neuroscience. It will also continue discussing ethical issues relating to the treatment of the aged and end-of-life care. Subjects discussed at past Council meetings (though not on the agenda for the present one) include: cloning, stem cell research, embryo research, assisted reproduction, reproductive genetics, IVF, ICSI, PGD, sex selection, inheritable genetic modification, patentability of human organisms, aging retardation, lifespan-extension, and organ procurement for transplantation. Publications issued by the Council to date include: *Human Cloning and Human Dignity: An Ethical Inquiry* (July 2002); *Beyond Therapy: Biotechnology and the Pursuit of Happiness* (October 2003); *Being Human: Readings from the President's Council on Bioethics* (December 2003); *Monitoring Stem Cell Research* (January 2004), and *Reproduction and Responsibility: The Regulation of New Biotechnologies* (March 2004).

DATES: The meeting will take place Thursday, September 9, 2004, from 9 a.m. to 4:30 p.m. ET; and Friday, September 10, 2004, from 8:30 a.m. to 12:30 p.m. ET.

ADDRESSES: Hyatt Regency Crystal City, 2799 Jefferson Davis Highway, Arlington, VA 22202.

Agenda: The meeting agenda will be posted at *http://www.bioethics.gov*.

Public Comments: The Council encourages public input, either in person or in writing. At this meeting, interested members of the public may address the Council, beginning at 11:30 a.m., on Friday, September 10. Comments are limited to no more than five minutes per speaker or organization. As a courtesy, please inform Ms. Diane Gianelli, Director of Communications, in advance of your intention to make a public statement, and give your name and affiliation. To submit a written statement, mail or e-mail it to Ms. Gianelli at one of the addresses given below.

FOR FURTHER INFORMATION CONTACT: Ms. Diane Gianelli, Director of Communications, The President's Council on Bioethics, Suite 700, 1801 Pennsylvania Avenue, Washington, DC 20006. Telephone: (202) 296–4669. E-mail: *info@bioethics.gov*. Web site: *http://www.bioethics.gov.*

Dated: August 11, 2004

Yuval Levin,

Acting Executive Director, The President's Council on Bioethics.

[FR Doc. 04–19286 Filed 8–23–04; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[Program Announcement 04274]

HIV/AIDS Surveillance in VCT/PMTCT Centers in Haiti Including Support of Annual Sero-Survey of Pregnant Women; Notice of Availability of Funds; Amendment

A notice announcing the availability of fiscal year (FY) 2004 funds for cooperative agreements for immunization projects was published in the **Federal Register** July 29, 2004, Volume 69, Number 145, pages 45322–45326. The notice is amended as follows:

Page 45323, Section II. Award Information: change Approximate Average Award to $550,000. (This amount is for the first 12-month budget period and includes direct costs.)

William P. Nichols,

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

[FR Doc. 04–19309 Filed 8–23–04; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

Reproductive Health Research

Announcement Type: New.

Funding Opportunity Number: RFA DP05–010.

Catalog of Federal Domestic Assistance Number: 93.946.

Key Dates:

Letter of Intent Deadline: September 23, 2004.

Application Deadline: November 8, 2004.

Executive Summary: The Division of Reproductive Health has four priority areas addressed by this announcement: (1) Maternal health, (2) infant health, (3) unintended and teen pregnancy prevention, and (4) women's reproductive health. This announcement seeks proposals for etiologic or interventional research that one or more of these four priority areas, especially as they relate to the problems of disparities in risk, prediction of risk, and prevention of preterm birth or unintended pregnancy. This program addresses the ''Healthy People 2010'' focus areas of Maternal, Infant, and Child Health and Family Planning.

I. Funding Opportunity Description

Authority: This program is authorized under Sections 301 (a) and 317 (k)(2) [42 U.S.C. 241 (a) and 247b (k)(2)] of the Public Health Service Act, as amended.

Purpose: The purpose of the program is to generate new knowledge to further the health of United States families and to eliminate disparities related to contraception, pregnancy, preterm delivery, and human reproduction.

Measurable outcomes of the program will be in alignment with one or more of the following performance goals (1) reduce maternal morbidity and mortality; or (2) identify biological and behavioral risk factors influencing prematurity; (3) increase the proportion of pregnancies that are intended; (4) reduce pregnancies among adolescent females; or (5) increase the proportion of adolescents who abstain from sexual intercourse or use condoms if currently sexually active.

Research Objectives:

(1) To gain a better understanding of the susceptibility to preterm delivery, in a public health framework, through research that explores:

- The social, behavioral, community, genetic, historical, and biologic determinants of preterm birth.
- The effect of gene variation within and between groups on the risk of preterm birth, and how the environment modifies that risk.
- The potential to predict the risk of preterm birth using combinations of social, behavioral, community, genetic, historical, and biologic determinants of preterm birth.
- To gain a better understanding of the clinical use of 17-alpha hydroxyprogesterone for the prevention of preterm delivery, evaluate barriers to its use, and develop capacity for future expanded studies of therapeutic effectiveness in the context of routine obstetrical care.

(2) To prevent unintended and teen pregnancy and to improve reproductive health among U.S. teens through innovative intervention research, non-intervention research, and research with Latino youth. Latinos are now the number one minority adolescent population and will continue to grow given the population demographics of such a young U.S. Latino population. Much of the data for Latinos are not disaggregated by ethnic subgroups or by first or subsequent generation and, therefore, preclude a discussion of differing risk factors and sexual health outcomes specific to each subgroup. Latinos have the highest teen pregnancy rate and over half of teenaged Latinos are sexually active. They are among the

least likely to use contraceptives at first intercourse. Latino youth are also disproportionately at risk for contracting sexually transmitted infections, including HIV. Such data suggest that they are an important target group for pregnancy prevention programs. However, very few programs have been evaluated that are directed specifically towards Latino teens.

(3) The principal objective of this research is the development of knowledge to support public health prevention programs and policies, including those that promote abstinence, reduce sexual risk taking, improve contraceptive use including STD prevention, and improve the delivery of reproductive health services. Proposals may include epidemiologic, behavioral, clinical, ethnographic, contextual-level, ecologic, and other research, both qualitative and quantitative. (Research that focuses primarily on school-based curriculum approaches will not be supported under this announcement.)

Activities:

Recipient activities for this program are as follows:

(1) *Preterm Delivery:*

• Using existing standardized assays, or creating new standard assays where standards do not exist, track the natural history of inflammatory biomarkers for preterm delivery through the course of pregnancy in an ethnically and racially diverse cohort of pregnant women in the United States. Biomarkers should include, but are not limited to, mediators of inflammation (cytokines, chemokines). Stored biologic specimens for women (blood, cervical swabs, vaginal swabs) and infant (cord blood, buccal swabs) dyads in this cohort will facilitate further analyses such as exploring the gene polymorphisms associated with variation in the inflammatory response. In addition to serial biological specimens, a broad range of social, behavioral, community, historical, and biologic determinants of preterm birth, and obstetrical data as well as pregnancy outcomes must be collected so that we might better understand the factors associated with an increased susceptibility to preterm delivery.

• Perform studies to explore the association between the presence of potential genetic markers for up-regulating or down-regulating inflammatory mediators and preterm birth in an ethnically and racially diverse cohort of U.S. women and their infants. The nature and design of these studies necessitate an existing cohort about which exists a broad range of social, behavioral, community, historical, and biologic determinants of preterm birth, and obstetrical data, stored biological samples for women and infant dyads, and pregnancy and neonatal outcomes.

• Describe the use of 17-alpha hydroxyprogesterone in the setting of routine clinical practice in representative sample of health care providers treating socially and racially diverse populations. Evaluate provider and patient acceptance of progesterone therapy. Examine patient compliance with weekly clinic visits and injections, according to obstetrical history, risk factors, social, behavioral, community, historical, and biologic determinants of preterm birth. Evaluate barriers to patient adherence and potential novel solutions. Develop capacity for possible future expanded assessments of therapeutic effectiveness of progesterone preparations in the context of routine clinical care.

(2) *Unintended and Teen Pregnancy Prevention:*

• *Intervention Research Objective:* To gain a better understanding of factors associated with successful programs to prevent unintended and teen pregnancy through rigorous, innovative intervention research. Potential projects could include:

○ Youth development or parent interventions which incorporate reproductive health promotion;

○ Innovative approaches to providing clinical services which incorporate behavior change interventions into clinical settings;

○ Programmatic ways to improve contraceptive practice and contraceptive adherence;

○ Intervention research tailored to the cultural circumstances of specific communities;

○ Culturally appropriate adaptations to teen pregnancy prevention programs to address the needs for culturally diverse youth;

○ Community-level interventions, such as use of radio drama or community outreach workers, to prevent unintended pregnancy and to promote reproductive health;

○ Interventions that target health care providers and youth service workers to better meet needs of clients in diverse populations.

• *Non-Intervention Research Objective:* To increase knowledge of factors associated with risk of unintended and teen pregnancy and related health consequences through innovative research. Potential projects could include:

○ Delayed initiation of first intercourse among teens or promotion of abstinence among sexually experienced teens;

○ Social and cultural forces that shape pregnancy intentions and reproductive decision-making including contraceptive use, childbearing, and HIV/STD prevention;

○ Sensitivity and appropriateness of unintended pregnancy measures in diverse and disempowered populations;

○ Determinants of incorrect or inconsistent use of contraception and factors associated with highly effective use;

○ Issues of gender and male involvement in sexual behavior and decision making, abstinence, contraceptive use, and pregnancy outcome;

○ Risks for unintended pregnancy and STDs among gay, lesbian, bisexual, transgender, and questioning youth;

○ Differences between racial and ethnic subgroups in adolescent pregnancy rates, antecedents, and associated factors;

○ Efforts to improve the measurement of pregnancy intentions and factors related to teen pregnancy and unintended pregnancy;

○ Methodological research designed to improve research approaches and public health surveillance for teen and unintended pregnancy;

○ Migration and acculturation processes as they relate to reproductive health outcomes and wantedness and intendedness of pregnancy;

○ Social and cultural influences, including gender dynamics, on abstinence, sexual risk behavior, and contraceptive use;

○ Longitudinal research projects examining sexual development, life planning, and pregnancy-related intentions and behaviors in diverse populations.

• *Latino Youth Objective:* To gain a better understanding of the risk for unintended and teen pregnancy and associated health outcomes among Latino youth through research. Potential projects could include:

○ Social and cultural determinants of pregnancy intentions, contraceptive use, and HIV/STD prevention among diverse Latino ethnic subgroups and in diverse settings, *e.g.*, along the U.S.-Mexico border;

○ Sensitivity and appropriateness of unintended pregnancy measures in Latino populations;

○ Ways that migration and acculturation interact with reproductive health behaviors and outcomes;

○ The meaning and measurement of acculturation processes as they relate to reproductive health outcomes and wantedness and intendedness of pregnancy among Latina youth;

○ Issues of gender and male involvement in sexual behavior and decision making, abstinence, contraceptive use, and pregnancy outcome;

○ Longitudinal research projects.

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) Assist in development of the research protocol by providing scientific consultation and technical assistance.

(2) Facilitate movement of the initial research protocol through CDC IRB as well as keeping CDC IRB abreast of protocol amendments and facilitating annual reviews.

(3) Assist in data analyses and interpretation and the presentation and publication of findings.

(4) Conduct site visits to recipient institution to determine the progress of the research and to monitor performance against approved project objectives.

(5) Establish agreements for sharing data and access to biological specimens.

(6) Facilitate distribution and dissemination of research findings, especially to state and local health departments and other grantees.

II. Award Information

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

Fiscal Year Funds: Fiscal Year 2005.

Approximate Total Funding: $4,500,000.

$1,500,000 for preterm delivery.

$3,000,000 for unintended and teen pregnancy prevention. (The estimated funding amount is pending availability of FY 2005 funds, and is subject to change.)

Approximate Number of Awards: At least six total, including a minimum of one for each of the three activities under preterm delivery and one for each of the three objectives under unintended and teen pregnancy prevention activities.

Approximate Average Award: $500,000 (This amount is for the first 12-month budget period, and includes both direct and indirect costs) for the preterm delivery and teen and unintended pregnancy intervention projects; and $300,000 for the teen and unintended pregnancy non-intervention and Latino projects.

Floor of Award Range: None.

Ceiling of Award Range: $600,000 for preterm delivery and teen and unintended pregnancy intervention projects; $350,000 for non-intervention and Latino projects.

Anticipated Award Date: January 15, 2005.

Budget Period Length: 12 months.

Project Period Length: Up to five years.

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

III. Eligibility Information

III.1. Eligible Applicants

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

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

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

Individuals Eligible to Become Principal Investigators: Any individual with the skills, knowledge, and resources necessary to carry out the proposed research is invited to work with their institution to develop an application for support. Individuals from underrepresented racial and ethnic groups as well as individuals with disabilities are always encouraged to apply for CDC programs.

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: *http://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): Your LOI must be written in the following format:

- *Maximum number of pages:* Two.
- *Font size:* 12-point unreduced.
- Single spaced.
- *Paper size:* 8.5 by 11 inches.
- *Page margin size:* One inch.
- Printed only on one side of page.
- Written in plain language, 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. For further assistance with the PHS 398 application form, contact PGO–TIM staff at 770–488–2700, or contact GrantsInfo, Telephone (301) 435–0714, E-mail: *GrantsInfo@nih.gov.*

Your research plan should address activities to be conducted over the entire project period.

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 on line 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 *http://www.dunandbradstreet.com* or call 1–866–705–5711.

For more information, see the CDC Web site at: *http://www.cdc.gov/od/pgo/funding/pubcommt.htm.*

This PA uses just-in-time concepts. It also uses the modular budgeting as well as non-modular budgeting formats. See: *http://grants.nih.gov/grants/funding/modular/modular.htm* for additional guidance on modular budgets. Specifically, if you are submitting an application with direct costs in each year of $250,000 or less, use the modular budget format. Otherwise, follow the instructions for non-modular budget research grant applications.

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

IV.3. Submission Dates and Times

LOI Deadline Date: September 23, 2004.

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

Application Deadline Date: November 8, 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 carriers 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 LOI and application content, 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.

IV.4. Intergovernmental Review of Applications

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

IV.5. Funding Restrictions

• 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 should be less than 12 months of age.

IV.6. Other Submission Requirements

LOI Submission Address: Submit your LOI by express mail, delivery service, fax, or E-mail to: Brenda Colley-Gilbert, Scientific Review Administrator, CDC, NCCDPHP, 4770 Buford Highway, NE.,Mail Stop K22,Atlanta, GA 30341–3717,Telephone: 770–488–6295,Fax: 770–488–7291,E-mail: *BJC4@cdc.gov.*

Application Submission Address: Submit the original and three hard copies of your application by mail or express delivery service to:Technical Information Management–RFA# DP05–010, CDC Procurement and Grants Office, 2920 Brandywine Road, Atlanta, GA 30341–3717.

At the time of submission, two additional copies of the application must be sent to: Brenda Colley-Gilbert, Scientific Review Administrator, CDC, NCCDPHP, 4770 Buford Highway, NE.,Mail Stop K22,Atlanta, GA 30341–3717,Telephone: 770–488–6295,Fax: 770–488–7291,E-mail: *BJC4@cdc.gov.*

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 injury, 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, well-integrated, and appropriate to the aims of the project? Does the applicant acknowledge potential problem areas and consider alternative tactics?

○ For preterm delivery only: It is critical to the design of this project that the study population be of sufficient ethnic and racial diversity to study differences in risk factors, biomarkers, and gene-environment interactions for white and black race and Hispanic ethnicity.

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?

○ For preterm delivery only: The principal investigator or the co-principal investigator must have a history of conducting competitively funded peer reviewed research directed at exploring the etiology or determinants of preterm delivery or directed at understanding the susceptibility of preterm delivery. The results of this research must have been published in peer reviewed journals within the last five years.

○ For preterm delivery only: In addition, the applicant's project team must include significant expertise in research on the relationships between infection and inflammation and preterm birth. For genetic studies, the team must include expertise in the area of the genetic regulation of the production of inflammatory mediators. At least one member of the project team must have laboratory experience in developing assays for inflammatory mediators (*e.g.* chemokines, cytokines), stress hormones (*e.g.* corticotrophin releasing hormone), and in the case of genetic studies, determination of polymorphism status (*e.g.* single and multiplex polymerase chain reaction).

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

○ For preterm delivery only: For studies involving prospectively-collected information, the applicant must document the existence of the appropriate institutional research infrastructure to carry out a large, complex project as well as the facilities to handle, store, and analyze biological samples for activities that require collection, storage, and analysis of such samples. There must be demonstrated ability to recruit women early in pregnancy and retain them throughout the course of their pregnancy.

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 women, 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 communities and recognition of mutual benefits.

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 by the National Center for Chronic Disease Prevention and Heath Promotion (NCCDPHP). Incomplete applications and applications that are non-responsive to the eligibility criteria will not advance through the review process. Applicants will be notified that their application did not meet submission requirements.

Applications that are complete and responsive to the PA will be evaluated for scientific and technical merit by an appropriate peer review group or charter study section convened by NCCDPHP in accordance with the review criteria listed above. As part of the initial merit review, all applications may:

- Undergo a process in which only those applications deemed to have the highest scientific merit, generally the top half of the applications under review, will be discussed and assigned a priority score.
- Receive a written critique.
- Receive a second level review by the NCCDPHP Extramural Research Review Group.

Award Criteria: Criteria that will be used to make award decisions include:

- Scientific merit (as determined by peer review).
- Availability of funds.
- Programmatic priorities.

V.3. Anticipated Award Date

CDC expects to make awards on or about January 15, 2005.

VI. Award Administration Information

VI.1. Award Notices

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

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

VI.2. Administrative and National Policy Requirements

45 CFR part 74 and part 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–4 HIV/AIDS Confidentiality Provisions.
- AR–5 HIV Program Review Panel Requirements.
- AR–6 Patient Care.
- AR–7 Executive Order 12372.
- 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–14 Accounting System Requirements.
• AR–15 Proof of Non-Profit Status.
• 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.

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, plus two hard copies of the following reports:

1. Interim progress report, (use form PHS 2590, OMB Number 0925–0001, rev. 5/2001 as posted on the CDC website) no less than 90 days before the end of the budget period. The progress report will serve as your non-competing continuation application, and must contain the following elements:

a. Current Budget Period Activities Objectives.
b. Current Budget Period Financial Progress.
c. New Budget Period Program Proposed Activity Objectives.
d. Budget.
e. Additional Requested Information.
f. Measures of Effectiveness.

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

3. Final financial and performance reports, no more than 90 days after the end of the project period.

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

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 issues, contact: Brenda Colley Gilbert, Extramural Project Officer, NCCDPHP/Deputy Associate Director for Extramural Research (DADER), 4770 Buford Highway, NE., Mail Stop K20, Atlanta, GA 30341–3717, Telephone: 770–488–6295, E-mail: *BColleyGilbert@CDC.GOV*.

For questions about peer review, contact: Brenda Colley Gilbert, Scientific Review Administrator, 4770 Buford Highway, NE., Mail Stop K20, Atlanta, GA 30341–3717, Telephone: 770–488–6295, E-mail: *BColleyGilbert@CDC.GOV*.

For financial, grants management, or budget assistance, contact: Tracey Sims, Grants Management Specialist, CDC Procurement and Grants Office, 2920 Brandywine Road, Atlanta, GA 30341, Telephone: 770–488–2739, E-mail: *Tsims3@cdc.gov*.

VIII. Other Information

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

Dated: August 17, 2004.

William P. Nichols,

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

[FR Doc. 04–19310 Filed 8–23–04; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2003P–0548]

Determination That DECADRON–LA (Dexamethasone Acetate Injection), Was Not Withdrawn From Sale for Reasons of Safety or Effectiveness

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) has determined that DECADRON–LA (dexamethasone acetate injection), 8 milligrams (mg)/milliliter (mL), was not withdrawn from sale for reasons of safety or effectiveness. As a result of this determination, FDA may approve abbreviated new drug applications (ANDAs) for dexamethasone acetate injection, 8 mg/mL.

FOR FURTHER INFORMATION CONTACT: Howard P. Muller, Center for Drug Evaluation and Research (HFD–7), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20855, 301–594–2041.

SUPPLEMENTARY INFORMATION: In 1984, Congress enacted the Drug Price Competition and Patent Term Restoration Act of 1984 (Public Law 98–417) (the 1984 amendments), which authorized the approval of duplicate versions of drug products approved under an ANDA procedure. ANDA sponsors must, with certain exceptions, show that the drug for which they are seeking approval contains the same active ingredient in the same strength and dosage form as the ''listed drug,'' which is typically a version of the drug that was previously approved under a new drug application (NDA). Sponsors of ANDAs do not have to repeat the extensive clinical testing otherwise necessary to gain approval of an NDA. The only clinical data required in an ANDA are data to show that the drug that is the subject of the ANDA is bioequivalent to the listed drug.

The 1984 amendments include what is now section 505(j)(7) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(j)(7)), which requires FDA to publish a list of all approved drugs. FDA publishes this list as part of the ''Approved Drug Products With Therapeutic Equivalence Evaluations,'' which is generally known as the ''Orange Book.'' Under FDA regulations, drugs are withdrawn from the list if the agency withdraws or suspends approval of the drug's NDA or ANDA for reasons of safety or effectiveness, or if FDA determines that the listed drug was withdrawn from sale for reasons of safety or effectiveness (§ 314.162 (21 CFR 314.162)).

Under § 314.161(a)(1), the agency must determine whether a listed drug was withdrawn from sale for reasons of safety or effectiveness before an ANDA that refers to that listed drug may be approved. If the agency determines that a listed drug was withdrawn for reasons of safety or effectiveness, the drug must be removed from the list of approved drug products, and ANDAs referencing that drug may not be approved (§ 314.162).

DECADRON–LA (dexamethasone acetate injection), 8 mg/mL, is the subject of approved NDA 16–675 held by Merck. In a letter to the agency dated June 25, 2002, Merck requested that NDA 16–675 be withdrawn because the drug is no longer marketed. Merck noted that the NDA was not withdrawn because of safety reasons. On December 5, 2003, Gray Cary submitted a citizen petition (Docket No. 2003P–0548/CP1) to FDA under 21 CFR 10.30 requesting that the agency determine whether DECADRON–LA (dexamethasone acetate injection), 8 mg/mL, NDA 16–675, was withdrawn from sale for reasons of safety or effectiveness.

The agency has determined that DECADRON–LA (dexamethasone acetate injection), 8 mg/mL, was not withdrawn from sale for reasons of