2038, Rockville, Maryland 20850, telephone (301) 427–1554.

Agenda items for this meeting are subject to change as priorities dictate.

Dated: July 11, 2005.

Carolyn M. Clancy,

Director.

[FR Doc. 05–14183 Filed 7–18–05; 8:45 am]

BILLING CODE 4160–10–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

Single Gene Disorders Resource Network

Announcement Type: New.

Funding Opportunity Number: AA092.

Catalog of Federal Domestic Assistance Number: 93.283.

Key Dates:

Letter of Intent (LOI) Deadline: July 29, 2005.

Application Deadline: August 18, 2005.

I. Funding Opportunity Description

Authority: This program is authorized under Sections 301, 311 and 317(C) of the Public Health Service Act [42 U.S.C. 241, 243, and 247b–4 as amended].

Background: There are over 6000 known single gene disorders, including over 1650 with identified genes. Single gene disorders occur in about one in 300 births, and account for 13 percent of in-patients in pediatric hospital and three to five percent of pediatric deaths. The National Center on Birth Defects and Developmental Disabilities (NCBDDD) seeks to ensure the optimal outcome of people with disabling or potential disabling pediatric single gene conditions and their families, by developing surveillance systems that meet challenges of single gene disorders, improving screening and diagnosis, and improving services to patients and families. Genetic disorders raise different issues for health care providers and families than do non-genetic disorders because genetic disorders have implications for other family members, and raise psychosocial issues (such as guilt, blame and stigmatization). Lessons learned from public health activities in single gene disorders can be applied to complex disorders as their etiologies become elucidated.

This cooperative agreement will fund the development of a national resource network for single gene disorders. Initial funding will support projects related to Duchenne and Becker Muscular Dystrophy (DBMD) and Fragile X syndrome (FXS). The proposed National Network will have the capacity to expand to other single gene disorders.

Purpose: The purpose of the program is to develop, implement, and evaluate a Network for Single Gene Disorders, focusing specifically on DBMD and FXS. This program addresses the ''Healthy People 2010'' focus areas of Disability and Secondary Conditions; Mental Health and Mental Health Disorders; and Maternal, Infant, and Child Health.''.

Measurable outcomes of the program will be in alignment with one (or more) of the following performance goal(s) for the National Center on Birth Defects and Developmental Disabilities (NCBDDD): Prevent birth defects and developmental disabilities, and improve the health and quality of life of Americans with disabilities.

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/opspoll1.htm.*

Activities:

Applicants may apply for funding under part A and/or part B. Please note that if applicants choose to apply for both part A and part B, applicants may submit consolidated applications addressing the requirements of both part A and part B under one application.

Awardee activities for part A of this program are as follows:

- Increase access to accurate and scientifically valid information on the etiology, diagnosis, and treatment of DBMD for end users including families, educators, health professionals, allied health caregivers, and the general public. The awardee will specifically assemble and/or develop informational materials that: (1) Reflect expert opinion, evidence-based knowledge and current clinical practice, and (2) respond to the needs of individuals and families affected by DBMD. These informational materials will be disseminated to the target populations.
- Assess current educational and outreach materials related to DBMD targeted at families with DBMD and the general public. Develop and/or modify, implement and evaluate educational materials for families with DBMD and the general public, including information on the etiology, clinical course, treatment options, and available services (including services supported by Health Resources and Services Administration, the Administration for Children and Families/Administration on Developmental Disabilities, and other DHHS-supported efforts that target families of children with disabilities). Content of materials includes issues specific to single gene disorders, such as genetic counseling.
- Assess current educational and outreach materials related to DBMD targeted at health care providers. Develop and/or modify, implement and evaluate educational materials for providers and students, focusing on recognition, diagnosis, referral and treatment. Content of materials includes current diagnostic and treatment standards or guidelines; and issues specific to single gene disorders, such as genetic counseling.
- Disseminate the information on DBMD widely within the targeted group including families, educators, health professionals, allied health caregivers, and the general public. This may be new or existing materials in a variety of formats including written, video, CD, and World Wide Web. Ensure the dissemination plan for the materials is developed, methods for reaching under-served and minority communities are described and justified; and accurate information about diagnosis and treatment of DBMD is available to various stakeholders, *i.e.*, practitioners, families, teachers, and other caregivers.
- Coordinate educational activities with other community-based and community-wide providers and organizations that offer services or direct education messages to U.S. residents that have DBMD and their providers.
- Hire and train staff as necessary to implement education and outreach activities for DBMD.
- Increase opportunities for regular and ongoing DBMD training and education available to persons within the targeted audiences.
- Identify core competencies about DBMD for medical and allied health students.
- Evaluate the core competencies for appropriateness and validity based on needs of the audiences and on scientific research.
- Develop methods to ensure that materials and resources for DBMD education and training are easily accessible.
- Coordinate activities with other awardees.

Awardee activities for part B of this program are as follows:

- Increase access to accurate and scientifically valid information on the etiology, diagnosis, and treatment of FXS for end users including health professionals, allied health caregivers, and students. The awardee will specifically assemble and/or develop

informational materials that: (1) reflect expert opinion, evidence-based knowledge and current clinical practice; and (2) respond to the needs of individuals and families affected by FXS. These informational materials will be disseminated to the target populations.

• Assess current educational and outreach materials related to FXS targeted at health care providers. Develop and/or modify, implement and evaluate educational materials for providers and students, focusing on recognition, diagnosis, referral and treatment. Content of materials includes current diagnostic and treatment standards or guidelines; and issues specific to single gene disorders, such as genetic counseling.

• Disseminate the information on FXS widely within the targeted group including health professionals, allied health caregivers, and students. This may be new or existing materials in a variety of formats including written, video, CD and World Wide Web. Ensure the dissemination plan for the materials is developed, methods for reaching under-served and minority communities are described and justified, and accurate information about diagnosis and treatment of FXS is available to various stakeholders, i.e., practitioners, teachers, and other caregivers.

• Coordinate educational activities with other community-based and community-wide providers and organizations that offer services or direct education messages to U.S. residents who have FXS and their providers.

• Hire and train staff as necessary to implement education and outreach activities for FXS.

• Increase opportunities for regular and ongoing FXS training and education available to persons within the targeted audiences.

• Identify core competencies about FXS for medical and allied health students.

• Evaluate the core competencies for appropriateness and validity based on needs of the audiences and on scientific research.

• Develop methods to ensure that materials and resources for FXS education and training are easily accessible.

• Coordinate activities with other awardees.

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:

• Assist recipients in monitoring program evaluation/performance; setting and meeting objectives; implementing methods, and complying with cooperative agreement requirements and other funding issues, through various methods including telephone consultation, site visits, and site visit reports.

• Assist recipients in coordination of activities where possible.

• Assist recipients in coordination of activities with those of related partner organizations, including HRSA maternal and child health, Community Health Centers and OPA family planning.

• Assist recipients in developing and maintaining working relationships with stakeholder organizations.

• Provide technical assistance in assessing and prioritizing training and educational needs and in planning, implementing, and evaluating training and educational activities.

• Provide technical assistance in developing and evaluating innovative curriculum approaches, instructional strategies, and materials.

II. Award Information

Part A: Duchenne and Becker Muscular Dystrophy

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

Fiscal Year Funds: 2005.

Approximate Total Funding: $600,000 (This amount is an estimate, and is subject to availability of funds.)

Approximate Number of Awards: One.

Approximate Average Award: $600,000 (This amount is for the first 12-month budget period, and includes both direct and indirect costs).

Floor of Award Range: $500,000.

Ceiling of Award Range: $600,000 (This ceiling is for the first 12-month budget period.)

Anticipated Award Date: August 30, 2005.

Budget Period Length: 12 months.

Project Period Length: Five years.

Part B: Fragile X Syndrome

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

Fiscal Year Funds: 2005.

Approximate Total Funding: $250,000 (This amount is an estimate, and is subject to availability of funds.)

Approximate Number of Awards: One.

Approximate Average Award: $250,000 (This amount is for the first 12-month budget period, and includes both direct and indirect costs).

Floor of Award Range: $200,000.

Ceiling of Award Range: $250,000 (This ceiling is for the first 12-month budget period.)

Anticipated Award Date: August 30, 2005.

Budget Period Length: 12 months.

Project Period Length: Five years.

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

Eligible applicants that can apply for this funding opportunity are listed below:

• Public nonprofit organizations
• Private nonprofit organizations
• For profit organizations
• Small, minority, women-owned businesses
• Universities
• Colleges
• Research institutions
• Hospitals
• Community-based organizations
• Faith-based organizations
• Federally recognized Indian tribal governments
• Indian tribes
• Indian tribal organizations
• State and local governments or their Bona Fide Agents (this includes the District of Columbia, the Commonwealth of Puerto Rico, 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)
• Political subdivisions of States (in consultation with States)

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 applying as a bona fide agent of a State or local government, a letter from the State or local government as documentation of the status is required. Place this documentation behind the first page of the application form.

III.2. Cost Sharing or Matching

Matching funds are not required for this program.

III.3. Other

A successful applicant must be an organization with a national scope of operations.

If a funding amount greater than the ceiling of the award range is requested, the application will be considered non-responsive and will not be entered into the review process. The applicant will be notified that the application did not meet the submission requirements.

Special Requirements:

If the application is incomplete or non-responsive to the special requirements listed in this section, it will not be entered into the review process. The applicant will be notified that the application did not meet submission requirements.

- Late applications will be considered non-responsive. See section ''IV.3. Submission Dates and Times'' for more information on deadlines.

- **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.

- Assistance will be provided only to a well-established non-profit organization with experience in: (1) Assisting parents and families of people with genetic disorders; (2) conducting a national medical and public education agenda that focuses on producing valuable literature for families with genetic disorders, health care providers, and allied health caregivers; and (3) communicating research findings effectively to national, regional, state and local level media outlets in coordination with partners.

IV. Application and Submission Information

IV.1 Address to Request Application Package

To apply for this funding opportunity use application form PHS 5161–1.

Electronic Submission:

CDC strongly encourages the applicant to submit the application electronically by utilizing the forms and instructions posted for this announcement on *http://www.Grants.gov*, the official Federal agency wide E-grant Web site. Only applicants who apply on-line are permitted to forego paper copy submission of all application forms. Application forms and instructions are available on the CDC web site, at the following Internet address: *http://www.cdc.gov/od/pgo/forminfo.htm*.

Paper Submission:

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

IV.2. Content and Form of Application Submission:

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 the page
- Written in English, avoid jargon

Your LOI must contain the following information:

- Name
- Address
- Telephone number
- Principal Investigator
- Number and title of this program announcement
- Intent to apply under part A and/or part B of this announcement
- Names of other key personnel
- Designations of collaborating institutions and entities
- Recruitment approach
- Expected Outcomes

Application: A project narrative must be submitted with the application forms. The narrative must be submitted in the following format:

- Maximum number of pages: 25 for part A or part B, 30 for parts A and B combined. 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
- Double spaced
- 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 narrative should address activities to be conducted over the entire project period, and must include the following items in the order listed:

- A demonstrated understanding of the problem of single gene disorders including DBMD and/or FXS and the justification of the need for establishment of the Single Gene Disorders Resource Network.
- A description of the goals and specific objectives of the project in time-framed, measurable terms.
- A detailed plan describing the approach to be taken in implementing the project and the methods by which the objectives will be achieved and evaluated, including their sequence. A comprehensive evaluation plan must be outlined.
- A description of the specific products to be developed and/or disseminated through the project.
- A description of the cooperative agreement's principal investigator's role and responsibilities.
- A description of all the project staff, regardless of their funding source. It should include their title, qualifications, experience, percentage of time each will devote to the project, as well as that portion of their salary to be paid by the cooperative agreement.
- A description of relationships with voluntary health organizations and other organizations that offer services or direct education messages to U.S. residents that have single gene disorders including DBMD and/or FXS and their providers dedicated; and a description of a plan to involve these organizations in the development, implementation and evaluation of this project.
- A detailed first year's budget for the cooperative agreement with future annual projections. Awards will be made for a project period of up to five years. (Budget justification is not included in narrative page limit).

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

- Curricula Vitae
- Letters of Support

The agency or organization is 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/grantmain.htm.* If the application form does not have a DUNS number field, please write the DUNS number at the top of the first page of the application, and/or include the DUNS number in the application cover letter.

Additional requirements that may require submittal of additional documentation with the application are listed in section ''VI.2. Administrative and National Policy Requirements.''

IV.3. Submission Dates and Times

Letter of Intent (LOI) Deadline Date: July 29, 2005.

CDC requests that you send a LOI if you intend to apply for this program. 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: August 18, 2005.

Explanation of Deadlines: Applications must be received in the CDC Procurement and Grants Office by 4 p.m. eastern time on the deadline date.

Applications may be submitted electronically at *http://www.grants.gov.* Applications completed on-line through Grants.gov are considered formally submitted when the applicant organization's Authorizing Official electronically submits the application to *http://www.grants.gov.* Electronic applications will be considered as having met the deadline if the application has been submitted electronically by the applicant organization's Authorizing Official to Grants.gov on or before the deadline date and time.

If submittal of the application is done electronically through Grants.gov (*http://www.grants.gov*), the application will be electronically time/date stamped, which will serve as receipt of submission. Applicants will receive an e-mail notice of receipt when CDC receives the application.

If submittal of the application is by the United States Postal Service or commercial delivery service, the applicant must ensure that the carrier will be able to guarantee delivery by the closing date and time. If CDC receives the submission 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, the applicant will be given the opportunity to submit documentation of the carrier's guarantee. If the documentation verifies a carrier problem, CDC will consider the submission as having been received by the deadline.

If a hard copy application is submitted, CDC will not notify the applicant upon receipt of the submission. If questions arise on the receipt of the application, the applicant should first contact the carrier. If the applicant still has questions, contact the PGO–TIM staff at (770) 488–2700. The applicant should wait two to three days after the submission deadline before calling. This will allow time for submissions to be processed and logged.

This announcement is the definitive guide on application content, submission address, and deadline. It supersedes information provided in the application instructions. If the submission does not meet the deadline above, it will not be eligible for review, and will be discarded. The applicant will be notified the application did not meet the submission requirements.

IV.4. Intergovernmental Review of Applications

Executive Order 12372 does not apply to this program.

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 pre-award costs is not allowed.

If requesting indirect costs in the budget, a copy of the indirect cost rate agreement is required. If the 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 express mail, delivery service, fax, or e-mail to: Michael Brown, Project Officer, Centers for Disease Control and Prevention (CDC), National Center on Birth Defects and Developmental Disabilities, Division of Human Development and Disability, 1600 Clifton Road NE, Mailstop E–88, Atlanta, GA 30333; Telephone: 404–498–3006; E-mail: *MABrown@cdc.gov.*

Application Submission Address:

Electronic Submission:

CDC strongly encourages applicants to submit applications electronically at *http://www.Grants.gov.* The application package can be downloaded from *http://www.Grants.gov.* Applicants are able to complete it off-line, and then upload and submit the application via the Grants.gov Web site. E-mail submissions will not be accepted. If the applicant has technical difficulties in Grants.gov, costumer service can be reached by E-mail at *http://www.grants.gov/CustomerSupport* or by phone at 1–800–518–4726 (1–800–518–GRANTS). The Customer Support Center is open from 7 a.m. to 9 p.m. eastern time, Monday through Friday.

CDC recommends that submittal of the application to Grants.gov should be early to resolve any unanticipated difficulties prior to the deadline. Applicants may also submit a back-up paper submission of the application. Any such paper submission must be received in accordance with the requirements for timely submission detailed in Section IV.3. of the grant announcement. The paper submission must be clearly marked: ''BACK-UP FOR ELECTRONIC SUBMISSION.'' The paper submission must conform to all requirements for non-electronic submissions. If both electronic and back-up paper submissions are received by the deadline, the electronic version will be considered the official submission.

It is strongly recommended that the applicant submit the grant application using Microsoft Office products (*e.g.,* Microsoft Word, Microsoft Excel, etc.). If the applicant does not have access to Microsoft Office products, a PDF file may be submitted. Directions for creating PDF files can be found on the Grants.gov Web site. Use of file formats other than Microsoft Office or PDF may result in the file being unreadable by staff.

OR

Paper Submission:

Applicants should submit the original and two hard copies of the application by mail or express delivery service to: Technical Information Management [RFA# AA092], CDC Procurement and Grants Office, 2920 Brandywine Road, Atlanta, GA 30341.

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.

The application will be evaluated against the following criteria:

1. *Capacity to Conduct Project Activities and Begin Project Operations in a Timely Fashion (30%)*

The extent to which the applicant has provided information to support its ability to conduct the activities of the cooperative agreement, including documentation of previous relevant experience; documentation of institutional support for the project; demonstrated ability to identify qualified personnel to fill key positions and begin project activities in a timely fashion; and the ability to identify adequate office space for the project as well as facilities for conducting training/educational sessions. The extent to which the organization has

with experience in: (1) Assisting parents and families of people with genetic disorders (2) conducting a national medical and public education agenda that focuses on producing valuable literature for families with genetic disorders, health care providers, and allied health caregivers (3) communicating research findings effectively to national, regional, state and local level media outlets in coordination with partners.

2. *Applicant's Understanding of the Problem (20%)*

The extent to which the applicant demonstrates an understanding of the resource needs related to single gene disorders, including DBMD and/or FXS, and the importance of educating medical and allied health students and practitioners about these conditions.

3. *Goals and Objectives (20%)*

The extent to which the project goals are clearly stated and the objectives are specific, measurable, and time-phased. Also, the extent to which a plan is presented for evaluating the objectives.

4. *Collaboration with Voluntary Health and Related Organizations (15%)*

The extent to which the applicant has provided a full and comprehensive description of partnerships with voluntary health organizations and other organizations that offer services or direct education messages to U.S. residents that have genetic disorders including DBMD and/or FXS and their providers; and a description of a plan to involve these organizations in the development, implementation and evaluation of this project.

5. *Plan of Operation (15%)*

The extent to which the applicant has provided a full and comprehensive description of the project they propose to undertake and a plan for how it will be accomplished. The applicant must also describe the methods by which the objectives will be achieved and evaluated.

6. *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.

7. *Human Subjects Review (not scored)*

Does the application adequately address the requirements of Title 45 CFR Part 46 for the protection of human subjects?

V.2. Review and Selection Process

Applications will be reviewed for completeness by the Procurement and Grants Office (PGO) staff, and for responsiveness by the National Center on Birth Defects and Developmental Disabilities (NCBDDD). 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 outside of the funding division, who will be randomly assigned applications to review and score. Applications will be funded in order by score and rank determined by the review panel. Applicants that apply under both part A and part B will receive separate scores for each part. CDC will provide justification for any decision to fund out of rank order. Subsequent to the formal review of all competitive applications, a second level of review will be conducted by senior CDC program staff. This review will not revisit the scientific merit of the applications, but will evaluate the overall budget implications of the applications against funding ceilings; they may not make recommendations as to the final ordering of the top ranked applications for part A and part B, and they may not actually change the ranking order (or scores). It is possible that the second level of review may recommend funding the highest ranked proposal under part A (or part B) and also funding that same organization under its application for the other part of the announcement. That could occur in the event that an organization with the highest ranking in one part ranks among the highest three applicants in the other part. This would be done to take into account economies of scale and establish the capacity to conduct non-redundant programs to best meet the purposes of this announcement. In such a case, the total approved budget may be less than the sum of the two applications due to staff time commitment duplications and other considerations.

V.3. Anticipated Announcement and Award Dates

August 31,2005 for a September 30, 2005 project start date.

VI. Award Administration Information

VI.1. Award Notices

Successful applicants will receive a Notice of Award (NoA) from the CDC Procurement and Grants Office. The NoA 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

Successful applicants must comply with the administrative requirements outlined in 45 CFR part 74 and part 92 as Appropriate. The following additional requirements apply to this project:

- AR–9—Paperwork Reduction Act Requirements
- AR–10—Smoke-Free Workplace Requirements
- AR–11—Healthy People 2010
- AR–12—Lobbying Restrictions

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*.

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*.

An additional Certifications form from the PHS5161–1 application needs to be included in the Grants.gov electronic submission only. Applicants should refer to *http://www.cdc.gov/od/pgo/funding/PHS5161–1–Certificates.pdf*. Once the applicant has filled out the form, it should be attached to the Grants.gov submission as Other Attachments Form.

VI.3. Reporting Requirements

The applicant must provide CDC with an original, plus two hard copies of the following reports:

1. Interim progress report, due 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. Budget.
e. Measures of Effectiveness.
f. 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.

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, 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: Michael Brown, Project Officer, Centers for Disease Control and Prevention (CDC), National Center on Birth Defects and Developmental Disabilities, Division of Human Development and Disability, 1600 Clifton Road NE., Mailstop E–88, Atlanta, GA 30333; Telephone: 404–498–3006; E-mail: *MABrown@cdc.gov*.

For financial, grants management, or budget assistance, contact: Mildred Garner, Grants Management Officer, CDC Procurement and Grants Office, 2920 Brandywine Road, Atlanta, GA 30341; Telephone: (770) 488–2745; E-mail: *mqg4@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: July 13, 2005.

Alan A. Kotch,

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

[FR Doc. 05–14166 Filed 7–18–05; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

Meetings: Disease, Disability, and Injury Prevention and Control Special Emphasis Panel

In accordance with Section 10(a)(2) of the Federal Advisory Committee Act (Pub. L. 92–463), the Centers for Disease Control and Prevention (CDC) announces the following meeting:

Name: Disease, Disability, and Injury Prevention and Control Special Emphasis Panel (SEP): Intervention for Individuals with Fetal Alcohol Syndrome: Transitioning Science to Community Project, Request for Application (RFA) #DD 05–079 and Implementing Community-Level Strategies for Fetal Alcohol Syndrome Prevention and Surveillance in South Africa, RFA #DD 05–118.

Times and Dates: 1 p.m.–5 p.m., August 3, 2005 (Closed).

Place: Teleconference.

Status: The meeting will be closed to the public in accordance with provisions set forth in Section 552b(c)(4) and (6), Title 5 U.S.C., and the Determination of the Director, Management Analysis and Services Office, CDC, pursuant to Public Law 92–463.

Matters To Be Discussed: The meeting will include the review, discussion, and evaluation of applications received in response to: Intervention for Individuals with Fetal Alcohol Syndrome: Transitioning Science to Community Project, Request for Application (RFA) #DD 05–079 and Implementing Community-Level Strategies for Fetal Alcohol Syndrome Prevention and Surveillance in South Africa, RFA #DD 05–118.

For Further Information Contact: Pamela J. Wilkerson, MPA, Scientific Review Administrator, 24 Executive Park Drive, NE., Mailstop E74, Atlanta, GA 30333, Telephone (404) 498–2556.

The Director, Management Analysis and Services Office, has been delegated the authority to sign **Federal Register** notices pertaining to announcements of meetings and other committee management activities, for both CDC and the Agency for Toxic Substances and Disease Registry.

Dated: July 12, 2005.

Alvin Hall,

Director, Management Analysis and Services Office, Centers for Disease Control and Prevention.

[FR Doc. 05–14162 Filed 7–18–05; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2003D–0167] (formerly Docket No. 03D–0167)

Guidance for Industry on Dispute Resolution Procedures for Science-Based Decisions on Products Regulated by the Center for Veterinary Medicine; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a guidance for industry (#79) entitled ''Guidance for Industry: Dispute Resolution Procedures for Science-Based Decisions on Products Regulated by the Center for Veterinary Medicine (CVM).'' This guidance document describes dispute resolution procedures by which sponsors, applicants, or manufacturers of FDA-regulated products for animals may request review of science-based decisions. This guidance does not address procedures for handling issues associated with FDA's new initiative to enhance pharmaceutical good manufacturing practices (GMPs).

DATES: Submit written or electronic comments on agency guidances at any time.

ADDRESSES: Submit written requests for single copies of the guidance to the Communications Staff (HFV–12), Center for Veterinary Medicine, Food and Drug Administration, 7519 Standish Pl., Rockville, MD 20855. Send one self-addressed adhesive label to assist that office in processing your requests.

Submit written comments on this guidance to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments to *http:///www.fda.gov/dockets/ecomments*. Comments should be identified with the full title of the guidance and the docket number found in brackets in the heading of this document. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the guidance document.

FOR FURTHER INFORMATION CONTACT: Marcia Larkins, Center for Veterinary Medicine (HFV–7), Food and Drug Administration, 7519 Standish Pl., Rockville, MD 20855, 301–827–4535, e-mail: *mlarkins@cvm.fda.gov*.

SUPPLEMENTARY INFORMATION:

I. Background

In the **Federal Register** of May 19, 2003 (68 FR 27094), FDA published a notice of availability for a draft guidance for industry entitled ''Dispute Resolution Procedures for Science-Based Decisions on Products Regulated by the Center for Veterinary Medicine (CVM)'' giving interested persons until August 4, 2003, to submit comments on the draft guidance and until July 18, 2003, to comment on the information collection. FDA considered all comments received and, where appropriate, made changes in the guidance.

II. Significance of Guidance

This level 1 guidance is being issued consistent with FDA's good guidance