Plough for 24 to 36 months or until Schering-Plough obtains USDA approvals. The consent order also prohibits AHP from suing Schering-Plough for patent infringements relating to the vaccines.

DATES: Complaint and Order issued May 16, 1997.[1]

FOR FURTHER INFORMATION CONTACT: Casey Triggs, FTC/S–2308, Washington, D.C. 20580. (202) 326–2804

SUPPLEMENTARY INFORMATION: On Wednesday, March 5, 1997, there was published in the **Federal Register,** 62 FR 10058, a proposed consent agreement with analysis In the Matter of American Home Products Corporation, for the purpose of soliciting public comment. Interested parties were given sixty (60) days in which to submit comments, suggestions or objections regarding the proposed form of the order.

No comments having been received, the Commission has ordered the issuance of the complaint in the form contemplated by the agreement, made its jurisdictional findings and entered an order to cease and divest, as set forth in the proposed consent agreement, in disposition of this proceeding.

(Sec. 6, 38 Stat. 721; 15 U.S.C. 46. Interpret or apply sec. 5, 38 Stat. 719, as amended; sec. 7, 38 Stat. 731, as amended; 15 U.S.C. 45, 18)

Benjamin I. Berman,

Acting Secretary.

[FR Doc. 97–17755 Filed 7–7–97; 8:45 am]

BILLING CODE 6750–01–M

FEDERAL TRADE COMMISSION

[Dkt. C–3741]

Schering-Plough Healthcare Products, Inc.; Prohibited Trade Practices, and Affirmative Corrective Actions

AGENCY: Federal Trade Commission.

ACTION: Consent order.

SUMMARY: In settlement of alleged violations of federal law prohibiting unfair or deceptive acts or practices and unfair methods of competition, this consent order prohibits, among other things, the Tennessee-based manufacturer of health care products from making certain claims about the effectiveness or length of protection provided by any children's sun protection product unless they possess scientific evidence to substantiate the claims, and from misrepresenting the existence, contents, validity, results or conclusions of any test or study concerning sun protection products. The consent order requires the respondent to produce and distribute 150,000 consumer education brochures regarding sunscreen protection for children.

DATES: Complaint and Order issued May 16, 1997.[1]

FOR FURTHER INFORMATION CONTACT: Mamie Kresses, FTC/S–4002, Washington, D.C. 20580. (202) 326–2070.

SUPPLEMENTARY INFORMATION: On Wednesday, March 5, 1997, there was published in the **Federal Register**, 62 FR 10059, a proposed consent agreement with analysis In the Matter of Schering-Plough Healthcare Products, Inc., for the purpose of soliciting public comment. Interested parties were given sixty (60) days in which to submit comments, suggestions or objections regarding the proposed form of the order.

No comments having been received, the Commission has ordered the issuance of the complaint in the form contemplated by the agreement, made its jurisdictional findings and entered an order to cease and to desist, as set forth in the proposed consent agreement, in disposition of this proceeding.

(Sec. 6, 38 Stat. 721; 15 U.S.C. 46. Interprets or applies sec. 5, 38 Stat. 719, as amended; 15 U.S.C. 45, 52)

Benjamin I. Berman,

Acting Secretary.

[FR Doc. 97–17756 Filed 7–7–97; 8:45 am]

BILLING CODE 6750–01–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[Program Announcement 735]

FY 1997 Epidemiologic Research Studies of Acquired Immunodeficiency Syndrome (AIDS) and Human Immunodeficiency Virus (HIV) Infection

Introduction

The Centers for Disease Control and Prevention (CDC) announces the availability of fiscal year (FY) 1997 funds for a cooperative agreement program for epidemiologic and behavioral research studies of AIDS and HIV infection. These include studies to examine factors related to: (I) manifestations and medical management of HIV infection in children and (II) acceptability of new prevention methods currently being tested that offer alternatives to male condoms for HIV/STD protection. The study of these research areas as they pertain to racial and ethnic minority populations (defined as Alaskan Native, African-American, Hispanic, Asian/Pacific Islander, and American Indian) is encouraged because minorities constitute more than 53 percent of all reported cases of AIDS and approximately 77 percent of all women and children with AIDS.

CDC is committed to achieving the health promotion and disease prevention objectives of Healthy People 2000, a national activity to reduce morbidity and mortality and improve the quality of life. This announcement is related to the priority area of HIV Infection. (To order a copy of ''Healthy People 2000,'' see the section Where to Obtain Additional Information.)

Authority

This program is authorized under Sections 301(a) and 317(k)(2) of the Public Health Service Act [42 U.S.C. 241(a) and 247b(k)(2)], as amended. Applicable program regulations are set forth in 42 CFR Part 52, entitled ''Grants for Research Projects.''

Smoke-Free Workplace

CDC strongly encourages all cooperative agreement recipients to provide a smoke-free workplace and promote the non-use of all tobacco products. Public Law 103–227, the Pro-Children Act of 1994, prohibits smoking in certain facilities that receive Federal funds in which education, library, day care, health care, and early childhood development services are provided to children.

Eligible Applicants

Eligible applicants include all public and private nonprofit organizations and governments and their agencies. Thus, universities; colleges; research institutions; hospitals and other public and private organizations; territories, District of Columbia, and State and local governments or their bona fide agents; federally recognized Indian tribal governments; Indian tribes or Indian tribal organizations; and small minority- or women-owned nonprofit businesses are eligible to apply.

Note: Organizations described in section 501(c)(4) of the Internal Revenue Code of 1986 that engage in lobbying are not eligible to receive Federal grant/cooperative agreement funds.

[1] Copies of the Complaint and the Decision and Order are available from the Commission's Public Reference Branch, H–130, 6th Street & Pennsylvania Avenue, N.W., Washington, D.C. 20580.

[1] Copies of the Complaint, the Decision and Order and statements by Commissioners Azcuenaga and Starek are available from the Commission's Public Reference Branch, H–130, 6th Street & Pennsylvania Avenue, N.W., Washington, D.C. 20580.

Availability of Funds

Approximately $1 million is available in FY 1997 to fund approximately two new awards and approximately $2 million is available to fund six competing continuation projects. It is expected that the average new awards will be range from $300,000 to $700,000 and continuation awards will be approximately $300,000. It is expected that awards will begin on or about September 30, 1997. Successful grantees will be funded for a 12-month budget period within a project period of up to three years. Continuation awards within the project period will be made on the basis of satisfactory programmatic progress and the availability of funds. Funding estimates may vary and are subject to change.

Use of Funds

Restrictions on Lobbying

Applicants should be aware of restrictions on the use of Department of Health and Human Services (HHS) funds for lobbying of Federal or State legislative bodies. Under the provisions of 31 U.S.C. Section 1352 (which has been in effect since December 23, 1989), recipients (and their subtier contractors) are prohibited from using appropriated Federal funds (other than profits from a Federal contract) for lobbying Congress or any Federal agency in connection with the award of a particular contract, grant, cooperative agreement, or loan. This includes grants/cooperative agreements that, in whole or in part, involve conferences for which Federal funds cannot be used directly or indirectly to encourage participants to lobby or to instruct participants on how to lobby.

In addition, the FY 1997 Departments of Labor, HHS, and Education, and Related Agencies Appropriations Act, which became effective October 1, 1996, expressly prohibits the use of 1997 appropriated funds for indirect or ''grass roots'' lobbying efforts that are designed to support or defeat legislation pending before State legislatures. Section 503 of this new law, as enacted by the Omnibus Consolidated Appropriations Act, 1997, Division A, Title I, Section 101(e), Pub. L. No. 104–208 (September 30, 1996), provides as follows:

Sec. 503(a) No part of any appropriation contained in this Act shall be used, other than for normal and recognized executive-legislative relationships, for publicity or propaganda purposes, for the preparation, distribution, or use of any kit, pamphlet, booklet, publication, radio, television, or video presentation designed to support or defeat legislation pending before the Congress, * * * except in presentation to the Congress or any State legislative body itself.

(b) No part of any appropriation contained in this Act shall be used to pay the salary or expenses of any grant or contract recipient, or agent acting for such recipient, related to any activity designed to influence legislation or appropriations pending before the Congress or any State legislature.

Background

The AIDS epidemic continues in the United States with 581,429 cases of AIDS, including 7,629 cases in children, 85,500 cases in women and 324,728 cases in men who have sex with men reported to the CDC as of December 1996. Approximately 62 percent of persons with AIDS have died.

Current estimates reflect that approximately 700,000 Americans have been infected with HIV, the etiologic agent of AIDS. More difficult to estimate is the number of incident HIV infections occurring yearly. Heterosexual transmission is now the leading cause of AIDS cases among U.S. women and is the fastest growing mode of transmission in newly infected persons. However, male-to-male exposure continues as the single greatest risk category among men. Fifty percent of cumulative AIDS cases and 40 percent of annual AIDS cases in 1996 were attributed exclusively to male-to-male sexual exposure. African-Americans, Hispanics, women, and adolescents are increasingly represented in both AIDS cases and new HIV infections.

Although it now may be possible to prevent most HIV transmission to children, there are approximately 15,000 children living with HIV infection in the U.S. and infected children will continue to be born despite prevention efforts. Timely prophylaxis and treatment are improving survival of these children but advances in diagnostics, prophylactic and treatment options, as well as ongoing changes in health care delivery (e.g., managed care) may add complexity to their medical management. Information is needed to monitor trends in medical management and progression of disease to evaluate implementation of treatment recommendations and their impact. Information is also needed to characterize HIV disease and social impact in children with long-term survival (into adolescence).

Additional studies of the epidemic of HIV are needed to guide prevention and control efforts. In particular, information that will guide development of new prevention technologies, including microbicides to prevent sexual transmission in women and men, is needed.

Purpose

The purpose of these awards is to help support researchers in the conduct of HIV-related epidemiologic and behavioral research studies that foster prevention of HIV infection or HIV-related disease. These include studies to monitor medical care, social circumstances, and clinical course of HIV-infected children and adolescents infected in childhood; and studies to examine behavioral and biomedical factors related to the acceptability of new products to prevent sexual transmission of HIV infection such as vaginal and rectal microbicides. The study of these research areas as they pertain to minority populations are of special interest.

Research Issues

Three research issues of programmatic interest to the health care community and to CDC for FY 1997 are listed below and are considered of significant importance in gaining a greater understanding of the epidemiology of AIDS and HIV infection. However, applications submitted by organizations that examine additional important HIV-related epidemiologic research issues will also be accepted and considered for funding.

Applicants addressing the same research issue should be willing to participate in collaborative studies with other CDC-sponsored researchers, including the use of common data collection instruments, specimen collection protocols, and data management procedures, as determined in post-award grantee planning conferences. Applicants are required to identify their proposed research issue on line one of the face page of the application form. (For more information on which form to use, see the section Application Submission and Deadline)

1. Pediatric HIV Infection: Spectrum of Disease, Medical Management, Secondary Prevention, and Social Impact

Applications are solicited for participation in an ongoing multi-site longitudinal medical record review study, the Pediatric Spectrum of HIV Disease (PSD) Project. Applications must address both Parts A and B below.

A. Prospective Studies Monitoring HIV-Infected Children

Applications are solicited for continued prospective monitoring, through repeated medical record review,

of: (i) trends in medical management of pediatric HIV infection (including treatment, prophylaxis for opportunistic infections, diagnostic testing and immunologic and virologic monitoring); (ii) clinical course of HIV infection,(e.g., occurrence of AIDS-defining conditions, other manifestations, and death); (iii) long-term outcomes, (i.e. clinical course in perinatally infected children who survive to adolescence); and (iv) social circumstances, (i.e. changes in caretakers and living arrangements, school attendance and knowledge/disclosure of HIV status).

Preference will be given to currently funded applicants with studies in which HIV-infected children have already been identified and are being systematically monitored, and with the capacity to begin monitoring newly identified HIV-infected children. Applicants must demonstrate adequate rates of follow-up of HIV-infected children, the capacity for timely completion of biannual medical record review, and must be willing to collaborate with other CDC PSD grantees in the study of HIV-infected children, including use of common data collection instruments and protocols and data management.

B. Monitoring HIV-Exposed Infants in the First Year of Life

Applicants must be able to identify infants born to HIV-infected mothers after December 1995, and to monitor their HIV-specific medical management in the first year of life through retrospective medical record review initiated after a child's first birthday, including (i) antiretroviral prophylaxis and treatment, (ii) prophylaxis to prevent opportunistic infections, (iii) diagnostic testing, and (iv) immunologic and virologic monitoring.

Applicants must have a plan for reporting (where required by law) HIV exposure, HIV infection status, or AIDS in children, including completion of CDC HIV/AIDS report forms, and entry and complete and timely transfer of case reports/updates to the State or local health department.

Acceptability of HIV/STD Prevention Methods Among Women and Men Who Have Sex With Men

Studies are underway to determine the safety and efficacy of prevention methods that may offer options for HIV/STD protection other than the male condom (e.g., female condom, vaginal and rectal products that might be used as microbicides). As new methods for HIV/STD prevention become available, information is needed on the acceptability of the methods to different populations and effective communication strategies for informing persons of multiple options for protection from HIV and other STDs. Applications are solicited that address: (1) acceptability of various HIV/STD prevention methods, characteristics of persons choosing different methods, and the conditions under which different methods are preferred; (2) comprehension and interpretation of prevention messages offering multiple HIV/STD prevention options and the impact of these messages on sexual behaviors and intentions; and (3) strategies for integrating multiple-option HIV/STD prevention messages into more conventional interventions that exclusively promote male condom use.

2. Acceptability of Prevention Methods Among Women at Risk for HIV/STD

Applications are sought that: (1) implement an HIV/STD prevention intervention that has previously been shown to be effective at increasing male condom use; (2) examine barriers to consistent condom use among women who have participated in the intervention; (3) describe characteristics of women who are unable to negotiate consistent condom use with male partners; and (4) determine if new HIV/STD prevention methods under development (e.g., female condom, products that might be used as vaginal microbicides) would be acceptable to these women. Applicants are sought who can enroll at least 750 women at risk for HIV or other STDs in a short-term longitudinal study to: (1) examine barriers to male condom use among women participating in a short-term intervention promoting male condom use; (2) determine acceptability of new HIV/STD prevention methods to women whose male partners are not using condoms after the intervention; (3) determine the conditions under which new methods would be acceptable and the characteristics of women and their partners who prefer the different methods; and (4) develop and test methods for presenting multiple HIV/STD options to women and for integrating these complex prevention messages into interventions promoting only male condom use.

3. Acceptability of HIV/STD Prevention Methods Among Men Who Have Sex With Men

To better understand the acceptability of alternative methods to condoms currently being tested for HIV/STD prevention among men who have sex with men, applications are solicited that propose examination of (1) features that are important in a prevention method for men who have sex with men, (2) the extent to which alternative prevention methods being tested would be used and the conditions under which these methods would be preferred over condom use, (3) the characteristics of men and their partners who are likely to use alternative methods, (4) effective messages for presenting risks and benefits of various prevention methods and (5) effect of message content and format on behavioral intentions.

Applicants are sought who can enroll at least 400 men who have sex with men in a cross-sectional study. Proposal should include study designs to collect: (1) survey data on current HIV/STD prevention practices among men who have sex with men, features that are desired in a prevention method, extent to which prevention methods being tested (e.g., products that could be used as rectal microbicide) are desirable, and the conditions under which these methods would be chosen; and (2) data on the influence of HIV/STD prevention message content, structure, and complexity on comprehension of the message, interpretation of effectiveness and potential risks associated with each HIV/STD prevention method contained in the message, and acceptability of the different methods.

Program Requirements

In conducting activities to achieve the purpose of this program, the recipient will be responsible for the activities listed under subparagraph 1., below, and CDC will be responsible for conducting activities listed under subparagraph 2., below:

1. Recipient Activities

A. Develop the research study protocol and data collection forms.

B. Identify, recruit, obtain informed consent from, and enroll an adequate number of study participants as determined by the study protocol and the program requirements.

C. Continue to follow study participants as determined by the study protocol.

D. Establish procedures to maintain the rights and confidentiality of all study participants.

E. Perform laboratory tests (when appropriate) and data analysis as determined in the study protocol.

F. Collaborate and share data and specimens (when appropriate) with other collaborators to answer specific research questions.

G. Conduct data analysis with all collaborators as well as present and publish research findings.

2. CDC Activities

A. Provide technical assistance in the design and conduct of the research.

B. Provide technical guidance in the development of study protocols, consent forms, and data collection forms.

C. Assist in designing a data management system.

D. Assist in performance of selected laboratory tests.

E. Coordinate research activities among the different sites.

F. Assist in the analysis of research information and the presentation and publication of research findings.

Technical Reporting Requirements

An original and two copies of the following reports are required to be submitted to the Grants Management Branch (GMB), CDC in accordance with the following guidelines. See the section Where to Obtain Additional Information for the address of the GMB.

1. Annual Progress Report

An annual progress report is required to be included in continuation applications for each year of the project. Continuation applications will be solicited each year by the Grants Management Branch, CDC. The progress reports must include the following for each program, function, or activity involved: (1) a comparison of actual accomplishments to the goals established for the period, including estimated performance for any time remaining in the budget period after submission of the application; (2) reasons for slippage if established goals are not likely to be met by the end of the budget period; and (3) other pertinent information including, when appropriate, analysis and explanation of any actual costs that significantly exceed budgeted levels.

2. Financial Status Reports (Standard Forms 269)

Financial Status Reports (FSRs) are required to be submitted annually within 90 days after the end of each budget period. The purpose of the FSR is to report actual costs incurred as opposed to budgeted and to establish any unobligated balances of prior-year funds. A final progress report summarizing the progress for the entire project is required within 90 days after the end of the project period.

Application Content

Applications must be developed in accordance with PHS Form 398, information contained in the program announcement and the instructions and format provided below.

Applicants are required to submit an original and five copies of the application. The application may not exceed 25 double-spaced pages in length, excluding appendices. Applicants should provide a one-page abstract of the proposal. Number all pages clearly and sequentially and include a complete index to the application and its appendices. The original and each copy of the application must be submitted UNSTAPLED and UNBOUND. Print all material, double spaced, in a 12-point or larger font on 8½″ by 11″ paper, with at least 1″ margins and printed on one side only.

The application should include a general introduction, followed by one narrative subsection per application content element in the order in which the elements appear below. Each narrative subsection should be labeled with the element title and contain all of the information needed to evaluate that element of the application (except for curriculum vita, references, and letters of support, which are appropriate for the appendices). The application content elements are outlined below for all research issues:

1. Pediatric HIV Infection: Spectrum of Disease, Medical Management, Secondary Prevention, and Social Impact

A. Familiarity With and Access to Study Population

(1) Describe the population to be prospectively monitored, including number, age distribution, and other relevant demographic characteristics for Part A; note procedures for identifying HIV-infected children (including, for example, death certificate review).

(2) Describe procedures for identifying children born to HIV-exposed mothers for Part B.

(3) Describe prior research with or service provision to the study populations for Part A and Part B.

(4) Demonstrate familiarity with issues regarding medical care for HIV exposure and infection in children, and progression of disease among and social circumstances of HIV-infected children.

(5) Describe linkages and collaboration with organizations providing medical and psychosocial services to the study population including plans to improve PSD's case finding and follow up of exposed and infected children.

(6) Document ability to monitor the study population prospectively for Part A and for the first year of life for Part B. As appropriate, include memoranda of agreement to document collaboration with organizations providing services to the study population; document ability to complete biannual review of medical records, and describe ability to track children who change care providers.

(7) Describe procedures for involving the service providers in the design and implementation of research activities under Part B and for reporting results of the research to collaborating service providers (Parts A and B).

B. Description and Justification of a Research Plan

(1) Based on review of the scientific literature, describe understanding of the overall research issues to be addressed by PSD and any specific research focus of interest to the applicant (Parts A and B). Research issues/topics may include participant characteristics (e.g., ethnicity, year of birth, clinical, immunologic, or social status), disease progression, survival, medical management, and developing and evaluating recommendations for medical care, including recommendations for preventing opportunistic infections.

(2) Specify the number of HIV-infected enrollees to be prospectively monitored, and expected attrition from deaths and losses to follow-up over the study period based on prior experience (Part A).

(3) Describe methods and procedures for data abstraction and assuring adequate follow-up and timely completion of data forms (Parts A and B).

(4) Describe proposed quality assurance measures including methods; protocols; supervision of data abstraction, entry, and cleaning; maintaining consistency of data abstraction; accuracy and completeness of record keeping; monitoring of study progress; and forming and maintaining collaborative relationships (Parts A and B).

(5) Describe plans to analyze local data using quantitative methods and statistical techniques and submit results and all data to CDC (Parts A and B).

(6) Describe procedures for tracking follow-up of HIV-infected children.

(7) Describe previous experience conducting data collection and management for PSD and PSD supplemental research projects.

(8) Describe procedures for obtaining Institutional Review Board (IRB) approval and maintaining participant confidentiality (Parts A and B).

(9) Identify and discuss any potential ethical issues associated with the proposed research and describe how these issues will be resolved (Parts A and B).

(10) Describe plans to disseminate research findings (Parts A and B).

C. Provision of HIV/AIDS Report Data to and Collaboration With Local Pediatric HIV/AIDS Surveillance Activities

(1) Describe procedures for collaborating with local health department pediatric HIV/AIDS surveillance staff to report children with HIV exposure, infection, and AIDS (depending on State law), including specific responsibilities and schedules for completion and computer entry of HIV/AIDS report forms, schedule for transfer of HIV/AIDS report data to State/local health department surveillance unit, and measures to protect confidentiality of HIV/AIDS report data. (For applicants in States without HIV reporting laws, describe intentions for use of HIV infection data.) Include a signed memorandum of agreement detailing the outlined division of responsibilities, joint activities to evaluate completeness, timeliness, validity of the HIV/AIDS report data, methods to ensure security and confidentiality of HIV/AIDS report data, and use of data.

(2) Describe measures to assure completeness of HIV/AIDS report forms, and quality and timeliness of data.

D. Demonstration of Staff's Capability to Conduct Research

(1) Summarize briefly the professional training and relevant research experience of the staff as it relates to their main responsibilities.

(2) Provide brief descriptions and major findings of HIV-related research studies conducted by members of the research staff.

(3) Include a table of current and previous relevant research projects, their status, sources and levels of funding, and principal investigators.

(4) Include in the appendix the curriculum vitae for key staff members as well as memoranda of agreement that clearly and specifically document activities to be performed by any external experts, consultants, or collaborating agencies under the cooperative agreement.

(5) Include copies of any publications on related research by study staff.

E. Staffing, Facilities, and Time Line

(1) Explain the proposed staffing, percentage of time each staff member commits to this and other projects, and division of duties and responsibilities for the project; include brief position descriptions for existing and proposed personnel.

(2) Identify and describe key roles of all study staff.

(3) Provide justification that base staffing is adequate to keep pace with biannual medical record review for the number of children to be monitored prospectively for Part A, and to complete abstraction of records for all children studied in Part B by 15 months of age.

(4) Describe support activities such as project oversight or data management that will contribute to the completion of all research activities.

(5) Provide a statement of willingness of project staff to work collaboratively with other study sites to develop final research protocols and to disseminate findings.

(6) Describe existing facilities, equipment, computer software, and data processing capacity.

(7) Describe the procedures to ensure the security of research data.

(8) Describe equipment and facilities to be used for data abstraction and follow-up tracking, data entry and analysis, and project management.

(9) Justify the need for any proposed consultants.

(10) Describe plans to communicate, ensure quality control and consistency, identify and resolve problems, and analyze data in collaboration with other sites.

(11) Provide a time line showing plan for completion of research activities and goals.

F. Budget

Provide a detailed, line-item budget for the project; justify each line-item with a budget narrative. Plan for at least one trip per year to Atlanta to meet with CDC representatives.

2. Acceptability of Prevention Methods Among Women At Risk for HIV/STD; 3. Acceptability of HIV/STD Prevention Methods Among Men Who Have Sex With Men; and 4. Other HIV/AIDS Epidemiology Research Studies

A. Familiarity With and Access to Study Population

(1) Describe prior research with or service provision to this population.

(2) Demonstrate familiarity with issues faced by the study population regarding prevention of sexually transmitted infections, sexual behaviors, and reproductive decisions and contraception through experience or review of the scientific literature.

(3) Describe how study participants will be referred to medical and psychosocial services that are requested by participants during study participation.

(4) Document ability to recruit the study population for the proposed research study. As appropriate, include memoranda of agreement to document collaboration with organizations providing services to the study population.

(5) Describe the characteristics of the study population and define the specific subgroup(s) that will be the primary focus of the proposed research. Using available data, provide a rationale for focusing on the proposed subgroup(s).

(6) Describe procedures for involving the target population, their advocates, or service providers in the design and implementation of research activities.

(7) 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 will be documented.

(8) The proposed plan for the inclusion of racial and ethnic minority populations for appropriate representation.

(9) The proposed justification when representation is limited or absent.

B. Description and Justification of Research Plans

(1) Based on review of the scientific literature, if relevant, describe the theoretical framework or previous research on which your plan is based and how this framework has been applied to the study design.

(2) Describe factors to be examined, including specific research questions and hypotheses to be tested.

(3) Define and describe type of study design.

(4) Describe methods for collecting qualitative and quantitative data, including outcome measures, types and content of data collection instruments, and data collection schedules.

(5) Specify the number research participants required, the recruitment and sampling plan, sample size estimates and power calculations based on justifiable assumptions about distributions of participant characteristics, and randomizations procedures, if appropriate.

(6) Describe proposed quality assurance measures including methods, protocols, supervision, quality assurance, consistency, confidentiality of participant information, accuracy and completeness of record keeping, documentation of study visits, monitoring of study progress, field safety, and forming and maintaining collaborative relationships.

(7) Describe procedures for obtaining informed consent and maintaining participant confidentiality.

(8) Identify and discuss potential ethical issues associated with the

proposed research and describe how these issues will be resolved.

(9) Discuss if design of the study is adequate to measure racial and ethnic differences, when warranted.

(10) Describe plans to analyze data using qualitative or quantitative methods and statistical techniques.

(11) Describe a plan to disseminate research findings.

C. Demonstrate Staff's Capability to Conduct Research

(1) Describe the professional training and relevant research experience of the staff.

(2) Provide descriptions and major findings of HIV-related research, behavioral and epidemiologic research studies conducted by members of the research staff.

(3) Include a table of current and previous relevant research projects, their status, sources and levels of funding, and principal investigators.

(4) Include in the appendix, the curriculum vitae for key staff members as well as memoranda of agreement that clearly and specifically document activities to be performed by any external experts, consultants, or collaborating agencies under the cooperative agreement.

(5) Include copies of any publications on related research by study staff.

D. Staffing, Facilities, and Time Line

(1) Explain the proposed staffing, percentage of time each staff member commits to this and other projects, and division of duties and responsibilities for the project; include brief position descriptions for existing and proposed personnel.

(2) Identify and describe key roles of all study staff.

(3) Describe support activities such as project oversight or data management that will contribute to the completion of all research activities.

(4) Provide a statement of willingness of project staff to work collaboratively with other study sites.

(5) Describe facilities, equipment, computer software, and data processing capacity.

(6) Describe the procedures to ensure the security of research data.

(7) Provide a time line for developing, implementing, and completing the research study, including data analysis and dissemination.

(8) Describe equipment and facilities to be used for participant recruitment and interviews, clinical and laboratory assessment, data entry and analysis, and project management.

(9) Justify the need for any proposed consultants.

(10) If project is multisite, describe experience with multisite research projects. Describe plans to communicate, ensure quality control and consistency, identify and resolve problems, and analyze data in collaboration with other sites.

E. Budget

Provide a detailed, line-item budget for the project; justify each line-item with a budget narrative. Plan for at least one trip to Atlanta to meet with CDC representatives.

Evaluation Criteria

All applications will be reviewed according to the criteria listed below for each research issue. Applicants will be ranked on a scale of 100 maximum points according to the three research issues listed above and a fourth category for all other HIV-related epidemiologic studies. All applicants must state which research category they are addressing. Applications should demonstrate the applicant's ability to address the research problem in a collaborative manner with other collaborators. Applications will be reviewed and evaluated based on the evidence submitted, which specifically describes the applicant's abilities to meet the following criteria:

1. Pediatric HIV Infection: Spectrum of Disease, Medical Management, Secondary Prevention, and Social Impact

A. Familiarity With and Access to Study Population (25 points)

(1) Extent of applicant's knowledge of issues faced by study population and experience in working with medical records of this population (Parts A and B).

(2) Existence of linkages to facilitate monitoring the study population (Parts A and B), including memoranda of agreement from the clinical facilities to permit record review.

(3) Ability to identify and follow for one year all HIV-exposed children in the catchment area.

(4) Feasibility of plans to improve linkages for PSD's follow-up of HIV-infected children (Part B).

(5) Feasibility of plans to involve service providers in the development and implementation of research activities and to inform them of research results (Parts A and B).

(6) Ability to monitor newly identified HIV-exposed children.

(7) Demonstrated collaboration with local health departments and pediatric HIV/AIDS surveillance staff.

B. Description and Justification of Research Plans (15 Points)

(1) Quality of the review of the scientific literature pertinent to the proposed activities, including justification for and relevance of research questions (Parts A and B).

(2) The applicant's understanding of the research objectives as evidenced by high quality of the proposed research plan (Parts A and B).

(3) Feasibility of plans to monitor study participants as evidenced by the experience of the investigator in enrolling and monitoring such children, and the comprehensiveness of the plan to protect the confidentiality of all participants (Parts A and B).

(4) Creativity and thoroughness of analysis plans and reasonableness for data collected (Parts A and B).

(5) Extent to which the study proposal demonstrates assurance of compliance with multisite research requirements (common protocol, data collection, and computer and data management systems) (Parts A and B).

(6) The degree to which the applicant has met the requirements regarding plans for the inclusion of ethnic and racial groups in the proposed research, and comprehensiveness of the plan to protect the rights and confidentiality of all participants.

C. Provision of HIV/AIDS Report Data To and Collaboration With Local Pediatric HIV/AIDS Surveillance Activities (20 Points)

(1) Feasibility of plans for completion and computer entry of HIV/AIDS report forms and complete and timely transfer of HIV/AIDS case reports to local HIV/AIDS surveillance unit.

(2) Adequacy of measures to assure completeness of HIV/AIDS report forms, data quality and timeliness, and protection of confidentiality.

D. Demonstration of Staff's Capability to Conduct Research (20 Points)

(1) Capacity to conduct the proposed activities as evidenced by previous experience with PSD and PSD supplemental studies (Parts A and B).

(2) Adequacy of base staff to keep pace with anticipated workload (Part A).

E. Staffing, Facilities, and Time Line (20 points)

(1) Availability of qualified personnel with realistic and sufficient percentage-time commitments; clarity of the described duties and responsibilities of project personnel with epidemiologic, administrative, clinical, laboratory, data management (including HIV/AIDS case reporting to local surveillance unit), and statistical responsibilities; adequacy of

clinical oversight of the project, especially supervision of data abstraction and entry.

(2) Adequacy of the facilities, equipment, data processing and analysis capacity, and systems for management of data security and participant confidentiality.

(3) Ability, willingness, and need to collaborate with researchers from other study sites in study design and analysis, including use of common forms, and sharing of data (Parts A and B).

F. Other (Not Scored)

(1) *Budget:* Will be reviewed to determine the extent to which it is reasonable, clearly justified, consistent with the intended use of funds, and allowable. All budget categories should be itemized.

(2) *Human Subjects:* Whether or not exempt from the DHHS regulations, are procedures adequate for the protection of human subjects? Recommendations on the adequacy of protections include the following: (a) protections appear adequate and there are no comments to make or concerns to raise, (b) protections appear adequate, but there are comments regarding the protocol, (c) protections appear inadequate and the Objective Review Group (ORG) has concerns related to human subjects; or (d) disapproval of the application is recommended because the research risks are sufficiently serious and protection against the risks are inadequate as to make the entire application unacceptable.

2. Acceptability of Prevention Methods Among Women at Risk for HIV/STD; 3. Acceptability of HIV/STD Prevention Methods Among Men Who Have Sex With Men; and 4. Other HIV/AIDS Epidemiology Research Studies Evaluation Criteria Include

A. Familiarity With and Access to Study Population (25 Points)

(1) Extent of applicant's knowledge of issues faced by study population and experience in working with this population.

(2) Existence of linkages to facilitate recruitment from and referral to programs providing services for the study population and letters of support.

(3) Feasibility of plans to involve the study population, their advocates, or service providers in the development of research and intervention activities and to inform them of research results.

(4) Evidence that plans for recruitment and outreach for study participants will include establishing partnerships with communities.

B. Description and Justification of a Research Plan (40 points)

(1) Quality of the review of the scientific literature pertinent to the proposed study, including theoretical basis for research, and relevance of research questions.

(2) The originality of research, the extent to which it does not replicate past or present research efforts (including ongoing efforts not yet described in publications), and relevance to guiding current HIV prevention efforts.

(3) Applicant's understanding of the research objectives as evidence by high quality of the proposed research plan with a study design that is appropriate to answer research questions.

(4) Quality of the study design, including appropriateness for answering the proposed research questions.

(5) Feasibility of plans to sample, recruit, enroll, test, interview and follow study participants, adequacy of sample size to address research questions. This includes demonstration of the availability of HIV-infected potential study participants and persons at risk for HIV infection and the experience of the investigator in enrolling and following such persons in a culturally and linguistically appropriate manner; 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, and comprehensiveness of the plan to protect the rights and confidentiality of all participants; and proposed justification when representation is limited or absent.

(6) Thoroughness of analysis plans, reasonableness for data collected, statistical rigor and complexity.

(7) Extent to which study proposal demonstrates assurance of compliance with multisite research requirements (e.g., common protocol, data collection, and computer and data management systems), if appropriate.

C. Demonstrate Staff's Capability To Conduct Research (20 points)

(1) Capacity to conduct study as evidenced by experience with similar or related research as evidenced by their previous related research.

(2) Extent of the team's productive working relations with proposed collaborators.

(3) Ability, willingness, and need to collaborate with researchers from other study sites in study design and analysis, including use of common forms, and sharing of specimens (when appropriate) and data.

D. Staffing, Facilities, and Time Line (15 points)

(1) Availability of qualified personnel with realistic and sufficient percentage-time commitments; clarity of the described duties and responsibilities of project personnel, with behavioral, epidemiologic, administrative, clinical, laboratory, data management, and statistical responsibilities.

(2) Adequacy of the facilities, equipment, data processing and analysis capacity, and systems for management of data security and participant confidentiality.

(3) Adequacy of time line.

E. Other (not scored)

(1) *Budget:* Will be reviewed to determine the extent to which it is reasonable, clearly justified, consistent with the intended use of funds, and allowable. All budget categories should be itemized.

(2) *Human Subjects:* Whether or not exempt from the DHHS regulations, are procedures adequate for the protection of human subjects? Recommendations on the adequacy of protections include the following: (a) protections appear adequate and there are no comments to make or concerns to raise, (b) protections appear adequate, but there are comments regarding the protocol, (c) protections appear inadequate and the Objective Review (OR) Group has concerns related to human subjects; or (d) disapproval of the application is recommended because the research risks are sufficiently serious and protection against the risks are inadequate as to make the entire application unacceptable.

Funding Preferences

Preference will be given to competing continuation applications from satisfactorily performing projects over applications for projects not already receiving support under the program. Projects will be awarded so that the composite of projects represents the geographic and demographic characteristics of the HIV-infected population.

Executive Order 12372 Review

Applications are subject to Intergovernmental Review of Federal Programs as governed by Executive Order (E.O.) 12372. E.O. 12372 sets up a system for State and local government review of proposed Federal assistance applications. Applicants (other than Federally recognized Indian tribal governments) should contact their State Single Point of Contact (SPOC) as early as possible to alert them to the prospective applications and receive

any necessary instructions on the State process. For proposed projects serving more than one State, the applicant is advised to contact the SPOC for each affected State. A current list of SPOCs is included in the application kit. If SPOCs have any State process recommendations on applications submitted to CDC, they should send them to Mr. Van Malone, Grants Management Officer, Grants Management Branch, Procurement and Grants Office, Centers for Disease Control and Prevention (CDC), Room 300, Mail Stop E–15, 255 East Paces Ferry Road, NE, Atlanta, GA 30305. Correspondence should arrive at CDC no later than 45 days after the application deadline date. The Program Announcement Number and Program Title should be referenced on the document. The granting agency does not guarantee to accommodate or explain State process recommendations it receives after that date.

Indian tribes are strongly encouraged to request tribal government review of the proposed application. If tribal governments have any tribal process recommendations on applications submitted to the CDC, they should forward them to Van Malone, Grants Management Officer, Grants Management Branch, Procurement and Grants Office, Centers for Disease Control and Prevention (CDC), 255 East Paces Ferry Road, NE., Room 300, Mailstop E15, Atlanta, GA 30305. This should be done no later than 30 days after the application deadline date. The granting agency does not guarantee to accommodate or explain for tribal process recommendations it receives after that date.

Public Health System Reporting Requirements

This program is subject to the Public Health System Reporting Requirements. Under these requirements, all community-based nongovernmental applicants must prepare and submit the items identified below to the head of the appropriate State and/or local health agency(ies) in the program area(s) that may be impacted by the proposed project no later than the receipt date of the Federal application. The appropriate State and/or local health agency is determined by the applicant. The following in information must be provided:

1. A copy of the face page of the application.

2. A summary of the project that should be titled ''Public Health System Impact Statement'' (PHSIS), not to exceed one page, and include the following:

A. A description of the population to be served;

B. A summary of the services to be provided; and

C. A description of the coordination plans with the appropriate State and/or local health agencies.

If the State and/or local health official should desire a copy of the entire application, it may be obtained from the State Single Point of Contact (SPOC) or directly from the applicant.

Catalog of Federal Domestic Assistance Number

The Catalog of Federal Domestic Assistance Number is 93.943, Epidemiologic Research Studies of Acquired Immunodeficiency Syndrome (AIDS) and Human Immunodeficiency Virus (HIV) Infection in Selected Population Groups.

Other Requirements

1. Paperwork Reduction Act

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

2. Human Subjects

This program involves research on human subjects. Therefore, all applicants must comply with the Department of Health and Human Services Regulations, 45 CFR Part 46, regarding the protection of human subjects. Assurance must be provided to demonstrate that the project or activity will be subject to initial and continuing review by an appropriate institutional review committee. The applicant will be responsible for providing assurance in accordance with the appropriate guidelines and form provided in the application kit.

In addition to other applicable committees, Indian Health Service (IHS) institutional review committees also must review the project if any component of IHS will be involved with or support the research. If any American Indian community is involved, its tribal government must also approve that portion of the project applicable to it.

3. HIV Program Review Panel

Recipients must comply with the document entitled Content of AIDS-Related Written Materials, Pictorials, Audiovisuals, Questionnaires, Survey Instruments, and Educational Sessions (June 1992) (a copy is in the application kit). To meet the requirements for a program review panel, recipients are encouraged to use an existing program review panel, such as the one created by the State health department's HIV/AIDS prevention program. If the recipient forms its own program review panel, at least one member must be an employee (or a designated representative) of a State or local health department. The names of the review panel members must be listed on the Assurance of Compliance form CDC 0.1113, which is also included in the application kit. The recipient must submit the program review panel's report that indicates all materials have been reviewed and approved.

4. Patient Care

Applicants must provide assurance that all HIV-infected patients enrolled in their studies will be linked to an appropriate local HIV care system that can address their specific needs such as medical care, counseling, social services, and therapy. Details of the HIV care system should be provided, describing how patients will be linked to the system. Funds will not be made available to support the provision of direct care for study participants.

5. Women, Racial and Ethnic Minorities

It is the policy of the CDC to ensure that individuals of both sexes and the various racial and ethnic groups will be included in CDC-supported research projects involving human subjects, whenever feasible and appropriate. Racial and ethnic groups are those defined in OMB Directive No. 15 and include American Indian, Alaskan Native, Asian/ Pacific Islander, Black and Hispanic. Applicants shall ensure that women, racial and ethnic minority populations are appropriately represented in applications for research involving human subjects. Where clear and compelling rationale exist that inclusion is inappropriate or not feasible, this situation must be explained as part of the application. This policy does not apply to research studies when the investigator cannot control the race, ethnicity or sex of subjects. Further guidance to this policy is contained in the **Federal Register**, Vol. 60, No. 179, Friday, September 15, 1995, pages 47947–47951 (a copy is included in the application kit).

Application Submission and Deadline

The original and five copies of the application packet PHS–398 (Revised 5/95, OMB No. 0925–0001) must be submitted to Van Malone, Grants Management Officer (ATTN: Kevin Moore, PA #735), Grants Management Branch, Procurement and Grants Office, Centers for Disease Control and Prevention (CDC), 255 East Paces Ferry

Road, NE., Room 320, Mail Stop E–15, Atlanta, Georgia 30305, on or before August 8, 1997.

1. *Deadline:* Applications will be considered as meeting the deadline if they are either:

A. Received on or before the stated deadline date; or

B. Sent on or before the deadline date and received in time for submission to the independent review group. (Applicants must request a legibly dated U.S. Postal Service postmark or obtain a legibly dated receipt from a commercial carrier or U.S. Postal Service. Private metered postmarks will not be accepted as proof of timely mailing.

2. *Late Applications:* Applications that do not meet the criteria in 1.A. or 1.B. are considered late applications. Late applications will not be considered in the current competition and will be returned to the applicant.

Where to Obtain Additional Information

A complete program description, information on application procedures, an application package, and business management technical assistance may be obtained from Kevin Moore, Grants Management Specialist, Grants Management Branch, Procurement and Grants Office, Centers for Disease Control and Prevention (CDC), 255 East Paces Ferry Road, NE., Room 320, Mail Stop E–15, Atlanta, Georgia 30305, telephone (404) 842–6550, E-mail address kgm1@cdc.gov. The announcement will be available on one of two Internet sites on the publication date: CDC's home page at http://www.cdc.gov, or at the Government Printing Office home page (including free access to the **Federal Register**) at http://www.access.gpo.gov.

Programmatic technical assistance may be obtained from Jeff Efird, Division of HIV/AIDS Prevention, National Center for HIV, STD, TB Prevention, Centers for Disease Control and Prevention (CDC), 1600 Clifton Road, NE., Mail Stop E–45, Atlanta, Georgia 30333, telephone (404) 639–6130, E-mail address jle1@cdc.gov. Eligible applicants are encouraged to call before developing and submitting their application. Please refer to Announcement Number 735 when requesting information.

Potential applicants may obtain a copy of ''Healthy People 2000'' (Full Report: Stock No. 017–001–00474–0) or ''Healthy People 2000'' (Summary Report: Stock No. 017–001–00473–1) referenced in the Introduction from the Superintendent of Documents, Government Printing Office, Washington, DC 20402–9325, telephone (202) 512–1800.

Dated: July 1, 1997.

Joseph R. Carter,

Acting Associate Director for Management and Operations, Centers for Disease Control and Prevention (CDC).

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[Program Announcement 761]

Replication and Dissemination of Effective Breast and Cervical Cancer Health Education Interventions

Introduction

The Centers for Disease Control and Prevention (CDC) announces the availability of funds in fiscal year (FY) 1997 for cooperative agreements to replicate and disseminate effective interventions for the early detection of breast and cervical cancer. These efforts should address health education for priority populations or professional education for health service providers. Activities under this Program Announcement are to be conducted in conjunction with the National Breast and Cervical Cancer Early Detection Program (NBCCEDP).

CDC is committed to achieving the health promotion and disease prevention objectives of Healthy People 2000, a national activity to reduce morbidity and mortality and to improve the quality of life. This announcement is related to the priority area of Cancer. (To order a copy of Healthy People 2000, see the section WHERE TO OBTAIN ADDITIONAL INFORMATION.)

Authority

This program is authorized by Sections 317(k)(2) and 1507 [42 U.S.C. 247b(k)(2) and 42 U.S.C. 300n–3] of the Public Health Service Act, as amended.

Smoke-Free Workplace

CDC strongly encourages all grant recipients to provide a smoke-free workplace and to promote the nonuse of all tobacco products, and Public Law 103–227, the Pro-Children Act of 1994, prohibits smoking in certain facilities that receive Federal funds in which education, library, day care, health care, and early childhood development services are provided to children.

Eligible Applicants

Assistance will be provided to nonprofit public or private organizations. Applicants must have affiliate/local offices or organizations in more than, or with access to, two or more States, U.S. territories, or Indian tribes or Indian tribal organizations. In addition, applicants must have a primary relationship to one or more of the priority populations or the health care providers who serve them. A primary relationship is one in which the organization's service to the priority population or to the health care providers who serve them is viewed as the most important component of its mission.

National organizations; professional associations of health care providers and their regional, State, and local constituents and affiliates; are eligible to apply. These organizations provide a unique opportunity to replicate and disseminate interventions that address barriers to screening, enhance the quality of care, and improve the priority population's access to and utilization of early detection programs.

* * Applicants must complete the enclosed Eligibility Assurance included in the application package and must attach documentation to support compliance with these eligibility criteria.

Note: Effective January 1, 1996, Public Law 104–65 states that an organization described in section 501(c)(4) of the Internal Revenue Code of 1986 which engages in lobbying activities shall not be eligible for the receipt of Federal funds constituting an award, grant (cooperative agreement), contract, loan, or any other form.

Glossary

Priority populations include uninsured or underinsured women, women who are aged 50 years and older; women who are racial, ethnic, and cultural minorities, such as American Indians, Alaskan Natives, African-Americans, Hispanics, Asian/Pacific Islanders, Lesbians, women with disabilities, and women who live in hard-to-reach communities in urban and rural areas. Priority populations, as defined above, will be used throughout this document.

Replication can include applying a proven, researched, and theoretically-based intervention proven to be effective:

(a) With one disease and one priority population and then adapted to breast and/or cervical cancer for another population or in a new geographic area;

(b) For increased screening for breast and cervical cancer and adapted for