research and on informing public health policy?

c. Leadership: Are the center director and other senior investigators at the forefront of their respective fields? Do they have the experience and authority to organize, administer and direct the center?

d. Research projects: Are the specific research projects of exceptional scientific merit?

e. Innovation: Does the Center propose to develop novel concepts, approaches, measures or methods in basic research that will inform and guide health promotion and disease prevention? Are the aims original and innovative? Do the projects extend existing approaches or develop new methodologies or technologies?

f. Study Populations: The degree to which the applicant has met the CDC Policy requirements regarding the inclusion of women, ethnic, and racial groups in the proposed research. This includes:

(1) The proposed plan for the inclusion of both sexes and racial and ethnic minority populations for appropriate representation.

(2) The proposed justification when representation is limited or absent.

(3) A statement as to whether the design of the study is adequate to measure differences when warranted.

(4) A statement as to whether the plans for recruitment and outreach for study participants include the process of establishing partnerships with community(ies) and recognition of mutual benefits.

g. Human Subjects: When applicable, the adequacy of the proposed means for protecting human subjects.

h. Budget: Reasonableness of proposed budget.

3. Recruitment and Outreach (Promote Training)

a. Does the applicant include a research development component for new, mid-career or transitional professionals through research training and career development mechanisms?

b. To what extent are special efforts made to recruit minority professionals and students to the CEHS?

A second-level review will be conducted by a panel of senior Federal officials. The following will be considered in making funding decisions: (1) Results of the initial review, (2) program balance, and (3) availability of funds.

J. Other Requirements

Technical Reporting Requirements

Provide CDC with the original plus two copies of:

1. Annual progress reports due 30 days after the end of the budget period;

2. Financial status report, no more than 90 days after the end of the budget period, and;

3. Final financial report and performance report, no more than 90 days of the project.

Send all reports to the Grants Management Specialist identified in the ''Where to Obtain Additional Information'' section of this announcement.

The following additional requirements are applicable to this program. (See Addendum I)

AR–1 Human Subjects Requirements
AR–2 Requirements for Inclusion of Women and Racial Ethnic Minorities in Research
AR–9 Paperwork Reduction Act Requirements
AR–10 Smoke-Free Workplace Requirements
AR–11 Healthy People 2000
AR–12 Lobbying Restrictions

K. Authority and Catalog of Federal Domestic Assistance Number

This program is authorized under section 306 of the Public Health Service Act, 42 U.S.C. section 242k as amended. The Catalog of Federal Domestic Assistance number is 93.283.

L. Where to Obtain Additional Information

The application kit and program announcement can be downloaded from the CDC home page on the Internet: http://www.cdc.gov. (Click on funding).

To receive additional written information and to request an application kit, call 1–888–GRANTS4 (1–888–472–6874). You will be asked to leave your name, address, and phone number and will need to refer to Announcement 99119. You will receive a complete program description, information on application procedures, and application forms. CDC will not send application kits by facsimile or express mail. Please refer to Program Announcement 99119 when you request information.

If you have questions after reviewing the contents of all documents business management and technical assistance may be obtained from: Victoria Sepe, Grants Management Specialist, Grants Management Branch, Procurement and Grants Office, Announcement 99119, Centers for Disease Control and Prevention, Room 3000, 2920 Brandywine Road, Atlanta, GA 30341, telephone (770) 488–2721, Email address: vxw1@cdc.gov.

For programmatic technical assistance, contact: Jennifer Madans, Ph.D. and/or Audrey Burwell, MS, National Center for Health Statistics, 6525 Belcrest Road, Room 1140, Hyattsville, MD 20782, Phone: 301–436–7016, Phone: 301–436–7062, Email: JHM4@cdc.gov, Email: AZB2@cdc.gov.

For additional programmatic information, see also the NCHS home page on the Internet: http://www.cdc.gov/nchswww.

Dated: April 30, 1999.

John L. Williams,

Director, Procurement and Grants Office, Centers for Disease Control and Prevention (CDC).

[FR Doc. 99–11338 Filed 5–5–99; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

President's Committee on Mental Retardation; Notice of Meeting

AGENCY HOLDING THE MEETING: President's Committee on Mental Retardation.

TIME AND DATE: May 23, 1999—9:30 a.m.–5 p.m.

PLACE: Hilton New Orleans Riverside Hotel, New Orleans, Louisiana.

STATUS: Full Committee Meetings are open to the public. An interpreter for the deaf will be available upon advance request. All meeting sites are barrier free.

TO BE CONSIDERED: The Committee plans to discuss critical issues concerning Federal Policy, Federal Research and Demonstration, State Policy Collaboration, Minority and Cultural Diversity and Mission and Public Awareness, relating to individuals with mental retardation.

The PCMR acts in an advisory capacity to the President and the Secretary of the U.S. Department of Health and Human Services on a broad range of topics relating to programs, services, and supports for persons with mental retardation. The Committee, by Executive Order, is responsible for evaluating the adequacy of current practices in programs and supports for persons with mental retardation, and for reviewing legislative proposals that impact the quality of life that is experienced by citizens with mental retardation and their families.

CONTACT PERSON FOR MORE INFORMATION: Jane L. Browning, Room 701 Aerospace Building, 370 L'Enfant Promenade, S.W., Washington, D.C. 20447, (202) 619–0634.

Dated: April 30, 1999.

Jane L. Browning,

Executive Director, PCMR.

[FR Doc. 11403 Filed 5–5–99; 8:45 am]

BILLING CODE 4184–01–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 99N–1010]

Agency Information Collection Activities: Proposed Collection; Comment Request; Investigational New Drug Regulations

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 requirements governing applications for FDA's approval to market a new drug.

DATES: Submit written comments on the collection of information by July 6, 1998.

ADDRESSES: Submit written comments on the collection of information to the Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. All comments should be identified with the docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Karen 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 in this document.

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.

Investigational New Drug (IND) Regulations—21 CFR Part 312 (OMB Control Number 0910–0014—Extension)

FDA is requesting OMB approval for the reporting and recordkeeping requirements contained in FDA's regulation ''Investigational New Drug Application'' (part 312 (21 CFR part 312)). This regulation implements provisions of section 505(i) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 355(i)) to issue regulations under which the clinical investigation of the safety and effectiveness of unapproved new drugs and biological products can be conducted.

FDA is charged with implementing statutory requirements that drug products marketed in the United States be shown to be safe and effective, properly manufactured, and properly labeled for their intended uses. Section 505(a) of the act provides that a new drug may not be introduced or delivered for introduction into interstate commerce in the United States unless FDA has previously approved a new drug application (NDA). FDA approves an NDA only if the sponsor of the application first demonstrates that the drug is safe and effective for the conditions prescribed, recommended, or suggested in the product's labeling. Proof must consist, in part, of adequate and well-controlled studies, including studies in humans, that are conducted by qualified experts. The IND regulations establish reporting requirements that include an initial application as well as amendments to that application, reports on significant revisions of clinical investigation plans, and information on a drug's safety or effectiveness. In addition, the sponsor is required to give FDA an annual summary of the previous year's clinical experience. Submissions are reviewed by medical officers and other agency scientific reviewers assigned responsibility for overseeing the specific study. The IND regulations also contain recordkeeping requirements that pertain to the responsibilities of sponsors and investigators. The detail and complexity of these requirements are dictated by the scientific procedures and human subject safeguards that must be followed in the clinical tests of investigational new drugs.

The IND information collection requirements provide the means by which FDA can: (1) Monitor the safety of ongoing clinical investigations; (2) determine whether the clinical testing of a drug should be authorized; (3) ensure production of reliable data on the metabolism and pharmacological action of the drug in humans; (4) obtain timely information on adverse reactions to the drug; (5) obtain information on side effects associated with increasing doses; (6) obtain information on the drug's effectiveness; (7) ensure the design of well-controlled, scientifically valid studies; and (8) obtain other information pertinent to determining whether clinical testing should be continued and information related to the protection of human subjects. Without the information provided by industry in response to the IND regulations, FDA cannot authorize or monitor the clinical investigations which must be conducted prior to authorizing the sale and general use of new drugs. These reports enable FDA to monitor a study's progress, to assure subject safety, to assure that a study will be conducted ethically, and to increase the likelihood that the sponsor will conduct studies that will be useful in determining whether the drug should be marketed and available for use in medical practice.

The following two forms are required under part 312: Form FDA–1571 entitled ''Investigational New Drug Application.''A person who intends to conduct a clinical investigation submits this form to FDA. It includes: (1) A cover sheet containing background information on the sponsor and investigator; (2) a table of contents; (3) an introductory statement and general investigational plan; (4) an investigator's brochure describing the drug substance;