never or rarely screened for breast and cervical cancer. The annual burden for this data collection is 2,343 hours.

Report	Number of respondents	Responses per respondent	Average burden per response (in hours)
Infrastructure Report (STAR)	71	1	25
Screening and Follow-up (MDE)	71	2	4

Dated: March 27, 2003.

Thomas Bartenfeld,

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

[FR Doc. 03–8046 Filed 4–2–03; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

Agency for Toxic Substances and Disease Registry

[Program Announcement 03012]

Public Health Conference Support Cooperative Agreement Program; Notice of Availability of Funds Amendment

A notice announcing the availability of Fiscal Year 2003 funds for a cooperative agreement program to support public health conferences was published in the **Federal Register** dated January 10, 2003, Volume 68, Number 7, pages 1463–1467. The notice is amended as follows:

Page 1466, first column, section ''G. Submission and Deadline,'' remove the sentence, ''Expected Award date: July 1, 2003.''

Page 1466, first column, subsection ''Deadline,'' remove the sentence, ''There will be one conference support review this year and awards will be made in the month of July, 2003.''

Dated: March 28, 2003.

Sandra R. Manning,

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

[FR Doc. 03–8063 Filed 4–2–03; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[Program Announcement 03034]

Public Health Laboratory Biomonitoring Implementation Program; Notice of Availability of Funds

Application Deadline: July 2, 2003.

A. Authority and Catalog of Federal Domestic Assistance Number

This program is authorized under sections 301 and 317 of the Public Health Service Act, 42 U.S.C. 241 and 247b, as amended. The catalog of Federal Domestic Assistance number is 93.283.

B. Purpose

The Centers for Disease Control and Prevention (CDC) announces the availability of fiscal year (FY) 2003 funds for cooperative agreements to establish or expand state public health laboratory biomonitoring capacity. This program addresses the ''Healthy People 2010'' focus areas of Environmental Health and Public Health Infrastructure. This program builds upon biomonitoring planning conducted by State public health laboratories during FY 2001 and FY 2002 under Program Announcement (PA) 01072, Public Health Laboratory Biomonitoring Planning Grant. PA 01072 can be viewed at *http://frwebgate.access.gpo.gov/cgi-bin/getdoc.cgi?dbname=2001_register&docid=01–11215-filed.*

The purpose of this program is to implement and expand State laboratory-based biomonitoring programs to assess human exposure to environmental toxicants, help prevent disease resulting from exposure to toxic substances, and determine estimates of background exposure to naturally occurring and industrial chemicals that have the potential to cause harm.

Measurable outcomes of the program will be in alignment with one or more of the following performance goals for the National Center for Environmental Health (NCEH):

1. Develop laboratory capacity to monitor human exposures to environmental chemicals.

2. Periodically determine the number of Americans exposed to environmental chemicals and the degree of their exposure.

3. Increase the capacity of State and local health departments to deliver environmental health services in their communities.

C. Eligible Applicants

Assistance will be provided only to public health laboratories of States or lead States of consortia that were recipients of CDC grants for biomonitoring planning in FY2001 and FY2002 under PA 01072 (*see* Attachment 3 as posted on the CDC Web site for a listing of funded grantees under PA 01072). No other applications are solicited.

Applications are only sought from those grantees under PA 01072, who have developed a biomonitoring plan and the necessary relationships and contacts to implement their plan. These grantees have spent two years on the development of their biomonitoring plans. New applicants would not have those plans in place, and therefore would not be ready to move into the implementation phase being funded by this new announcement.

States, territories, or protectorates that do not meet the preceding requirement may participate by entering into a consortium or other agreement with an eligible State or an eligible consortium of States.

Only one application per State or consortium may be submitted. A State may apply as an individual State or as the lead member of a consortium, but not both. Members of a consortium may not apply as individual States.

Note: Title 2 of the United States Code section 1611 states that an organization described in section 501c(4) of the Internal Revenue Code that engages in lobbying activities is not eligible to receive Federal funds constituting an award, grant or loan.

D. Funding

Availability of Funds

Approximately $5,000,000 is available in FY 2003 to fund approximately ten awards. Funding will range from $200,000, up to $3,000,000 per award. Funding estimates may change. It is expected that the awards will begin on or about September 15, 2003, and will be made for an initial 9-month budget period, which will end on June 30, 2004. Future budget periods will be 12 months in duration for a total project period of up to four years and nine months.

Continuation awards within an approved project period will be made on the basis of the availability of funds and satisfactory progress as evidenced by required reports.

Funding will be awarded in two categories:

Individual States: Maximum award of up to $1,000,000 for individual States.

Consortia: Maximum award of up to $3,000,000 based upon the number of States within the consortium. A range of $200,000–$600,000 per State consortium member is anticipated.

Applications exceeding the foregoing maxima will be returned without review. Eligible applicants are only allowed to apply for one of the two categories described above.

Use of Funds

Funds may be used to develop and implement a biomonitoring program, conduct demonstration projects, purchase equipment and supplies, hire and train personnel, conduct appropriate and relevant travel, hire consultants, pay for services, and renovate or modify existing laboratory areas. Funds provided by CDC under this cooperative agreement may not be used for construction of new laboratory space. Funds may not be used to support activities otherwise funded, or eligible to be funded, through the Superfund Program or the Agency for Toxic Substances and Disease Registry. However, because toxicants from Superfund sites may contribute to the total exposures of a given population, funds may be used to assess the exposure status of populations not already addressed under Superfund.

Funding Preferences

Preference for awards will be given to ensure geographic diversity, distribution, and balance among laboratories which serve people living in various settings such as urban, rural, agricultural, and industrial communities; among laboratories that have various levels of expertise, experience, capacity, and need for biomonitoring. Preference will be given to applications with the greatest need for biomonitoring expansion or implementation based on documented or suspected environmental toxicant exposures among persons living within the applicant's area of responsibility.

Recipient Financial Participation

Matching funds are not required for this program.

E. Program Requirements

In conducting activities 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. Implement and apply biomonitoring laboratory capacity by following, as closely as possible, the biomonitoring plan(s) that the recipient developed with funding under PA 01072, Public Health Laboratory Biomonitoring Planning Grant.

b.Address the needs for, and proposed application of, biomonitoring within the community served by the applicant and distinguish between those needs that are single issue and those that exist on an on-going basis. Collaborate with other public health partners, including public health physicians and epidemiologists, in making this needs assessment. Special consideration should be given to evaluating exposures in under-served population groups that may be at increased risk from exposure. (*E.g.* minorities, the very young, and the elderly may have a greater risk of exposure or harmful effects.)

c. Incorporate the application of laboratory data to respond to important public health issues as listed in items 1. through 6. of Attachment 2, ''Biomonitoring and Complementary Programs.'' Please see all attachments referenced in this announcement as posted with the full announcement on the CDC Web site: *http://www.cdc.gov/od/pgo/funding/grantmain.htm.* Uses may include population based or targeted health exposure surveys, health effects studies, sentinel monitoring of at-risk populations, case-control studies, studies involving analyses of stored specimens, or other recognized epidemiologic tools. The applicant must develop complete study protocols after award of a cooperative agreement and prior to commencing the study.

d. Meet requirements for local Institutional Review Board (IRB) or Human Subjects review and obtain approval for any such projects which constitute research as defined in 45 CFR part 46. (*See http://ohrp.osophs.dhhs.gov/humansubjects/guidance/45cfr46.htm#46.102*)

e. Biomonitoring research projects that the applicant plans to undertake without substantial CDC involvement do not require CDC IRB approval. However, the applicant will be required to submit a copy of their proposed protocol and a copy of their IRB approval letter (and all subsequent approval renewals) to CDC. Research projects that applicants wish to undertake with substantial CDC involvement will require joint development of detailed protocols with CDC and approval from both CDC IRB and the applicant's local IRB. **Note:** CDC IRB may defer to the local IRB or the local IRB may defer to CDC IRB. Because funds currently available to support the biomonitoring implementation program under this cooperative agreement are limited and are primarily intended for biomonitoring capacity building, applicants are discouraged from relying on this agreement to fund complex and costly epidemiologic studies. Rather, activities should be limited to demonstration projects, pilot surveys, and preliminary investigations. More detailed and costly epidemiologic studies employing biomonitoring should be developed jointly and in detail among the interested laboratories, their epidemiology partners, and others with funding sought from other sources as stand-alone projects.

f. Implement the plan for developing (or expanding) and applying biomonitoring capacity in the public health laboratory. This implementation must follow the specific, measurable, and time-framed goals and objectives presented in the plan.

g. Develop an evaluation plan by which the recipient may conduct periodic and on-going assessments of progress in expanding the laboratory's biomonitoring capacity and to assess the impact of biomonitoring measurements on addressing the identified public health needs within the state(s) or community.

h. Participate in external proficiency testing and quality control programs, perform biomonitoring pilot and demonstration studies (including performance of biomonitoring analyses on previously collected samples), participate in the prospective planning and conduct of biomonitoring research projects or population exposure surveys, and perform other activities that enhance the recipient's ability to implement a biomonitoring program.

2. CDC Activities:

a. Provide technical assistance, guidance, and training in biomonitoring, including information about analytical methods and instrumentation used by CDC for biomonitoring.

b. Provide information about sources for reagents, supplies, standards, quality assurance materials, equipment, etc. These sources may include commercial vendors, other Federal, State, or international agencies, professional societies or standard-setting bodies, contractors to CDC, and CDC laboratories, as appropriate.

c. Provide analytical support as requested for biomonitoring studies initiated by the recipient (subject to availability and competing national priorities).

d. Assist in the development of a research protocol for projects in which CDC provides a staff member to serve as principal investigator or co-investigator or when CDC conducts sample analysis. IRB approval will be required from all institutions participating in the research. CDC IRB must review and approve the protocol initially and at least on an annual basis until the research project is completed. For those research projects that do not have a CDC staff member serving as the principal investigator or co-investigator, technical assistance in the form of advice, recommendations, and expert opinions will be provided.

F. Content

Letter of Intent (LOI)

A LOI is optional for this program. The Program Announcement title and number must appear in the LOI. The narrative should be no more than one page, single-spaced, printed on one side, with one-inch margins, and unreduced 12-point font. The LOI will be used for CDC planning purposes. The LOI must indicate whether the applicant plans to apply as an individual state applicant or as the lead member of a consortium and should identify the states that are anticipated to be consortium partners.

Applications

The Program Announcement title and number must appear in the application. Use the information in the Program Requirements, Content, Other Requirements, and Evaluation Criteria sections to develop the application content. The application will be evaluated on the criteria listed, so it is important to follow them in laying out the program plan. The narrative should be no more than 25 pages, double-spaced, printed on one side, with one-inch margins, and unreduced 12-point font.

The narrative should consist of, at a minimum, a Workplan, Objectives, Methods, Personnel, Evaluation Scheme, and Budget. A two- to three-page executive summary of the applicant's plan developed under PA 01072 shall be included preceding the narrative. The application must also include, as an attachment, a full copy of the plan from the planning grant. The page limitation is exclusive of the attached copy of the plan.

The application must also:

1. Discuss how the recipient will develop, implement, and apply biomonitoring laboratory capacity by following the biomonitoring plan that was developed with funding under PA 01072.

2. Outline how biomonitoring will be applied within the community served by the applicant and distinguish between those needs that are single issue and those that exist on an on-going basis. Describe how collaboration with other public health partners, including public health physicians and epidemiologists in making this needs assessment will be accomplished. Special consideration should be given to evaluating exposures in under-served population groups that may be at increased risk from exposure.

3. Discuss how the program will use biomonitoring laboratory data to answer the important public health questions as listed in items 1. through 6. of Attachment 2 as posted on the CDC Web site. The application should not include complete study protocols, as they will be developed after award of a cooperative agreement and prior to commencing the study.

4. Tell how requirements for local IRB or Human Subjects review will be met and how approval for any such projects which constitute research as defined in 45 CFR part 46 will be obtained. (*See http://ohrp.osophs.dhhs.gov/humansubjects/guidance/45cfr46.htm#46.102.*)

5. Provide an inventory of existing biomonitoring methods in use by the applicant, and for each method specify: Toxic substance(s) measured; method of measurement (*e.g.*, GC–MS, atomic absorption); current instrumentation used; the limit of detection for each analyte (and how the limit of detection was determined); known interferences; description of method's quality control; any external proficiency testing program in which the laboratory currently participates for the method; an approximate sample throughput per day; and the approximate number of human specimens analyzed in the past 12 months. Emphasize in this section how the existing biomonitoring capacity will be used to address needs identified in the paragraphs above. As part of this explanation, specify the collaborations with public health partners (State and local health officials, schools of public health, academic centers, community groups, etc.) who will work with the laboratory to use biomonitoring data to help address these public health needs. Include documentation from each public health partner of its willingness to collaborate. Acceptable documentation may be letters of support or formal agreements among partners.

6. For each new biomonitoring method needed, describe additional requirements for personnel, instrumentation, and facilities modification or expansion. Provide cost estimates for facilities modification or expansion, if applicable.

7. Describe specimen management and security protocols that are in place or that are to be implemented to support the biomonitoring program.

8. Describe the data management and communications resources and plans available or needed to support the biomonitoring program. The relationship (or lack thereof) with other public health data management and communications initiatives (*e.g.*, National Electronic Disease Surveillance System, Health Alert Network, etc.) should be discussed.

9. Discuss requirements for compliance with the Clinical Laboratory Amendments of 1988 (CLIA).

10. Develop an evaluation plan to provide periodic and on-going assessment of progress in expanding the laboratory's biomonitoring capacity and to assess the impact of biomonitoring measurements on addressing the identified public health needs within the State(s) or community.

11. Applications from consortia must provide documentation from each member of the consortium of their willingness to collaborate, to share resources, and/or to perform work within the consortium under reciprocal arrangements, to pool data from each site in their proposed consortium as appropriate to the goals of the consortium, and to participate in periodic meetings (or conferences via electronic media) among consortium laboratories for the purpose of planning, conduct of consortium business, training, and technology transfer. Acceptable documentation may be letters of support or formal agreements among the consortium members.

12. Discuss anticipated problems with the implementation of the biomonitoring plan and outline proposed solutions. Potential problems might include state restrictions on

hiring of personnel, travel restrictions, and shortages of qualified personnel.

G. Submission and Deadline

Letter of Intent (LOI) Submission

On or before May 5, 2003, submit the LOI to the Grants Management Specialist identified in the ''Where to Obtain Additional Information'' section of this announcement.

Application Forms

Submit the signed original and two copies of PHS Form 5161—

1. Forms are available at the following Internet address: *http://www.cdc.gov/od/pgo/forminfo.htm.*

If you do not have access to the Internet, or if you have difficulty accessing the forms on-line, you may contact the CDC Procurement and Grants Office Technical Information Management Section (PGO–TIM) at: 770–488–2700. Application forms can be mailed to you.

Submission Date, Time, and Address

The application must be received by 4 p.m. eastern time on July 2, 2003. Submit the application to: Technical Information Management—PA03034, Procurement and Grants Office, Centers for Disease Control and Prevention, 2920 Brandywine Rd, Atlanta, GA 30341–4146. Applications may not be submitted electronically.

CDC Acknowledgement of Application Receipt

A postcard will be mailed by PGO–TIM, notifying you that CDC has received your application.

Deadline

Letters of intent and applications shall be considered as meeting the deadline if they are received before 4 p.m. eastern time on the deadline date. Any applicant who sends their application by the United States Postal Service or commercial delivery services must ensure that the carrier will be able to guarantee delivery of the application by the closing date and time. If an application is received up to two weeks after the closing date, due to (1) carrier error, when the carrier accepted the package with a guarantee for delivery by the closing date and time, or (2) significant weather delays or natural disasters, CDC will upon receipt of proper documentation, consider the application as having been received by the deadline.

Any application that does not meet the above criteria will not be eligible for competition, and will be discarded. The applicant will be notified of their failure to meet the submission requirements.

H. Evaluation Criteria

Application

Applicants are required to provide measures of effectiveness that will demonstrate the accomplishment of the various identified objectives of the cooperative agreement. Measures of effectiveness must relate to the performance goals as stated in section ''A. Purpose'' of this announcement. Measures must be objective and quantitative and must measure the intended outcome. These measures of effectiveness shall be submitted with the application and shall be an element of evaluation.

An independent review group appointed by CDC will evaluate each application against the following criteria:

1. Understanding the Requirements for Implementing a Biomonitoring Plan (30 Percent)

Does the application reflect the biomonitoring plan developed by the applicant and is a copy of the biomonitoring plan included as an attachment? (**Note:** If the application is from a consortium that includes members previously funded as individual planning grantees, the application must reflect the planning of those consortium members and discuss how those plans will be integrated.) The extent to which the applicant describes the need for a biomonitoring program, and an understanding of the purpose of conducting exposure assessment by measurement of human biological samples (blood, hair, urine, saliva) to identify internal human dose from contact with hazardous environmental chemicals. The applicant's understanding of the analytical challenges associated with identifying the extent of exposure based on data obtained from human samples, especially challenges presented by the differences in physiological makeup of individuals, specimen collection, and pharmacokinetic and pharmacodynamic factors. The demonstration of understanding the problems related to estimating or extrapolating ''internal dose'' from ''external dose'' data, and the value of biomonitoring through direct measurement of samples from humans to provide information that is more meaningful.

2. Goals and Objectives (20 Percent)

The extent to which the applicant clearly states biomonitoring program goals and objectives which are consistent with the Purpose and Program Requirements sections as presented in this announcement, and the degree to which the goals and objectives reflect an understanding of the need to reach beyond the laboratory to achieve balanced input from the broader public health community in implementation of the biomonitoring plan. These goals and objectives shall include a discussion of the implementation of biomonitoring laboratory capacity and application of this capacity to specific environmental chemical exposure problems.

3. Program and Methodology (20 Percent)

Describe in detail how the biomonitoring laboratory plan will be implemented. This must include a description of space allocation, staffing requirements and training, instrumentation and instrumentation maintenance, analytical methods, specimen storage and security, supply accession, facilities, quality assurance and quality control, logistical support and data management. The applicant shall provide a phased timeline of activities leading to implementation or expansion of a biomonitoring program by the applicant. Does this description of activities fully cover the anticipated four-year, nine-month project period? Does the application adequately address the CDC Policy requirements regarding the inclusion of women, ethnic, and racial groups in the proposed research? This includes:

a. The proposed plan for the inclusion of both sexes and under-served 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.

d. 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.

4. Collaborative Efforts (15 Percent)

Describe anticipated collaborative efforts related to this program among the applicant laboratory(ies), other components of the public health structure of the community, including epidemiologists, environmental health professionals, other state or local health agencies, health services providers, and academic institutions such as schools of public health, medicine, university departments of chemistry or biochemistry, community and citizens groups, and other interested parties. Letters of support from anticipated collaborators must be provided as

attachments to the application package. The page limitation is exclusive of the attached letters of support. The applicant must discuss how collaborators propose to employ biomonitoring to address public health issues/concerns. The applicant shall discuss complementary and competing programs if applicable, such as environmental testing programs, terrorism preparedness programs, environmental public health tracking programs, and other activities that may add to or detract from biomonitoring capacity.

5. Evaluation Plan (10 Percent)

The extent to which the applicant describes how progress towards achieving the applicant's goals and objectives will be evaluated, and how, during the implementation phase, new public health needs will be assessed and the program (and the underlying plan) will be modified to adjust to these changing public health needs and priorities. The application's approach to evaluating the impact of the program on environmental health and human exposure issues in the applicant's community will also be evaluated.

6. Staffing, Management System, and Facilities (5 Percent)

The extent to which the applicant describes the staff that is available or anticipated to conduct these activities and how they will be managed and evaluated. The applicant must describe the organizational setting and facilities available to support the biomonitoring program; to access, transport, store, inventory, process and manage biological specimens from people; and to accumulate, process, store, and analyze data and other information related to the implementation of this program. Applicants must also describe planning to provide IRB review when biomonitoring programs are implemented, and discuss the impact of the requirements of CLIA on their plan.

7. Budget (Not Scored)

The extent to which the applicant provides a detailed budget and narrative justification consistent with stated objectives and program activities.

You are encouraged to use Out-of-State travel funds to send one staff person to attend the sixth National Environmental Health Conference to be held on December 3–5, 2003, at the Hilton Atlanta, 255 Courtland Street, NE., Atlanta, GA. If additional written justification is needed to support attendance at the above meeting, please contact your project officer. Review the CDC/NCEH Web site for additional information concerning the conference: *http://www.cdc.gov/nceh/default.htm.*

8. Human Subjects (Not Scored)

Does the application adequately address the requirements of title 45 CFR part 46 for the protection of human subjects? Not scored; however, an application can be disapproved if the research risks are sufficiently serious and protection against risks is so inadequate as to make the entire application unacceptable.

I. Other Requirements

OMB Clearance Requirements

Projects that involve the collection of information from 10 or more individuals and funded by the cooperative agreement will be subject to review and approval by the Office of Management and Budget (OMB) under the Paperwork Reduction Act.

Technical Reporting Requirements

Provide CDC with original plus two copies of:

1. Interim progress report, no less than 90 days before the end of the budget period. The progress report will serve as a non-competing continuation application, and must contain the following elements:

a. Current Budget Period Activities Objectives.

b. Current Budget Period Financial Progress.

c. New Budget Period Program Proposed Activity Objectives.

d. Detailed Line-Item Budget and Justification.

e. Additional Requested Information.

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

3. Final financial and performance reports, no more than 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.

Additional Requirements

The following additional requirements are applicable to this program. For a complete description of each, *see* Attachment 1 of the program announcement as posted on the CDC Web site.

AR–1 Human Subjects Requirements
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 2010
AR–12 Lobbying Restrictions
AR–22 Research Integrity

J. Where To Obtain Additional Information

This and other CDC announcements, the necessary applications, and associated forms can be found on the CDC Web site, Internet address: *http://www.cdc.gov.*

Click on ''Funding'' then ''Grants and Cooperative Agreements''.

For interested applicants, a telephone conference call for pre-application technical assistance will be held on April 21, 2003, at 1 p.m. eastern time. Potential applicants are requested to call in using only one telephone line. The conference can be accessed by calling 1–800–311–3437 or 404–639–3277 and entering conference code 824087 when prompted. The purpose of the conference call is to help potential applicants to:

1. Understand the scope and intent of the Program Announcement for the Public Health Laboratory Biomonitoring Implementation Program.

2. Be familiar with the Public Health Services funding policies and application and review procedures.

Participation in this conference call is not mandatory. At the time of the call, if problems are encountered accessing the conference call, please call 404–639–7550. For further information, please contact Charles Buxton at (770) 488–4160 or Barry E. Smith at (770) 488–7968.

For general questions about this announcement, contact: Technical Information Management, CDC Procurement and Grants Office, 2920 Brandywine Rd, Atlanta, GA 30341–4146. Telephone: 770–488–2700.

For business management and budget assistance, contact: Mildred S. Garner, Grants Management Officer, Procurement and Grants Office, Centers for Disease Control and Prevention, 2920 Brandywine Road, (MS E–13), Atlanta, GA 30341–4146. Telephone: (770) 488–2745. E-mail address: *mqg4@cdc.gov.*

For program technical assistance, contact: Charles H. Buxton, MT(ASCP)SBB, National Center for Environmental Health, Centers for Disease Control and Prevention, 4770 Buford Highway, NE. (MS F–20), Atlanta, GA 30341–3724. Telephone: (770) 488–4160. E-mail address: *zpl1@cdc.gov.*

Or:

Barry E. Smith, National Center for Environmental Health, Centers for Disease Control and Prevention, 4770 Buford Highway, NE. (MS F–20),

Atlanta, GA 30341–3724. Telephone: (770) 488–7968. E-mail address: *bas4@cdc.gov.*

Dated: March 27, 2003.

Sandra R. Manning,

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

[FR Doc. 03–8062 Filed 4–2–03; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Clinical Pharmacology 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: Clinical Pharmacology Subcommittee of the Advisory Committee for Pharmaceutical Science.

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

Date and Time: The meeting will be held on April 22, 2003, from 8:30 a.m. to 5 p.m. and April 23, 2003, from 8:30 a.m. to 12:30 p.m.

Location: Center for Drug Evaluation and Research Advisory Committee Conference Room, rm. 1066, 5600 Fishers Lane, Rockville, MD.

Contact Person: Kathleen Reedy, Center for Drug Evaluation and Research (HFD–21), Food and Drug Administration, 5600 Fishers Lane (for express delivery, 5630 Fishers Lane, rm. 1093), Rockville, MD 20857, 301-827–7001, e-mail: REEDYK@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: On April 22, 2003, the subcommittee will discuss: (1) Quantitative risk-benefit analysis using exposure-response for determining dose adjustment for special populations; and (2) pediatric population pharmacokinetics study design template and analyses of the FDA pediatric database. On April 23, 2003, the subcommittee will discuss: (1) Pharmacogenetics: improvement of existing drug treatments, and (2) drug interactions: metabolism and transport-based.

Procedure: Interested persons may present data, information, or views, orally or in writing, on issues pending before the subcommittee. Written submissions may be made to the contact person by April 15, 2003. Oral presentations from the public will be scheduled between approximately 12:45 p.m. and 1:15 p.m. on April 22, 2003, and 11:30 a.m. to 12 noon on April 23, 2003. Time allotted for each presentation may be limited. Those desiring to make formal oral presentations should notify the contact person before April 15, 2003, and submit a brief statement of the general nature of the evidence or arguments they wish to present, the names and addresses of proposed participants, and an indication of the approximate time requested to make their presentation.

Persons attending FDA's advisory committee meetings are advised that the agency is not responsible for providing access to electrical outlets.

FDA welcomes the attendance of the public at its advisory committee meetings and will make every effort to accommodate persons with physical disabilities or special needs. If you require special accommodations due to a disability, please contact Kathleen Reedy at least 7 days in advance of the meeting.

FDA regrets that it was unable to publish this notice 15 days prior to the Clinical Pharmacology Subcommittee of the Advisory Committee for Pharmaceutical Science meeting. Because the agency believes there is some urgency to bring these issues to public discussion and qualified members of the Clinical Pharmacology Subcommittee of the Advisory Committee for Pharmaceutical Science were available at this time, the Commissioner of Food and Drugs concluded that it was in the public interest to hold this meeting even if there was not sufficient time for the customary 15-day public notice.

Notice of this meeting is given under the Federal Advisory Committee Act (5 U.S.C. app. 2).

Dated: March 25, 2003.

Linda Arey Skladany,

Associate Commissioner for External Relations.

[FR Doc. 03–8011 Filed 4–2–03; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 99D–1738]

Draft Guidance for Industry: Bioavailability and Bioequivalence Studies for Nasal Aerosols and Nasal Sprays for Local Action; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a draft guidance for industry entitled ''Bioavailability and Bioequivalence Studies for Nasal Aerosols and Nasal Sprays for Local Action.'' This draft document provides recommendations to applicants planning product quality studies to document bioavailability (BA) or bioequivalence (BE) in support of new drug applications (NDAs), or abbreviated new drug applications (ANDAs) for locally acting drugs in nasal aerosols (metered-dose inhalers) and nasal sprays (metered-dose spray pumps). The draft guidance was originally issued for comment on June 24, 1999. Since many substantive changes have been made to the guidance, it is being reissued for comment as a level 1 draft guidance.

DATES: Submit written or electronic comments on the draft guidance by July 2, 2003. General comments on agency guidance documents are welcome at any time.

ADDRESSES: Submit written requests for single copies of the draft guidance for industry to the Division of Drug Information (HFD–240), Center for Drug Evaluation and Research, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857. Send one self-addressed adhesive label to assist that office in processing your requests. Submit written comments on the draft guidance to the Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments to http://www.fda.gov/dockets/ecomments. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance document.

FOR FURTHER INFORMATION CONTACT: Wallace P. Adams, Center for Drug Evaluation and Research (HFD–350), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–594–5651.

SUPPLEMENTARY INFORMATION: