval 0190–0014.

The primary purpose of this collection of information is to determine if the research studies are being conducted in accordance with required regulations. If these studies were not reviewed, human subjects could be subjected to inappropriate radiation and/or safety risks. Respondents to this information collection are the chairperson(s) of each individual Radioactive Drug Research Committee, investigators, and participants in the studies.

The source of the burden estimates was a phone survey of three committee chairpersons who were selected from different geographical areas and of varying levels of Radioactive Drug Research Committee membership and activities. These chairpersons were asked for their assessment of time expended, cost and views on completing the necessary reporting forms.

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

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN [1]

21 CFR section	Form	No. of respondents	Annual frequency per response	Total annual responses	Hours per response	Total hours
361.1(c)(3)	FDA 2914	100	1.0	100	1.0	100
361.1(c)(3)	FDA 2915	62	3.5	217	3.75	814
361.1(d)(5)		62	3.5	217	0.1	22
361.1(d)(8)		62	3.5	217	0	0
Totals						936

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

TABLE 2.—ESTIMATED ANNUAL RECORDKEEPING BURDEN [1]

21 CFR section	Form	Number of recordkeepers	Annual frequency per recordkeeping	Hours per recordkeeper	Total hours
361.1(c)(2)	FDA 2914 and 2915	100	1 per qtr=4 per yr	10	1,000
Total					1,000

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

Dated: January 2, 1998.

William K. Hubbard,

Associate Commissioner for Policy Coordination.

[FR Doc. 98–590 Filed 1–8–98; 8:45 am]

BILLING CODE 4160–01–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Indian Health Service

Statement of Mission, Organization, Functions and Delegation of Authority

Part G, of the Statement of Organization, Functions, and Delegations of Authority of the Department of Health and Human Services, as amended at 60 FR 56606, November 9, 1995, and most recently amended at 61 FR 67048, December 19, 1996, is amended to reflect a realignment of the California Area Indian Health Service. The changes are as follows:

Delete the functional statements for the California Area Indian Health Service in their entirety and replace with the following:

Section GFG–00, California Area Indian Health Service—Mission

The California IHS provides a comprehensive health services delivery system for American Indians and Alaska Natives (AI/AN) with opportunity for maximum tribal involvement in developing and managing programs to meet their health needs. The goal of the California Area IHS is to raise the health level of the AI/AN people to the highest possible level.

Section GFG–10, Functions. Office of the Director (GFGA)

Provides overall direction and leadership for the California Area Indian Health Service (IHS) by: (1) Encouraging maximum consultation and participation by California Area tribes and tribal and urban Indian organizations in establishing the goals and objectives of the California Area IHS, and in developing the policies of the California Area IHS; (2) coordinates the California Area IHS activities and resources internally and externally with those of other Federal, State, local and privately funded health care programs to maximize quality health care services to tribal and urban Indians in the State of California; (3) ensuring compliance to the IHS guidelines and administrative procedures pertinent to Indian Self-Determination contracting processes and Tribal Self-Governance compacting; (4) assuring that Indian Tribes and Indian organizations are informed regarding pertinent health policy and program management issues and coordinates meetings and other communications with tribal delegations; (5) advocating for the health needs and concerns of American Indians and Alaska Natives (AI/AN); (6) developing and demonstrating methods and techniques for continuous improvement of health services management and delivery by California Area tribes and tribal and urban Indian organizations; (7) ensuring that the principles of Equal Employment Opportunity laws and the Civil Rights Act are applied in the management of the human resources of the California Area IHS, and (8) advises the Director, IHS, of issues and potential issues, relevant to the California Area, or to the IHS in general, and recommending and participating in actions to prevent or correct problems.

Office of Management Support (GFGAB)

(1) Provides advice to the Area Director and functional area managers on California Area IHS administrative and management policy and procedures requirements, delegations of authority, documenting the organizations and functions of the California Area IHS, personnel administration and management, and agency agreements management; (2) develops, recommends and implements processes for management accountability and the periodic assessment of managerial performance; (3) provides guidance and support to Area managers regarding resources, personal property, acquisition management; (4) provides a full complement of administrative services in support of the Area-wide health services delivery and management systems, i.e., forms management, travel management, communications management, supplies management, printing, mail management, etc.; (5) advises the Area Director and functional area managers on the civil service and commissioned corps personnel programs' administration and management requirements; (6) directs the personnel security and suitability clearance, and other ethics in employment programs, for the California Area IHS, and (7) provides advice, consultation, and assistance to tribal officials and tribal organizations on tribal health program personnel policy issues.

Resources Management Staff (GFGAB–1)

(1) Develops and submits the budget for the California Area IHS; (2) distributes, coordinates, and monitors resource allocations; (3) interprets policies, guidelines, manual issuances, and OMB circulars relevant to budget development, presentation and execution for the Area Director, functional area managers, and tribal and urban program officials; (4) directs the collection, review, and analysis of program and financial data to determine resource requirements; (5) recommends and coordinates Area budget execution; (6) maintains fund control; and (7) prepares reprogramming requests.

Acquisition Management Staff (GFGAB–2)

(1) Develops and recommends policies and procedures specific to acquisition operations in the California Area IHS that are consistent with higher echelon and government oversight agency policy issuances; (2) provides advice, technical consultation, and training to California Area managers and staff; (3) reviews and makes recommendations for approval/disapproval of contract-related documents such as: pre- and post-award documents, unauthorized commitments, procurement planning documents, Justification for Other Than Full and Open Competition, waivers, and deviations; (4) executes and administers contracts for the California Area IHS; (5) reviews, recommends, and issues delegations of acquisition authority in the California Area IHS, and (6) supports and maintains the IHS Contract Information System and controls entry of data into the HHS Contract Information System.

Office of Public Health (GFGAC)

(1) Provides leadership and consultation to tribal and urban public health programs on the IHS goals, objectives, policies, program standards, and priorities; (2) serves as the primary source of technical and policy advice to the Area Director, Area office staff, and tribal and urban health program officials on the full scope of clinical health care programs, including their quality assurance and preventive aspects, and tort claims; (3) participates in identifying and articulating the health needs of the AI/AN population in the State of California; (4) coordinates the availability and accessibility of Medicare and Medicaid programs, and other managed care programs' services, to AI/AN in the State of California; (5) provides consultation and technical support to tribal and urban public health programs including, but not limited to, dental services, diabetes and other chronic disease prevention, nutrition services, and nursing services, alcohol/substance abuse prevention and treatment, including the coordination of the Youth Regional Treatment Center