Dated: December 5, 2003.

Alvin Hall,

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

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BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

Efficacy Trials of Parenting Programs for Fathers

Announcement Type: New.

Funding Opportunity Number: 04055.

Catalog of Federal Domestic Assistance Number: 93.136.

Key Dates: Letter of Intent Deadline: January 16, 2004.

Application Deadline: February 18, 2004.

I. Funding Opportunity Description

Authority: This program is authorized under section 391(a)(1) of the Public Health Service Act, [42 U.S.C. section 280b(a)(1), as amended].

Purpose: The purpose of the program is to examine the efficacy of parenting programs for high-risk fathers, expectant fathers, or father surrogates of children age birth to two and/or age three to five for the prevention of child maltreatment and the promotion of positive parenting behaviors. This program addresses the ''Healthy People 2010'' focus area of Injury and Violence Prevention.

Measurable outcomes of the program will be in alignment with the following performance goal for the National Center for Injury Prevention and Control: Conduct a targeted program of research to reduce injury-related death and disability.

Outcomes to be assessed include:

- Knowledge and attitudes towards parenting, including perceptions of self-reported parenting competence;
- Changes in daily parental behavior and parenting style;
- Mothers' perceptions of fathers' support;
- Mothers' and fathers' reports of fathers' involvement in care giving;
- Incidence of neglect, and physical, sexual, and emotional abuse; and
- Incidence of unintentional injuries.

Research Objectives: Research suggests that most cases of serious child physical abuse and fatality are caused by fathers or father figures (Anderson, Ambrosino, Valentine, & Lauderdale, 1983; Bergman, Larsen, & Mueller, 1986; Brewster *et al.*, 1998; Daley & Piliavin, 1982; Hicks & Gaughan, 1995; Jason & Andereck, 1983; Rosenthal, 1988). Although there is little research on the determinants of abuse among fathers or father figures, it appears that they may have similar characteristics to those of physically abusive mothers: greater perceived stress and distress, greater physiological reactivity, lack of social support, negative perceptions of their children, and inaccurate knowledge or expectations of developmentally appropriate complex child behaviors (Milner, 1998).

Recruiting fathers in prevention programs is a major challenge. However, some prevention and awareness programs have been developed to teach experienced and new fathers the basics in caring for infants and young children. Such programs provide men with a safe environment to discuss their concerns about fatherhood and learn basic childcare skills. Participants report high rates of satisfaction and show low levels of attrition. However, more rigorous evaluation of such programs is needed to establish their potential impact.

Research funded under this announcement is expected to address this important gap in the prevention literature (*i.e.*, efficacy studies of interventions that are designed to reduce the above types of parenting characteristics). The ultimate aim of such an approach is to assess whether interventions designed to teach expectant, new, experienced, and surrogate fathers the basics in caring for infants and young children, can reduce risk factors for child maltreatment.

At a minimum, competitive applicants will provide theoretical rationale and empirical evidence in support of a specific extant parenting course directed toward fathers whose intimate partners are currently expecting or have children under the age of five, and conduct a rigorous efficacy study.

Priority will be given to efficacy studies of primary prevention parenting programs that focus on the determinants of abuse among expectant, new, experienced or surrogate fathers, over those that focus on criminal justice responses (*e.g.*, arrest strategies).

Priority will also be given to proposals that:

- Propose more stringent and rigorous evaluation designs, including: Experimental and quasi-experimental designs with appropriate baseline/pre-intervention data, post-intervention data, and at least one follow-up collection point; data from at least one comparison or control group; and data from multiple sources.
- Propose data analytic plans that are appropriate to the intervention, research design and hypotheses, data collection measures, and project period, and that anticipate and evaluate the effect of threats to the internal and external validity of the specified research design.
- Target traditionally underserved communities.

Activities: Awardee activities for this program are as follows:

1. Design and conduct research, including formative research and pilot testing to address the described goals of this cooperative agreement.
2. Collaborate with CDC scientists in the development of the human subjects protocol for the CDC Institutional Review Board (IRB) by all cooperating institutions participating in the research project.
3. Obtain approval of the study protocol by the recipient's local IRB.
4. Implement and evaluate project delivery.
5. Write and disseminate reports of research activities to regional, state, and local partners.
6. Conduct one reverse site visit to meet with CDC staff in Atlanta on an annual basis.
7. Complete all required reports as specified under ''Reporting''.
8. Analyze data and publish findings in peer-reviewed journals.

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:

(1) Provide scientific and programmatic consultation. CDC will collaborate with project staff on decision-analyses, programmatic issues, and dissemination of the study results in publications and presentations.

(2) Assist in the development of a research protocol for Institutional Review Board (IRB) review by all cooperating institutions participating in the research.

(3) The CDC IRB will review and approve the protocol initially and on at least an annual basis until the research project is completed.

(4) CDC staff will monitor and review scientific and operational accomplishments of the project through conference calls, site visits, and review of technical reports.

II. Award Information

Type of Award: Cooperative Agreement. CDC involvement in this program is listed in the Activities Section above. Fiscal Year Funds: 2004 Approximate Total Funding: $500,000.

Approximate Number of Awards: One.

Approximate Average Award: N/A.

Floor of Award Range: $250,000.

Ceiling of Award Range: $500,000.

Anticipated Award Date: September 1, 2004.

Budget Period Length: 12 months.

Project Period Length: Four 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: Applications may be submitted by public and private nonprofit and for profit organizations and by governments and their agencies, such as:

- 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 you are applying as a bona fide agent of a State or local government, you must provide a letter from the State or local government as documentation of your status. Place this documentation behind the first page of your application form.

III.2. Cost Sharing or Matching: Matching funds are not required for this program.

III.3. Other Eligibility Requirements: If your application is incomplete or non-responsive to the requirements listed below, it will not be entered into the review process. You will be notified that your application did not meet submission requirements. The following applicant requirements are:

- A principal investigator who has documented prior training and experience in conducting efficacy and effectiveness trials.
- A principal investigator who has conducted research, published the findings in peer-reviewed journals, and has specific authority and responsibility to carry out the proposed project.
- Demonstrated experience on the applicant's project team in conducting, evaluating, and publishing violence prevention and related research in peer-reviewed journals.
- Effective and well-defined working relationships within the performing organization and with outside entities, which will ensure implementation of the proposed activities.
- The overall match between the applicant's proposed research objectives and the program priorities as described under the heading, ''Research Objectives''.
- The requested funding amount should not be greater than the ceiling of the award range.
- It is especially important to include an abstract that reflects the study's focus, because the abstract will be used to help determine the responsiveness of the application.
- Principal investigators (PI's) are encouraged to submit only one proposal in response to this program announcement. With few exceptions (*e.g.*, research issues needing immediate public health attention), only one application per PI will be funded under this announcement.

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 398 (OMB number 0925–0001 rev. 5/2001). Forms and instructions are available in an interactive format on the CDC web site, at the following Internet address: *www.cdc.gov/od/pgo/forminfo.htm*.

Forms and instructions are also available in an interactive format on the National Institutes of Health (NIH) web site at the following Internet address: *http://grants.nih.gov/grants/funding/phs398/phs398.html*.

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 Application Submission: Letter of Intent (LOI): 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, your LOI will be used to gauge the level of interest in this program, and to allow CDC to plan the application review. Your LOI must be written in the following format:

- Maximum number of pages: Two;
- Single spaced;
- Font size: 12-point unreduced;
- 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:

- Descriptive title of the proposed research;
- Name, address, e-mail address and telephone number of the Principal Investigator;
- Names of other key personnel;
- Participating institutions;
- Number and title of this Program Announcement (PA).

Application: Follow the PHS 398 application instructions for content and formatting of your application. See Attachment 1 of this announcement for guidance on how to complete Form 398 for this Program Announcement.

You must include a research plan with your application. The research plan should be no more than 25 pages (8.5 inches by 11 inches), single-spaced, printed on one side only, with one-inch margins on all sides, and unreduced 12 point font.

Your application will be evaluated on the criteria listed under Section V. Application Review Information, so it is important to follow them, as well as the Research Objectives and the Administrative and National Policy Requirements (AR's), in laying out your research plan.

Your research plan should address activities to be conducted over the entire project period. The research plan should consist of the following information: 1. Abstract. It is especially important to include an abstract that reflects the study's focus, because the abstract will be used to help determine the responsiveness of the application.

2. Program Goals and Objectives. Describe the goals and objectives the proposal is designed to achieve in the short and long term. Specific research

questions and hypotheses should also be included.

3. Program Participants. Describe the population from which the sample will be drawn and the method by which they will be selected. In addition, the proposal should provide evidence that the recipient (or collaborating partner) has access to the target population, and that participation in the fathering program will be adequate.

4. Intervention. Describe the proposed strategies or components of the intervention and the plan for implementing the efficacy study. Proposals should explicate the theoretical and empirical justification for the potential effectiveness of the intervention for reducing child maltreatment. The proposal should describe incidence, prevalence, morbidity, and/or mortality rates associated with child maltreatment within the location or setting in which the intervention component(s) will occur, and describe the relevance of this setting to the strategy and desired outcomes.

5. Evaluation Design. Describe the proposed design, methods and analysis plan for assessing the efficacy of the intervention. The specific type of evaluation method chosen should reflect the nature of the intervention, feasibility, and ethical considerations. Potential threats to the validity of the study should be described along with how such threats will be recognized and addressed. The status of all necessary measurement instruments should be described. If any materials are not extant, the methods and time frame for measure development, pilot testing, and validation should be given. For data collected from archival records (*e.g.*, hospital records, police records, etc.) the proposal should discuss issues of accessibility, reliability, and validity of those data.

6. Project Management. Provide evidence of the expertise, capacity, and community support necessary to successfully implement the efficacy study of programs for fathers or father surrogates. Each existing or proposed position for the project should be described by job title, function, general duties, level of effort and allocation of time. Management operation principles, structure, and organization should also be noted.

7. Collaborative Efforts. List and describe the current and proposed collaborations with government, health, or children's agencies, community- or faith-based organizations, minority organizations, and other researchers. Include letters of support and memoranda of understanding that specify the nature of past, present, and proposed collaborations, and the products/services/activities that will be provided by and to the applicant.

8. Data sharing and release: Describe plans for the sharing and release of data (See AR–25 for additional information).

9. Project Budget. Provide a detailed budget for each activity undertaken, with accompanying justification of all operating expenses that is consistent with the stated objectives and planned activities of the project. This program announcement does not use the modular budget format.

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. Your DUNS number must be entered in item 11 of the face page of the PHS 398 application form. 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 *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.*

IV.3. Submission Dates and Times: LOI Deadline Date: January 16, 2004. *Application:* February 18, 2004.

Explanation of Deadlines: Applications must be received in the CDC Procurement and Grants Office by 4 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 carrier's guarantee. If the documentation verifies a carrier problem, CDC will consider the application as having been received by the deadline.

This announcement is the definitive guide on application submission address and deadline. 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 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.

4. Intergovernmental Review of Applications: Executive Order 12372 does not apply to this program.

5. Funding Restrictions: Restrictions, which must be taken into account while writing your budget, are as follows: None.

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 must be less than 12 months of age.

6. Other Submission Requirements: LOI Submission Address: Submit your LOI by express mail, delivery service, fax, or e-mail to: Robin Forbes, CDC, NCIPC, 4770 Buford Hwy, NE, Mailstop K–62, Atlanta, GA 30341, Phone: 770–488–4037, Fax: 770–488–1662, Email: *CIPERT@cdc.gov.*

Application Submission Address: Submit the signed original and five copies of your application by mail or express delivery service to: Technical Information Management—PA# 04055, 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: You 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 goals of CDC-supported research are to advance the understanding of biological systems, improve the control and prevention of disease, and enhance health. In the written comments, reviewers will be asked to evaluate the application in order to judge the likelihood that the proposed research will have a substantial impact on the pursuit of these goals.

The scientific review group will address and consider each of the following criteria in assigning the application's overall score, weighting

them as appropriate for each application. The application does not need to be strong in all categories to be judged likely to have major scientific impact and thus deserve a high priority score. For example, an investigator may propose to carry out important work that by its nature is not innovative, but is essential to move a field forward.

The criteria are as follows:

Significance: Does this study address an important problem? If the aims of the application are achieved, how will scientific knowledge be advanced? What will be the effect of these studies on the concepts or methods that drive this field?

Approach: Are the conceptual framework, design, methods, and analyses adequately developed, scientifically rigorous, well integrated, and appropriate to the aims of the project? Does the applicant acknowledge potential problem areas and consider alternative tactics?

Innovation: Does the project employ novel concepts, approaches or methods? Are the aims original and innovative? Does the project challenge existing paradigms or develop new methodologies or technologies?

Investigator: Is the investigator appropriately trained and well suited to carry out this work? Is the work proposed appropriate to the experience level of the principal investigator and other researchers (if any)?

Environment: Does the scientific environment in which the work will be done contribute to the probability of success? Does the proposed research take advantage of unique features of the scientific environment or employ useful collaborative arrangements? Is there evidence of institutional support?

Additional Review Criteria: In addition to the above criteria, the following items will be considered in the determination of scientific merit and priority score:

Intervention: Is the potential effectiveness of the proposed intervention within the target community theoretically justified and supported with epidemiologic, methodological, and behavioral research? How feasible is the implementation of the intervention as proposed? Can the intervention reasonably be predicted to produce the expected reductions in risk factors for child maltreatment? Is the setting of implementation appropriate?

Protection of Human Subjects From Research Risks: Does the application adequately address the requirements of title 45 CFR part 46 for the protection of human subjects? This will not be 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.

Inclusion of Women and Minorities in Research: Does the application adequately address the CDC Policy requirements regarding the inclusion of woman, ethnic, and racial groups in the proposed research? This includes: (1) The proposed plan for the inclusion of both sexes and racial and ethnic minority populations for appropriate representation; (2) The proposed justification when representation is limited or absent; (3) A statement as to whether the design of the study is adequate to measure differences when warranted; and (4) A statement as to whether the plans for recruitment and outreach for study participants include the process of establishing partnerships with community(ies) and recognition of mutual benefits.

Inclusion of Children as Participants in Research Involving Human Subjects: The NIH maintains a policy that children (*i.e.*, individuals under the age of 21) must be included in all human subjects research, conducted or supported by the NIH, unless there are scientific and ethical reasons not to include them. This policy applies to all initial (Type 1) applications submitted for receipt dates after October 1, 1998.

All investigators proposing research involving human subjects should read the ''NIH Policy and Guidelines'' on the inclusion of children as participants in research involving human subjects that is available at: *http://grants.nih.gov/grants/funding/children/children.htm.*

Budget: The reasonableness of the proposed budget and the requested period of support in relation to the proposed research.

V.2. Review and Selection Process: Applications will be reviewed for completeness by the Procurement and Grants Office (PGO) and for responsiveness of eligibility information by the National Center for Injury Prevention and Control (NCIPC). Incomplete applications and applications that are non-responsive to the eligibility criteria will not advance through the review process. You will be notified that your application did not meet submission requirements.

Applications that are complete and responsive to the PA will be subjected to a preliminary evaluation (streamline review) by a peer review committee, the Initial Review Group (IRG), convened by NCIPC to determine if the application is of sufficient technical and scientific merit to warrant further review by the IRG. CDC will withdraw from further consideration applications judged to be noncompetitive and promptly notify the principal investigator or program director and the official signing for the applicant organization. Those applications judged to be competitive will be further evaluated by a dual review process:

1. The primary review will be a peer review conducted by the IRG. All applications will be reviewed for scientific merit in accordance with the review criteria listed above. Applications will be assigned a priority score based on the National Institutes of Health (NIH) scoring system of 100–500 points.

2. The secondary review will be conducted by the Science and Program Review Subcommittee (SPRS) of NCIPC's Advisory Committee for Injury Prevention and Control (ACIPC). The ACIPC Federal agency experts will be invited to attend the secondary review, and will receive modified briefing books (*i.e.*, abstracts, strengths and weaknesses from summary statements, and project officer's briefing materials). ACIPC Federal agency experts will be encouraged to participate in deliberations when applications address overlapping areas of research interest, so that unwarranted duplication in federally funded research can be avoided and special subject area expertise can be shared. The NCIPC Division Associate Directors for Science (ADS) or their designees will attend the secondary review in a similar capacity as the ACIPC Federal agency experts to assure that research priorities of the announcement are understood and to provide background regarding current research activities. Only SPRS members will vote on funding recommendations, and their recommendations will be carried to the entire ACIPC for voting by the ACIPC members in closed session. If any further review is needed by the ACIPC, regarding the recommendations of the SPRS, the factors considered will be the same as those considered by the SPRS.

The committee's responsibility is to develop funding recommendations for the NCIPC Director based on the results of the primary review, the relevance and balance of proposed research relative to the NCIPC programs and priorities, and to assure that unwarranted duplication of federally funded research does not occur. The secondary review committee has the latitude to recommend to the NCIPC Director, to reach over better-ranked proposals in order to assure maximal impact and balance of proposed research.

3. All applicants will receive a written critique. The factors to be considered will include:

a. The results of the primary review including the application's priority score as the primary factor in the selection process.

b. The relevance and balance of proposed research relative to the NCIPC programs and priorities.

c. The significance of the proposed activities in relation to the priorities and objectives stated in ''Healthy People 2010,'' the Institute of Medicine report, ''Reducing the Burden of Injury,'' and the ''CDC Injury Research Agenda.''

All awards will be determined by the Director of the NCIPC based on priority scores assigned to applications by the IRG, recommendations by the secondary review committee, *e.g.*, NCIPC's Advisory Committee for Injury Prevention and Control (ACIPC), consultation with NCIPC senior staff, and the availability of funds.

VI. Award Administration Information

VI.1. Award Notices: If your application is to be funded, you 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.

VI.2. Administrative and National Policy Requirements: 45 CFR Part 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–1 Human Subjects Requirements
- AR–2 Requirements for Inclusion of Women and Racial and Ethnic Minorities in Research
- AR–8 Public Health System Reporting Requirements
- AR–9 Paperwork Reduction Act Requirements
- AR–10 Smoke-Free Workplace Requirements
- AR–11 Healthy People 2010
- AR–12 Lobbying Restrictions
- AR–13 Prohibition on Use of CDC Funds for Certain Gun Control Activities
- AR–14 Accounting System Requirements
- AR–15 Proof of Non-Profit Status
- AR–16 Security Clearance Requirement
- AR–21 Small, Minority, and Women-Owned Business
- AR–22 Research Integrity
- AR–23 States and Faith-Based Organizations
- AR–24 Health Insurance Portability and Accountability Act Requirements
- AR–25 Release and Sharing of Data

Starting with the December 1, 2003 receipt date, all NCIPC funded investigators seeking more than $500,000 in total costs in a single year are expected to include a plan describing how the final research data will be shared/released or explain why data sharing is not possible. Details on data sharing/release, including the timeliness and name of the project data steward, should be included in a brief paragraph immediately following the Research Plan Section of the PHS 398 form. References to data sharing/release may also be appropriate in other sections of the application (*e.g.*, background and significance, human subjects requirements, etc.) The content of the data sharing/release plan will vary, depending on the data being collected and how the investigator is planning to share the data. The data sharing/release plan will not count towards the application page limit and will not factor into the determination scientific merit or priority scores. Investigators should seek guidance from their institutions, on issues related to institutional policies, local IRB rules, as well as local, State and Federal laws and regulations, including the Privacy Rule.

Further detail on the requirements for addressing data sharing in applications for NCIPC funding may be obtained by contacting NCIPC program staff or visiting the NCIPC internet web site: at *http://www.cdc.gov/ncipc/osp/sharing_policy.htm*.

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: You must provide CDC with an original, two copies, and a disk of the following reports:

1. Interim progress report, (PHS 2590, OMB Number 0925–0001, rev. 5/2001) 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. 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.

VII. Agency Contacts

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 scientific/research program technical assistance, contact: Joanne Klevens, PhD., Epidemiologist, Prevention Development and Evaluation Branch, Division of Violence Prevention, National Center for Injury Prevention and Control, 4770 Buford Highway, NE., M/S: K–60, Atlanta, GA 30341, Telephone: (770) 488–1386, E-mail: *DZK8@cdc.gov*.

For questions about peer review, contact: Gwen Cattledge, Scientific Review Administrator, Centers for Disease Control and Prevention, National Center for Injury Prevention and Control, 4770 Buford Highway, NE., Mailstop: K–02, Atlanta, GA 30341, Telephone: (770) 488–1430, E-mail: *gxc8@cdc.gov*.

For budget assistance, contact: Van King, Grants Management Specialist, CDC Procurement and Grants Office, 2920 Brandywine Road, Atlanta, GA 30341, Telephone: (770) 488–2751, E-mail: *vbk5@cdc.gov*.

VIII. Other Information

Attachment 1

Errata Sheet:

Special Instructions for PHS–398, Rev. 11/2002

ANNOUNCEMENT #04055

SECTION I—PREPARING YOUR APPLICATION

B. GENERAL INSTRUCTIONS (Page 3)

Use English only and avoid jargon and unusual abbreviations. Type the application.

FORMAT SPECIFICATIONS

The content section of the Program Announcement refers to ''the Research Plan.'' The research plan should consist of items listed in the program announcement. Use only standard size fonts in black print that can be photocopied and easily read, do not use photo reduction or compressed print. Draw all graphs, diagrams, tables, and charts in black ink. Do not include photographs, oversized documents, or materials that cannot be photocopied in the body of the application.

The ONLY item that should be used to keep the application together is a rubber band. Please do not use spiral binders, 3-ring notebooks, envelopes, binder clips, etc.

Do not submit an incomplete application. An application will be considered incomplete and returned if it is illegible, if it fails to follow the instructions, or if the material presented is insufficient to permit an adequate review. Unless specifically required by these instructions (*e.g.*, human subjects certification, changes in other support), do not send supplementary or corrective material pertinent to the application after the receipt date without its

being specifically solicited or agreed to by prior discussion with the Grants Management Specialist.

PAGE LIMITATIONS AND CONTENT REQUIREMENTS (Page 4)

Disregard Page Limits under Research Plan, Sections a–d and adhere to the prescribed guidance in the Program Announcement.

C. SPECIFIC INSTRUCTIONS BUDGET INSTRUCTIONS (Page 11)

This Announcement does not use the modular budget format. Disregard instructions regarding the dollar limitations. PHS 398 Form Page 4 and Form Page 5 are required to be submitted by all applications regardless of the dollar amount requested.

Human Subject Research (Section 8.e, Pages 18–19)

Ensure that the application addresses the issue of Inclusion of Women and Ethnic and Racial Minorities in Research Involving Human Subjects. The application could be determined as non-responsive if this issue is not covered within the research plan.

SECTION II—SUBMITTING YOUR APPLICATION

Send the Application to the following address: Technical Information Management—PA# 04055 CDC Procurement and Grants Office, 2920 Brandywine Road, Atlanta, Georgia 30341–4146.

PLEASE DO NOT SEND THE APPLICATION TO THE NATIONAL INSTITUTES OF HEALTH

Disregard all instructions under Section A. INSTRUCTIONS (Page 31)

Disregard Sections B–D (Pages 34–35). Please refer to the Program Announcement Application Review Information (Section V) for the applicable CDC review process.

Disregard Section M, First Paragraph (Pages 53–54); Section N (Pages 54–55) and Section O (Pages 55–56); and all pages following Page 56.

Dated: December 10, 2003.

Edward Schultz,

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

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BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2003D–0092]

Food and Cosmetic Security Guidances; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a guidance document related to food security entitled ''Retail Food Stores and Food Service Establishments: Food Security Preventive Measures Guidance'' (food security guidance) and a guidance document related to cosmetics security entitled ''Cosmetics Processors and Transporters: Cosmetics Security Preventive Measures Guidance'' (cosmetics security guidance). The food security preventive Measures Guidance'' is designed as an aid to operators of retail food stores and food service establishments (e.g., bakeries, bars, bed-and-breakfast operations, cafeterias, camps, child and adult day care providers, church kitchens, commissaries, community fund raisers, convenience stores, fairs, food banks, grocery stores, interstate conveyances, meal services for homebound persons, mobile food carts, restaurants, and vending machine operators). It identifies the kinds of preventive measures that operators may take to minimize the risk that food under their control will be subject to tampering or other malicious, criminal, or terrorist actions. The cosmetics security guidance is designed as an aid to operators of cosmetics establishments (e.g., firms that process, store, repack, relabel, distribute, or transport cosmetics or cosmetics ingredients). It identifies the kinds of preventive measures that operators may take to minimize the risk that cosmetics under their control will be subject to tampering or other malicious, criminal, or terrorist actions.

DATES: You may submit written or electronic comments on the guidance documents at any time.

ADDRESSES: Submit written requests for single copies of the guidance document entitled ''Retail Food Stores and Food Service Establishments: Food Security Preventive Measures Guidance,'' or ''Cosmetics Processors and Transporters: Cosmetics Security Preventive Measures Guidance'' to John Kvenberg, Center for Food Safety and Applied Nutrition (HFS–600), Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740. Include a self-addressed adhesive label to assist that office in processing your request.

Submit written comments on the documents 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*. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the guidance documents.

FOR FURTHER INFORMATION CONTACT: John Kvenberg, Center for Food Safety and Applied Nutrition (HFS–600), Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740, 301–436–2359, e-mail: *jkvenberg@cfsan.fda.gov* or Donald W. Kraemer, Center for Food Safety and Applied Nutrition (HFS–400), Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740, 301–436–2300, e-mail: *dkraemer@cfsan.fda.gov*.

SUPPLEMENTARY INFORMATION:

I. Background

Operators of retail food store, food service, and cosmetics establishments are encouraged to review their current security procedures and controls in light of the potential for tampering or other malicious, criminal, or terrorist actions and make appropriate improvements.

FDA announced the availability of two guidance documents related to food security in the **Federal Register** of January 9, 2002 (67 FR 1224). They were entitled ''Food Producers, Processors, Transporters, and Retailers: Food Security Preventive Measures Guidance'' and ''Importers and Filers: Food Security Preventive Measures Guidance.'' The agency solicited public comment, but indicated that the two guidance documents would be implemented immediately in accordance with § 10.115(g)(2) (21 CFR 10.115(g)(2)). The two guidance documents were prompted by the tragedies of September 11, 2001, and the resulting scrutiny of, and interest in, food safety and security that followed.

A number of the comments on the two guidance documents urged FDA to issue guidance that was specifically tailored for the retail food store and food service sector. In response to these comments, the agency announced in the **Federal Register** of March 21, 2003 (68 FR 13932), the availability of a draft guidance document entitled ''Retail Food Store and Food Service Establishments: Food Security Preventive Measures Guidance.'' This draft guidance document identified the kinds of preventive measures that operators of retail food store and food service establishments (e.g., bakeries, bars, bed-and-breakfast operations, cafeterias, camps, child and adult day care providers, church kitchens, commissaries, community fund raisers, convenience stores, fairs, food banks, grocery stores, interstate conveyances, meal services for homebound persons, mobile food carts, restaurants, and vending machine operators) can take to minimize the risk that food under their control will be subject to tampering or other malicious, criminal, or terrorist actions.