

ADDRESSES: Application kits are available by writing to the U.S. Department of Health and Human Services, Administration on Aging, Washington, DC 20201, by calling 202/357-3447, or online at <http://www.grants.gov>.

Applications may be mailed to the U.S. Department of Health and Human Services, Administration on Aging, Office of Grants Management, Washington, DC 20201, attn: Margaret Tolson (AoA-04-08).

Applications may be delivered to the U.S. Department of Health and Human Services, Administration on Aging, Office of Grants Management, One Massachusetts Avenue, NW., Room 4604, Washington, DC 20001, attn: Margaret Tolson (AoA-04-08).

If you elect to mail or hand deliver your application you must submit one original and two copies of the application; an acknowledgement card will be mailed to applicants.

Instructions for electronic mailing of grant applications are available at <http://www.grants.gov>.

FOR FURTHER INFORMATION CONTACT: U.S. Department of Health and Human Services, Administration on Aging, Office of Grants Management, Washington, D.C. 20201, Telephone: (202) 357-3440.

SUPPLEMENTARY INFORMATION: All grant applicants are required to obtain a D-U-N-S number from Dun and Bradstreet. It is a nine-digit identification number, which provides unique identifiers of single business entities. The D-U-N-S number is free and easy to obtain from <https://eupdate.dnb.com/requestoptions.html>.

Dated: August 2, 2004.

Josefina G. Carbonell,

Assistant Secretary for Aging.

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BILLING CODE 4154-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

Delivery of Prevention of Mother to Child Transmission of HIV (PMTCT) Products in River State, Nigeria

Announcement Type: New.

Funding Opportunity Number: PA 04260.

Catalog of Federal Domestic Assistance Number: 93.941.

DATES: *Application Deadline:* September 7, 2004.

I. Funding Opportunity Description

Authority: This program is authorized under Sections 307 and 317(k)(2) of the Public Health Service Act, [42 U.S.C. Sections 242l and 247b(k)(2)] as amended and under Public Law 108-25 (United States Leadership Against HIV/AIDS, Tuberculosis and Malaria Act of 2003) [22 U.S.C. 7601].

Purpose: The purpose of the program is to improve the quality of life of people living with HIV/AIDS (PLWHAs) and their families. Nigeria has a population of 120 million and a current HIV sero-prevalence rate of 5.8 percent, thus making it the country with the largest number of HIV infected persons in Sub Saharan Africa (3.4 million HIV infected persons). As part of its response to the epidemic, the Government of Nigeria, in 2001, requested that the national Prevention of Mother to Child Transmission (PMTCT) task force team and the newly convened Antiretroviral (ARV) committee develop guidelines and protocols for implementing pilot PMTCT programs and ARV treatment and care programs respectively. The Centers for Disease Control and Prevention (CDC) announces the availability of Fiscal Year (FY) 2005 funds for a cooperative agreement program to increase United States support to countries in which the CDC's Global AIDS Program (GAP) is operating. In coordination with host (or "in-country") GAP program staff, the applicant will assist in addressing the devastating impact of HIV/AIDS on individuals, families, and communities in Nigeria. The funded organization will provide technical assistance (TA) to implement, monitor, and evaluate the delivery of PMTCT products in River State, Nigeria, to reduce HIV transmission from mother to child and to prolong the lives of parents infected with HIV/AIDS.

The GAP has established field operations to support national HIV/AIDS control programs in 25 countries. The CDC's GAP exists to help prevent HIV infection, improve care and support, and build capacity to address the global AIDS pandemic. GAP provides financial and TA through partnerships with governments, community- and faith-based organizations, the private sector, and national and international entities working in the 25 resource-constrained countries. CDC/GAP works with the Health Resources and Services Administration (HRSA), the National Institutes of Health (NIH), the U.S. Agency for International Development (USAID), the Peace Corps, the Departments of State, Labor and Defense, and other agencies and

organizations. These efforts complement multilateral efforts, including The Joint United Nations Programme on HIV/AIDS (UNAIDS), the Global Fund to Combat HIV, TB and Malaria, World Bank funding, and other private sector donation programs.

The U.S. Government seeks to reduce the impact of HIV/AIDS in specific countries within sub-Saharan Africa, Asia, and the Americas through the President's Emergency Plan for AIDS Relief (PEPFAR). Through this new initiative, CDC's GAP will continue to work with host countries to strengthen capacity and expand activities in the areas of: (1) Primary HIV prevention; (2) HIV care, support, and treatment; and (3) capacity and infrastructure development, especially for surveillance and training. Targeted countries represent those with the most severe epidemics where the potential for impact is greatest and where U.S. government agencies are already active. Nigeria is one of these targeted countries.

To carry out its activities in these countries, CDC is working in a collaborative manner with national governments and other agencies to develop programs of assistance to address the HIV/AIDS epidemic. CDC's program of assistance to Nigeria focuses on several areas of national priority including scaling up of prevention and care strategies for HIV prevention, care, and treatment.

The measurable outcomes of the program will be in alignment with goals of the National Center for HIV, STD and TB Prevention (NCHSTP) to reduce HIV transmission and improve care of PLWHAs. They also will contribute to the goals of the PEPFAR which are: (1) Within five years treat more than two million HIV-infected persons with effective combination anti-retroviral therapy (ART); (2) care for ten million HIV-infected and affected persons including those orphaned by HIV/AIDS; and (3) prevent seven million infections in 14 countries throughout the world.

Activities: The project sites for this cooperative agreement are:

1. College of Health Technology Clinic (PMTCT Implementation Center) and three affiliated satellite centers:

- Civil Servants Hospital, Port Harcourt.

- Comprehensive Health Center, Rumuigbo.

- General Hospital, Okrika.

2. General Hospital Buguma (PMTCT Implementation Center) and three affiliate satellite centers:

- General Hospital, Degema.
- General Hospital, Abonnema.
- General Hospital, Emohua.

Awardee activities for this program are as follows:

- Provide PMTCT Training of Trainers (TOTS) to at least 30 individuals, including health care workers, at the following locations:
 - PMTCT Implementation Centers (2): 10 trainees
 - Other Hospitals: 12 trainees
 - Contractor's Staff: 5 trainees
 - Non-Governmental Organizations/Community Based Organizations/Reproductive Health Services Outlets (NGO/CBO/RHSO) Faith-based organizations: 3 trainees
 - Total TOT Trainees: 30 trainees
- The beneficiaries of the Training of Trainers will provide training to other health care workers, from their respective institutions:
 - PMTCT Implementation Centers (2) × 10: 20
 - Contractor's Staff Capacity Building Training Workshop (training of NGOs/CBOs/RHSOs): 30
 - Total Health Care Workers Trained: 50
- Increase awareness of HIV/AIDS and PMTCT through posters, radio jingles, counseling services and other media. The grantee is expected to make 30,000 persons aware of HIV/AIDS and PMTCT.
- Provide PMTCT counseling services (both group and one-on-one counseling services) to 20,000 pregnant women within 12 months from all participating PMTCT health centers and satellites under this initiative in Rivers State.
- Provide PMTCT counseling and Management of HIV/AIDS to 1,000 pregnant women who have tested positive for HIV/AIDS within 12 months from all participating PMTCT health centers and satellites under this initiative in Rivers State.
- Provide Voluntary HIV testing to 50 percent or 10,000 of counseled PMTCT pregnant women within the 12-month period. The distribution should be 6,000 tested in Port Harcourt and 4,000 tested in Buguma.
- Provide PMTCT services to 1,000 pregnant women testing positive for HIV/AIDS.
- Provide ARV treatment and management of 100 pregnant HIV infected women with symptoms/diagnosis of AIDS.
- Provide Nevirapine treatment (200 mg) to 1,000 pregnant HIV infected women at the onset of labor and continue treatment for the duration of ten months.
- Provide Nevirapine treatment (syrup 2 mg/kg) to 1,000 infants within 24–72 hours of birth.
- Provide Breast Milk Supplement (BMS) to 100 HIV infected mothers

opting not to breast feed their babies within the first six months of delivery.

- Test 1,000 infants for HIV at age 15 months.

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:

- Collaborate with the award recipient, the Nigerian Ministry of Health (MOH) and other in-country and international partners in the development of plans for program assistance based on the country needs, the CDC TA portfolio, and HIV prevention activities conducted by other partners.
- Provide consultation, scientific and technical assistance based on the "CDC GAP Technical Strategies" document to promote the use of best practices known at the time.
- Facilitate in-country planning and review meetings for the purpose of ensuring coordination of country-based program TA activities. CDC will act as liaison and assist in coordinating activities as required between the applicant and other NGOs, government of Nigeria agencies, and other CDC, GAP partners.

TA and training may be provided directly by CDC staff or through organizations that have successfully competed for funding under a separate CDC contract.

II. Award Information

Type of Award: Cooperative Agreement.

CDC involvement in this program is listed in the Activities Section above.

Fiscal Year Funds: FY 2004.

Approximate Total Funding: \$200,000.

Approximate Number of Awards: One.

Approximate Average Award: \$200,000. (This amount is for the first 12-month budget period, and includes both direct and indirect costs).

Floor of Award Range: None.

Ceiling of Award Range: \$200,000.

Anticipated Award Date: September 1, 2004.

Budget Period Length: 12 months.

Project Period Length: Three 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 organizations and by governments and their agencies, such as:

- Private nonprofit organizations.
- Community-based organizations.
- Faith-based organizations.

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. Applicants must:

1. Have experience in community HIV/AIDS programs in the Niger Delta Region of Nigeria.
2. Have at least three years experience working in the Niger Delta Region of Nigeria relative to development assistance.

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

IV. Application and Submission Information

IV.1. Address To Request Application Package

To apply for this funding opportunity use application form PHS 5161. Application forms and instructions are available on the CDC Web site, at the following Internet address: <http://www.cdc.gov/od/pgo/forminfo.htm>.

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

IV.2. Content and Form of Submission

Application: You must submit a project narrative with your application forms. The narrative must be submitted in the following format:

- Maximum number of pages: 25 If your narrative exceeds the page limit, only the first pages which are within the page limit will be reviewed.

- Double spaced.
- Font size: 12 point un-reduced.
- Paper size: 8.5 by 11 inches.
- Page margin size: One inch.
- Printed only on one side of page.
- Held together only by rubber bands or metal clips; not bound in any other way.

- Must be submitted in English.

Your narrative should address activities to be conducted over the entire project period, and must include the following items in the order listed:

- Plan.
- Objectives.
- Activities.
- Methods of Monitoring the Project.
- Methods of Project Evaluation.
- Summary budget by line item along with a budget justification.

The budget justification will not be counted in the page limit stated above.

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

- Organizational Chart.
- Curriculum Vitae/Resumes of Current Staff.

- Proposed staffing pattern (include qualifications) required to carry out program activities.

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

For more information, see the CDC Web site at: <http://www.cdc.gov/od/pgofunding/pubcomm.htm>.

If your application form does not have a DUNS number field, please write your DUNS number at the top of the first page of your application, and/or include your DUNS number in your application cover letter.

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

IV.3. Submission Dates and Times

Application Deadline Date:

September 7, 2004.

Explanation of Deadlines:

Applications must be received in the

CDC Procurement and Grants Office by 4 p.m. eastern time on the deadline date. If you send your application by the United States Postal Service or commercial delivery service, you must ensure that the carrier will be able to guarantee delivery of the application by the closing date and time. If CDC receives your application after closing due to: (1) Carrier error, when the carrier accepted the package with a guarantee for delivery by the closing date and time, or (2) significant weather delays or natural disasters, you will be given the opportunity to submit documentation of the carrier's guarantee. If the documentation verifies a carrier problem, CDC will consider the application as having been received by the deadline.

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

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

IV.4. Intergovernmental Review of Applications

Executive Order 12372 does not apply to this program.

IV.5. Funding Restrictions

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

- Funds may be spent for reasonable program purposes, including personnel, travel, supplies, and services. Equipment may be purchased if deemed necessary to accomplish program objectives; however, prior approval by CDC officials must be requested in writing.

- All requests for funds contained in the budget shall be stated in U.S. dollars. Once an award is made, CDC will not compensate foreign grantees for currency exchange fluctuations through the issuance of supplemental awards.

- The costs that are generally allowable in grants to domestic organizations are allowable to foreign institutions and international organizations, with the following

exception: With the exception of the American University, Beirut, and the World Health Organization, Indirect Costs will not be paid (either directly or through sub-award) to organizations located outside the territorial limits of the United States or to international organizations regardless of their location.

- The applicant may contract with other organizations under this program; however the applicant must perform a substantial portion of the activities (including program management and operations, and delivery of prevention services for which funds are required).

- You must obtain an annual audit of these CDC funds (program-specific audit) by a U.S.-based audit firm with international branches and current licensure/authority in-country, and in accordance with International Accounting Standards or equivalent standards(s) approved in writing by CDC.

- A fiscal Recipient Capability Assessment may be required, prior to or post award, in order to review the applicant's business management and fiscal capabilities regarding the handling of U.S. Federal funds.

- Antiretroviral Drugs—The purchase of ARVs, reagents, and laboratory equipment for ARV treatment projects require pre-approval from the GAP headquarters.

- Needle Exchange—No funds appropriated under this Act shall be used to carry out any program of distributing sterile needles or syringes for the hypodermic injection of any illegal drug.

- Prostitution and Related Activities The U.S. Government is opposed to prostitution and related activities, which are inherently harmful and dehumanizing, and contribute to the phenomenon of trafficking in persons.

Any entity that receives, directly or indirectly, U.S. Government funds in connection with this document ("recipient") cannot use such U.S. Government funds to promote or advocate the legalization or practice of prostitution or sex trafficking. Nothing in the preceding sentence shall be construed to preclude the provision to individuals of palliative care, treatment, or post-exposure pharmaceutical prophylaxis, and necessary pharmaceuticals and commodities, including test kits, condoms, and, when proven effective, microbicides. A recipient that is otherwise eligible to receive funds in connection with this document to prevent, treat, or monitor HIV/AIDS shall not be required to endorse or utilize a multisectoral approach to combating HIV/AIDS, or to

endorse, utilize, or participate in a prevention method or treatment program to which the recipient has a religious or moral objection. Any information provided by recipients about the use of condoms as part of projects or activities that are funded in connection with this document shall be medically accurate and shall include the public health benefits and failure rates of such use.

In addition, any foreign recipient must have a policy explicitly opposing, in its activities outside the United States, prostitution and sex trafficking, except that this requirement shall not apply to the Global Fund to Fight AIDS, Tuberculosis and Malaria, the World Health Organization, the International AIDS Vaccine Initiative or to any United Nations agency, if such entity is a recipient of U.S. Government funds in connection with this document.

The following definitions apply for purposes of this clause:

- Sex trafficking means the recruitment, harboring, transportation, provision, or obtaining of a person for the purpose of a commercial sex act. 22 U.S.C. 7102(9).

- A foreign recipient includes an entity that is not organized under the laws of any State of the United States, the District of Columbia or the Commonwealth of Puerto Rico. Restoration of the Mexico City Policy, 66 FR 17303, 17303 (March 28, 2001).

All recipients must insert provisions implementing the applicable parts of this section, "Prostitution and Related Activities," in all subagreements under this award. These provisions must be express terms and conditions of the subagreement, acknowledge that each certification to compliance with this section, "Prostitution and Related Activities," are a prerequisite to receipt of U.S. Government funds in connection with this document, and must acknowledge that any violation of the provisions shall be grounds for unilateral termination of the agreement prior to the end of its term. In addition, all recipients must ensure, through contract, certification, audit, and/or any other necessary means, all the applicable requirements in this section, "Prostitution and Related Activities," are met by any other entities receiving U.S. Government funds from the recipient in connection with this document, including without limitation, the recipients' sub-grantees, sub-contractors, parents, subsidiaries, and affiliates. Recipients must agree that HHS may, at any reasonable time, inspect the documents and materials maintained or prepared by the recipient in the usual course of its operations that

relate to the organization's compliance with this section, "Prostitution and Related Activities."

All primary grantees receiving U.S. Government funds in connection with this document must certify compliance prior to actual receipt of such funds in a written statement referencing this document (e.g., "[Recipient's name] certifies compliance with the section, 'Prostitution and Related Activities.'"') addressed to the agency's grants officer. Such certifications are prerequisites to the payment of any U.S. Government funds in connection with this document.

- Recipients' compliance with this section, "Prostitution and Related Activities," is an express term and condition of receiving U.S. Government funds in connection with this document, and any violation of it shall be grounds for unilateral termination by HHS of the agreement with HHS in connection with this document prior to the end of its term. The recipient shall refund to HHS the entire amount furnished in connection with this document in the event it is determined by HHS that the recipient has not complied with this section, "Prostitution and Related Activities."

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.

Awards will not allow reimbursement of pre-award costs.

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

IV.6. Other Submission Requirements

Application Submission Address: Submit the original and two hard copies of your application by mail or express delivery service to: Technical Information Management—PA# 04260, CDC Procurement and Grants Office, 2920 Brandywine Road, Atlanta, GA 30341. Applications may not be submitted electronically at this time.

V. Application Review Information

V.1. Criteria

You are required to provide measures of effectiveness that will demonstrate the accomplishment of the various identified objectives of the cooperative agreement. Measures of effectiveness must relate to the performance goals stated in the "Purpose" section of this announcement. Measures must be objective and quantitative, and must

measure the intended outcome. These measures of effectiveness must be submitted with the application and will be an element of evaluation.

Your application will be evaluated against the following criteria:

1. Ability to Carry Out the Project (25 Points)

Does the applicant document demonstrated capability to achieve the purpose of the project?

2. Understanding of the Problem (20 Points)

Does the applicant demonstrate a clear and concise understanding of the nature of the problem described in the Purpose section of this announcement? Does the proposal specifically include a description of the public health importance of the planned activities to be undertaken and realistic presentation of proposed objectives and projects?

3. Technical Approach (20 Points)

Does the applicant's proposal include an overall design strategy, including measurable time lines? Does the proposal address regular monitoring and evaluation, and the potential effectiveness of the proposed activities in meeting objectives?

4. Personnel (20 Points)

Are the professional personnel involved in this project qualified, including evidence of experience in working with PMTCT, voluntary counseling and testing (VCT), and HIV/AIDS?

5. Plans for Administration and Management of Projects (15 Points)

Are there adequate plans for administering the project?

6. Budget (Not Scored)

Is the itemized budget for conducting the project, along with justification, reasonable and consistent with stated objectives and planned program activities?

V.2. Review and Selection Process

Applications will be reviewed for completeness by the Procurement and Grants Office (PGO) staff, and for responsiveness by NCHSTP/GAP. Incomplete applications and applications that are non-responsive to the eligibility criteria will not advance through the review process. Applicants will be notified that their application did not meet submission requirements.

An objective review panel will evaluate complete and responsive applications according to the criteria listed in the "V.1. Criteria" section above.

V.3. Anticipated Announcement and Award Dates

September 1, 2004.

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-4 HIV/AIDS Confidentiality Provisions.
- AR-6 Patient Care.
- AR-9 Paperwork Reduction Act Requirements.
- AR-14 Accounting System Requirements.

Additional information on these requirements can be found on the CDC web site at the following Internet address: <http://www.cdc.gov/od/pgofunding/ARs.htm>.

VI.3. Reporting Requirements

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

1. Interim progress report, no less than 90 days before the end of the budget period. The progress report will serve as your non-competing continuation application, and must contain the following elements:
 - a. Current Budget Period Activities Objectives.
 - b. Current Budget Period Financial Progress.
 - c. New Budget Period Program Proposed Activity Objectives.
 - d. Budget.
 - e. Additional Requested Information.
 - f. Measures of Effectiveness.
2. Financial status no more than 90 days after the end of the budget period.
3. Final financial and performance reports, no more than 90 days after the end of the project period.

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

VII. Agency Contacts

For general questions about this announcement, contact: Technical Information Management Section, CDC Procurement and Grants Office, 2920 Brandywine Road, Atlanta, GA 30341, telephone: 770-488-2700.

For program technical assistance, contact: Wayne Duncan, Country Director, CDC Global AIDS Program—Nigeria, Metro Plaza, Zakariya Maimalari Street, Plot 992, Central Business District, Abuja, Nigeria, telephone: 234-09-670-0798. e-mail: wcd2@cdc.gov.

For financial, grants management, or budget assistance, contact: Diane Flournoy, Grants Management Specialist, CDC Procurement and Grants Office, 2920 Brandywine Road, Atlanta, GA 30341, telephone: 770-488-2072. e-mail: dmf6@cdc.gov.

VIII. Other Information

None.

Alan A. Kotch,

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

[FR Doc. 04-18099 Filed 8-4-04; 10:33 am]

BILLING CODE 4163-18-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Endocrinologic and Metabolic Drugs Advisory Committee; Notice of Meeting

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

This notice announces a forthcoming meeting of a public advisory committee of the Food and Drug Administration (FDA). The meeting will be open to the public.

Name of Committee: Endocrinologic and Metabolic Drugs Advisory Committee.

General Function of the Committee: To provide advice and recommendations to the agency on FDA's regulatory issues.

Date and Time: The meeting will be held on September 8, 2004, from 8 a.m. to 5 p.m.

Location: On September 8, 2004, the meeting will be held at the Holiday Inn, Versailles Ballrooms, 8120 Wisconsin Ave., Bethesda, MD.

Contact Person: Dornette Spell-LeSane, Center for Drug Evaluation and Research (HFD-21), Food and Drug Administration, 5600 Fishers Lane, (for express delivery, 5630 Fishers Lane, rm. 1093) Rockville, MD 20857, 301-827-7001, FAX: 301-827-6776, e-mail: spelllesaned@cder.fda.gov, or FDA Advisory Committee Information Line, 1-800-741-8138 (301-443-0572 in the Washington, DC area), code 3014512536. Please call the Information Line for up-to-date information on this meeting.

Agenda: On September 8, 2004, the committee will discuss the FDA draft guidance document entitled "Guidance for the Clinical Evaluation of Weight-Control Drugs," issued September 24, 1996 (see 69 FR 3588, January 26, 2004, including solicitation for comments [Docket No. 2003D-0570], see also the FDA Internet at <http://www.fda.gov/cder/guidance/index.htm> under the heading "Clinical/Medical (Draft)").

Procedure: Interested persons may present data, information, or views, orally or in writing, on issues pending before the committee. Written submissions may be made to the contact person by August 31, 2004. Oral presentations from the public will be scheduled between approximately 11 a.m. and 12 noon. Time allotted for each presentation may be limited. Those desiring to make formal oral presentations should notify the contact person before August 31, 2004, and submit a brief statement of the general nature of the evidence or arguments they wish to present, the names and addresses of proposed participants, and an indication of the approximate time requested to make their presentation.

Persons attending FDA's advisory committee meetings are advised that the agency is not responsible for providing access to electrical outlets.

FDA welcomes the attendance of the public at its advisory committee meetings and will make every effort to accommodate persons with physical disabilities or special needs. If you require special accommodations due to a disability, please contact Dornette Spell-LeSane, at least 7 days in advance of the meeting.

Notice of this meeting is given under the Federal Advisory Committee Act (5 U.S.C. app. 2).

Dated: July 30, 2004.

William K. Hubbard,

Associate Commissioner for Policy and Planning.

[FR Doc. 04-17949 Filed 8-5-04; 8:45 am]

BILLING CODE 4160-01-S