## GENERAL SERVICES ADMINISTRATION

### Maximum Per Diem Rates for the Continental United States (CONUS)

**AGENCY:** Office of Governmentwide Policy, General Services Administration (GSA).

**ACTION:** Notice of Per Diem Bulletin 05–1, Fiscal Year (FY) 2005 continental United States (CONUS) per diem rates.

**SUMMARY:** An analysis of lodging data reveals that the FY 2005 maximum per diem rates for locations within the continental United States (CONUS) should be updated to provide for the reimbursement of Federal employees' expenses covered by per diem. Per Diem Bulletin 05–1 increases/decreases the maximum lodging amounts in existing per diem localities, increases the standard CONUS lodging amount from $55 to $60 (which results in the deletion of several existing per diem localities), and adds new per diem localities due to requests by Federal agencies. The per diems prescribed in Bulletin 05–1 may be found at http://www.gsa.gov/perdiem. In an effort to improve the ability of the per diem rates to meet the lodging demands of Federal travelers, the General Services Administration (GSA) has integrated average daily rate cost data obtained from lodging industry sources into the per diem rate-setting process. The use of such data in the per diem rate setting process enhances the Government's ability to obtain policy compliant lodging where it is needed. Bulletin 05–1 also contains a listing of pertinent information that must be submitted through an agency for GSA to restudy a location if a CONUS per diem rate is insufficient to meet necessary expenses.

**DATES:** This notice is effective October 1, 2004, and applies for travel performed on or after October 1, 2004.

**FOR FURTHER INFORMATION CONTACT:** For clarification of content, contact Adlore Chaudier, Office of Governmentwide Policy, Travel Management Policy, at (202) 501–3859. Please cite Notice of Per Diem Bulletin 05–1.

**SUPPLEMENTARY INFORMATION:**

#### A. Background

After an analysis of additional data, GSA has determined that current lodging rates for certain localities do not adequately reflect the lodging economics in those areas.

#### B.Change in standard procedure

GSA issues/publishes the CONUS per diem rates, formerly published in Appendix A to 41 CFR chapter 301, solely on the internet at http://www.gsa.gov/perdiem. This process, implemented in 2003, ensures more timely increases or decreases in per diem rates established by GSA for Federal employees on official travel within CONUS. Notices published periodically in the **Federal Register**, such as this one, now constitute the only notification of revisions in CONUS per diem rates to agencies.

Dated: August 25, 2004

**John G. Sindelar,**

*Deputy Associate Administrator.*

[FR Doc. 04–19826 Filed 8–30–04; 8:45 am]

**BILLING CODE 6820–14–S**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Office of the Secretary

### Notice of Meeting: Secretary's Advisory Committee on Genetics, Health, and Society

Pursuant to Public Law 92–463, notice is hereby given of the fifth meeting of the Secretary's Advisory Committee on Genetics, Health, and Society (SACGHS), U.S. Public Health Service. The meeting will be held from 8:30 a.m. to 5 p.m. on October 18, 2004 and 8:30 a.m. to 3 p.m. October 19, 2004 at the Marriott Hotel Bethesda at 5151 Pooks Hill Road, Bethesda, Maryland. The meeting will be open to the publc with attendance limited to space available. The meeting will be webcast.

The first half of the first day will be devoted to a session to receive testimony from individuals who have been affected by genetic discrimination in health insurance and employment. The second half of the first day will include presentations related to and discussion of a revised draft report on coverage and reimbursement for genetic technologies and services and the development of recommendations on the issues identified in the report. Discussion of the draft coverage and reimbursement report will continue throughout the first half of the second day. The second day will end with a status report on the National Academy of Sciences' study of genomics and patents and discussions of future plans for Committee action on the issues of pharmacogenomics and large population studies. Time will be provided each day for public comments.

Under authority of 42 U.S.C. 217a, Section 222 of the Public Health Service Act, as amended, the Department of Health and Human Services established SACGHS to serve as a public forum for deliberations on the broad range of human health and societal issues raised by the development and use of genetic technologies and, as warranted, to provide advice on these issues. The draft meeting agenda and other information about SACGHS, including information about access to the webcast, will be available at the following Web site: *http://www4.od.nih.gov/oba/sacghs.htm*.

The Committee would welcome hearing from anyone wishing to provide public comment on any issue related to genetics, health and society. In addition, the Committee is specifically seeking written public comment from individuals who have experienced genetic discrimination in health insurance or in employment, who fear genetic discrimination, or who have paid out of pocket for services to keep genetic information out of medical records. Individuals who would like to provide public comment or who plan to attend the meeting and need special assistance, such as sign language interpretation or other reasonable accommodations, should notify the SACGHS Executive Secretary, Ms. Sarah Carr, by telephone at 301–496–9838 or E-mail at *sc112c@nih.gov*. The SACGHS office is located at 6705 Rockledge Drive, Suite 750, Bethesda, MD 20892.

Dated: August 19, 2004.

**LaVerne Stringfield,**

*Director, Office of Federal Advisory Committee Policy.*

[FR Doc. 04–19850 Filed 8–30–04; 8:45 am]

**BILLING CODE 4140–01–M**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Centers for Disease Control and Prevention

### Population-Based Birth Defects Surveillance Programs and the Utilization of Surveillance Data by Public Health Programs

*Announcement Type:* New.

*Funding Opportunity Number:* RFA 05009.

*Catalog of Federal Domestic Assistance Number:* 93.283.

*Key Dates:*

*Letter of Intent Deadline:* September 27, 2004.

*Application Deadline:* October 20, 2004.

#### I. Funding Opportunity Description

**Authority:** This program is authorized under sections 311, 317(k)(2), and 317(C) of the Public Health Service Act [42 U.S.C. 243, 247(k)(2), and 247b-4], as amended.

*Purpose:* The purpose of this program is to support: (1) The development, implementation, expansion, and evaluation of state's population-based birth defects surveillance systems; (2) the development and implementation of population-based programs to prevent birth defects; (3) the development and implementation or expansion of activities to improve the access of children with birth defects to health services and early intervention programs; and (4) the evaluation of the effectiveness of the referral activities and the impact on the affected children and families. This program addresses the ''Healthy People 2010'' focus area of Maternal, Infant, and Child Health.

Measurable outcomes of the program will be in alignment with the following performance goal for the National Center on Birth Defects and Developmental Disabilities (NCBDDD):

• Increase the number of United States births covered by birth defects monitoring programs which use these data to plan services for children and evaluate prevention strategies.

Applicants may apply under one of two categories: Category 1—States/territories/tribes with nonexistent or less than three year old birth defects surveillance systems; or Category 2—States/territories/tribes with ongoing surveillance systems.

This announcement is only for non-research activities supported by CDC/ATSDR. If research is proposed, the application will not be reviewed. For the definition of research, please see the CDC Web site at the following Internet address: *http://www.cdc.gov/od/ads/opspolll.htm.*

*Activities:* Awardee activities for this program are as follows: In conducting activities to achieve the purpose of this program, the recipient will be responsible for the activities under (1) recipient activities for States with nonexistent or less than three year old birth defects surveillance systems; or (2) Recipient activities for States with ongoing surveillance systems. CDC will be responsible for the activities under (3) CDC activities.

(1) Recipient Activities for States with nonexistent or less than three year old birth defects surveillance systems:

a. Develop and begin implementation of a population-based surveillance system to ascertain cases and generate timely population-based data of major birth defects occurring in the State.

b. Analyze and disseminate the surveillance data generated by the system in a timely fashion including rates and trends of major birth defects.

c. Develop and implement a plan to evaluate the surveillance methodology used.

d. Involve the appropriate partners within the State, including the State's organization receiving Title V federal funds, to develop a plan and begin implementation of a birth defects prevention program (*i.e.*, Neural Tube Defects (NTD) occurrence and recurrence prevention). Share results with appropriate organizations within the State and with other States.

e. Develop a plan to evaluate your prevention activities.

f. Involve the appropriate partners within the State to develop a plan and begin implementation of activities to improve the access of children with birth defects to comprehensive, community-based, family-centered care (*e.g.*, establish linkages with other programs like Children with Special Health Care Needs).

g. Develop a plan to evaluate the identification of and/or timeliness of referral to services among eligible children or families.

(2) Recipient Activities for States with ongoing surveillance systems:

a. Broaden methodologies and approaches which will improve and expand the capacity of the existing population-based surveillance system to ascertain cases and generate timely population-based data of major birth defects occurring in the State.

b. Analyze and disseminate the surveillance data generated by the system in a timely fashion including rates and trends of major birth defects (*e.g.*, publish a report on the surveillance data).

c. Evaluate the surveillance methodology used.

d. Involve the appropriate additional partners within the State, including the State's organization receiving Title V federal funds, to expand birth defects prevention programs (*i.e.*, Neural Tube Defects (NTD) occurrence and recurrence prevention). Share results with appropriate organizations within the State and with other States.

e. Evaluate the prevention progress.

f. Involve the appropriate partners within the State to expand activities to improve the access of children with birth defects to comprehensive, community-based, family-centered care (*e.g.*, establish linkages with other programs like Children with Special Health Care Needs).

g. Evaluate the progress on improving access to services (*e.g.*, identification of children and families eligible for services; evaluate the timeliness of referral to services).

h. Evaluate the effectiveness of the referral activities and the benefit/impact on the affected children and families.

(3) In a cooperative agreement, CDC staff is substantially involved in the program activities, above and beyond routine grant monitoring. CDC Activities for this program are as follows:

a. Provide technical assistance such as presenting the need, benefits, and description of a birth defects surveillance, prevention, and intervention program, reviewing draft legislation, etc. to state agencies and interested parties.

b. Assist in designing, developing, and evaluating methodologies and approaches used for population-based birth defects surveillance. Discuss the advantages and disadvantages of different case ascertainment methods.

c. Assist in analyzing surveillance data related to birth defects.

d. Assist in designing, developing, and evaluating plans for prevention programs.

e. Assist in designing, developing, and evaluating plans to improve the access of children with birth defects to health services and intervention programs.

f. Provide a reference point for sharing regional and national data and information pertinent to the surveillance and prevention of birth defects.

**II. Award Information**

*Type of Award:* Cooperative Agreement. CDC involvement in this program is listed in the Activities Section above.

*Fiscal Year Funds:* 2005.

*Approximate Total Funding:* $2,500,000 (This amount is an estimate, and subject to the availability of funds.)

*Approximate Number of Awards:* Fifteen; Two—Eight Category 1 awards and Six—Fourteen Category 2 awards.

*Approximate Average Award:* $120,000 for Category 1 awards and $190,000 for Category 2 awards (This amount is for the first 12-month budget period, and includes both direct and indirect costs.)

*Floor of Award Range:* $100,000 for Category 1 awards and $150,000 for Category 2 awards.

*Ceiling of Award Range:* $140,000 for Category 1 awards and $220,000 for Category 2 awards (This ceiling is for the first 12 month budget period.)

*Anticipated Award Date:* March 1, 2005.

*Budget Period Length:* Twelve months.

*Project Period Length:* Five years; 3/1/05–2/28/10. Throughout the project

period, CDC's commitment to continuation of awards will be conditioned on the availability of funds, evidence of satisfactory progress by the recipient (as documented in required reports), and the determination that continued funding is in the best interest of the Federal Government.

**III. Eligibility Information**

*III.1. Eligible Applicants*

Applications may be submitted by governments and their agencies, such as:

- Federally recognized Indian tribal governments
- Indian tribes
- Indian tribal organizations
- State governments or their Bona Fide Agents (this includes the District of Columbia, the Virgin Islands, the Commonwealth of the Northern Marianna Islands, American Samoa, Guam, the Federated States of Micronesia, the Republic of the Marshall Islands, and the Republic of Palau)

A Bona Fide Agent is an agency/organization identified by the state as eligible to submit an application under the state eligibility in lieu of a state application. If you are applying as a bona fide agent of a state government, you must provide a letter from the state as documentation of your status. Place this documentation behind the first page of your application form. Applications that fail to submit the evidence requested above will be considered non-responsive and returned without review.

*III.2. Cost Sharing or Matching*

Matching funds are not required for this program. Applicants are encouraged to list other sources of funding such as state funds, in-kind funds, partner funds, etc. that will be used to support this program announcement's activities.

*III.3. Other*

*Special Requirements:* If your application is incomplete or non-responsive to the special requirements listed in this section, it will not be entered into the review process. You will be notified that your application did not meet the submission requirements.

- If you request a funding amount greater than the ceiling of the award range, your application will be considered non-responsive.
- Late applications will be considered non-responsive. See section ''IV.3. Submission Dates and Times'' for more information on deadlines.
- If you are applying as a bona fide agent of a state government, you must provide a letter from the state as documentation of your status. Place this documentation behind the first page of your application form. Applications that fail to submit the evidence requested above will be considered non-responsive.
- Recipients funded under CDC Program Announcement 03019 (Population-Based Birth Defect Surveillance Programs and the Utilization of Surveillance Data by Public Health Programs) and Program Announcement 02081 (Centers for Birth Defects Research and Prevention) are not eligible. See Attachment I, as posted on the CDC Web site, for a list of the States currently funded under these program announcements. The eligible States are: Alabama, Alaska, Colorado, Connecticut, Delaware, District of Columbia, Georgia, Hawaii, Idaho, Indiana, Kansas, Kentucky, Louisiana, Maine, Maryland, Michigan, Minnesota, Mississippi, Missouri, Montana, Nebraska, Nevada, New Hampshire, New Mexico, North Dakota, Oklahoma, Oregon, Pennsylvania, Rhode Island, South Carolina, South Dakota, Tennessee, Virginia, Washington, West Virginia, Wisconsin, and Wyoming.

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

**IV. Application and Submission Information**

*IV.1. Address To Request Application Package*

To apply for this funding opportunity use application form PHS 5161. Application forms and instructions are available on the CDC Web site, 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) staff at: 770–488–2700. Application forms can be mailed to you.

*IV.2. Content and Form of Submission*

*Letter of Intent (LOI):* Your LOI must be written in the following format:

- Maximum number of pages: two
- Font size: 12-point unreduced
- Single spaced
- Paper size: 8.5 by 11 inches
- Page margin size: One inch
- Printed only on one side of page
- Written in English, avoid jargon

Your LOI must contain the following information:

1. This program announcement number.
2. Applicant's legal name and address.
3. Principal Investigator's name, address, telephone number, and e-mail address.
4. Identification of which category applicant is submitting.
5. A brief description of the number of state-wide births and current birth defects surveillance system.
6. A brief description of the planned statement of work.

*Application:* This program announcement is the definitive guide on application format, content, and deadlines. It supersedes information provided in the application instructions. If there are discrepancies between the application form instructions and the program announcement, adhere to the guidance in the program announcement.

You must include a project narrative with your application forms. Your narrative must be submitted in the following format:

- Maximum number of pages: 30. If your narrative exceeds the page limit, only the first pages which are within the page limit will be reviewed.
- Font size: 12 point unreduced
- Paper size: 8.5 by 11 inches
- Page margin size: One inch
- Printed only on one side of page
- Held together only by rubber bands or metal clips; not bound in any other way.

The applicant should provide a detailed description of first-year activities and briefly describe future-year objectives and activities. Your narrative should address activities to be conducted over the entire project period. Your application must include the following items in the order listed:

1. Cover Letter: A one page cover letter should indicate whether the applicant is applying for Category 1 or Category 2. Additionally, if the applicant is not the State health agency, the applicant must provide a letter from the appropriate State health agency designating the applicant as a bona fide agent. This information should be placed directly behind the cover letter of the application.
2. A one-page, single-spaced, typed abstract in 12-point font must be submitted with the application. The heading should include the title of the grant program, project title, organization, name and address, project director and telephone number. The abstract should clearly state which option the applicant is applying for: Category 1 or Category 2. The abstract should briefly summarize the program for which funds are requested, the

activities to be undertaken, and the applicant's organization structure. The abstract should precede the program narrative. A table of contents that provides page numbers for each of the following sections should be included. All pages must be numbered.

3. Narrative: The narrative should be no more than 30 double-spaced pages, printed on one side, with one-inch margins, and unreduced font (12-point). The required detailed budget, detailed budget justification, and appendices are not considered to be part of the program narrative. The narrative should specifically address item 1. or 2. in the ''Program Requirements'' and should contain the following sections:

a. Use of Surveillance Data for Improving Access to Health Services and Early Intervention Programs.

b. Use of Surveillance Data for Prevention Activities.

c. Impact on Population-Based Birth Defects Surveillance.

d. Organizational and Program Personnel Capability.

e. Understanding of the Public Health Impact of Birth Defects.

f. Human Subjects Review.

4. Budget and Budget Justification—Provide a detailed budget which indicates the anticipated costs for personnel, fringe benefits, travel, supplies, contractual, consultants, equipment, indirect, and other items. Please provide detailed budget and budget justifications for each subcontractor/subawardee.

Additional information may be included in the application appendices. The appendices will not be counted toward the narrative 30-page limit. This additional information can include:

- Birth surveillance legislation
- Most current calendar year birth surveillance data
- International Classification of Diseases codes
- Percent coverage of births
- Memorandums with neighboring states
- Folic acid educational materials
- Curriculum Vitaes/Resumes
- Organizational Charts
- Letters of Support
- Subcontractor/Subawardee budget justification
- Scientific articles and publications

You are required to have a Dun and Bradstreet Data Universal Numbering System (DUNS) number to apply for a grant or cooperative agreement from the Federal government. The DUNS number is a nine-digit identification number, which uniquely identifies business entities. Obtaining a DUNS number is easy and there is no charge. To obtain a DUNS number, access *http://www.dunandbradstreet.com* or call 1–866–705–5711.

For more information, see the CDC Web site at: *http://www.cdc.gov/od/pgo/funding/pubcommt.htm.* If your application form does not have a DUNS number field, please write your DUNS number at the top of the first page of your application, and/or include your DUNS number in your application cover letter.

Additional requirements that may require you to submit additional documentation with your application are listed in section ''VI.2. Administrative and National Policy Requirements.''

*IV.3. Submission Dates and Times*

*LOI Deadline Date:* September 27, 2004.

CDC requests that you send a LOI if you intend to apply for this program. Although the LOI is not required, not binding, and does not enter into the review of your subsequent application, the LOI will be used to gauge the level of interest in this program, and to allow CDC to plan the application review.

*Application Deadline Date:* October 20, 2004.

*Explanation of Deadlines:* Applications must be received in the CDC Procurement and Grants Office by 4:00 p.m. Eastern Time on the deadline date. If you send your application by the United States Postal Service or commercial delivery service, you must ensure that the carrier will be able to guarantee delivery of the application by the closing date and time. If CDC receives your application after closing 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, you will be given the opportunity to submit documentation of the carriers guarantee. If the documentation verifies a carrier problem, CDC will consider the application as having been received by the deadline.

This program announcement is the definitive guide on application format, content, and deadlines. It supersedes information provided in the application instructions. If your application does not meet the deadline above, it will not be eligible for review, and will be discarded. You will be notified that your application did not meet the submission requirements.

CDC will not notify you upon receipt of your application. If you have a question about the receipt of your LOI or application, first contact your courier. If you still have a question, contact the PGO-TIM staff at: 770–488–2700. Before calling, please wait two to three days after the application deadline. This will allow time for applications to be processed and logged.

*IV.4. Intergovernmental Review of Applications*

Your application is subject to Intergovernmental Review of Federal Programs, as governed by Executive Order (EO) 12372. This order sets up a system for state and local governmental review of proposed federal assistance applications. You should contact your state single point of contact (SPOC) as early as possible to alert the SPOC to prospective applications, and to receive instructions on your state's process. Click on the following link to get the current SPOC list: *http://www.whitehouse.gov/omb/grants/spoc.html.*

*IV.5. Funding Restrictions*

Restrictions, which must be taken into account while writing your budget are as follows:

- Funds may not be used for research.
- Reimbursement of preaward costs is not allowed.
- These awards may be used for personnel services, equipment, travel, and other costs related to project activities. Project funds may not be used to supplant State funds available for birth defects surveillance or prevention, health care services, patient care, nor construction.
- Award recipients agree to use cooperative agreement funds for travel by project staff selected by CDC to participate in CDC-sponsored workshops, or other called meetings such as regional or annual meetings.

If you are requesting indirect costs in your budget, you must include a copy of your indirect cost rate agreement. If your indirect cost rate is a provisional rate, the agreement should be less than 12 months of age.

Guidance for completing your budget can be found on the CDC Web site, at the following Internet address: *http://www.cdc.gov/od/pgo/funding/budgetguide.htm.*

*IV.6. Other Submission Requirements*

*LOI Submission Address:* Submit your LOI by mail, express delivery service, fax, or E-mail to: (Regular Mail) Bill Paradies, CDC, NCBDDD, 1600 Clifton Road, M/S E–86, Atlanta, GA 30333, Telephone: 404.498.3919, Fax: 404.498.3040 or 3550. (Direct/Overnight) Bill Paradies, CDC, NCBDDD, 12 Executive Park Drive, Atlanta, GA 30329. E-mail: *wep2@cdc.gov.*

*Application Submission Address:* Submit the original and two hard copies of your application by mail or express delivery service to: Technical Information Management–RFA# 05009, CDC Procurement and Grants Office, 2920 Brandywine Road, Atlanta, GA 30341.

Applications may not be submitted electronically at this time.

**V. Application Review Information**

*V.1. Criteria*

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 stated in the ''Purpose'' section of this announcement. Measures must be objective and quantitative, and must measure the intended outcome. These measures of effectiveness must be submitted with the application and will be an element of evaluation.

Your application will be evaluated against the following criteria:

1. Use of surveillance data for improving access to health services and early intervention programs (30 points): The feasibility of the applicant's plans to develop and implement or expand existing activities to improve the access of children with birth defects to health services and early interventions. The current and proposed activities evaluated in this element are specific for Category 1 and Category 2.

a. Evaluation criteria for Category 1 (States with nonexistent or less than 3 year old birth defects surveillance systems):

(1) Identification of appropriate programs within the State for referral to health services (*e.g.*, provide letters of support, Memorandums of Agreement/ Understanding).

(2) Plan for linking programs or developing other approaches to increase identification of children or families eligible for health services.

(3) Plan to evaluate the implementation process.

b. Evaluation criteria for Category 2 (States with ongoing birth defects surveillance systems):

(1) Ability to integrate programs within the State (*e.g.*, provide letters of support, Memorandums of Agreement/ Understanding, documentation of numbers of eligible children or families referred for and percent receiving services).

(2) Improve and expand approaches to increase identification of children or families eligible for health services.

(3) Evaluate the effectiveness of the referral services and the outcomes of children and families who receive services.

2. Use of the surveillance data for prevention activities (25 points): The applicant's feasibility and completeness of the plans for using surveillance data to develop and implement or expand existing programs to prevent birth defects. The current and proposed activities evaluated in this element are specific for Category 1 and Category 2.

a. Evaluation criteria for Category 1 (States with nonexistent or less than 3 year old birth defects surveillance systems):

(1) Ability to work with appropriate partners in the State (*e.g.*, provide letters of support, Memorandums of Agreement/Understanding).

(2) Plan for using the surveillance data to develop prevention programs.

(3) Plan for sharing surveillance data (*e.g.*, personal identifiers and contact information) with programs or agencies so that children or families can be enrolled in prevention programs.

(4) Letter from the State's organization receiving Title V federal funds that describe the data linkages and other collaborative activities with the applicant.

b. Evaluation criteria for Category 2 (States with ongoing birth defects surveillance systems):

(1) Ability to work with appropriate partners in the State (*e.g.*, provide letters of support, Memorandums of Agreement/Understanding).

(2) Use of surveillance data to expand prevention programs.

(3) Sharing the surveillance data (*e.g.*, personal identifiers and contact information) with programs or agencies so that children or families are enrolled in prevention programs.

(4) Evaluation of progress made in the prevention of birth defects.

(5) Letter from the State's organization receiving Title V federal funds that describe the data linkages and other collaborative activities with the applicant.

3. Impact on population-based birth defects surveillance (25 points): The accuracy and completeness of the applicant's description of the anticipated level of impact this cooperative agreement will have on birth defects surveillance activities in the State. The current and proposed activities evaluated in this element are specific for Category 1 and Category 2.

a. Evaluation criteria for Category 1 (States with nonexistent or less than 3 year old birth defects surveillance systems):

(1) Plans for developing population-based birth defects surveillance.

(2) Methods of case ascertainment.

(3) Timeliness of case ascertainment.

(4) Level of coverage of the population.

(5) Specific birth defects ascertained.

(6) Plans for analyzing and reporting surveillance data to appropriate State, local, and federal health officials.

(7) Plans for evaluating the surveillance methodology and the quality of the surveillance data.

(8) 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:

(a) The proposed plan for the inclusion 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.

(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.

b. Evaluation criteria for Category 2 (States with ongoing birth defects surveillance systems):

(1) Ability to improve/expand population-based birth defects surveillance.

(2) Methods of case ascertainment.

(3) Timeliness of case ascertainment.

(4) Level of coverage of the population.

(5) Specific birth defects ascertained.

(6) Analyzing and reporting surveillance data to appropriate State, local, and federal health officials.

(7) Evaluating the surveillance methodology and quality of the surveillance data.

(8) 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:

(a) The proposed plan for the inclusion 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.

(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. Organizational and program personnel capability (15 points):

a. Whether the applicant has the appropriate experience, skills, and ability to develop and improve birth defects surveillance and use surveillance data to develop prevention programs and improve access to health services or early intervention programs.

b. The adequacy of the present staff and/or the capability to assemble competent staff to either implement or improve upon a birth defects surveillance system and develop programs for prevention or improving access to health services and early intervention programs. If it is necessary to hire staff to conduct program activities, provide plans for identifying and hiring qualified applicants on a timely basis. Also, provide plans for how work on program activities will be conducted prior to hiring necessary staff.

c. The applicant shall identify all current and potential personnel who will work on this cooperative agreement including qualifications and specific experience as it relates to the requirements set forth in this announcement.

5. Applicant's understanding of the public health impact of birth defects (5 points): The adequacy of the applicant's description of a clear, concise understanding of the requirements, objectives, and purpose of the cooperative agreement. This application shall reflect the applicant's understanding of the public health impact of birth defects in their State and the purpose and complexities of birth defects surveillance as it relates to their State.

6. Human Subjects Review (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 are so inadequate as to make the entire application unacceptable.)

7. Budget justification and adequacy of facilities (not scored): The budget will be evaluated for the extent to which it is reasonable, clearly justified, and consistent with the intended use of the cooperative agreement funds. The applicant shall describe and indicate the availability of facilities and equipment necessary to carry out this project.

*V.2. Review and Selection Process*

Applications will be reviewed for completeness by the Procurement and Grants Office staff and for responsiveness by the National Center on Birth Defects and Developmental Disabilities. Incomplete applications and applications that are non-responsive to the eligibility criteria will not advance through the review process. Applicants will be notified that their application did not meet submission requirements. An objective review panel will evaluate complete and responsive applications according to the criteria listed in the ''V.1. Criteria'' section above. The objective review panel will consist of CDC employees who will be randomly assigned applications to review and score. Category 1 and Category 2 applications will be funded respectively in order by score and rank as determined by the review panel. CDC will provide justification for any decision to fund out of rank order.

*V.3. Anticipated Award Date*

February 2005 for a March 1, 2005 project start date.

**VI. Award Administration Information**

*VI.1. Award Notices*

Successful applicants will receive a Notice of Grant Award (NGA) from the CDC Procurement and Grants Office. The NGA shall be the only binding, authorizing document between the recipient and CDC. The NGA will be signed by an authorized Grants Management Officer, and mailed to the recipient fiscal officer identified in the application.

Unsuccessful applicants will receive notification of the results of the application review by mail.

*VI.2. Administrative and National Policy Requirements*

45 CFR Parts 74 and 92

For more information on the Code of Federal Regulations, see the National Archives and Records Administration at the following Internet address: *http://www.access.gpo.gov/nara/cfr/cfr-table-search.html*.

The following additional requirements apply to this project:

- AR–7 Executive Order 12372
- AR–9 Paperwork Reduction Act Requirements
- AR–10 Smoke-Free Workplace Requirements
- AR–11 Healthy People 2010
- AR–12 Lobbying Restrictions
- AR–24 Health Insurance Portability and Accountability Act Requirements

Additional information on these requirements can be found on the CDC Web site at the following Internet address: *http://www.cdc.gov/od/pgo/funding/ARs.htm*.

*VI.3. Reporting Requirements*

You must provide CDC with an original, plus two copies of the following reports:

1. Interim progress report, no less than 90 days before the end of the budget period. The progress report will serve as your 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. Measures of Effectiveness.

f. Additional Requested Information.

2. Financial status report and annual progress 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.

These reports must be mailed to the Grants Management or Contract Specialist listed in the ''Agency Contacts'' section of this announcement.

**VII. Agency Contacts**

We encourage inquiries concerning this announcement. For general questions about this announcement, contact: Technical Information Management Section, CDC Procurement and Grants Office, 2920 Brandywine Road, Atlanta, GA 30341, Telephone: 770–488–2700.

For program technical assistance, contact: Cara Mai/Bill Paradies, Project Officers, 1600 Clifton Road, Mailstop E–86, Atlanta, GA 30333, Telephone: 404–498–3918/3919, Fax: 404–498–3040 or 3550, E-mail: *cmai@cdc.gov* and *wep2@cdc.gov*.

For financial, grants management, or budget assistance, contact: Susan B. Kiddoo, Grants Management Officer, CDC Procurement and Grants Office, 2920 Brandywine Road, Room 3000, Atlanta, GA 30341, Telephone: 770–488–2605, Fax: 770–488–2777, E-mail: *scb7@cdc.gov*.

**VIII. Other Information**

This and other CDC funding opportunity announcements can be found on the CDC Web site, Internet address *http://www.cdc.gov*. Click on ''Funding'' then ''Grants and Cooperative Agreements.''

Dated: August 25, 2004.

**William P. Nichols,**

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

[FR Doc. 04–19799 Filed 8–30–04; 8:45 am]

**BILLING CODE 4163–18–P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

### Animal Models and Correlates of Protection for Plague Vaccines; Public Workshop

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice of public workshop.

The Food and Drug Administration (FDA) is announcing the following public workshop: ''Animal Models and Correlates of Protection for Plague Vaccines.'' The purpose of this workshop is to provide a public forum to discuss the animal models that may be most appropriate for evaluating new plague vaccines; the critical immune responses that may correlate with protection against plague; and the kinds of experimental and clinical assays that will need to be developed to measure these critical immune responses both in animals and in humans. The workshop will develop information that may be critical to the design of the pivotal studies required to assess plague vaccine efficacy.

*Date and Time*: This 1 1/2-day public workshop will be held on October 13, 2004, from 8:30 a.m. to 5 p.m., and October 14, 2004, from 8:30 a.m. to 12 noon.

*Location*: The workshop will be held at the Marriott Gaithersburg Washingtonian Center, 9751 Washingtonian Blvd., Gaithersburg, MD.

The Marriott Gaithersburg Washingtonian Center is located approximately 30 minutes from Ronald Reagan Washington National and Washington Dulles International airports. Directions to the hotel can be found at *http://marriott.com/property/propertyPage/WASWG*.

*Contact Person*: *Regarding the public workshop*: Robert J. Watson, Science Applications International Corp., 5340 Spectrum Dr., suite N, Frederick, MD 21703, 301–228–3148, FAX: 301–698–5991, e-mail: *robert.j.watson@saic.com*.

*Regarding this document*: Nathaniel L. Geary, Center for Biologics Evaluation and Research (HFM–17), Food and Drug Administration, 1401 Rockville Pike, suite 200N, Rockville, MD 20852–1448, 301–827–6210.

*Registration*: Registration is required; however, there is no registration fee for this public workshop. The deadline for registration is Wednesday, October 6, 2004. There will be no onsite registration. Information about the workshop and online registration can be found at *https://www.seeuthere.com/event/m2c640–122589588204*.

If you need special accommodations due to a disability, please contact Robert Watson (see *Contact Person*) at least 7 days in advance of the workshop.

**SUPPLEMENTARY INFORMATION:** FDA's Center for Biologics Evaluation and Research; the National Institutes of Health, National Institute of Allergy and Infectious Diseases; and the Department of Health and Human Services, Office of Research Development and Coordination are sponsoring a public workshop. The workshop will be divided into interactive sessions in which leaders in the plague research field will present topics of particular relevance to plague vaccines. The sessions will include the following topics: (1) Introduction to the ''Animal Rule,'' (2) pathogenesis of plague, (3) plague vaccines and assessment of immune responses, (4) human disease and relevant animal models, and (5) implementation of the ''Animal Rule'' for plague vaccines. In addition, an expert panel will discuss the issues that will be critical for the development and eventual licensure of plague vaccines. The workshop's goal is to expedite the development and licensure of new plague vaccines by providing information critical to the development of the following: (1) Appropriate animal models, (2) immuno-assays, and (3) testing plans for vaccine evaluation.

*Transcripts*: Transcripts of the workshop may be requested in writing from the Freedom of Information Office (HFI–35), Food and Drug Administration, 5600 Fishers Lane, rm. 12A–16, Rockville, MD 20857, approximately 15 working days after the workshop at a cost of 10 cents per page. Additionally, the transcript will be placed on the FDA Internet at *http://www.fda.gov/cber/minutes/workshop-min.htm*.

Dated: August 24, 2004.

**Jeffrey Shuren,**

*Assistant Commissioner for Policy.*

[FR Doc. 04–19776 Filed 8–30–04; 8:45 am]

**BILLING CODE 4160–01–S**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

### Food Advisory Committee; Tentative Schedule of Meetings for 2004; Amendment of Notice

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) is announcing an amendment to the tentative schedule of meetings for 2004. This document was announced in the **Federal Register** of December 31, 2003 (68 FR 75574 through 75577). The amendment is being made to reflect the following change: The Center for Food Safety and Applied Nutrition is canceling the tentatively scheduled meeting for the Dietary Supplements Subcommittee of the Food Advisory Committee on September 14 and 15, 2004.

**FOR FURTHER INFORMATION CONTACT:** Carolyn E. Jeletic, Center for Food Safety and Applied Nutrition (HFS–006), Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740, 301–436–2397.

**SUPPLEMENTARY INFORMATION:** You may also obtain up-to-date meeting information by calling the Advisory Committee Information Line, 1–800–741–8138 (301–443–0572 in the Washington, DC area).

Dated: August 24, 2004.

**Lester M. Crawford,**

*Acting Commissioner of Food and Drugs.*

[FR Doc. 04–19777 Filed 8–30–04; 8:45 am]

**BILLING CODE 4160–01–S**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

**[Docket No. 2004N–0366]**

### From Concept to Consumer: Center for Biologics Evaluation and Research Working With Stakeholders on Scientific Opportunities for Facilitating Development of Vaccines, Blood and Blood Products, and Cellular, Tissue, and Gene Therapies; Public Workshop

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice of public workshop; request for comments.

The Food and Drug Administration (FDA), is announcing a public workshop entitled ''From Concept to Consumer: Center for Biologics Evaluation and