Federal Coal Mine & Safety Act of 1969), the Public Health Service has developed a nationwide autopsy program (NCWAS) for underground coal miners. The Consent Release and History Form is primarily used to obtain written authorization from the next-of-kin to perform an autopsy on the deceased miner. The study is a service program to aid surviving relatives in establishing eligibility for black lung compensation. Because a basic reason for the post-mortem exam is research (both epidemiological and clinical), included are a minimum of essential information regarding the deceased miner, his occupational history, and his smoking history. The data collected will be used by the staff at NIOSH for research purposes in defining the diagnostic criteria for coal workers' pneumoconiosis (black lung) and will be correlated with pathologic changes and x-ray findings.

It is estimated that only 5 minutes is required for the pathologist to put a statement on the invoice affirming that no other compensation is received for the autopsy. From past experience, it is estimated that 15 minutes is required for the next-of-kin to complete form CDC/NIOSH 2.6. In as much as an autopsy report is routinely completed by a pathologist, the only additional burden is the specific request of abstract of terminal illness and final diagnosis relating to pneumoconiosis. Therefore, only 5 minutes of additional burden is estimated for the autopsy report. The total annual burden hours are 62.5.

Respondents	Number of respondents	Number of responses/ respondent	Avg. burden of response (in hrs.)
Pathologist:			
Invoice	150	1	5/60
Report	150	1	5/60
Next-of-Kin	150	1	15/60

Dated: February 2, 2000.

Nancy Cheal,

Acting Associate Director for Policy, Planning and Evaluation, Centers for Disease Control and Prevention (CDC).

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BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[Program Announcement 00033]

Childhood Lead Poisoning Prevention Programs (CLPPP); Notice of Availability of Funds

A. Purpose

The Centers for Disease Control and Prevention (CDC) announces the availability of fiscal year (FY) 2000 funds for a cooperative agreement program for new State and competing continuation State and local programs to develop and improve Childhood Lead Poisoning Prevention activities which include building Statewide capacity to conduct surveillance of blood lead levels in children. This program addresses the ''Healthy People 2000'' priority area of Environmental Health.

The purpose of this program is to provide the impetus for the development, implementation, expansion, and evaluation of State and local childhood lead poisoning prevention program activities which include Statewide surveillance capacity to determine areas at high risk for lead exposure. Also, this cooperative agreement is to carry out the core public health functions of Assessment, Policy Development, and Assurance in childhood lead poisoning prevention programs.

Funding for this program will be to:

1. Develop and/or enhance a surveillance system that monitors all blood lead levels.

2. Assure screening of children who are potentially exposed to lead and follow-up care for children who are identified with elevated blood lead levels (BLLs).

3. Assure awareness and action among the general public and affected professionals in relation to preventing childhood lead poisoning.

4. Expand primary prevention of childhood lead poisoning in high-risk areas in collaboration with other government and community-based organizations.

As programs shift emphasis from providing direct screening and follow-up services to the core public health functions, cooperative agreement funds may be used to support and emphasize health department responsibilities to screen high risk children and provide appropriate follow-up services. This includes improving coalitions and partnerships; conducting better and more sophisticated assessments; developing and evaluating policies, program performance, and effectiveness based on established goals and objectives.

B. Eligible Applicants

Applicant eligibility is divided into Part A (New Applicants), Part B (Competing Continuation), and Part C (Supplemental Funding for Alternative Surveillance Assessment/Screening Recommendation Evaluation) defined in the following section. In the future, CDC plans to shift its program emphasis toward State funding for childhood lead poisoning prevention activities. However, the top five metropolitan statistical areas (SMSAs)/largest cities will be eligible for direct funding for childhood lead poisoning prevention activities indefinitely. They are New York City, Los Angeles, Chicago, Philadelphia, and Houston.

Part A: Eligible applicants are State health departments or other State health agencies or departments not currently funded by CDC and any eligible SMSA not currently receiving direct funding from CDC for childhood lead poisoning prevention activities. Also eligible are health departments or other official organizational authority (agency or instrumentality) of the District of Columbia, the Commonwealth of Puerto Rico, any territory or possession of the United States, and all federally-recognized Indian tribal governments. Please note: Local health departments are not eligible to apply for cooperative agreement funding under Part A of this program announcement.

Applicants encouraged to apply under Part A are: Alaska; Arkansas; Georgia; Hawaii; Idaho; Kansas; Kentucky; Mississippi; Nevada; North Dakota; Oklahoma; South Dakota; Tennessee; Texas and Wyoming.

Part B: Eligible applicants are those currently funded by the Centers for Disease Control and Prevention whose project period will expire June 30, 2000. These applicants are: Alabama; Arizona; California; Delaware; Detroit, MI; Houston, TX; Indiana; Iowa; Maine; Marion County, IN; Michigan; New Hampshire; Pinellas County, FL; Salt

Lake City, UT; Virginia and Westchester, NY. In the future, CDC plans to shift its program emphasis towards State and large metropolitan statistical areas (SMSAs) which includes Houston, TX funding for childhood lead poisoning prevention activities. Consequently, local applicants eligible for Part B will only receive funding for a two-year project period based on satisfactory program performance. These are Detroit, MI; Marion County, IN; Pinellas County, FL; Salt Lake City, UT; and Westchester, NY.

Part C: Eligible applicants are those State applicants that apply under Part B. Funding under Part C will only be considered if the Part B application: (1) Is successful and chosen for funding and (2) has met the program requirement of submitting data to CDC's national surveillance database.

Additional information for all State applicants. If a State agency applying for grant funds is other than the official State health department, written concurrence by the State health department must be provided (for example, the State environmental health agency).

C. Availability of Funds

Part A: New Applicants

Up to $2,500,000 will be available in FY 2000 to fund up to 8 new applicants. CDC anticipates that awards for the first budget year will range from $75,000 to $800,000.

Part B: Competing Continuations

Up to $8,000,000 will be available in FY 2000 to fund up to 17 competing continuation applicants. CDC anticipates that awards for the first budget year will range from $75,000 to $1,500,000.

Part C: Supplemental Studies

Up to $400,000 will be awarded in FY 2000 to fund up to 4 assessment/evaluation studies with a three-year project period. These funds will be awarded to support the development of alternative surveillance assessments and/or to conduct evaluation of the impact of lead screening recommendations. Awards are expected to range from $70,000 to $100,000, with the average award being approximately $85,000. Funds will be awarded for assessment/evaluation studies that address one of the following:

1. Alternative Surveillance Assessment—Assessment of lead exposure in a jurisdictional population or sub-population using an approach to surveillance that differs from the Statewide CBLS system described in this announcement.

2. Screening Recommendation Evaluation—Evaluation of the impact of lead screening recommendations on screening for high-risk children.

Funding for State applicants: To determine the type of program activities and the associated level of funding for an individual State applicant for Part A or Part B, please refer to the table below. These are suggested funding guidelines and should not be regarded as absolute funding limits. Addendum 2 in the application package provides an explanation of the factors used to develop categorical funding recommendations. Addendum 3 provides an explanation of the program activities required for each funding category.

Suggested Funding Categories Based on Projected Level of Effort Required To Provide Prevention and Surveillance Activies to a State Population

Alabama—2
Alaska—3
Arizona—3
Arkansas—2
California*—1
Colorado—3
Connecticut—2
Delaware—3
Florida*—3
Georgia—2
Hawaii—3
Idaho—3
Illinois—1
Indiana*—3
Iowa—2
Kansas—2
Kentucky*—3
Louisiana—2
Maine—3
Maryland—2
Massasschusette—2
Michigan*—2
Minnesota—2
Mississippi—2
Missouri—2
Montana—3
Nebraska—2
Nevada—3
N. Hampshire—3
New Jersey—2
New Mexico—3
New York*—2
N. Carolina—2
North Dakota—3
Ohio—1
Oklahoma—2
Oregon—3
Pennsylvania—1
Rhode Island—2
S. Carolina—2
South Dakota—2
Tennessee—2
Texas*—1
Utah*—3
Vermont—3
Virginia—2
Washington—2
West Virginia—2
Wisconsin—2
Wyoming—3

*Projected level of effort adjusted to account for currently funded locales.

Funding State Applicants—Part A or Part B: Determine your funding category (Category 1, 2, or 3) according to the table below. The range and average of awards for each funding category follows:

Category 1: $800,000–$1,500,000, average award $1,000,000
Category 2: $250,000–$800,000, average award $520,000
Category 3: $75,000–$250,000, average award $150,000

Awards for Local Applicants (under Part B only): The suggested range of awards for local applicants is $250,000 to $450,000.

Additional Information on Funding for all Applicants for Part A, Part B, and Part C New awards are expected to begin on or about July 1, 2000, and are made for 12-month budget periods within project periods not to exceed 2-years for local programs or 3-years for State programs. Estimates outlined above are subject to change based on the actual availability of funds and the scope and quality of applications received. Continuation awards within the project period will be made on the basis of satisfactory progress and availability of funds. Awards cannot supplant existing funding for CLPP or Supplemental Funding Initiatives. Funds should be used to enhance the level of expenditures from State, local, and other funding sources.

Note: Funds may not be expended for medical care and treatment or for environmental remediation of sources of lead exposure. However, the applicant must provide a plan to ensure that these program activities are carried out.

Not more than 10 percent (exclusive of Direct Assistance) of any cooperative agreement or contract through the cooperative agreement may be obligated for administrative costs. This 10 percent limitation is in lieu of, and replaces, the indirect cost rate.

D. Program Requirements

Special Requirement regarding Medicaid provider status of applicants: Pursuant to section 317A of the Public Health Service Act (42 U.S.C. 247b–1), as amended by Sec. 303 of the ''Preventive Health Amendments of 1992'' (Public Law 102–531), applicants AND current grantees must meet the

following requirements: For CLPP program services which are Medicaid-reimbursable in the applicant's State:

Applicants who directly provide these services must be enrolled with their State Medicaid agency as Medicaid providers.

Providers who enter into agreements with the applicant to provide such services must be enrolled with their State Medicaid agency as providers. An exception to this requirement will be made for providers whose services are provided free of charge and who accept no reimbursement from any third-party payer. Such providers who accept voluntary donations may still be exempted from this requirement.

In order to satisfy this program requirement, please provide a copy of a Medicaid provider certificate or Statement as proof that you meet this requirement. Failure to include this information would result in your application being returned. Please place this information immediately behind the budget and budget justification pages.

Cooperative Activities

Part A and Part B: New and Competing Continuations

To achieve the purpose of this cooperative agreement program, the recipient will be responsible for the activities listed under 1. Recipient Activities and CDC will be responsible for the activities listed under 2. CDC Activities.

1. Recipient Activities

a. Establish, maintain, or enhance a Statewide surveillance system in accordance with CDC guidance. For local applicants (under Part B), enhance a data management system that links with the State's surveillance system or develop an automated data management system to collect and maintain laboratory data on the results of blood lead analyses and data on follow-up care for children with elevated BLLs. State recipients should ensure receipt of data from local programs. Local recipients should transfer relevant data to the appropriate State entity in a timely manner for annual submission to CDC.

b. Manage, analyze and interpret individual State surveillance data, and present and disseminate trends and other important public health findings.

c. Develop, implement and evaluate a Statewide/jurisdiction-wide childhood blood lead screening plan consistent with CDC guidance provided in ''Screening Young Children for Lead Poisoning: Guidance for State and Local Public Health Officials''. For local applicants, participate in the Statewide planning process. Make screening recommendations and appropriate local screening strategies available and known to health care providers.

d. Assure appropriate follow-up care is provided for children identified with elevated blood lead levels.

e. Establish effective, well-defined working relationships within public health agencies and with other agencies and organizations at national, State, and community levels (*e.g.,* housing authorities; environmental agencies; maternal and child health programs; State Medicaid Early Periodic Screening, Diagnosis, and Treatment (EPSDT) programs; community and migrant health centers; community-based organizations providing health and social services in or near public housing units, as authorized under Section 330(i) of the PHS Act; State and local epidemiology programs; State and local housing rehabilitation programs; schools of public health and medical schools; and environmental interest groups).

f. For State Programs, provide managerial, technical, analytical, and program evaluation assistance to local agencies and organizations in developing or strengthening their CLPP programs activities.

2. CDC Activities

a. Provide technical, and scientific assistance and consultation on program development, implementation and operational issues.

b. Provide technical assistance and scientific consultation regarding the development and implementation of all surveillance activities including data collection methods and analysis of data.

c. Assist with data analysis and interpretation of individual State surveillance data and release of national reports. Reports will include analysis of national aggregate data as well as State-specific data.

d. Assist cooperative agreement recipients with communication and coordination among Federal agencies, and other public and private agencies and organizations.

e. Conduct ongoing assessment of program activities to ensure the use of effective and efficient implementation strategies.

Part C: Supplemental Studies

To achieve the purpose of this program, the recipient will be responsible for the activities listed under 1. Recipient Activities and CDC will be responsible for the activities listed under 2. CDC Activities.

1. Recipient Activities

a. Develop and implement a study protocol to include the following: methodology, sample selection, field operation, and statistical analysis. Applicants must provide a means of assuring that the results of the study will be published.

b. Revise, refine, and carry out the proposed methodology for conducting Supplemental Funding Studies.

c. Monitor and evaluate all aspects of the assessment activities.

d. Conduct and evaluate public health programs and/or have access to professionals who are knowledgeable in conducting such activities.

2. CDC Activities

a. Provide technical and scientific consultation on activities related to overall program requirements of supplemental funding activities.

b. Provide technical assistance to program manager and/or principal investigator regarding revision, refinement, and implementation of study design and proposed methodology for conducting supplemental funding activities.

c. Assist program manager and/or principal investigator with data interpretation and analysis issues.

E. Application Content

Use the information in the Program Requirements, Other Requirements, and Evaluation Criteria sections to develop the application content. Your application will be evaluated on the criteria listed, so it is important to follow them in laying out your program plan:

Applications must be developed in accordance with PHS Form 5161–1.

Part B applicants also competing for Part C funds must submit separate applications.

Application pages must be clearly numbered, and a complete index to the application and its appendices must be included. The original and two copies of the application set must be submitted UNSTAPLED and UNBOUND. All material must be typewritten, double spaced, printed on one side only, with unreduced font (10 or 12 point font only) on 8½″ by 11″ paper, and at least 1″ margins and heading and footers. All graphics, maps, overlays, etc., should be in black and white and meet the above criteria.

A one-page, single-spaced, typed abstract must be submitted with the application. The heading should include the title of the program, project title, organization, name and address, project director, telephone number, facsimile number, and e-mail address.

The main body of the CLPP program application (Parts A or B) must include the following: budget/budget justification; Medicaid certification; progress report (Part B applicants only); understanding the problem; surveillance/data-management activities; Statewide/jurisdiction-wide planning and collaboration; core public health functions; goals and objectives; program management and staffing; and program evaluation.

The main body of the supplemental funding project application (Part C) must include the following: study protocol, project personnel, and project management.

Each application should not exceed 75 pages. The abstract, budget narrative, and budget justification pages are not included in the 75 page limit. Supplemental information should be placed in appendices and is not to exceed 25 pages.

Part B applicants must submit a progress report no longer than 10 pages in their competing continuation application. This report should be placed immediately after the budget and budget justification.

Provide qualified staff, other resources, and knowledge to implement the provisions of the program. Applicants requesting cooperative agreement supported positions must provide assurances that such positions will be authorized to be filled by the applicant's personnel system.

F. Submission and Deadline

Submit the original and two copies of the PHS 5161–1 (OMB Number 0937–0189) on or before April 12, 1999. Forms are in the application kit.

Submit the application to: Mattie B. Jackson, Grants Management Specialist, Grants Management Branch, Procurement and Grants Office, Program Announcement 00033, Centers for Disease Control and Prevention (CDC), 2920 Brandywine Road, Room 3000, Atlanta, GA 30341–4146.

Applications shall be considered as meeting the deadline if they are either: (1) Received on or before the deadline date, or (2) sent on or before the deadline date and received in time for submission for the review process. Applicants must request a legibly dated receipt from a commercial carrier or U.S. Postal Service. Private metered postmarks shall not be acceptable as proof of timely mailing.

Applications which do not meet the criteria above are considered late applications. Late applications will not be considered in the current competition and will be returned to the applicant.

G. Evaluation Criteria

The review of applications will be conducted by an objective review panel as they relate to the applicant's response to either Part A, Part B, or Part C. The applications will be evaluated according to the following criteria:

Part A: New Applicants

1. Understanding of the Problem (15 points)

The extent to which the applicant's description and understanding of the burden and distribution of childhood lead exposure or elevated BLLs in their jurisdiction, using evidence (as available) of incidence and/or prevalence and demographic indicators, including a description of the Medicaid population.

2. Surveillance Activities (20 points)

The applicant's ability to develop a childhood blood lead surveillance system that includes; (a) a flow chart that describes data transfer, (b) a mechanism for tracking lead screening services to children, especially Medicaid children, and (c) a mechanism for reporting data annually to the CDC's national surveillance database. The clarity, feasibility, and scientific soundness of the surveillance approach. Also, the extent to which the proposed time table for accomplishing each activity and methods for evaluating each activity are appropriate and clearly defined. The following elements will be specifically evaluated:

a. How laboratories report Blood Lead Levels (BLLs), including ability to identify and assure reporting from private laboratories which perform lead testing.

b. How data will be collected and managed.

c. How quality of data and completeness of reporting will be assured.

d. How and when data will be analyzed.

e. How summary data will be reported and disseminated on a regular basis (*i.e.,* newsletters, fact sheets, annual reports).

f. Protocols for follow-up of individuals with elevated BLLs.

g. Provisions to obtain denominator data (results of all laboratory blood lead tests, regardless of level).

h. Time line and methods for evaluating the Childhood Blood Lead Surveillance (CBLS) approach.

i. Plans to convert paper-based components of the system to electronic data manipulation.

j. Use of data including evaluation of prevention activities, especially to target screening and prevention efforts.

3. Statewide Planning and Collaboration (20 points)

The applicant's ability to develop Statewide screening recommendations with appropriate local strategies. The following elements will be specifically evaluated:

a. The proposed approach to developing and carrying out an inclusive Statewide screening plan as outlined in ''Screening Young Children for Lead Poisoning: Guidance for State and Local Health Officials''.

b. The extent to which the applicant plans to utilize surveillance and program data to produce a Statewide screening recommendation, with specific attention given to the Medicaid population.

c. The ability of the applicant to involve collaborators in the development of a screening plan and implementation of strategies to strengthen childhood lead poisoning prevention activities.

d. The applicant's demonstrated ability to collaborate with principal partners, including managed-care organizations, State Medicaid agency, child health-care providers and provider groups, insurers, community-based organizations, housing agencies, and banking, real estate, and property-owner interests, must be demonstrated by letters of support, memoranda of understanding, contracts, or other documented evidence of relationships.

4. Capacity To Carry Out Public Health Core Functions (10 points)

The applicant's ability to describe the approach and activities necessary to achieve a balance among health department roles in CLPP, including assessment, program and policy development, and monitoring, evaluating, and ensuring the provision of all necessary components of a comprehensive CLPP activities within their respective categories.

5. Goals and Objectives (15 points)

The extent to which the applicant's goals and objectives relate to the CLPP activities in their respective categories. Objectives must be relevant, specific, measurable, achievable, and time-framed. There must be a formal work plan with a description of methods, a timetable and program staff responsible for accomplishment of each objective, and the evaluation of each proposed objective.

6. Project Management and Staffing (10 points)

The extent to which the applicant has documented the skills and ability to develop and carry out a comprehensive

CLLP program. Specifically, the applicant should:

a. Describe the proposed health department staff roles in CLPP, their specific responsibilities, and their level of effort and time. Include a plan to expedite filling of all positions and assure that requested positions have been or will be approved by applicant's personnel system.

b. Describe the plan to provide training and technical assistance to health department personnel and consultation to collaborators outside the health department, including proposed design of information-sharing systems.

7. Program Evaluation (10 points)

The extent to which the applicant proposes to measure the overall impact of health department CLPP activities. Specific criteria should include:

a. The plan for evaluating the impact or outcome of CLPP activities, including evaluation design, methods, and activities.

b. Description of how the project will assess changes in public policy and measure the effectiveness of collaborative activities.

c. Progress made in childhood lead poisoning prevention which resulted from planned health department strategies.

8. Budget justification (not scored)

The extent to which the budget is reasonable, clearly justified, and consistent with the intended use of funds.

Part B: Competing Continuations

1. Understanding of the Problem (15 points)

The extent to which the applicant's description and understanding of the burden and distribution of childhood lead exposure or elevated BLLs in their jurisdiction, using evidence (as available) of incidence and/or prevalence and demographic indicators, including a description of the Medicaid population.

2. Surveillance Activity (20 points)

For State Applicants: The applicant's ability to expand its childhood blood lead surveillance system that includes tracking lead screening for Medicaid children, evaluating the existing system, and reporting data to the CDC's national surveillance database. The clarity, feasibility, and scientific soundness of the surveillance approach. Also, the extent to which the proposed time table for accomplishing each activity are appropriate and clearly defined. The following elements will be specifically evaluated:

a. How laboratories report BLLs, including ability to identify and assure reporting from private laboratories which perform lead testing.

b. How data are collected and managed.

c. How quality of data and completeness of reporting are assured.

d. How and when data are analyzed.

e. How summary data are reported and disseminated on a regular basis (*i.e.,* newsletters, fact sheets, annual reports).

f. Protocols for follow-up of individuals with elevated BLLs.

g. Provisions to obtain denominator data (results of all laboratory blood lead tests, regardless of level).

h. Time line and methods for evaluating the Childhood Blood Lead Surveillance (CBLS) approach.

i. Process used to convert paper-based components of the system to electronic data.

j. Use of data including evaluation of prevention activities, especially to target screening and prevention efforts.

For local applicants (Part B only): The applicant's ability to expand their data management system, including the approach to participating in the State CBLS, if applicable. The clarity, feasibility, and scientific soundness of the approach to data management. Also, the extent to which the proposed schedule for accomplishing each activity and method for evaluating each activity are clearly defined and appropriate. The following elements will be specifically evaluated:

a. How laboratories report Blood Lead Levels (BLL), including ability to identify and assure reporting from private laboratories which perform lead testing.

b. How data are collected and managed.

c. How quality of data and completeness of reporting are assured.

d. How and when data are analyzed.

e. How summary data are reported and disseminated on a regular basis (*i.e.,* newsletters, fact sheets, annual reports).

f. Protocols for follow-up of individuals with elevated BLLs.

g. Provisions to obtain denominator data (results of all laboratory blood lead tests, regardless of level).

h. Time line and methods for evaluating the Childhood Blood Lead Surveillance (CBLS) approach.

i. Process used to convert paper-based components of the system to electronic data.

j. Use of data including evaluation of prevention activities, especially to target screening and prevention efforts.

3. Statewide/Jurisdiction-wide Planning and Collaboration (20 points)

The applicant's ability to develop Statewide/jurisdiction-wide screening recommendations with appropriate local strategies. The following elements will be specifically evaluated:

a. The approach to developing and carrying out an inclusive State-or jurisdiction-wide screening plan as outlined in ''Screening Young Children for Lead Poisoning: Guidance for State and Local Health Officials''.

b. The extent to which the applicant utilized surveillance and program data to produce Statewide/jurisdiction-wide screening recommendations and target the Medicaid population.

c. Description of how collaborations facilitated the development of a screening plan and strengthened childhood lead poisoning prevention strategies.

d. Evidence of collaboration with principal partners, including managed-care organizations, State Medicaid agency, child health-care providers and provider groups, insurers, community-based organizations, housing agencies, and banking, real-estate, and property-owner interests. These collaborations must be demonstrated by letters of support, memoranda of understanding, contracts, or other documented evidence of relationships.

Note: For applicants under Part B, describe progress in developing and implementing the screening plan based upon each of the elements listed above.

4. Capacity to Carry Out Public-Health Core Functions (10 points)

The ability to describe the approach and activities taken to achieve a balance among health-department roles in CLPP, including assessment, program and policy development, and monitoring, evaluating, and ensuring the provision of all CLPP activities within their respective categories (for example, Category 3 requires screening plans, surveillance systems, assure follow-up care, and evaluation).

5. Goals and Objectives (10 points)

The extent to which the applicant's goals and objectives relate to the CLPP activities in their respective categories under which they applied. Objectives must be relevant, specific, measurable, achievable, and time-framed. There must be a formal work plan with a description of methods and a timetable and program staff responsible for accomplishment of each objective.

6. Project Management and Staffing (10 points)

The extent to which the applicant has the skills and ability to develop and carry out a comprehensive CLLP program. Specifically the applicant should:

a. Describe the proposed health department staff roles in CLPP, their specific responsibilities, and their level of effort and time. Include a plan to expedite filling of all positions and assure that requested positions have been or will be approved by the applicant's personnel system.

b. Describe the plan to provide training and technical assistance to health department personnel and consultation to collaborators outside the health department, including proposed design of information-sharing systems.

7. Program Evaluation (10 points)

The extent to which the applicant measures the overall impact of health department CLPP activities. Specific criteria should include:

a. Description of the progress made to evaluate the impact and outcome of collective CLPP activities, including the evaluation design, methods, and tasks.

b. Description of the changes in the effectiveness of collaborative activities.

c. Progress made in childhood lead poisoning prevention which resulted from planned health department strategies.

8. Budget Justification (not scored)

The extent to which the budget is reasonable, clearly justified, and consistent with the intended use of funds.

Part C: Supplemental Funding—Factors To Be Considered

1. Study Protocol (45 points)

The applicant's ability to develop a scientifically sound protocol (including adequate sample size with power calculations), quality, feasibility, consistency with project goals, and soundness of the evaluation plan (which should provide sufficient detail regarding the way the protocol will be implemented). The degree to which the applicant has met the CDC policy requirements regarding the inclusion of women, ethnic, and racial groups in the proposed project. This includes: (a) the proposed plan to include of both sexes and racial and ethnic minority populations for appropriate representation; (b) the proposed justification when representation is limited or absent; (c) a Statement as to whether the design of the study is adequate to measure differences when warranted; and (d) a Statement as to whether the plans for recruitment and outreach for study participants includes establishing partnerships with community-based agencies and organizations. Benefits of the partnerships should be described.

2. Project Personnel (20 points)

The extent to which personnel involved in this project are qualified, including experience in conducting relevant studies. In addition, the applicant's ability to commit appropriate staff time needed to carry out the study.

3. Project Management (35 points)

The applicant's ability to implement and monitor the proposed study to include specific, attainable, and realistic goals and objectives, and evaluation plan.

4. Budget Justification (not scored)

The extent to which the budget is reasonable, clearly justified, and consistent with the intended use of cooperative agreement funds.

5. Human Subjects (not scored)

The extent to which the applicant complies with the Department of Health and Human Services regulations (45 CFR Part 46) on the protection of human subjects.

H. Other Requirements

Technical Reporting Requirements

Provide CDC with the original plus two copies of:

1. Quarterly progress reports, which are required of all grantees. The quarterly report narrative should not exceed 25 pages. Time lines for the quarterly reports will be established at the time of award, but are typically due 30 days after the end of each quarter.

2. Calendar year surveillance data and a written surveillance summary report must be submitted annually to CDC in the approved OMB format to be disseminated to State and local public health officials and congressional personnel. Data must be submitted to CDC by March 31st in the required format for analysis.

3. Financial Status Reports, are due within 90 days of the end of the budget period.

4. Final financial reports and performance reports are due within 90 days after the end of the project period.

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

Note: Data collection initiated under this cooperative agreement program has been approved by the Office of Management and Budget under OMB number (0920–0337), ''National Childhood Blood Lead Surveillance System'', Expiration Date: March 31, 2001.

The following additional requirements are applicable to this program. For a complete description of each, see Addendum 1 in the application package.

AR–1 Human Subjects Requirement
AR–2 Requirements for Inclusion of Women and Racial and Ethnic Minorities in Research
AR–7 Executive Order 12372 Review
AR–9 Paperwork Reduction Act Requirements
AR–10 Smoke-Free Workplace Requirements
AR–11 Healthy People 2000
AR–12 Lobbying Restrictions

I. Authority and Catalog of Federal Domestic Assistance Number

This program is authorized under sections 301(a), 317A and 317B of the Public Health Service Act [42 U.S.C. 241(a), 247b–1, and 247b–3], as amended. Program regulations are set forth in Title 42, Code of Federal Regulations, Part 51b. The Catalog of Federal Domestic Assistance number is 93.197.

J. Pre-Application Workshop for New and Competing Continuation Applicants

In addition, for interested applicants, a telephone conference call for pre-application technical assistance will be held on Wednesday, February 16, 2000, from 1:30 p.m. to 3:30 p.m, Eastern Standard Time. The bridge number for the conference call is 1–800–311–3437, and the pass code is 350892. For further information about all workshops, please contact Claudette Grant-Joseph at 404–639–2510.

K. Where To Obtain Additional Information

This and other CDC announcements may be downloaded through the CDC homepage on the Internet at http://www.cdc.gov. Please refer to program announcement number 00033 when requesting information. 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 00033. 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.

If you have questions after reviewing the contents of all documents, business management technical assistance may be obtained from: Mattie B. Jackson, Grants Management Specialist, Grants Management Branch, Procurement and Grants Office, Centers for Disease Control and Prevention (CDC), 2920 Brandywine Road, Room 3000, Atlanta, GA 30341–4146, telephone (770) 488–2718, Internet address mij3.@cdc.gov

For programmatic technical assistance, contact: Claudette A. Grant-Joseph, Chief, Program Services Section, Lead Poisoning Prevention Branch, Division of Environmental Hazards and Health Effects, National Center for Environmental Health, Centers for Disease Control and Prevention (CDC), 1600 Clifton Road, NE, Mailstop E–25, Atlanta, GA 30333, telephone (404) 639–2510, Internet address cag4@cdc.gov

Dated: February 4, 2000.

John L. Williams,

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

[FR Doc. 00–3062 Filed 2–9–00; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 99N–2250]

Agency Information Collection Activities; Announcement of OMB Approval; Current Good Manufacturing Practices for Blood and Blood Components; Notification of Consignees Receiving Blood and Blood Components at Increased Risk for Transmitting HIV Infection

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a collection of information entitled ''Current Good Manufacturing Practices for Blood and Blood Components; Notification of Consignees Receiving Blood and Blood Components at Increased Risk for Transmitting HIV Infection'' has been approved by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995.

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: In the **Federal Register** of November 4, 1999 (64 FR 60212), the agency announced that the proposed information collection had been submitted to OMB for review and clearance under 44 U.S.C. 3507. An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. OMB has now approved the information collection and has assigned OMB control number 0910–0336. The approval expires on January 31, 2003. A copy of the supporting statement for this information collection is available on the Internet at http://www.fda.gov/ohrms/dockets.

Dated: February 3, 2000.

William K. Hubbard,

Senior Associate Commissioner for Policy, Planning, and Legislation.

[FR Doc. 00–3013 Filed 2–9–00; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 99N–0407]

Agency Information Collection Activities; Announcement of OMB Approval; Reclassification Petitions for Medical Devices

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a collection of information entitled ''Reclassification Petitions for Medical Devices'' has been approved by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995.

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 the **Federal Register** of December 10, 1999 (64 FR 69270), the agency announced that the proposed information collection had been submitted to OMB for review and clearance under 44 U.S.C. 3507. An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. OMB has now approved the information collection and has assigned OMB control number 0910–0138. The approval expires on January 31, 2003. A copy of the supporting statement for this information collection is available on the Internet at http://www.fda.gov/ohrms/dockets.

Dated: February 3, 2000.

William K. Hubbard,

Senior Associate Commissioner for Policy, Planning, and Legislation.

[FR Doc. 00–3015 Filed 2–9–00; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Nonclinical Studies Subcommittee of the Advisory Committee for Pharmaceutical Science; Notice of Meeting

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

This notice announces a forthcoming meeting of a public advisory committee of the Food and Drug Administration (FDA). The meeting will be open to the public.

Name of Committee: Nonclinical Studies Subcommittee of the Advisory Committee for Pharmaceutical Science (formerly the Generic Drugs Advisory Committee).

General Function of the Committee: To provide advice and recommendations to the agency on FDA regulatory issues.

Date and Time: The meeting will be held on March 9, 2000, 8:30 a.m. to 5:30 p.m.

Location: Center for Drug Evaluation and Research conference room 1066, 5630 Fishers Lane, Rockville, MD.

Contact Person: Kimberly L. Topper, Center for Drug Evaluation and Research (HFD–21), Food and Drug Administration, 5600 Fishers Lane Rockville, MD 20857, 301–827–7001, e-mail: TOPPERK@cder.fda.gov, or FDA Advisory Committee Information Line, 1–800–741–8138 (301–443–0572 in the Washington, DC area), code 12539. Please call the Information Line for up-to-date information on this meeting.

Agenda: The subcommittee meeting will discuss collaborative approaches to scientific research issues of common interest to the pharmaceutical industry, universities, the public, and FDA. Specific areas of focus will be in the nonclinical studies areas of: (1) Interspecies biomarkers of toxicity and (2) noninvasive imaging.

Procedure: Interested persons may present data, information, or views, orally or in writing, on issues pending before the committee. Written submissions may be made to the contact person by February 25, 2000. Oral presentations from the public will be scheduled between approximately 1 p.m. to 2 p.m. Time allotted for each presentation may be limited. Those desiring to make formal oral presentations should notify the contact person before February 25, 2000, and